MIGRAINE WORLD SUMMIT

INTERVIEWS WITH WORLD-LEADING EXPERTS

TRANSCRIPT

10 STEPS TO MIGRAINE MANAGEMENT YOUR DOCTOR SHOULD BE TAKING

MESSOUD ASHINA, MD

Introduction (00:05): Well, the 10-steps plan is very important because it's quite intuitive, right? When you have 10 steps and very concrete steps, then you can follow that. This is, I would say, also kind of [an] educational tool. So, it can be also adapted to medical schools, you know, when you teach migraine diagnosis and management. And the idea is also it is important for the primary care.

Paula K. Dumas (00:34): Ever wonder what playbook your doctor is referencing before recommending a treatment plan for your migraine care? So do we. You know, for decades, physicians have only had some general guidelines from the medical societies to reference before choosing from dozens of pharmaceutical, behavioral, device, and lifestyle approaches. And that all changed this year when a team of European researchers published an evidence-based 10-step approach for migraine management. It might just give you and your physician a road map for how to get control of your pain and other symptoms. Joining us today to explain the 10 steps to migraine management is one of the study's authors and the most recent past president of the International Headache Society, Dr. Messoud Ashina. Dr. Ashina, welcome to the Migraine World Summit.

Dr. Ashina (01:27): Thank you, Paula. Thank you for inviting me.

Paula K. Dumas (01:28): Tell us, when was this 10-step plan developed and how?

Dr. Ashina (01:35): Well, there was some years ago — in fact, inspired by some of my junior scientists: I was told that, "Why don't we do 10 steps for migraine?" because they found literature on other diseases and they said, "Well, this is something we're missing." And you know, if you want to be, let's say, contemporary, you have to listen to what your junior scientists are telling you. And [if] they say that this is something missing, [then] you have to look at it. First, I said, "Well, I'm too busy [for] that," but they said, "No, you have to read some literature." Then I read the literature and I must admit that I was impressed by their persistence. And I said, "Well, let's do it." So, the first step was that we had some brainstorming. We would like to have it, let's say, very friendly: the 10 steps [that] everybody can apply ... of course, based on some experience and the literature.

Dr. Ashina (02:39): But we also found out that we needed a consensus statement, OK, because not everything is evidence-based. And it is important to have a consensus statement, but as one society or the one center, we cannot just present 10 steps; we need some partners and experts from the different countries. So, we decided ... we initiated as a project from the Danish Headache Society. And then we approached the European Headache Federation and European Academy of Neurology. And we suggested that this is a consensus statement, and it would be great if they also endorse this consensus statement.

Paula K. Dumas (03:21): Right. So why was it important to create a 10-step plan?

Dr. Ashina (03:26): Well, the 10-steps plan is very important because it's quite intuitive, right? When you have 10 steps and very concrete steps, then you can follow that. This is, I would say, [it's] also kind of [an] educational tool. So, it can be also adapted to medical schools, you know, when you teach migraine diagnosis and management. And the idea is also it is important for the primary care because most of the migraine patients we are talking [about] are seen by our general practitioners, and they need something very concrete because as you know, the GPs are quite busy. They don't have hours and hours sitting there with their patients [to] discuss the migraine diagnosis and management. It should be quite [a] fast track and clear cut. So just, you

know, with a simple first-step way to suspect migraine, it's very easy. And we give them this opportunity with very deductive, I would say, clear-cut bullet points that this is the way you do it. If you are interested to read it more, you can read the whole paper. But what we decided that it was important also to have a kind of figure or table showing these 10 steps. So primarily for the GPs.

Paula K. Dumas (04:56): It's very important. I encourage people when they go to see their GP, even if they have a neurologist or specialist who's taking care of them, [to] have the conversation about migraine because many of our patient advocates really know much more about migraine even than their GP, or at least different spheres of knowledge. Now migraine is so varied in its expression. Could one approach possibly work for all types of migraine?

Dr. Ashina (05:25): This is a very good question, Paula. The problem is that we have also rare subtypes of migraine. I would say that these rare subtypes of migraine ... I mean, you can't easily use these 10 steps in these rare subtypes — let's say if you have familial hemiplegic migraine; so, this is not a case that you can use the 10 steps. It's a more specialized task for the specialist in headache medicine. They should see these patients. So, this is, as I said, more straightforward for the common types of migraine: migraine with and without aura.

Paula K. Dumas (06:03): OK. That's great. So, while there's 10 steps, there are actually three major phases into which those 10 steps fall: the diagnosis, treatment, and then follow-up care. So, I want to unpack each one of those individually with you. Let's start with diagnosis, where all things begin. The first step is when to suspect migraine and what's important. Are light sensitivity or nausea relevant here?

Dr. Ashina (06:29): Yeah, the so-called migraine features — such as the light sensitivity, sound sensitivity — is important, but what is [also] important is to understand that the migraine is a recurrent disorder. And then there is also some other symptoms which can, in fact, straighten your confidence in diagnosis, such as gender — we know that it's more prevalent in women than in men. Age. We also know about the genetics of migraine. You can ask about the family history: "Do you have any relatives, first-degree relatives, suffering from any recurrent headaches?" Well, then you have, suddenly, all these symptoms together, plus history — and history is taken; you know, you have to ask these questions — then you have a diagnosis. One important point is also ... of course it requires, also, knowledge about the diagnostic criteria, right? But if you follow these steps, if you follow this logic, then it's very easy to confirm that with the diagnostic criteria, which is available online absolutely free, everybody can see. So, you can confirm your diagnosis, in five minutes, something like that, after you have, of course collected all the data.

Paula K. Dumas (07:49): Got it. So, step two is the diagnosis of migraine. And you talked about a number of the criteria there, but is there anything else you look for and is neuroimaging appropriate?

Dr. Ashina (08:00): You don't need imaging. But if you can't exclude ... and if something also ... your gut feeling says that this is something wrong and there's some red flags here — and we have a list of red flags — then you refer [the] patient to neuroimaging. But in ... most of the cases, the vast majority of cases, you don't need imaging.

Paula K. Dumas (08:19): Well said. So, step three: I'm a big fan of patient centricity and education, probably often skipped in actual practice. But how important is it to set reasonable expectations?

Dr. Ashina (08:32): We have to spend some time to explain [to] them about migraine and also to provide appropriate reassurance that here we have a condition which can be managed ... of course there is no guarantee, but we will do our best to manage your condition. And also, realistic objectives, you know? Sometimes when it's very chronic, I would say very frequent, even [a] 30% reduction in terms of the frequency or intensity or duration of the migraine attacks can be a result. So, we have to be also realistic about that, right? And talking about the trigger factors, it is something that in one hand, we can do something about that; on the other hand, maybe we can't do that because trigger factors are very — how to say? — complex, because some of them [are] not really trigger factors because they are not really consistent. And just telling the patients: "Avoid this, avoid this," we can also impair their quality of life. So, this is also important. And also, the strategy, you know, should be individualized because patients are unique, each patient's unique. And there are so many other aspects we have to take it into account when we start planning the treatment. So, I would say step three is very, very important.

Paula K. Dumas (09:59): It is. It can be life-changing for many people. So, step four is what often gets all the attention: the acute treatment. Is there any reason why everyone shouldn't use something like a triptan or a ditan or a gepant? Or is there a role for devices in treating attacks?

Dr. Ashina (10:19): Not everybody is happy with the first-line medications that we showed in our article, for instance, NSAIDs. You know, they could be effective. The diclofenac potassium could be very effective, but in case that it's not effective, you have to think about the triptans. How it's possible after 30 years of having triptans on the market ... we still have a quite large number group of patients [that have] never tried triptans, or [have] tried only one triptan. And with the invention ... the introduction of the new medications, such as gepants and ditans, we will be forced to try triptans because of the reimbursement rules — it could be different things — and in most of the cases, of course. And this is very important. That's why the optimization of acute treatment should be something every neurologist and also GP must remember.

Dr. Ashina (11:15): And if patients are not responding to triptans — they tried some of the triptans, or they have contraindications, or they cannot tolerate, at least in some countries we have now new drugs, and they open up new possibilities. Gepants, ditans — lasmiditan is one of the ditans, it's [the] only one in fact — so we can use that. And many people also ask for medication for nausea or vomiting, you know, during the attacks — not because it can enhance your effect of the acute medications, such as triptans or NSAIDs, it's just because it works. And it can also help your patient, you know, let's say, to ... intake the medication, you know, the oral medication, because they have [such] severe, let's say nausea or vomiting. So acute treatment is very, very important.

Dr. Ashina (12:07): And about other modalities we didn't put here ... you asked about the neuromodulations. Well, in most of the cases, again, you can manage that. And there is so much room for improvement only for this step you can't imagine, Paula. So that's why this is a focus, and we focus most here on the pharmacological treatments. But there are some status showing that [there] might be some effect of the neuromodulation, but I would say that based on the evidence and therapeutic gain, we focused on pharmacological [options] here.

Paula K. Dumas (12:45): Right. And we should say that every year there are new therapies coming out. There's a new one this year that's a DHE device that's used in the nasal cavity. So, this is an area where there's continued development, as well as step five: preventive. We're

getting new preventive options every year. Talk about why CGRPs are considered third-line for preventives.

Dr. Ashina (13:13): Yeah, I would say the reason that the CGRP monoclonal antibodies are considered as third-line medications in our step five is only because of the price — because these medications are very expensive. In an ideal world, if the price ... means nothing, you know, they could be used as a first-line because these medications are designed, developed for migraine prevention, right? All other medications are nonspecific.

Paula K. Dumas (13:48): Well, we have a whole talk on preventive care, but I do want to ask you why this step is so important and why it's often missed.

Dr. Ashina (13:58): If you look back and see, even in the countries, let's say, with quite developed headache medicine, such as U.S. and Denmark, we still have a lot of patients [who have] never tried preventive medications. It's unbelievable. So, forget about the other countries, you know, and especially if you take the rest of the world; you take low-income countries — even worse situations for our patients there, OK. So that's why this step is very important. And by providing some of the first-line medications — such as the beta blockers, which are available in all countries around the world — can you imagine how many people we can help around the world? So, it's not only about the rich countries, but also about the rest of the world. These patients are struggling, you know, and they're fighting with their migraines. They can get these drugs. And some of them are very cheap, such as the beta blockers, let's say. So, this is a very important step, step number five.

Paula K. Dumas (14:57): And thank you so much for bringing up the rest of the world because we oftentimes talk about things that are available in the U.S., but we reach people in over 90 countries. And there are people all around the world watching what you're saying right now saying, "Well, what options do I have and ... why should I bother with preventive?" Is it true that preventive also helps your acute medication work better?

Dr. Ashina (15:22): This is ... let's say, some clinical impression that we have: So, they work better. But the most important thing [is that] the preventive medications [are] not only working on the reduction of frequency, intensity, and duration, but also working on reduction of number of days where you take acute medications. And why [that's] important? Because by taking less acute medication, you can also avoid so-called medication overuse.

Paula K. Dumas (15:55): Excellent point. So, step six is special populations: older adults, children, pregnant … , people with menstrual migraine. What special considerations apply that a physician or patient should think about here?

Dr. Ashina (16:11): Yeah, I mean, this is also [a] very important step, but I would say that this step is, we're going more to the specialized clinics or more the neurologists seeing the patients. Because the GPs, sometimes they hesitate in this with this group of patients. So, they send this group, [this] special population, to the specialists. And here, there are some important points. For instance, when we talk about older people, we have to think about the secondary headaches. We have to think that even [if] it's a primary headache, with age, we unfortunately have more comorbidities, right? And our tolerability changes over the age; and this is also important to take it into account when we have older patients. And also ... for most of the drugs almost, you don't have good evidence in this group. Women, you know, during pregnancy and breastfeeding, I would say, fortunately, it is a not so frequent [of a] problem because most of

the women have wonderful [times], you know, during the pregnancy because the migraine ... almost goes away and sometimes they forget about migraine. But unfortunately, it comes back again and it could be challenging during breastfeeding, in terms of treatment. But during the pregnancy, we also do have some patients having very frequent migraines, you know, bad migraines in terms of intensity. It's really challenging, and our, let's say, treatment possibilities are very limited. We try to avoid preventive medications; in few, few cases, you know, individually, we can do that, but this is not something that I would advise the GPs to do. It's a specialist's, let's say, task, and it should be managed by experts.

Paula K. Dumas (18:20): So, we've talked about the first six steps, which included diagnosis and treatment, and for the last four steps we're really focused on follow-up care. So, what happens in step seven when you experience treatment failure?

Dr. Ashina (18:37): Yeah. In order to prove the treatment failure and also to have more, let's say, reliable data, we need to use some instruments, and they're quite easy. Using the headache calendars are very easy. It could be a paper calendar. It could be just [an] app on your iPhone. I mean, young people, they tend to use apps, and the older population, they use still paper calendars, but they're very good. In the paper calendar, they can indicate their intensity of their attacks, frequency, and also there is a place they can put in acute medications, right? So, you can follow on all three parameters: intensity, frequency, and use of the acute medications, OK; this is very, very important. So, when the patient is back, received, let's say, a beta blocker or topiramate or CGRP monoclonal antibody — it doesn't matter which treatment — you can follow, you can see effects of the treatment on these particular variables, parameters.

Dr. Ashina (19:43): And we can also ask the patients about the adverse events. That's why follow up is very, very important, OK? And when we see something, let's say, failures, then we can also change the strategy. We can change the medication. We don't have to wait ages for that. We can do it pretty fast and try again to find something which will be optimal for our patient. Again, it's always individual cases, OK? Or sometimes we have a problem, and we need to reevaluate our diagnosis. That's not so often, but [it] can be, you know, that we have to reevaluate the diagnosis. So that's why the follow ups are also important. And also, if we are in the GP practice, then we can decide whether these patients should be referred to the specialist.

Paula K. Dumas (20:40): And you hinted at step eight, managing complications, and step nine, managing comorbidities. Are these things that you feel like GPs can do, or does this really take a specialist?

Dr. Ashina (20:52): You know, it all depends. I've seen some GPs with a great interest in headache medicine. So, they're really good in that, and they're doing an excellent job. But we have to respect also their work; the GPs are very busy.

Paula K. Dumas (21:06): Yes. And step 10: We don't want to underestimate long-term follow up, which really means consistent follow up, right? Because migraine is not going to just go away. Is there a point at which it's appropriate to return to the care of a GP after seeing a specialist?

Dr. Ashina (21:24): You know, I'll start by saying that almost 90% of the patients with migraine ... they must be seen by the GPs, and they can be managed in the GP practice. This is, let's say, the optimal dream situation. But if the patients are in specialists' care, we need to have a long-term plan. It's very, very important. And again, being fair to our colleagues, [in] general practice, we

need to provide them a clear-cut plan about the steps — one, two, three, four ... — what to do in this case. So, when they go back to the GP, they can manage that easily.

Paula K. Dumas (22:06): Perhaps you can advise us on how you would apply the 10-step plan. So, Elizabeth says: "I'm 61, and I have had migraine all my life, chronic since my 20s. Since June 2019, I have had nonstop migraine symptoms. The pain varies from mild to agonizing, but the other symptoms are continual: nausea, dizziness, and vertigo. The pain is horrible, but these ongoing symptoms are very debilitating. I don't know what's going on." So how could Elizabeth and her doctor use this 10-step plan?

Dr. Ashina (22:41): I think that we are now managing ... I mean, we are now in the step [where] I would say when we need to talk about preventive treatment, OK? Because the most likely diagnosis here is chronic migraine. And it is a very classical situation when the patient starts with, let's say, frequent or less frequent migraine — a low-frequency migraine — then gradually evolves and becomes never-ending migraine, every day headache and every day, let's say, other symptoms that could be some migraine features, could be not migraine features. So, it's very, very important to say here at this step that we have diagnosis confirmed, and it is chronic migraine. And again, as a neurologist, I would always ask some extra questions to exclude [a] secondary cause. It is unlikely in this case because it gradually developed over time, but any changes, you know, must give some red flags in my mind, just to check — to make sure that there is nothing wrong here; it is not a secondary headache.

Dr. Ashina (23:58): So, it is likely migraine, chronic migraine. So, we need to, again, decide where this patient should be seen, because in any case, we need to talk about realistic objectives here — you know, what we can do for this patient. And then we should accurately assess an acute treatment the patient gets, including the frequency of intake of acute medication, just to make sure that there is no medication overuse here. And if there is medication overuse here, it will bring us automatically to step five, when we have to decide about preventive medications. This will require also ... in this particular case I would say it should be [a] neurologist because it's quite complicated. This will require a review [of] all the medications [the] patient previously failed — or maybe not failed; maybe it was effective 10 years ago, 15 years ago — to assess that, and then make a decision: Which of the preventive treatments should we introduce here?

Paula K. Dumas (25:03): So, Dr. Ashina, who should consider this 10-step approach?

Dr. Ashina (25:09): I think that the 10-steps approach should be considered by general practitioners and neurologists.

Paula K. Dumas (25:17): And which patient groups should consider the 10-step approach?

Dr. Ashina (25:23): This particular 10-step approach is for the patients with common subtypes of migraine: migraine without aura and migraine with aura, and also patients with chronic migraine.

Paula K. Dumas (25:35): Is it appropriate for children?

Dr. Ashina (25:38): These steps are also appropriate for children. And that's why we also included managing migraine in special populations with some modifications, of course. But basically, all the main points are also very relevant for children, as well. The only thing that when

we talk about realistic objectives, we include also parents in this, let's say, situation, and sometimes we can also include teachers from the schools. But this is usually conveyed by parents to teachers, the discussions with the physicians, and the results of the assessment. But you can apply that. Absolutely.

Paula K. Dumas (26:16): So, this is a new approach ... or it's a new plan, maybe not a new approach — you may have just codified it in this plan. And so, many people will be seeing a health care provider who isn't familiar with this. How would you recommend that they share this respectfully?

Dr. Ashina (26:36): I think that ... first of all, this is open access. So, everybody can access this article around the world. And one thing I would like to make sure that [is] not misunderstood, Paula: Because when I say GPs and practitioners, again, I'm talking about the countries where these systems of care provide this service. But in many, many countries, this is not possible, OK. So, if we go to Africa and some African countries, you know, there are some people not necessarily practicing headache medicine. They're general neurologists, or they're internal medicine people; they see patients with headache, and they have also to treat them, so they can also use that.

Paula K. Dumas (27:23): I have found that when I'm talking to a physician who is not a specialist about this, it helps me to print it out. Since it's open access, as you point out, to print out the medical journal in which it appears — and we can add a link to this below your talk — print out the medical journal, so they can see it's from a respected medical journal and the physicians who are associated with it. And then they see the plan in front of them, and they think about, "Well, this is how we could apply this," right? And so sometimes it's the patient bringing those things in, and you want to respect the doctor and their role and not, you know, simply quote something that they're not familiar with. So that might help some people.

Dr. Ashina (28:07): If I was alone and coming with something, that will be questionable; that will be based only on my experience. But here we have many other really good physicians, you know, talking together, working together, and helping with this consensus. This is important. That's why consensus papers are important.

Paula K. Dumas (28:28): Well, I agree, but I'll respectfully highlight a couple of things where I think communication breaks down between a doctor and a patient. One of those is in step three, in setting the right expectations. And another one is basically skipping preventive therapies that can oftentimes help people. And the other one is step seven: When there's treatment failure or complications that come up, some doctors just throw their hands up and say, "Well, there's nothing else I can do for you." And that just slays the patient, who's like, "Ugh, please, you know. I'm counting on you to help me." So, I do love this plan for that reason, that it helps create a dialogue between a patient and their physician in a way that ensures that those steps are not missed.

Dr. Ashina (29:23): Absolutely. As I also pointed out, step three is essential. It's so important because this alliance, you know, and realistic expectations, everything, the chemistry between physician and the patient, is extremely important; it starts from there, OK. It's a best standing point, you know, and if you're successful there, you'll be happy and your patient will be happy.

Paula K. Dumas (29:48): And sometimes I think that these situations, these kinds of appointments, are education one appointment at a time. And just simply leaving behind that

plan for a time when the physician has more time to digest it, understand it, and think about it, could help so many more patients who walk in after I do. Then it's worth it. It's worth it. And maybe the next appointment will be better. And maybe if it's not, you need to find another physician. But these are real things that people deal with, so I thought it was important to bring that up.

Paula K. Dumas (30:22): Dr. Ashina, thank you so much, first of all, for all your advocacy, for your leadership in this field, and for creating this plan, which could really be a game changer for so many people struggling to operate within our health care system.

Dr. Ashina (30:38): Thank you so much, Paula. Thank you for inviting me.

Paula K. Dumas (30:41): My pleasure.