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CLARIFYING THE CLINICAL APPLICATIONS OF PHOTODYNAMIC THERAPY:

CURRENT CONCEPTS AND USE IN 2018

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Clarifying the Clinical Applications of Photodynamic Therapy: Current Concepts and Use in 2018

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CONTENT SOURCE

This continuing medical education (CME) activity captures content from a roundtable discussion.

ACTIVITY DESCRIPTION

Eye care professionals may not know how to effectively identify patients who will benefit from photodynamic therapy (PDT) or understand all of the clinical scenarios in which the use of PDT alone or in combination with anti-VEGF can be a more efficacious treatment option. This educational activity is a result of a roundtable discussion focusing on the clinical situations where PDT is appropriately implemented as well as the associated challenges with the use of this therapy.

TARGET AUDIENCE

This certified CME activity is designed for ophthalmologists and retina specialists involved in the treatment and management of patients with retinal disorders.

LEARNING OBJECTIVES

Upon completion of this activity, the participant should be able to:

- **Describe** the clinical benefits of PDT, especially in patients who have a poor response to anti-VEGF therapy.
- **Discuss** methods for effective PDT, including dosing, infusion periods, and determination of treatment size.
- **Differentiate** the benefits of half-fluence PDT and full-fluence PDT.
- **Discuss** the application of PDT in the clinic.

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1. PLEASE RATE YOUR CONFIDENCE IN YOUR ABILITY TO APPLY CONCEPTS IN PHOTODYNAMIC THERAPY (PDT) IN THE CLINIC. (BASED ON A SCALE OF 1 TO 5, WITH 1 BEING NOT AT ALL CONFIDENT AND 5 BEING EXTREMELY CONFIDENT).

a. 1
b. 2
c. 3
d. 4
e. 5

2. PLEASE RATE HOW OFTEN YOU INTEND TO APPLY ADVANCES IN PDT IN THE CLINIC. (BASED ON A SCALE OF 1 TO 5, WITH 1 BEING NEVER AND 5 BEING ALWAYS).

a. 1
b. 2
c. 3
d. 4
e. 5

3. HOW DO YOU TREAT A PATIENT WITH NEW POLYPS POST-PDT?

a. Combination anti-VEGF and PDT
b. Anti-VEGF monotherapy
c. Re-treat the patient with PDT
d. Thermal laser photocoagulation

4. WHICH TRIAL ILLUSTRATED THAT COMBINATION PDT AND ANTI-VEGF RANIBIZUMAB CAN ACHIEVE A COMPLETE REGRESSION OF POLYPS IN PATIENTS WITH MACULAR POLYPOIDAL CHOROIDAL VASCULOPATHY (PCV)?

a. CATT
b. EVEREST
c. FOCUS
d. TAP
e. PLANET

5. WHEN IS IT APPROPRIATE TO USE REDUCED-FLUENCE VERSUS FULL-FLUENCE PDT?

a. In patients who are extrafoveal
b. In patients whose fovea can be spared
c. In patients with a thin choroid
d. In patients with 20/40 or better vision

6. WHAT IS YOUR BIGGEST CHALLENGE TO INCORPORATING PDT IN THE CLINIC?

a. The intravitreal injection workload in the clinic
b. The age of the lasers
c. The lack of lasers available
d. Incorporating PDT workflow into the clinic

7. MR. SMITH IS A 52-YEAR-OLD EXECUTIVE WHO IS THE SOLE FINANCIAL SUPPORT FOR HIS FAMILY. HE HAS BEEN DIAGNOSED WITH CLASSIC LESIONS. AS SUCH, HE MAY BE AN IDEAL CANDIDATE FOR _____.

a. Combination anti-VEGF and PDT.
b. PDT monotherapy.
c. Anti-VEGF monotherapy.
d. Laser photocoagulation.

8. IT IS RECOGNIZED THAT PCV IS INCREASING IN PREVALENCE IN WHICH GROUP OF PATIENTS WITH AGE-RELATED MACULAR DEGENERATION (AMD)?

a. Asian and Caucasian patients with dry AMD
b. African-American patients with wet AMD
c. Asian and Caucasian patients with wet AMD
d. African-American patients with dry AMD

9. WHAT DIAGNOSTIC TOOL IS THE GOLD STANDARD FOR PCV DIAGNOSIS?

a. OCT
b. OCT angiography
c. Fluorescein angiography
d. Indocyanine green angiography

10. HOW MANY PDT TREATMENTS ARE TYPICALLY NECESSARY IN A PATIENT WITH CENTRAL SEROUS RETINOPATHY?

a. One to two
b. Two to three
c. Three to four
d. More than five

Clarifying the Clinical Applications of Photodynamic Therapy: Current Concepts and Use in 2018

Age-related macular degeneration (AMD) is the third leading cause of visual impairment worldwide. Although its clinical features are distinct, polypoidal choroidal vasculopathy (PCV) is considered a subtype of AMD.[1-3] *Before anti-VEGF drugs were approved to treat AMD, the preferred treatment was verteporfin photodynamic therapy (PDT). However, once anti-VEGF drugs emerged, PDT became less commonly used despite studies finding that combination anti-VEGF therapy and PDT provides advantages over anti-VEGF therapy alone for PCV treatment.* Retina Today *convened experts in the field of retina to review the clinical situations for which PDT is appropriate, the unique, modern-day challenges associated with the therapy, and cases in which PDT was used successfully.*

— Gregg T. Kokame, MD, Moderator

USING PDT IN THE CLINIC

GREGG T. KOKAME, MD: Nearly 20 years ago, the TAP trial was among the first to study verteporfin for the treatment of subfoveal choroidal neovascularization (CNV) caused by AMD.[4-6] A total of 609 patients were randomly assigned to PDT or placebo with a 24-month follow-up. At 2 years, 77% of patients in the verteporfin group had no disease progression, and 51% had no leakage.[5] Therapy was effective for 5 years.[6]

In recent years, there has been a renewed interest in PDT alone or combination PDT for the treatment of PCV. It has been recognized that, even with the great success of anti-VEGF therapy, there is often persistent disease activity later on in the course of therapy. For example, in the CATT study, 51% of patients treated with ranibizumab had subretinal fluid at 2 years.[7] Further, 67% of patients treated with bevacizumab had residual subretinal fluid at 2 years. The PLANET study compared intravitreal aflibercept monotherapy with intravitreal aflibercept with rescue PDT depending on strict criteria for retreatment.[8] Retreatment required an ETDRS VA of worse than 20/40, vision gain of fewer than 5 ETDRS letters, persistent subretinal fluid on OCT, and active polyps on indocyanine green (ICG) angiography (ICGA). While VA gain was 10.7 letters with aflibercept monotherapy and 10.8 letters with aflibercept and rescue PDT, only 15% of patients in the rescue PDT group had rescue PDT. Comparatively, 85% of the rescue PDT group only had aflibercept monotherapy, so the PLANET study could not determine the potential role of adding PDT to aflibercept monotherapy in the treatment of PCV.[9]

Combination PDT and anti-VEGF therapy has been studied as an effective means of managing neovascular AMD. For example, the FOCUS study combined PDT 7 days before anti-VEGF therapy and found that patients in the combination group had a nearly 5-letter gain while patients in the PDT-only group lost 7.8 letters.[9] Recent results from the EVEREST II study specifically for PCV identified by ICGA showed that combination PDT with ranibizumab can achieve more complete regression of polyps in patients with macular PCV than ranibizumab monotherapy. EVEREST II showed more significant improvement in vision and significantly fewer injections with combination PDT and ranibizumab than ranibizumab monotherapy.[1,10-12] There was a significant VA improvement difference of 9.6 letters with combination therapy versus 5.1 letters with ranibizumab monotherapy at 2 years. There was also a 57% complete polyp regression rate with combination therapy at 2 years compared with 27% in the monotherapy ranibizumab group. Significantly, there was half the number of injections required to achieve these results, with only six injections in the combination group versus 12 injections in the ranibizumab monotherapy group at 24 months. What are your thoughts on these results and the recent increased interest in PDT?

RISHI P. SINGH, MD: PDT was a method we used for many years with much success because it is designed to treat classic CNV without incurring the damage caused by laser photocoagulation. It's more selective, which has its advantages for treating subfoveal lesions.[13] I recall when I was first trained on PDT and intravitreal injections of triamcinolone acetate on patients with exudative AMD. We had positive outcomes with those initial patients, with patients receiving very few treatments over time.

In the anti-VEGF era, we have somewhat forgotten about PDT for a few reasons. Initially, it was because of the lack of lasers available. Then anti-VEGF treatment outcomes were far superior in various disease states, although we lost the ability to find specifically which patients would benefit from PDT. And lastly, the fellows coming up through the ranks are so accustomed to using anti-VEGF therapy that they have become the anti-VEGF generation. They haven't had the experience that ophthalmologists later in their careers have had, in that we have done both PDT and anti-VEGF therapy.

PDT is a viable option for specific patients, for example, patients who are juxtafoveal or extrafoveal. Several studies have shown that PDT in juxtafoveal or extrafoveal patients can result in long-term stability and VA improvement.[14-16] I wouldn't necessarily subject those patients to continual anti-VEGF therapy when PDT done once or twice would be equally effective and less burdensome on those patients over time.

GAURAV K. SHAH, MD: We need to admit that anti-VEGF therapy is a positive option but that it does not work for everyone. We need to perform fluorescein angiography (FA) and ICG, while also examining an OCT in a different fashion in these patients; many of these patients do not respond to the extent that you would

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—Rishi P. Singh, MD

typically see. When I see someone with a polypoidal lesion or retinal angiomatous proliferation (RAP), I inform them that anti-VEGF therapy will be the mainstay, but depending on your response and duration of the treatment, we will utilize PDT. This tells the patient other therapies besides anti-VEGF may be required.

EDWIN RYAN, MD: I completely agree, particularly with the point that we are trending toward a strictly anti-VEGF world. Many of the therapies we select are driven by the crushing volume that we have in the clinic. Our patient volume makes it difficult to pause and obtain the FA or ICGA and consider a treatment other than anti-VEGF.

Additionally, as Dr. Singh mentioned, I have seen and used multiple generations of treatment. Clearly, PDT in combination with anti-VEGF (usually bevacizumab) was quite effective in many cases. One particular anatomic variant is peripapillary CNV, which I believe is very sensitive to PDT and thermal laser. However, when I asked my fellow about PDT treatment for peripapillary CNV, he had not yet seen a PDT performed despite being with us for 11 months.

This is a real problem. Fellows need to know how to perform PDT. It may not be used often, but it is used for central serous retinopathy (CSR), PCV, and the occasional peripapillary CNV. But the challenge is that people have gotten into the habit of exclusively using anti-VEGF therapy, and it is a difficult habit to break.

ADRIAN KOH, MBBS, FRCS, MMed, FRCO, FAMS: The use of PDT in general has declined due to several factors. First, the availability and ease of anti-VEGF administration. Second, the lack of expertise and personnel to administer PDT. Third, the underdiagnosis of PCV in wet AMD cases. And finally, a lack of technical support and sales of PDT lasers.

DR. KOKAME: The newer physicians have grown up in the anti-VEGF era, and they don't see or understand when or how PDT can be used effectively. Early-career clinicians simply don't see PDT being used. Those are some of the challenges that we face in terms of using PDT in the future.

There is recent recognition that PCV is more prevalent than previously thought in patients with wet AMD, especially in Asian and Caucasian patients.[17] In Brazil, about 25% of exudative AMD patients of predominantly Caucasian ancestry had PCV.[18] In Switzerland, 21.5% of their wet AMD patients who were somewhat resistant to anti-VEGF therapy had PCV.[19] Furthermore, we conducted a study in Hawaii and found that 31% of our Caucasian patients with wet AMD had PCV on ICGA.[20] What do you make of this? What is your impression of PCV diagnosis at the present time?

DR. SINGH: PCV is clearly underdiagnosed. The first issue is that ICG, the gold standard for diagnosing PCV, isn't commonly used. There is reluctance to use ICG for a few reasons, one of them being that the fluorescein is the first test patients receive, and clinicians feel that test is enough. The second issue is that there have been ICG shortages at times in the United States, so people have rationed ICG for surgical uses and not necessarily for office-based uses. Lastly, it is my impression while most of us are well trained in FA, we are not as well trained to read ICGs. We must do a better job at classifying these patients. We can do so either through high-speed ICG or OCT angiography (OCT-A). If a clinician sees signs of PCV characteristics on the OCT, it might prompt additional testing for PCV confirmation.

DR. KOKAME: When diagnosing PCV, multimodality imaging is critical in terms of trying to define the results and to make the diagnosis. When you have the scanning laser ophthalmoscope, you can do point-to-point correlation. The polyps will look like this inverted U-shaped elevation of the retinal pigment epithelium (RPE) with heterogeneous reflectivity. The branching vascular network will look like a slight elevation of the RPE—they refer to it as a double line sign, which can help in delineating the size of the lesion, as well as determining what you want to treat and what you don't want to treat. On the ICG, it is important to use an image 3 to 5 minutes after injection, because it becomes confusing in later stages; many parts start to stain. For that reason, it is important to look at that 3- to 5-minute window.

We also have some new diagnostic techniques to diagnose the polypoidal variant now. The *en face* OCT is helpful, however our studies have illustrated a relatively low sensitivity rate of about 30%. It was difficult to make the PCV diagnosis based only on *en face* OCT.[21,22] OCT-A is improving, but it also has about a 30% sensitivity.[21] Improving the technology will enable us to diagnose more easily with noninvasive techniques. Currently, however, ICG remains the gold standard. Do you still use ICG?

DR. KOH: When any of my patients present with exudative maculopathy, they receive both FA and ICGA at baseline. In my practice population, 40% to 50% will have underlying PCV, and the rest have

CNV and RAP (10%). When combination therapy has been selected for PCV cases, I usually repeat the FA and ICGA at 3 months to determine if repeat combination therapy is required. If there are no polyps present, then follow-up will be similar to treating CNV, meaning I'll use OCT and OCT-A.

DR. SHAH: I use ICG selectively, but whenever I suspect I am not observing the anti-VEGF response needed for my patients, I'll use it. We have ICG at two of our 14 offices; I inform patients that, in order to be treated with the best information, they will have to drive. I use ICG at least one to three times per week, depending on the disease entity. It is important that you have a skilled photographer who can obtain the images. FA and ICG skills have deteriorated recently since their use has dwindled. It is important to have ICG, but it is critical that you have a usable test.

DR. RYAN: We have ICG available in two of our seven offices, which is not an uncommon ratio. There are several issues that make ICG use less common than perhaps it should be. Firstly, unless the pathology is quite obvious, I have found it difficult to diagnose PCV. Results are subject to interpretation at times. Secondly, because ICG is not available in all offices, we often make clinical decisions without the use of that modality. Further, our officers have stopped obtaining OCT-A because we are not convinced it is clinically useful. Instead, we are using spectral-domain OCT (SD-OCT), which can offer you a good deal of information, particularly regarding choroidal thickness.

The patients I see with a polypoidal variant are often people with a choroid that is thicker than normal. They're outside the usual Caucasian AMD patient, who typically has a very thin choroid. Having an enhanced-depth imaging OCT (EDI-OCT) scan steers you in that direction because you can often see polyps. It is those patients who end up being treated using PDT with that in mind. We usually start them on an anti-VEGF therapy, such as aflibercept. If that is not working, then they will visit another office for an ICG, and we will make some decisions from there. Typically, they will get a PDT treatment.

DR. KOKAME: That is exactly our situation. We have the scanning laser ophthalmoscope ICG (SLO ICG) available at one out of five of our offices, so using it is challenging. We do have an ICG fundus camera available at every office, but I have found that technology to be much weaker and less sensitive than the SLO ICG. SLO ICG is still the gold standard, but, unfortunately, it is not available to all patients at all offices. That is going to be the challenge ahead. Do you have any input at all on using PDT for the treatment of chronic CSR?

DR. SINGH: PDT is a great option for CSR treatment. Typically, we use oral pills for patients with bilateral diffuse disease, but if there are focal areas of leakage, then we do offer PDT to those patients. Patients don't typically need many treatments, either; one or two treatments are often all that is required. The subretinal fluid regresses very quickly, and they can be followed on a less frequent basis or repeated if necessary again in 3 months. We also have to discuss the potential side effects to the macular ischemia, which we mainly pulled away from the AMD studies and not from the CSR studies. I do believe macular ischemic episodes can be reduced by the use of half-fluence PDT, and since these patients don't have a choroidal lesion, unlike AMD, they have less likelihood of developing this condition. Personally speaking, I haven't had macular ischemia in any patient I've treated thus far, but it is a concern.

The use of PDT in general has declined due to several factors. First, the availability and ease of anti-VEGF administration. Second, the lack of expertise and personnel to administer PDT. Third, the underdiagnosis of PCV in wet AMD cases. And finally, a lack of technical support and sales of PDT lasers.

— Adrian Koh, MBBS, FRCS, MMed, FRCO, FAMS

DR. KOH: My preferred settings for PDT are half-fluence (30 mJ/cm^2) with full-dose and 83-seconds laser exposure. I attempt to attain ICGA before treatment to determine the area of ICGA hyperfluorescence and apply the PDT laser to cover the zone, rather than base the treatment on leakage points on the FA alone.

DR. SHAH: To me, PDT is really underused in CSR, and for my patients, it is the treatment of choice. I don't typically wait a few months for fluid to resolve since patients want to be functional as quickly as possible. I will typically wait a few weeks, and if the patient hasn't improved, I will obtain an FA and ICG and treat them with PDT. These are some of the most content patients, since we cannot always eliminate all their symptoms, but we can make them more functional.

DR. KOKAME: CSR patients tend to have thicker choroids, so that may be why we don't see this choroidal ischemia in CSR or PCV after PDT. It is a very good option in CSR patients.

DR. RYAN: Choroidal thickness as protection against ischemia is something that I hadn't previously considered. However, thinking back on the patients who had poor central vision loss, they were all patients with RAP lesions or with a thin choroid. It is possible a thick choroid is protective.

DR. KOKAME: Has anyone used PDT for hemangiomas, either choroidal or retinal?

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—Gaurav K. Shah, MD

DR. RYAN: My experience has been mostly with choroidal hemangioma outside the fovea. The choroidal hemangioma was about 4 mm thick. After one treatment with full-fluence PDT, the hemangioma essentially vanished. I was very impressed.

DR. KOH: In clinical practice, choroidal hemangiomas are extremely rare, and I see only one or two cases per year. I almost always use full-fluence PDT to treat these lesions because PDT is effective in reducing the size and height of the lesion and inducing resolution of fluid. Most recently, I had an 8-year-old girl with choroidal osteoma and active RPE leakage, a condition in which PDT is contraindicated since PDT can cause rapid dispersion of calcific deposits in the subretinal space, leading to massive fibrosis and RPE hypertrophy.

DR. SHAH: I have limited personal experience, but I have used it in several of my patients for choroidal hemangioma, and it works quite well. The fluid can recur, but with retreatment these patients have done quite well.

DR. KOKAME: I agree. I have used it for multiple retinal capillary hemangiomas, but they often have marked exudation and can start to have exudative detachment. However, after one or two PDT treatments, it vanishes. It is a very effective treatment for hemangioma, and this has been well reported in the literature.

PDT TECHNIQUES

Q | **DR. KOKAME:** PDT is a two-step process, typically beginning with an injection of 6 mg/m^2 verteporfin, followed by laser exposure at 50 J/cm^2 for full-fluence PDT.[23] There are many variables at play that can impact PDT effectiveness, such as verteporfin dosing, laser light dosing (full-fluence or half-fluence), infusion period and timing, and the lesion size.[24-27]

In EVEREST II, the researchers used a different technique than what we were familiar with in the early stages of PDT for AMD.[10] They used the ICG in order to define the size of the lesion and either used only the exact size or only a small, 300-µ border. This was a much smaller spot size than what we used to use when we based the spot size on the FA and added a 1,000-µ additional border to calculate the greatest linear dimension. That is a significant change for the PDT technique now commonly utilized for PCV. First, the spot size is based on the ICG and not the fluorescein. Second, the spot size covers the exact size of the lesion without a large border as was previously used. This new technique may be the reason that recent studies have obtained the positive results they did because you can often spare the fovea if you treat a much smaller area. Do you have any thoughts on this study or its PDT technique?

DR. SHAH: I typically start with reduced-fluence PDT since we are doing targeted PDT, but I will use full-fluence PDT if the patient doesn't respond and if the area being treated is outside the foveal avascular zone. Pigmentation of the patient does makes a difference; sometimes the response may be different in terms of a blonde or pigmented fund. I have personally not seen the dreaded severe vision loss from PDT with either full- or reduced-fluence recently, but we are performing limited and directed PDT.

DR. SINGH: I've always treated with a 1,000-µ spot size in addition to the lesion size. I've trained my residents and my fellows on that technique. Recently when I sat with Joan Miller, MD, from Massachusetts Eye and Ear, she stated she is not using the 1,000-µ border in her patients; rather, she examines the size based on the optic disc size. In addition, the most recent ophthalmic photography systems lack the PDT measuring that we had in previous versions. Currently, we have to go to the camera and measure the lesion size on the camera before treating the patient. By eliminating the border, the workflow will certainly be faster.

DR. KOKAME: Many clinicians have questions about full-fluence versus reduced-fluence PDT. I typically use full-fluence PDT for lesions that are extrafoveal or in patients where you can at least spare the fovea with the size of the spot size. I use reduced-fluence PDT in patients with good vision—20/40 or better. However, if they have worse vision than that, then I use full-fluence PDT even if it is under the fovea. In EVEREST II, zero patients had a decrease in vision, even in the subfoveal patients who had full-fluence therapy.[10] It may be that this is a much smaller risk in the PCV patients with a thicker choroid with PDT. Have you seen decreased vision after foveal treatment with PDT?

DR. RYAN: Yes. I looked at this a few years ago when we were just starting with combination therapy. The initial combination therapy was PDT with intravitreal steroid. If you recall from that era, there

was a certain percentage of the population who had an infarction of the choroid underneath in the area of the treatment. I observed that in our practice, and I found that we had a huge number of patients who had a dark hole in the back of the eye on FA, which was very worrisome. Studies have found that reduced-fluence PDT was equally as effective as full-fluence.[24,25,27-29] I began using reduced-fluence PDT on every patient starting in 2003, and we didn't observe that issue again. You would occasionally have patients who would have an inflammatory response, and they would get worse vision for a few days or 1 week, but they all recovered.

After anti-VEGF therapy, specifically bevacizumab, entered the market, I began using a half-fluence PDT laser spot that treated the lesion only, along with bevacizumab. I have been treating patients with lesion size-specific half-fluence PDT for 15 years. The biggest challenge I have is that I don't know what to treat in some CSR patients. Do you treat the area of the leakage? Do you treat what's visible on FA versus the ICG?

DR. KOH: The current evidence shows clear efficacy and safety of full-fluence PDT for PCV cases, especially if the objective is to ensure complete occlusion of polyps. At present, no other treatment modality achieves 70% to 80% closure rates for polyps.[1,10] Reduced-fluence has several advantages, including reduced post-PDT exudation, an almost zero incidence of acute visual loss following PDT, and a reduced risk of RPE atrophy and secondary CNV formation.

However, there is a lower polyp closure rate compared to full-fluence PDT. I use half-fluence PDT (full-dose, half-fluence, normal duration) for the following indications: PCV with normal to near-normal VA (better than 20/40); large treatment zones (> 4,000 µm); and CSR.

PDT SCHEDULING WORKFLOW

Q | DR. KOKAME: Scheduling PDT, as well as drug delivery and IV access, can be challenging. In my practice, our PDT laser is in the hospital next to our office, so we have the hospital staff do it for us. After the procedure, the patient comes to our office and has an injection. The procedures are done at different sites of service; therefore both procedures are covered by insurance, and the patient can receive the treatment in 1 day. How do you usually schedule your PDT cases? What is your typical process like?

DR. SHAH: I typically schedule PDT on the separate day that I am going to be in the office to ensure we have all the paperwork and personnel that are needed for the treatment. If I'm treating AMD, I administer the anti-VEGF and have patients return a week or so later for the PDT. If they are scheduled in the office, I have patients come either at beginning or end of day, so it is not disruptive to the office flow. If there is opportunity, time, and ability to do same-day treatment for CSR, we will try to accommodate, as some of our patients travel a far distance to our offices.

DR. RYAN: We have seven offices, and three of the offices are set up for PDT. We have three lasers. The lasers are old, and it is difficult to find someone to repair them. We check them quarterly to make sure that they're working. We have dedicated staff in each office who are competent enough in the PDT protocol. The PDT workflow is somewhat disruptive, so we can't always do it all in 1 day. Patients come in, get diagnosed, and then come back later for the PDT. On the day of PDT, the patient comes in, and the staff gets me at about 2.5 minutes prior to the treatment, which gives me time to set up. The challenge is we don't perform PDTs that often. Each one is a bit of an adventure, which isn't optimal. If that trend continues and treatments become decreasingly frequent, we may only have one PDT office, so that the staff does it often enough to be fully competent.

DR. SINGH: Like Dr. Ryan, we schedule them on separate days as well. When we do a fluorescein, we have them leave the IV in and use the same IV access for the PDT. That makes it much easier because we aren't replacing the IV for the PDT infusion.

DR. KOH: I try to avoid needing the patient to return for another visit for the PDT treatment. The majority of my patients have the angiography performed on the same day, while leaving the IV cannula in place in case they require PDT. I then proceed to administer PDT and, if necessary, follow with an anti-VEGF injection (without the use of strong surgical illumination).

One variation I have been using with positive effects is to administer verteporfin (Visudyne, Bausch + Lomb) as a bolus over 1 minute rather than use the infusion pump over 15 minutes. The pump is cumbersome and often clogs and causes delays. In addition, you need a member of the staff in the room while the infusion is ongoing, and that can challenge our resources.

DR. KOKAME: One challenge will be reintroducing PDT into practice because every situation is different. Many practices will be doing PDT in their clinic, and that is going to be a challenge for a number of reasons. The lasers are 20 years old. There is hope for a new laser in the future, but nothing has been announced. The lack of laser access will be a problem in the future if the rest of the lasers start to break down. In Hawaii, we have access to two lasers. How many PDT lasers are in your area that you have access to?

DR. SINGH: We have one. There have been no major equipment failures so far. But I do see that as being a problem until there's a new

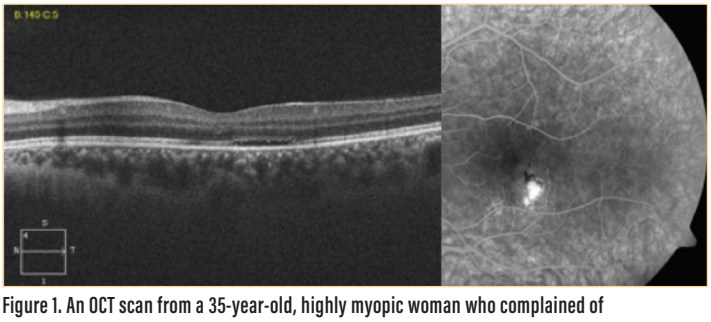

Figure 1. An OCT scan from a 35-year-old, highly myopic woman who complained of metamorphopsia. The OCT scan at presentation to the clinic shows a small amount of subretinal fluid and some ellipsoid zone disruption.

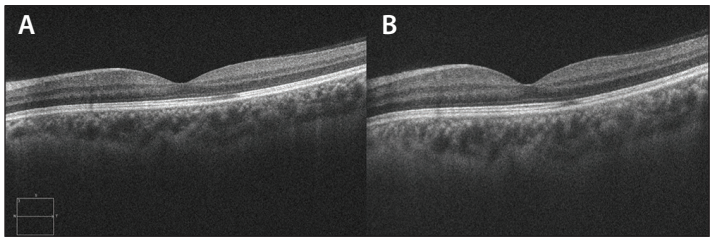

Figure 2. A 35-year-old, highly myopic woman treated with PDT at 2 and 8 months posttreatment, respectively. Complete resolution of subretinal fluid is shown, but some ellipsoid zone disruption at 2 months posttreatment is visible (A). A slight disruption of an outer retinal area is shown, but the patient experiences good VA with no complaints of metamorphopsia 8 months posttreatment (B).

laser and there are parts available. Our current system works well, but if a laser breaks down, we are in trouble.

DR. KOKAME: The biggest challenge to bringing PDT into practice will be the tremendous workload we have with the intravitreal injections for patients with retinal diseases. It is also going to be challenging to have the proper people available and comfortable with doing PDT in the clinic. The first step is getting a new laser commercially available in the United States. Without newer technology, the future is questionable for PDT. I will say there is a new laser by Quantel Medical available outside the United States. We can't obtain it because they're not planning to commercialize it in the United States, but it is interesting that the rest of the world has access to a newer-generation PDT laser.

CASE 1: OCCULT CNV AND PED

DR. KOKAME: The first case is an 85-year-old Asian man with occult CNV. He presented with blurry vision for 5 months and had decreased vision associated with pigment epithelial detachment (PED) and serous detachment. He was offered monotherapy treatment every 5 weeks initially versus PDT or intravitreal bevacizumab and dexamethasone. He made the decision for us. He decided he didn't want a multiple-injection regimen and only wanted PDT.

There was evidence of superior temporal area PCV associated with a PED that was highly elevated in the fovea. There was also evidence of serous detachment on the sides of the PED. We treated him with a reduced-fluence PDT with intravitreal bevacizumab and dexamethasone on the same day. The greatest linear dimension was 4,200 µ, and the spot size I chose was about 4,500 µ, which did involve the fovea. I couldn't completely exclude the fovea and ensure that I got the whole lesion.

The patient did very well after treatment. One month later, his vision improved to 20/30, but there was still fluid and a collapsing PED. At 3 months, everything had flattened, and the fluid and PED were gone. We did intravitreal bevacizumab and dexamethasone two more times after that to ensure that we had a stable anatomic situation. The patient is now 5 years after the first PDT, and his vision is 20/30. He has not developed recurrence, his vision is doing well, and he is happy. There is an atrophic scar temporally, but it does spare the fovea.

This case is a good example of what combination therapy can do.

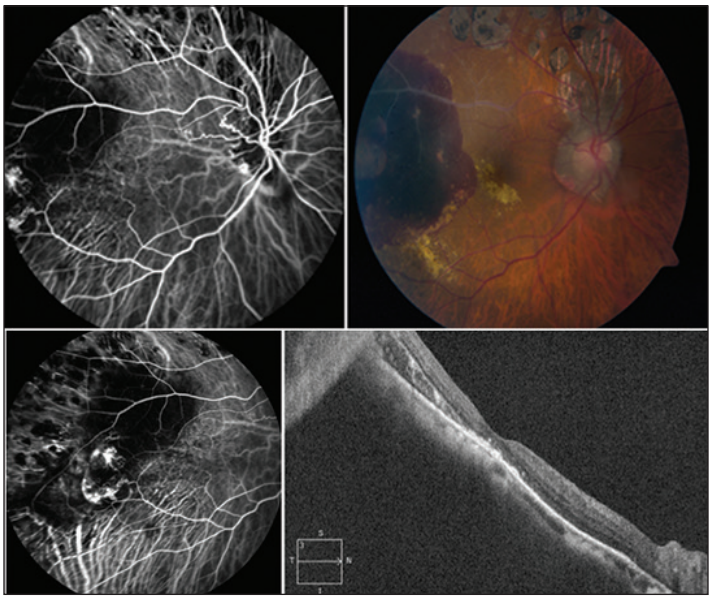

Figure 3. An 82-year-old, African-American woman who presented complaining of a dark spot in her right eye. She had a large CNV that was present below a significant amount of subretinal hemorrhage.

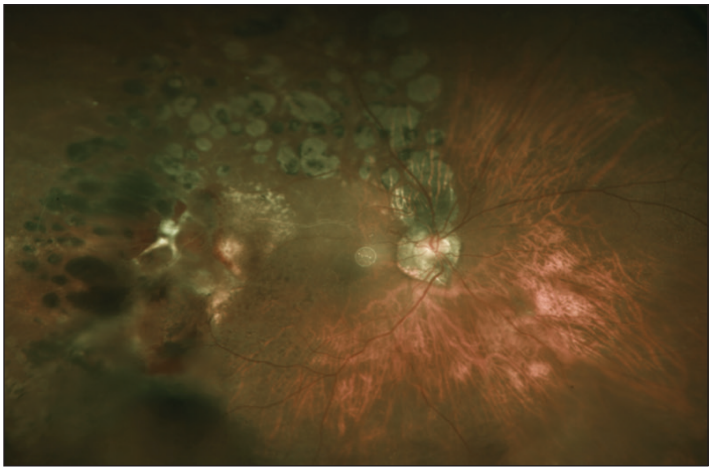

Figure 4. An 82-year-old, African-American woman, 6 months after PDT treatment for a large CNV.

It highlights the EVEREST II trial and the results showing better vision with less treatment frequency.[1,10-12]

DR. SINGH: How often were you seeing this patient in follow-up?

DR. KOKAME: Initially, we saw him every 2 to 3 months in case there was recurrent leakage. We currently see him every 4 months.

DR. SINGH: What is the timeline for resolution of fluid in the OCT era? People become too anxious when fluid doesn't regress immediately. Even though the lesion is closed, with PDT there is a slow progression of subretinal fluid. Some clinicians see this as a persistence of fluid when that may not be the case.

DR. KOKAME: The goal of PDT is to close the polyps but not

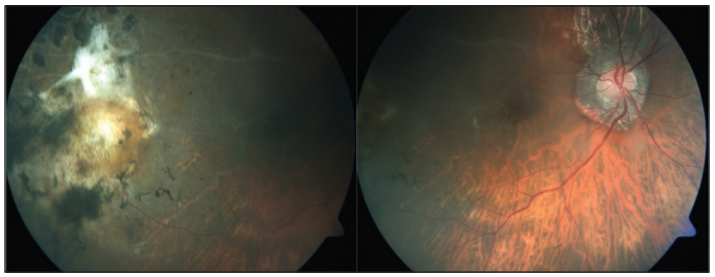

Figure 5. An 82-year-old, African-American woman, 5 years after PDT treatment for a large CNV. There is a fibrotic scar temporally, but the lesion maintained its stability.

necessarily the branching vascular network because that usually persists. If the polyps are gone, we don't typically re-treat with PDT. We would, however, re-treat with PDT if there were persistent polyps or new polyps. If it's leaking from the branching vascular network, then we perform injections after the combination treatment. If there's persistent fluid, it could be because the branching vascular network is still leaking. That's when antiangiogenic therapy is helpful.

CASE 2: CLASSIC LESIONS BY FA

DR. SINGH: Our next case is a 35-year-old female who is a high myope with a -7.00 D refractive error in her right eye and -6.50 D in her left eye. She initially complained of metamorphopsia and came in for an examination in September 2017. Her initial VA was 20/25. On the OCT is a tiny bit of subretinal fluid and some ellipsoid zone disruption (Figure 1). It does go into the subfoveal space, but if you look at the lesion on the angiogram, it is just outside the foveal avascular zone. This is a small, classic lesion by FA. She is a working adult with a full-time job.

How do you treat this patient? Will she be able to commit to monthly anti-VEGF therapy? Or should we take a less invasive route because of the favorable location and size of the lesion?

I decided to treat this patient with PDT. I treated a 700-µ section of the lesion. After 2 months, she had complete resolution of subretinal fluid but did still have some ellipsoid zone disruption (Figure 2A). Her VA returned to 20/20, and her metamorphopsia improved. Eight months later, her VA was 20/20. She had slight disruption of an outer retina, good VA, and no complaints of metamorphopsia (Figure 2B). Almost 1 year later her VA has been maintained, and she has no recurrence of subretinal fluid.

This is why PDT has its benefits. If we treated this patient with anti-VEGF therapy, we would be seeing her monthly and evaluating her monthly, determining if she needed treatment. With myopic CNV, you would be treating on a prn basis, which is concerning to me because you have to consistently monitor the patient monthly. It is a huge burden to the patient.

DR. KOKAME: Treatment burden is an important consideration, especially for a patient who is working full-time. Your case reminded me of another situation where frequent treatment would be a problem. I published on two cases where I had juvenile CNV.[30] We had patients with subfoveal CNV, one female, age 11, and one male, age 12. It wasn't realistic to inject them every 4 to 6 weeks,

Figure 6. A 69-year-old Caucasian woman with polyps and hemorrhage on FA.

so we did combination therapy of PDT and an intravitreal antiangiogenic agent. They tolerated the treatment well in both cases. I've observed both of them now for more than 10 years, and they haven't recurred. What have your experiences been like treating juvenile CNV?

DR. RYAN: I've had some cases of juveniles with CNV. The most recent case was a male patient age 8 with peripapillary, and he responded well to anti-VEGF therapy. He initially went into the OR and had general anesthetic for the first injection, which was miserable. I did the next injection in the office, and he did fine. I didn't use PDT because the contact lens and set-up would have been challenging.

CASE 3: BRVO, PRP, AND LARGE CNV

DR. SINGH: Our next case is an 82-year-old, African-American female who presented complaining of a dark spot in her right eye. She has a history of some laser treatment in her right eye for a branch retinal vein occlusion (BRVO) but no history of injections. She had a significant amount of panretinal photocoagulation (PRP) performed in her right eye for either a heavy grid or nonperfusion. Her fovea wasn't involved, but she did have a large CNV that was present below a significant amount of subretinal hemorrhage.

In this case, I wasn't certain what caused it. Was it a laser CNV from the heavy PRP? Were there other polypoidal considerations in this patient? The FA did show a significant area of blood without a true area of leakage seen below (Figure 3).

I gave her three doses of ranibizumab to see if I could better localize the lesion. After three doses, her VA improved to 20/40. I ultimately decided to go with PDT in this patient because the blood could be visually threatening if it entered the fovea. Six months after the PDT, she continued to have good vision (Figure 4). I saw her most recently in 2017, now many years later. You can see that she

has a fibrotic scar temporally, but that lesion maintained its stability without current hemorrhage or fluid present (Figure 5).

DR. KOKAME: Do you typically use combination therapy? And, if so, how do you time your injection and your PDT?

DR. SINGH: I don't typically use combination therapy. I used it in this case because I was trying to localize the lesion to treat with PDT below the blood.

DR. KOKAME: I had a patient who was seen in Vietnam and was diagnosed with BRVO. She was treated with a macular laser there. When she presented to me, she actually had occult fluorescein leakage from a PCV lesion involving the superonasal macula. She was actually misdiagnosed; it wasn't BRVO, and the macular laser treatment didn't help the leakage. Her lesion resolved without PDT, but it is an example showing that some cases of PCV will be misdiagnosed.

CASE 4: MULTIPLE TREATMENTS FOR PCV

DR. RYAN: Our next case is a 69-year-old Caucasian female. I first saw her in 2009, and she presented with a PED in her left eye. She had 20/20 vision in her right eye and 20/25 vision in her left eye. We treated her in an office that did not have an ICG. At the time, we only had time-domain OCT available. It took me some time to diagnose it, but she had obvious polyps with hemorrhage, and the pattern fit with PCV. The FA showed the polyps fairly well, which is unusual (Figure 6).

She was initially treated with bevacizumab with little success. I then moved to combination therapy, and she had multiple treatments. I do combination therapy in my patients on the same day. This is a relatively remote office that requires patients to travel long distances to visit. Our technique is as follows: we give them a little subconjunctival lidocaine, perform the PDT procedure, and then give the anti-VEGF agent after a baseline preparation. We have done this many times without consequences related to the timing.

This patient had treatment three times. She had a very good response to the treatment, but she had a recurrence 2 years later. That has been my experience with this Caucasian variant of PCV. You're not curing patients; you're giving them long-term relief.

DR. KOKAME: There is definitely a high risk of recurrence. The case that I presented is unusual in that the patient went 5 years without recurrence, but I do agree that these patients often have recurrence and new episodes of bleeding. The PCV complex can actually grow in a totally new direction. Our treatments aren't curative at all, but PDT can decrease the treatment burden significantly.

Thank you all for your time and insights. I look forward to working with you again. ■

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ACTIVITY TITLE: CLARIFYING THE CLINICAL APPLICATIONS OF PHOTODYNAMIC THERAPY: CURRENT CONCEPTS AND USE IN 2018

Release Date: August 2018
Expiration Date: August 2019

INSTRUCTIONS FOR CME CREDIT

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Address _____

City _____ State _____ Zip _____

License Number _____

DEMOGRAPHIC INFORMATION

Profession
___ MD/DO
___ NP
___ Nurse/APN
___ PA
___ Other

Years in Practice
___ >20
___ 11-20
___ 6-10
___ 1-5
___ <1

Patients Seen Per Week (with the disease targeted in this activity)
___ 0
___ 1-5
___ 6-10
___ 11-15
___ 15-20
___ 20+

Region
___ Northeast
___ Northwest
___ Midwest
___ Southeast
___ Southwest

Setting
___ Solo Practice
___ Community Hospital
___ Government or VA
___ Group Practice
___ Other
___ I do not actively practice

Models of Care
___ Fee for Service
___ ACO
___ Patient-Centered Medical Home
___ Capitation
___ Bundled Payments
___ Other

Training of Fellows ___ Yes ___ No

LEARNING OBJECTIVES

DID THE PROGRAM MEET THE FOLLOWING EDUCATIONAL OBJECTIVES?	AGREE	NEUTRAL	DISAGREE
Describe the clinical benefits of photodynamic therapy (PDT), especially in patients who have a poor response to anti-VEGF therapy.	_____	_____	_____
Discuss methods for effective PDT, including dosing, infusion periods, and determination of treatment size.	_____	_____	_____
Differentiate the benefits of half-fluence PDT and full-fluence PDT.	_____	_____	_____
Discuss the application of PDT in the clinic.	_____	_____	_____

POSTTEST QUESTIONS

1. **PLEASE RATE YOUR CONFIDENCE IN YOUR ABILITY TO APPLY CONCEPTS IN PHOTODYNAMIC THERAPY (PDT) IN THE CLINIC BASED ON THIS ACTIVITY. (BASED ON A SCALE OF 1 TO 5, WITH 1 BEING NOT AT ALL CONFIDENT AND 5 BEING EXTREMELY CONFIDENT).**
   a. 1
   b. 2
   c. 3
   d. 4
   e. 5

2. **PLEASE RATE HOW OFTEN YOU INTEND TO APPLY ADVANCES IN PDT IN THE CLINIC. (BASED ON A SCALE OF 1 TO 5, WITH 1 BEING NEVER AND 5 BEING ALWAYS).**
   a. 1
   b. 2
   c. 3
   d. 4
   e. 5

3. **HOW DO YOU TREAT A PATIENT WITH NEW POLYPS POST-PDT?**
   a. Combination anti-VEGF and PDT
   b. Anti-VEGF monotherapy
   c. Re-treat the patient with PDT
   d. Thermal laser photocoagulation

4. **WHICH TRIAL ILLUSTRATED THAT COMBINATION PDT AND ANTI-VEGF RANIBIZUMAB CAN ACHIEVE A COMPLETE REGRESSION OF POLYPS IN PATIENTS WITH MACULAR POLYPOIDAL CHOROIDAL VASCULOPATHY (PCV)?**
   a. CATT
   b. EVEREST
   c. FOCUS
   d. TAP
   e. PLANET

5. **WHEN IS IT APPROPRIATE TO USE REDUCED-FLUENCE VERSUS FULL-FLUENCE PDT?**
   a. In patients who are extrafoveal
   b. In patients whose fovea can be spared
   c. In patients with a thin choroid
   d. In patients with 20/40 or better vision

6. **BASED ON THE DISCUSSION, WHAT WILL BE THE BIGGEST CHALLENGE TO INCORPORATING PDT IN THE CLINIC?**
   a. The intravitreal injection workload in the clinic
   b. The age of the lasers
   c. The lack of lasers available
   d. Incorporating PDT workflow into the clinic

7. **MR. SMITH IS A 52-YEAR-OLD EXECUTIVE WHO IS THE SOLE FINANCIAL SUPPORT FOR HIS FAMILY. HE HAS BEEN DIAGNOSED WITH CLASSIC LESIONS. AS SUCH, HE MAY BE AN IDEAL CANDIDATE FOR _____.**
   a. Combination anti-VEGF and PDT.
   b. PDT monotherapy.
   c. Anti-VEGF monotherapy.
   d. Laser photocoagulation.

8. **IT IS RECOGNIZED THAT PCV IS INCREASING IN PREVALENCE IN WHICH GROUP OF PATIENTS WITH AGE-RELATED MACULAR DEGENERATION (AMD)?**
   a. Asian and Caucasian patients with dry AMD
   b. African-American patients with wet AMD
   c. Asian and Caucasian patients with wet AMD
   d. African-American patients with dry AMD

9. **WHAT DIAGNOSTIC TOOL IS THE GOLD STANDARD FOR PCV DIAGNOSIS?**
   a. OCT
   b. OCT angiography
   c. Fluorescein angiography
   d. Indocyanine green angiography

10. **HOW MANY PDT TREATMENTS ARE TYPICALLY NECESSARY IN A PATIENT WITH CENTRAL SEROUS RETINOPATHY?**
    a. One to two
    b. Two to three
    c. Three to four
    d. More than five

ACTIVITY EVALUATION/SATISFACTION MEASURES

Your responses to the questions below will help us evaluate this continuing medical education (CME) activity. They will provide us with evidence that improvements were made in patient care as a result of this activity as required by the Accreditation Council for Continuing Medical Education (ACCME).

Rate your knowledge/skill level prior to participating in this course: 5 = High, 1 = Low _____

Rate your knowledge/skill level after participating in this course: 5 = High, 1 = Low _____

This activity improved my competence in managing patients with this disease/condition/symptom. _____ Yes _____ No

I plan to make changes to my practice based on this activity. _____ Yes _____ No

Please identify any barriers to change (check all that apply):

_____ Cost

_____ Lack of administrative support

_____ Lack of time to assess/counsel patients

_____ Reimbursement/insurance issues

_____ Patient compliance issues

_____ Other. Please specify: _____

_____ Lack of consensus or professional guidelines

_____ Lack of experience

_____ Lack of opportunity (patients)

_____ Lack of resources (equipment)

_____ No barriers

The design of the program was effective for the content conveyed. ___ Yes ___ No

The content supported the identified learning objectives. ___ Yes ___ No

The content was free of commercial bias. ___ Yes ___ No

The content was relative to your practice. ___ Yes ___ No

The faculty was effective. ___ Yes ___ No

You were satisfied overall with the activity. ___ Yes ___ No

Would you recommend this program to your colleagues? ___ Yes ___ No

Please check the Core Competencies (as defined by the ACCME) that were enhanced through your participation in this activity:

_____ Patient Care

_____ Practice-Based Learning and Improvement

_____ Professionalism

_____ Medical Knowledge

_____ Interpersonal and Communication Skills

_____ System-Based Practice

Additional comments:

_____

_____ I certify that I have participated in this entire activity.

This information will help evaluate this CME activity; may we contact you by email in 3 months to see if you have made this change? If so, please provide your email address below.

_____


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