

Merging Sleep Diagnostics with Therapy is the Way of the Future

If sleep apnea is a chronic condition, shouldn't it be treated as such? After all, says *Hani Kayyali, President of CleveMed*, hypertension patients regularly monitor their blood pressure and diabetics keep track of glucose levels. In a recent conversation, Kayyali contends that CPAP therapy should also be regularly checked to ensure that patients receive optimum therapy.

IS THERE ANYTHING WE SHOULD CHANGE OR ADD TO THE CURRENT CPAP SYSTEM?

The actual CPAP systems are doing just fine for titration, for treatment of OSA, or improving some of the complex patients (BiPAP, ASV, etc). The potential change lies in how to expand their utility into other applications, such as home auto-titrations, in a manner that can facilitate patient's lives without compromising care. AutoCPAP's have been around for many years and while they can not, and should not, auto-titrate all sleep disordered breathing (SDB) patients especially those with serious comorbidities, many OSA patients may truly benefit from home titration. CMS and many other insurance companies and providers have worked very hard to shift baseline PSG evaluation from the lab to the home but shied away from giving CPAP titration the same attention. So, patients will still have to go to the sleep lab anyways for titration before CPAP can be initiated. Adoption of home auto-titration has been limited, rightfully so, due to concerns that the machines are running "solo" without adequate documentation of the patient response during pressure fluctuations. One project we are completing is to wirelessly integrate our home sleep monitors with CPAPs so that a comprehensive sleep study can be generated during therapy. The most intriguing part is that our "HST during CPAP" technology is actually easier to implement in the home than baseline HST. With just three external sensors that patients can easily self-administer a sleep study with up to 10 channels can be generated. We all know that if any home testing technology is ever to succeed it must be extremely easy to self-administer. Many, including CleveMed, are addressing this ease-of-use issue for the first night study, but HST during CPAP is rarely discussed.

WHAT ABOUT COMPLEX SLEEP APNEA (CSA), IS IT FOR REAL AND DO WE NEED NEW TREATMENTS FOR IT?

Much research by reputable groups like those in Mayo and Beth Israel have shown that not only is it for real but it is somewhat common, with prevalence as high as 15% to 20% in some articles. So, yes I believe it is for real and is another sign of the complexity of sleep disordered breathing. The ASV at this point is showing some benefit, however there is research demonstrating that ASV might not be beneficial to all complex sleep apnea patients. There is a need to develop new treatment modalities for CSA patients, and potentially for patients with other comorbidities. We have a CPAP research project that tackles CSA in a way that is different from any other commercial

technique. Call it the next level ASV to treat central and complex disease; we are working with clinicians at Beth Israel on this project. We received NIH funding to test 12 patients in the first phase, and another 100 patients in the second phase. It is carbon dioxide-based, so we would be injecting small amounts of carbon dioxide to prevent hypocapnic episodes. But that is a long-term project.

WHAT IS THE MOST IMPORTANT PART OF A CPAP TITRATION OR A CPAP TEST?

The most important part, whether it is in the lab or the home, is the resolution of the OSA without inducing or generating the central events—which is what titration is all about. And in reaching that fine compromise, CPAP is effective in resolving the obstructive part of the story. The critical part is how can this be done and re-titrated if needed in the home, which was discussed earlier!

ONCE THE PATIENT IS HOME, WHAT CAN WE DO TO HELP COMPLIANCE?

There are two areas to improve upon. The first is education. Stay close to patients. Call them up. Make sure they are using the device, and make sure they know about the benefits of the CPAP machine. At least in the first few weeks, patients need to be in close contact with the provider. Many DME providers already have excellent follow-up programs.

The other component, however, is not as widely discussed, but it is just as important if not moreso. In addition to educating the patient, we should adequately monitor therapy efficacy especially in the long-term when CPAP had been paid for, phone follow-up had dwindled and attention has shifted to the next patient. Documenting treatment benefit is central to the new CPAP reimbursement ruling although payers settled on a pretty low threshold for such documentation. At least for now, CPAP usage time is all that is required to prove therapy efficacy. The argument is that patients using CPAP even for a few hours a night must mean that they are benefiting from it. Generally speaking this is true during the weeks following the titration study since factors that alter response to CPAP such as weight gain, life style changes, emergent comorbidities do not develop quickly. But the critical question is not whether there is benefit or not, it is how much benefit is being received. Making sure therapy is optimized, not just utilized, will maximize outcome and ensure continued compliance months and years down the road.

A HST during CPAP is the ideal way to comprehensively assess benefit, which must be our "therapy efficacy" target, especially for long-term follow-up. Applying HST during CPAP months and years after therapy initiation is needed for SDB. Of course, to succeed in such higher standard follow-up, two factors must be met: 1) it must be inexpensive, and 2) easy-to-administer in the home. That is where CleveMed comes in.

The same technology I described earlier can be mailed to the patient. A complete sleep study with AHI measures generated, and therapy tracked effectively.

It took us a long time to recognize that sleep apnea is a chronic disease, but now the next wave of discussion and technology development is not going to be as much about baseline evaluation, or even initiating CPAP, but about maintaining CPAP and managing patients.

CPAP COMPLIANCE, HOME TESTING AND TESTING FOR EFFICIENT PRESSURE

Look at other chronic disease states, "How is hypertension done right now?". We don't leave these patients without monitoring their blood pressure. Some patients monitor their blood pressure in the clinic routinely, some at home using diaries or telehealth. Diabetes is the same thing; the patient's glucose level is continually monitored. In both instances, therapy dosages will be affected by how high or low are the follow-up measurements. It is not sufficient to simply know that medication is being utilized! SDB is exactly the same

way, using CPAP is a good start but quantifying benefit must follow, which may impact intervention. Another reason for conducting HST during CPAP is to potentially offer a replacement to the 90 day doctor visit. A recent article highlighted that some patients don't even go back after 90 days to the PCP or sleep doc because it is a hassle. Patients say, "I'm on CPAP and doing everything you are telling me, and now I have to go back just so I can see the doctor for a few minutes and you can get this document you need for reimbursement." A self-administered, easy home sleep test that can quantify patient performance during CPAP may help physicians determine whether a face-to-face visit is still warranted.

CleveMed's main objective is to simplify access to disease management (diagnosis, titration and follow-up) without compromising care and without adding costs.

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