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Perspective

IOP Control - Serial Monitoring

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It is possible to imagine a day in the future when a student or resident will ask, "is it really true that there was a time when the progression of glaucoma and treatment relied exclusively on IOP measurements once every three months?" The answer will of course have to be: "Yes." That same future student may ask, "And, is it true that there was no way for a patient to monitor IOP at home?" Again, the answer will have to be, "Yes."

As far back as the October 2003 issue of Eye World, in an article titled, "Wanted: Reliable Home Tonometer," the author wrote, "A take-home tonometer that could reliably measure diurnal IOP fluctuations is the missing link in attempts to control glaucoma progression."Then, more than a decade ago, Sanjay G. Asrani, MD, agreed. Dr. Asrani, associate professor of ophthalmology at Duke University. And his team gave 64 patients tonometers to take home with instructions to measure or have measured their IOP five times a day for five days [1].

The researchers found that the mean office IOP and mean home IOP readings were similar. But pressures measured at home over various times of the day, the IOP ranged above 6 mmHg from maximum and disease progression followed. Patients who experienced a wider spread of their daily eye pressures were worsening at about six times the rate of those who had more stable pressures, "regardless of their mean pressures as measured in the office," Dr. Asrani said.

That raises the obvious question; why are so few if any eye care practitioners, providing serial tonometry or even considering the diurnal variations of intraocular pressure? In the face of documented studies [2-7], today follow-up visits for glaucoma suspects are still routinely scheduled months away. As a matter of fact, intraocular pressure is measured so infrequently, that the diurnal variations in intraocular pressures seem to be almost irrelevant. Even for patients with confirmed glaucoma, the IOP is monitored usually once, that day and at the appointment time only, every time that patient visits the eye care professional. Based on that cursory assessment, if the IOP measurement does not deviate much, anti-glaucoma medications will be evaluated once again, "In six weeks."

The fact is that current "monitoring," is done according to a combination of the patients' convenience and appointment book management based on the availability of the day and time for the follow-up visit. This generally reflects what is presently done and follows existing understanding of how the service is reimbursed by most healthcare systems and insurance companies in the United States. That's simply not enough. Do most readers know that there is an ICD-10 coding for Serial Tonometry?

By contrast, in Germany, in-patient diurnal IOP monitoring is being reimbursed and may encompass nighttime IOP measurements if equipment, expertise and logistics allow. This may be one of the reasons why in Germany we tend to see significantly fewer normal tension glaucoma cases reported. That is because many patients, in a study, who were diagnosed with normal IOPs, had elevated IOPs outside of the standard eye care professional's office hours and, hence, are subsequently reclassified as primary open angle cases. This phenomenon was reported by Gloor and Meier-Gibbons in 1996 [8].

Based on numerous articles, studies and on-going research, the current practice-paradigm is not sufficient. There is comprehensive evidence that intraocular pressure fluctuates considerably during the 24-hour diurnal curve; leaning toward the readings being somewhat higher in the early morning hours. Without serial monitoring at various times of the day, over a span of at least two weeks, it is my contention that we can only guess what the real intraocular pressure of the individual patient may be, and how efficient a medication or

treatment plan may be. In truth, every optometrist or ophthalmologist who specializes in glaucoma, is in reality simply an ophthalmic plumber. And, every plumber can use a helper; here the helper should be the patient.

Patient involvement is a need that remains unfulfilled. We are striving to acquire a more comprehensive understanding of what is going on with the pressure of the individual patient with glaucoma. To do that, we need to check pressures more often than once, and ideally outside the "office hours." Unfortunately, it should not be assumed that in the future IOP monitoring at the hospital setting is going to be introduced in many countries owing to cost considerations. Clearly, without involving the patient in their own care the true IOP values remain largely unknown. Intraocular pressure is a dynamic, continuously changing value which depends on changes in aqueous exchange, blood filling of intraocular vessels, on outer pressure on the eyeball, and even changes in cerebral spinal fluid pressure - as NASA has found. The same holds true during sports, when blowing up a balloon or blowing into a musical instrument or while a patient is moving from vertical to a horizontal position; think of doing sit-ups.

In addition, new reliable IOP measurement technologies are needed. One such is an IOP-sensitive, disposable silicone contact lens with a built-in micro-electromechanical system, which measures alterations in corneal curvature presumably induced by IOP variations. An antenna mounted around the patient's eye receives the data, which are then transmitted to a recorder. Although the authors reported encouraging first results, a recent study found that the arbitrary units produced had no apparent correlation with Goldmann IOP readings. Another device is an intraocular monitoring implant which is in the very early development stage. Also, the ICare Home and the Diatron have proven to be a very well accepted in-clinic models but due to FDA approval and mountains of regulatory requirements and development costs both are not ready for prime-time at-home use in the U.S. yet.

For any new IOP technology significant issues remain to be addressed with regard to reliability, cost, and the fact that all new technologies rely on antiquated Goldmann technology to prove accuracy. "Goldmann," you say…inaccurate, outdated? But, isn't Goldmann the "Gold" Standard (Cue trumpets in the background). Sorry, the 60 year old Goldmann is not.

An article, "Reconsidering the Gold Standard of Tonometry," was penned by Dr. Dan Eisenberg in the journal Glaucoma Today – March 2011. Dr. Eisenberg wrote, "The Goldmann tonometer, has been considered the gold standard of tonometry, yet this instrument's inaccuracy and imprecision are well documented. Why is it still considered a gold standard? Many common issues render this tonometer unusable. The main advantages of the Goldmann tonometer are its simple mechanics and relatively low cost." So, think about it. We are measuring new technology against an almost 60-year-old technology that is "Unusable."

However, the conundrum is that Goldmann applanation tonometry, with all of its warts, has been the reigning standard for routine measurement of IOP for as long as most of us have practiced and we have no new gold standard. For now, we're stuck with it. "Another gold standard is what we're trying to develop," said Brian A. Francis, MD, assistant professor of ophthalmology, University of Southern California, who is testing the devices in three investigations. "I think we're near that," he said, adding that these promising technologies still need to undergo big trials.

Murray Fingeret, OD, writes, "While Goldmann tonometry is 50 years old, we are comfortable with the data we receive and understand how to use it. While not perfect, it will take a while before the newer instruments are adopted."

Arthur B. Epstein, OD, wrote in his Blog, "Despite a variety of advances in measuring intraocular pressure, almost all agree that Goldmann tonometry remains the gold standard for measuring IOP. I've performed Goldmann so many times I've long ago lost count, but a recent experience has shaken my confidence a bit…While our Goldmanns remain the gold standard, we now pay a lot more attention to their maintenance."

Unusable or not, Goldmann findings, when combined with several other diagnostic tests, are solely an aid in confirming the presence of one of the glaucomas. The truth is that a Goldmann provides nothing more than a number; a number correlated in mmHg; a simple baseline number that we call the IOP; nothing more than a point from where to gauge treatment. Best-practice treatment that should be regularly monitored care, combined with serial tonometry – and when conceivable, combined with at-home monitoring.

To do that, an at-home unit needs to be affordable, durable, with safe over the lid use (not unlike the Diatron), and as simple to use as any other accepted at-home modality; a blood pressure cuff, a glucose monitor, a pregnancy test or thermometer. With a simple pass/fail monitor, not a tonometer, all the patient needs is an indication that his or her IOP is controlled. Patients don't need to interpret IOP levels; if the device registers a "Fail" before the next visit, it's easily reported to the doctor. Doctors diagnose, decide treatment and future care – not patients, and today information can be exchanged by an APP, email, Facetime, Skype and cellphone telemedicine.

In the U.S., to code for serial tonometry, one must perform several tonometry tests, you do not have to perform them all on the same day. But you can only report 92100; serial tonometry as a separate procedure with multiple measurements of intraocular pressure over an extended time period with the interpretation and report on the same day. As usual, confusing but doable. There are also telemedicine reimbursements on the horizon. As usual, always check with your billing expert first.

Long ago, The Advanced Glaucoma Intervention Study (AGIS) investigators reported that IOP fluctuation remains significantly associated with progression. We have known that for so many years and yet we fail to plot IOP fluctuation. It remains my contention that progression needs to be monitored through serial tonometry at points along the 24-hour diurnal curve, and that one reading taken during an eye exam or taken at 6-week intervals during treatment, is not enough.

The Eye World article was published thirteen years ago with a simple request; "A take-home tonometer that could reliably measure diurnal IOP fluctuations." Today we have two instruments that could possibly be used by the patient her or himself, at home when approved, and some that a family member could learn to use. However, there even then there are concerns with breakability, those requiring direct electrical power or batteries, each prone to human error, the requirement of anesthetic, the risk of corneal insult and infection, the need of constant maintenance and calibration….and last but surely not least…the cost. How many glaucoma patients will or can pay $3000 to $14000 or more for at-home devices? These are not the "Do-it-Yourself" missing link.

World-wide, reducing intraocular pressure is the only tool we have in the box. I jest, but when it comes to IOP control, we are ophthalmic plumbers no matter if we treat with topical anti-glaucoma medications, laser, shunts, tubes in the canal or any other technology – the desired outcome is IOP reduction. IOP numbers obtained from a high-tech instrument that costs tens of thousands of dollars is no more valuable than a pass/fail indication on a simple biomechanical monitor. Either will indicate the presence of elevated IOP and the efficacy of treatment, and nothing more.

Serial IOP readings over the 24-hour diurnal curve, with patient participation, is the missing link [9].

Disclaimer

Dr. Michael L. Cohen is the CEO and Founder of MLC Medical Ophthalmic Innovations, developer of the Tonomonitor, one-use disposable Alger Brush and Lid-Genie for MGD care.

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