

**SANJAY PATEL:** I was on a clinical practice guidelines committee for the American Academy of Sleep Medicine, which gave me the opportunity to review a lot of data that I'm going to present to you on just how to manage patients with obstructive sleep apnea. In terms of background, most of you probably are well aware of this but obstructive sleep apnea is extremely common. Recent data from epidemiologic studies suggests that among middle aged Americans, 33% have some level of obstructive sleep apnea and 13% have moderate to severe obstructive sleep apnea.

This is much more common than estimates from 20 years ago, and that has primarily-- well, it has some to do with the aging of America, but much more to do with the fact that we're a much more obese country than we were 20 years ago. But these prevalence numbers suggest that sleep apnea is the most common respiratory disorder that exists. These numbers are much higher than prevalences for COPD or asthma. And so obviously this is something of relevance to pulmonologists.

We also know that there are established treatments for sleep apnea. CPAP, as you all know, is first line therapy. There's many randomized trials that show that CPAP improves sleep quality, daytime functioning, blood pressure, and there's some mixed data as far as cardiovascular risk with a lot of studies still going on in that area. Despite the fact that we have an established treatment, population studies suggest that only about 5% of people with obstructive sleep apnea are on treatment. And that's due both to the fact that they're suboptimal diagnosis-- the vast majority of people with sleep apnea don't know they have the disease-- and also suboptimal treatment.

In many cohort studies where people as part of research have sleep studies, and they're told, and their physicians get a letter saying they have sleep apnea, when those people are followed up five and 10 years later, the number of people who are on treatment, even though their doctors have been told and the patients have been told, is still only 5% to 10%. So we do a poor job both in diagnosing the disease and treating the disease.

And a big part of that has to do with our health care delivery model. So this has sort of been our traditional model for the last 40 years on how to treat patients with obstructive sleep apnea. If somebody has symptoms that suggests sleep apnea, we schedule them to come into the sleep lab for a sleep study and then we schedule them to come back into the sleep lab for CPAP titration study to figure out what settings on their CPAP they should have. And then only after that do they finally get any treatment. And so this leads to a lot of delays and a lot of patients just giving up.

So again the traditional pathway, the limitations of it are you can't get patients through fast enough because you're limited by the number of beds and the number of technicians. And so this leads to long waiting times. And our own sleep lab here at Montefiore has waiting times in excess of two months. So if you think about getting a sleep study and then getting a CPAP titration study, you're talking about patients waiting four to five months to start treatment.

It's also inconvenient to most patients, particularly those who have caregiver responsibilities. So if you have single parents with small children, they can't really leave their kids home alone at night. Those who are shift workers who work at night and sleep during the day, they can't really come into the sleep lab to sleep during the normal schedule. People who live far away from the sleep lab, which is a large proportion of our patient population, it's inconvenient for them to drive 60 miles to spend the night here and then drive 60 miles to go to work. And again, these long delays in initiating treatment reduce uptake of therapy.

And so there's been a lot of work over the last 10 to 15 years on developing easier ways to make a diagnosis, and home sleep testing has really come a long way. This picture just shows what an in-lab sleep study setup looks like in terms of having all of these electrodes on the head to measure EEG, muscle tone, eye movements as opposed to a home sleep monitor which really focuses on just respiratory channels. So nasal cannula in the nose to measure airflow, a band either over the chest and/or abdomen to measure effort, and then a pulse ox to measure oxygen saturation. And this is something simple enough that people can do by themselves in their home.

In addition to developing the home sleep testing, there's been the development of auto titrating CPAP machines. And these were developed to try to lower the pressure that patients need over the course of the night by finding the right pressure needed to keep the airway open over the night. And what these devices do is they send flow coming out of the patient as well as impedance, and they adjust the pressure up or down to maintain an open airway through the night.

And as you can see in this schematic here, what they can do is really adjust the pressure. It starts at a low pressure, it goes up over the course of the night to this sort of maximal pressure when the person may be laying on his back and in REM sleep. And then as they go into other stages of sleep where they don't need as much pressure, the pressure comes back down. And using this, you're able to decrease pressure by an average of two centimeters of water. This was developed thinking that this would make CPAP more comfortable, but really where it's proven to be useful is that you don't need to do a CPAP titration study anymore because you have a computer algorithm that can figure out the pressure the patient requires.

And there have been a lot of trials, this is just a meta analysis of over 20 trials comparing auto titrating CPAP to CPAP where a technician has found the pressure required for the patient. And overall, the meta analysis suggests that there are small differences, but in general they favor auto trading CPAP. Compliance increases by 11 minutes, sleepiness as assessed by the upper sleepiness score drops by about half a point. You can argue whether these are clinically important, but everything suggests that APAP is not worse than CPAP, and it may be a little bit better.

So the new paradigm for diagnosing and treating people with sleep apnea is if somebody has possible sleep apnea, you get a home sleep test. If the test is positive, you start them on APAP. They don't need to come into the sleep lab at all. And in our clinic, when we see somebody in clinic, we can give them a home sleep test that same day before they leave clinic, get the study scored within a week, and get them started on treatment and save five months. And then if the test is negative, we can evaluate for alternative diagnoses. And so this is much more in line with how we treat asthma or COPD. So they've been-- go ahead.

**AUDIENCE:** In that algorithm, do you need the patient to come back to get to that next step of prescribing the APAP?

**SANJAY PATEL:** No, because the APAP is delivered by a DME company. So they need to return the home sleep test either in person or they mail it back. You download the data, get a result just like you would interpret the PFDs, and then based on those results you can send a prescription to the DME, and the DME will arrange for an appointment to start the patient on APAP.

**AUDIENCE:** And they'll train them [INAUDIBLE]?

**SANJAY PATEL:** They'll have the patient come to the DME. It used to be the DMEs went to patients' homes, but as reimbursement has gone down because of Medicare rules, the DMEs don't do that anymore generally. So there've been a number of trials comparing a home based versus a lab based strategy. These are four trials that followed patients for 90 days. They all recruited patients who are at high risk for obstructive sleep apnea, and they evaluated patients who were found to have moderate to severe obstructive sleep apnea.

And this first trial was from Canada, the next two were from the US, one in the VA system and one in a regular academic health care system multi-center trial, and then the last trial was done in Hong Kong. And in all of these settings, you can see if you look at CPAP adherence, all of them tended to have better adherence with the home based strategy. So the Canadian study 6 versus 5.4 hours, and you can see all of these tended to favor the home based strategy. If you look at the sleepiness improvement or the quality of life improvement, there's really no significant difference between any of these studies. There are two shorter term trials that were less than 90 days. They also found no difference between a home based strategy and a lab based strategy. So there's really been no study that suggests that patients have better outcomes if they go through the lab.

Now, what are the limitations? All of these studies excluded patients who were at high risk of other forms of sleep disorder breathing. So if you have patients who are at high risk of central sleep apnea because they have severe heart failure or are on opiates or hyperventilation because they have significant COPD, we don't really have any data on those patients.

The other limitation is that all these studies really focused on patients who are at high risk for obstructive sleep apnea. And so that left people saying, well, maybe those who are low risk for sleep apnea shouldn't really get evaluated because you may have a false negative with the home test. And also there's a question of how do you manage those with negative home studies? Some of the guidelines would suggest that patients with a negative home sleep test should get an in-lab sleep study to follow up, and that sort of defeats the purpose of doing the home test if you're going to end up sending them to the lab anyway.

So there's two trials that have come out in the last year that really try to answer the second set of questions. The first trial is from Australia. It's a multi-center trial where they really recruited anybody who was being referred for evaluation of obstructive sleep apnea, whether they were low or high risk. And they had all these people have an in lab sleep study because that's what their health system is structured around, but what they did do is they limited the data that they gave the provider.

So people were randomized to either get all of the in lab sleep study results to their physician, just what you would get from a home test, or just overnight oximetry and say let's see how the physicians do with only limited amount of data to make treatment decisions. At the end of four months, both in terms of looking at the clinical response the patient had to the original treatment plan as well as seeing all of the data, the physicians could change their treatment plan and their diagnosis.

And so in this trial, you can see the percentage of people who were initially diagnosed with moderate to severe obstructive sleep apnea was identical whether you had a full sleep study home sleep test or oximetry. It's not hard to miss that diagnosis. And really, probably oximetry is good enough to make that diagnosis. But for mild obstructive sleep apnea, the home sleep tests tended to overdiagnose mild sleep apnea in this trial while there was people who were given non respiratory diagnoses were under diagnosed compared to the PSG.

After four months when they unblinded the physicians, you can see the mild sleep apnea diagnoses went down a little bit with the home sleep testing, but they went up a little bit with the sleep study. So the truth is probably somewhere in between what the full sleep study and the home sleep tests were giving people. And when you looked at what treatments patients got, there really was no difference in the treatment options that patients were given by their physicians depending on what data the physicians had.

When we looked at outcomes that patients care about, you can see quality of life improve the same amount in the home sleep versus in lab arms, oximetry didn't improve as much. In terms of sleepiness, again, the oximetry didn't improve as much while there was no difference between the full sleep study and the home sleep test. CPAP usage, again, was also identical in the full sleep test versus the home sleep test arms, so really suggests that even low risk patients do fine with home sleep tests.

A second study really fully tested the idea of just doing home sleep testing. This was a multi-center trial out of Spain that basically randomized people to actually get a home sleep test versus a full sleep study. And then based on those results, if they were going to get treated for sleep apnea, they got APAP since Spain has pretty much moved to everyone just getting an APAP.

In this study, they did a good job of not having any crossover. So if a person had a negative home sleep test, they just didn't get treated for sleep apnea. They didn't follow up with a full sleep study to make sure they didn't have sleep apnea. In this study, unlike the Australian study, the number of patients who were started on CPAP was a little bit higher with the in lab sleep studies compared to the home sleep test, and the thought is that the in lab sleep studies were a bit more sensitive for picking up mild sleep apnea than home sleep tests.

Nevertheless, when you look at patient outcomes, the quality of life, and sleepiness, there is really no difference in the improvement seen with the in lab arm versus the home arm. Similarly, no differences in blood pressure, CPAP adherence, traffic accidents, hospitalizations, cardiovascular events. And when you looked at costs, the cost per patient was half as much using a home sleep test arm versus a full sleep study. And again, none of these patients came back to the sleep lab for CPAP titration, they all got APAP. So to compare this to our traditional treatment arm, the cost difference would be even greater.

So I think the take home messages is really a home based strategy should be your default for evaluating patients with sleep apnea, and you should really only use the lab if there is a real reason to do so. So again, some of the reasons are if you think that a person may have a disease other than obstructive sleep apnea like central sleep apnea hypoventilation, narcolepsy, or something else. So-- yeah?

**AUDIENCE:** I assume that auto titrating CPAP costs more than a regular CPAP machine? And if that's true, are there issues with home care providers?

**SANJAY PATEL:** So I'll tell you that more and more home care providers are using auto titrating CPAP machines because it's easier for them to adjust settings down the line. Even though there's a higher upfront cost to them, the amount that's billed to insurance is the same. So the amount patients feel is the same. And they've decided it's a cost effective solution for them because they don't have to send technicians to adjust pressures down the line. I think one of the benefits of this is over the lifetime of the machine if a patient gains 20 pounds, you don't need to do another study or re-evaluate the patient because it's auto titrating, it will automatically adjust the pressure on the patient. Medicare, which is our most common DME, automatically sets everybody up on an auto titrating machine even if you prescribe a fixed pressure.

So want to turn to CPAP adherence, and this is sort of the big bugaboo in managing patients with sleep apnea is how do you get the patient to use their CPAP. We know from a number of studies that 10% of patients who you prescribe CPAP to don't fill the prescription, another 10% just throw it away or stick it in their closet after one day, and up to 50% of patients abandon CPAP after one year. And so one of the big challenges is how do we do a better job of getting patients to use the treatment?

And there's been a lot of work in this area, and they follow down one to two strategies. One is to try to make the machine better, and the other is to make the patient better. And probably in the next 20 minutes I'd like to convince you that trying to work on the patient is a lot more effective a strategy than trying to work on the machine, even though the respiratory therapists in us like to play around with the machines.

So probably the most effective thing that you can do in terms of the machine is pick the right mask. And so those of you who haven't seen a whole lot of masks, these are the three basic categories of mask. The nasal pillows that go in your nostril, the nasal mask that covers your nose, and then the full face mask that patients call the Darth Vader mask.

This was a study done by a company that was trying to develop and brand an oral mask. Nobody really uses oral mask, but I think this study is instructive in that they had patients on a nasal mask and a full face mask in the study. And so what they did is they actually allowed patients to try all three types of masks, and see what it felt like, and then choose one to take home. And then after three weeks, they came back for CPAP titration and they were followed for six months.

And so when patients get to choose what kind of mask they think is most comfortable, they overwhelmingly choose a nasal mask. And very few choose a full face mask. And I think this is really important because for some reason, respiratory therapists, sleep techs, physicians are obsessed about using full face mask. I don't know if that comes from what we do in the ICU or why, but patients don't like the Darth Vader mask. And I think if you put on the mask, it becomes really obvious why they don't like the full face mask.

But interestingly, when they looked at the pressure required, the patients required higher pressures if they're on a full face mask, their adherence was lower if they're on a full face mask, and they were much more likely to give up and stop using their CPAP if they've gotten a full face mask. There's been only one randomized trial comparing nasal mask to full face mask. It was a small British study of 20 patients, but it was a crossover trial, so really you're comparing patients to themselves. They used either a nasal mask or a full face mask in one order or the opposite order. When they use a nasal mask, their usage was one hour a night greater. Their sleepiness was nearly two points lower. And when you ask patients at the end of it which one did you prefer, 95% of patients prefer a nasal mask. I think that's the take home message for all the fellows.

This is a study from France, just a big registry of patients who get care for sleep apnea in multiple hospitals throughout France. Over 2000 patients-- in their clinical practice, 62% of patients get nasal masks and about a quarter get full face mask. And what they found was that adherence was lower if you were on a full face mask compared to a nasal mask with pillows, and the pressure was higher if you're on a full face mask. And adjusting for side effects and everything else, you were twice as likely to be non adherent with CPAP if you were given a full face mask.

This is a study from Australia where sleep techs choose what kind of mask the patients get, and this unfortunately reflects a practice similar to the US where patients-- when the techs get to choose, they give people full face masks a lot more than patients would choose. But any patient who got a full face mask, they tended to have higher pressures and higher residual HIs, so they tended to have a harder time getting their sleep apnea treated.

And that was especially true-- if you looked at people who required CPAP pressures that were greater than 15 centimeters, 80% of them were on a full face mask. And this has led to a questioning of whether full face masks cause obstruction of the airway and lead people to needing higher pressures. And there's been case series to suggest that this is the case for some patients. So these are four patients who are failing CPAP because they had a high residual HI even on CPAP, and you can see at least three of them were on really high pressures. And despite these high pressures-- 18 centimeters of water, 19 centimeters of water-- their HI was really high, and in many cases about equivalent to what their untreated HI was.

And when these people-- all they did is they switched them from a full face mask to a nasal mask, they were able to get control of their sleep apnea. Their HI dropped remarkably, and often they were able to drop their pressures, as well. And the point is when you put a full face mask on, the mask is pushing the mandible back and obstructing the airway. And so as you increase the pressure, you're also increasing the obstruction, and you can never get to a point where you can open the obstruction in these patients.

**AUDIENCE:** So in that group of four patients, the one patient that I think is most like our patients is patient 4, the high BMI, looks like a high prescribed level of CPAP. Is there any data on whether the compliance is the same across severity of sleep apnea?

**SANJAY PATEL:** So in general as severity goes up, compliance goes up. And that's probably mediated through symptoms. The strongest predictor of adherence is symptoms.

**AUDIENCE:** So you can use a nasal mask in someone with very high pressures?

**SANJAY PATEL:** Yeah. I think this is sort of a fallacy is that the engineers-- the lawyers for the CPAP manufacturers have told the manufacturers to say in some of their technical writing that the masks have only been tested-- the nasal mask and pillows have only been tested up to a certain pressure, and so people have taken that to mean that you can't use it at high pressures. It's just that the manufacturers are trying to get out of being legally liable. And so the lawyers have written things saying this has only been tested up to a CPAP of 15. But there's no reason that-- there's no reason to think, and if you talk to the manufacturers off the record, they have no concerns about using the nasal pillows at 18 or 19.

**AUDIENCE:** We use it in almost all of our neuromuscular people were pressing like 35, 40, and it works better if we get similar data with the full [INAUDIBLE].

**AUDIENCE:** They just have really [SNIFFS] cleared out after that.

**AUDIENCE:** That's kind of what I was going to ask, do you ever have issues with nasal congestion in these patients being a significant problem that you couldn't use a nasal mask because of it?

**SANJAY PATEL:** Oh sure, so there are people who have significant nasal pathology. Most people, though, have nasal congestion, and it's kind of a hit or miss thing. Some people after you put them on the nasal mask they say, oh, my nasal congestion has gotten so much better because I'm wearing my CPAP now and it's blowing open my airways, and some patients say it's worse. I mean, I think it's better to try using the nasal mask, maybe give them some Flonase and see how it goes. And if they fail, then maybe try the full face mask rather than saying, oh, well you have a lot of nasal congestion, so you must need a full face mask.

**AUDIENCE:** I guess with data that's like this, that it's pretty convincing that a nasal mask is better, why is the recommendation that a full face mask is even an option?

**SANJAY PATEL:** I think it's an option because there are patients who, you know, they played hockey, and broke their nose five times, and they can't breathe through their nose. Right. The take home message is don't use full face mask unless the patient really has failed a nasal mask. I want to talk about bilevel PAP or BPAP now. As many of you know, Mark Sanders invented it here at Pitt. And so it's-- I can tell you it's much more popular here than in Boston where I was before here because of that local history.

As I think all of you know, the idea of bilevel is that it gives a higher pressure during inspiration and lower pressure during expiration, and obviously has lifesaving abilities in patients who have respiratory failure and helping ventilate patients. Mark actually developed it to try to increase adherence to CPAP by saying, oh, patients will feel more comfortable if they feel the pressure is lower during expiration for obstructive sleep apnea.

I think he developed something really important, but he had the wrong ideas about it. Because in obstructive sleep apnea, the evidence that it helps is not very strong. So here is a trial from the Mayo Clinic where they randomized people to CPAP versus BPAP, and you can see that compliance is exactly the same, 5.6 hours versus 5.6 hours.

There's been four trials of bilateral PAP versus CPAP as primary treatment of obstructive sleep apnea, and you can see the summary from the Cochrane meta analysis that black diamond is right exactly on 0. You couldn't plan for it to be any better. There's an additional study where they took people who had failed CPAP and had them try CPAP versus BPAP and asked them which they preferred, and you can see there's no real preference. 40% preferred CPAP, 40% BPAP, and 20% just said, get me away from this.

In addition to the BPAP data, there's just sort of been this idea from the CPAP manufacturers. Again, there is this prevailing theory about 10 years ago that if you reduce expiratory pressures, you'd make PAP therapy more comfortable. And so the CPAP manufacturers developed this expiratory pressure relief. And what this is is basically the idea that you reduce extra pressure only an early exhalation when the person is actually trying to exhale, and then you allow it to come back up towards end exhalation when there's very little flow. And that way you don't run the risk of allowing the airway to collapse. But you do give the patient the opportunity to exhale against the lower pressure. So when they need to the pressure to be lower, it's lower.

So all the CPAP manufacturers have this feature now, and it's standard in CPAP machines that you can use. There have been about five trials comparing CPAP without this feature to CPAP with this feature, and they've all shown no effect of this. But the manufacturers still market it and do promotional lunches and stuff. This is the biggest trial from France, over 200 patients. And you can see using the expiratory pressure release, their trademark for this manufacturer, C-Flex. The adherence goes up by 0.07 hours, which is not significant. The sleepiness is not different. There's also no difference in symptom side effects or comfort.

And I think the idea is that it's really a very small percentage of people who have trouble using CPAP because they have difficulty exhaling. The issues are much more related to psychological issues of accepting that they're sick, or have an illness, or how this makes me look to my partner, and just sort of those issues are the reasons that are much more common for why people don't use their CPAP as opposed to I can't exhale against this.

That having been said, there was this trial, it was a multi-center. We were one of the sites, Pat Strollo was involved, looking at patients who had truly failed CPAP. And the nice thing that they did is they didn't just say, oh, the patient says I don't like using my CPAP, but they actually work with the patient to educate the patient on the importance of using the CPAP, troubleshooting what was wrong, giving them a new mask. And when they did that, 25% of patients became compliant. Of the remainder, they then randomized them to CPAP versus bilevel. And when they did that, there was an improvement in compliance rates, 49% with BPAP, 28% with CPAP. You can see you still got another 25% compliant by just giving them more time.

But there are clearly some patients who can't tolerate CPAP who will eventually, after you've tried everything else, do better by giving them some lower pressure during expiration. But it's a small percentage. And I think now that expiratory pressure relief is standard on all CPAP machines, instead of having the patient buy a new machine, spend another \$1,000, you can just turn on the expiratory pressure relief if the person is having problems. And so I think there's clearly no reason for a routine use for bilevel PAP.

If the patient does have pressure and tolerance, and is clearly stating that they can't exhale against the pressure, that expiratory pressure relief is a lot quicker and cheaper to do, you can do it remotely. So if a person calls you on the phone, you can just do it and turn it on, then ordering the person and BiPAP machine. And so there's not much use for BiPAP in obstructive sleep apnea as opposed to other diseases.

**AUDIENCE:** Can I ask a question about that? Is there any data you get from the machine that can tell you objectively if this is an issue or not? There may not be, but I'm just wondering about effort measurements against expiratory pressure, something like that besides that are sort of subjective?

**SANJAY PATEL:** No, I mean, it's really based on history. I mean, usually if you get-- I mean, often patients say I have trouble breathing and you really have to get them to think through is it that I am having trouble where I feel like the air's too much, or am I having trouble breathing out against it to sort it out. But from the device itself I don't think you can tell.

**AUDIENCE:** So if you have signs of chronic retention like on blood gas or something like that--

**SANJAY PATEL:** CO2 retention?

**AUDIENCE:** Yes, [INAUDIBLE] CO2 retention, that still would be reason to start with an auto titrating CPAP before BiPAP?



**SANJAY PATEL:** So I'm talking about obstructive sleep apnea only, I'm not talking about hypoventilation syndrome. So if you have a patient with obesity hypoventilation syndrome, I think there's some data to suggest that helping that patient ventilate with BiPAP may improve functional status quicker than CPAP.

**AUDIENCE:** [INAUDIBLE] comment in a titration study where someone could switch from CPAP to BiPAP?

**SANJAY PATEL:** Yeah, and I think that's done prematurely. I think the patient says, you know, you wake the person up at 1 o'clock in the morning, say you have a horrible sleep apnea, we're going to put this mask on your face. And they say, oh my God, I'm having trouble breathing. And then you're like, oh, you can't tolerate CPAP, let's switch you to BiPAP. I think that's not giving the person enough time, and educating them enough, and switching to BiPAP too quickly.

**AUDIENCE:** So just say shut up and go to sleep.

**SANJAY PATEL:** I mean, I think it's just habituating the person.

**AUDIENCE:** But it sounds like mostly now we should be doing these at home with an auto CPAP, and giving them some time, it sounds like.

**SANJAY PATEL:** Right, yeah. So so there is a practical reason to use BiPAP, and that's that you can-- is Medicare has these weird rules where you have 90 days to be compliant or Medicare takes away your machine. And if they take away your machine, you then have one of two options. You can start over from the beginning, and order another sleep study, and prove they still have sleep apnea which they had three months ago, or you can prescribe them BiPAP. And so there's no evidence for it, but there's no evidence for anything Medicare does.

All right, so we'll talk about improving the patient. Most of this is kind of obvious and applies to basically every chronic disease. Clearly educating patients about their disease, and why it's bad for them, and why treatment is good for them improves adherence to every treatment-- every disease. So with sleep apnea, the point is to make sure patients understand what sleep apnea is, why it's bad for you, and how CPAP treats it, and what benefits patients can expect to get from it.

Like with many other diseases, there have been some studies to suggest that patients with sleep apnea don't really understand what their disease is and have sort of doubts about it. I think it's particularly true for sleep disorders like sleep apnea because the patient is unconscious when most of their symptoms are happening. So they tend to underestimate the severity of their disease.

They think that, you know, their spouse or the other family members who are saying he snores like crazy, and stops breathing, and is choking, they think that they're overestimating it and their symptoms are not as bad as their family members are saying. And they don't-- they tend not to trust in lab studies because they say my sleep was different there. In my experience, when you do a home studies they still sort of say I'm not sure I trust that either. I think patients just have a lot of ambivalence about this.

A lot of studies have shown that doing an educational intervention improves CPAP adherence. It makes sense. But I think the issue is that oftentimes patients are sort of told your HI is 23, you have sleep apnea, you should get treated, and no one stops to explain what that is. And I think spending time to explain what sleep apnea is and physiologically what's happening, and that their oxygen levels are dropping, and what that does goes a long way towards improving adherence. There is a recent study from Colorado that suggested that showing people their sleep study results improves adherence. That when they see their own sleep tracings, and see their apneas, and see the oxygen desaturations, they're more accepting that they do have something wrong with them that needs treatment.

So adherence monitoring has become really popular. One of the advantages of sleep apnea versus other chronic diseases is that we can track people's usage of their CPAP. The devices all send data remotely to a server that all of us can access. So you can see exactly how much people use their CPAP each night. This was a trial by [INAUDIBLE] Fox at University of British Columbia when she was a graduate student, and what she did she basically randomized people to usual care versus a monitoring strategy where every morning she would go in, and log in, and look at her patient's CPAP compliance. And if they didn't use their CPAP for two days in a row, she called them up and said, hey, what's wrong, why didn't you use your CPAP? And when she did that, she got people to increase their usage by 90 minutes a day. So clearly if you track people and let them know that you're watching-- [LAUGHTER]

**AUDIENCE:** Has anybody done integration of mobile apps with this kind of stuff where the patient actually gets to control some of the feedback?

**SANJAY PATEL:** You're stealing my thunder.

**AUDIENCE:** Oh, I'm sorry. [LAUGHTER]

**SANJAY PATEL:** I'm going to get there, yeah. So obviously, the problem though is not all of us have a graduate student working on graduate student wages to do this. But there have been a bunch of trials trying to come up with different strategies, some of them using machines. So just kind of a computer that calls people when it sees that you haven't used your CPAP. It's generally shown that watching people closely and intervening when you first see that they're having problems has a lot more of an effect rather than having them wait a month or two because you have a window of opportunity where patients are starting to get frustrated and you can intervene and change their behavior. But if you wait a month, they basically give up and don't come back to see you.

Behavior change is another strategy that's been used in a lot of chronic diseases developed in-- motivational interviewing, for example, is developed in addiction therapy. It's been shown to be really useful in smoking cessation. But it applies to CPAP use in sleep apnea, as well. And so the point is that patients are ambivalent. They know they have a problem, but they also know that CPAP is not something they enjoy. And so whether or not they should use it kind of is sort of an area that they're not completely excited about.

To get people to use CPAP, the theory is that you have to get them to want to change, and you have to get them to believe that they can change. And that second part is something that we tend to do a poor job of. So the goals are to resolve the ambivalence, and make patients want to change, and to increase their self-efficacy, the belief that they can master how to use their CPAP and overcome the problems they're having with it.

So this is a trial I was involved in where we took patients-- we basically recruited patients out of cardiology clinics, screened them for sleep apnea. If they had sleep apnea, we randomized them to just usual care with CPAP versus a motivational enhancement intervention where they met with a psychologist twice and then got five phone calls over six months to just try to increase their motivation to say, hey, you can do this. And by doing that, we were able to increase adherence by an hour at six months, and that persisted out to a year in the subgroup that were followed up that long.

Again, the challenge is how do you do this in a feasible way in general clinical care? And there's a lot of work trying to develop, sort of figure out what's the least dose of motivation you can use. But I think it's pretty clear that trying to use these sort of strategies and regular care by the physician can only help.

So some meta analysis again from the Cochrane group that suggests that there is a significant improvement with a lot of these behavioral interventions. And when you look at the effect sizes of these behavioral and-- these different interventions, you can see education, which is clearly the most feasible, increases adherence by 35 minutes a night, troubleshooting by 50 minutes, and behavioral modification by 86 minutes overall. So I'd argue that these strategies deserve a lot more time spent on them rather than playing around with the EPR or thinking about BiPAP or not.

So again, spending time with the patient does work. And then to get to Ian's point, I think, again, with a lot of behavioral interventions, it's clear that patients who understand what they're doing are much more likely to be adherent. So if you want somebody to lose weight, the first key is to have them count calories. Because when they're counting their calories, they know whether they're above or below their target, and they're much more likely to change their behavior to hit their target.

So this is a trial from the University of Pennsylvania where they randomized patients starting CPAP to either usual care with a login where they could log in and see how much they were using their CPAP or both of those things plus a financial incentive where they got paid. And what you can see is when people had the ability to see how much they were using their CPAP, they used their CPAP more-- 1 and 1/2 hours more per night one week and over an hour more at three months. And interestingly, when you paid them you didn't increase it any further.

**AUDIENCE:** How much did it pay?

**SANJAY PATEL:** It wasn't-- yeah, this was-- [LAUGHTER] they paid them sort of-- it was kind of like \$5 per login. But you could argue, they recruited patients in the main line of Philadelphia who \$5 may not mean a whole lot. But the CPAP manufacturers have created these mobile apps that will-- you can put on your phone, and it will let patients know how much their CPAP usage is. And so you can see every morning how much you used your CPAP.

And these are retrospective analyses from the two leading manufacturers. Both of them show that patients who use their app have much higher adherence levels than patients who don't use the app. And so you could argue that-- there's obviously some selection bias in that the patients who use the app are probably more engaged to begin with, but I think combined with University of Pennsylvania study and the fact that these apps are free, there's really little downside to using these. They can only help, and they will get patients more engaged. They don't have to have a smartphone. You can sign up and then just log in if you're worried about the manufacturer tracking you.

And the manufacturers have developed a lot more bells and whistles. So currently this is one of the apps. Not only does it show how many hours you used, but it shows how well your mask fit, what your residual HI is. And so if you have an engaged patient, they'll call you and say, hey, my residual HI was 15. I think there's something wrong. Can I come in and see you?

They also used some motivational enhancement ideas by giving patients gold stars, and trophies, and things like that for setting goals. So just like the weight loss apps, you can set a personal goal to say, my goal is to use my CPAP for 10 days in a row, and then you get a lot of positive feedback for hitting those goals. Which again, in a lot of chronic diseases has been shown to help. I think the point of self monitoring in a lot of diseases has been shown to increase adherence, and it does appear to do that in sleep apnea, as well. And the fact that it's free means there's really little reason to not use this.

So I'll summarize again just saying home based strategies is just as good and quicker than an in lab strategy for diagnosing, getting people started on treatment. There's a lot of evidence that full face masks don't work as well as nasal masks. BiPAP is rarely the answer. Enabling patients is much more effective than tweaking their machine, and then every patient should really be tracking their own usage. And I think it makes sense to encourage patients to download the app and sort of take control of their disease.