Photodynamic Therapy and Superficial Radiation Therapy for Non-Melanoma Skin Cancers

A look at where these modalities fit into the treatment approach in 2018.

BY MICHAEL H. GOLD, MD

When asked to comment on what’s new and where things are in dermatology with regards to Photodynamic Therapy (PDT) and Superficial Radiation Therapy (SRT) for non-melanoma skin cancers (NMSC), I pondered on where we have been with these therapies and where we are going in 2018. While PDT remains a very useful modality for the treatment of actinic keratoses (AKs) in the US market, we have not progressed very far, to date, with the use of PDT in the treatment of NMSC. There is no question that with the proper photosensitizer, and with the proper light source, we can use PDT to eradicate NMSC and have very long-term cure rates.

Then, when I think of SRT and its use in the treatment of NMSC, I am pleasantly surprised by how it has been adopted by some of us, how those who use it regularly in clinics have found a very nice place for its use with those patients who suffer from NMSC.

Let’s dig deeper into both of these modalities and see where we are in regard to their use and their apparent place in dermatology offices in 2018.

PHOTODYNAMIC THERAPY

PDT came to the US in the late 1990s with an FDA approval to treat non-hyperkeratotic AKs of the face and scalp with a blue light source after an appropriate drug incubation on the skin with a 20% aminolevulinic acid (ALA) solution. AKs cleared nicely with this modality and PDT has become one of the more commonly used modalities in the US to treat patients with multiple AKs. The original FDA indication was for the individual treatment of these AKs. Many clinical studies since then have shown full-face and scalp treatment, as well as treatment of the extremities in a full-field manner, have resulted in a very nice treatment option for these lesions. At the same time, patients being treated with PDT for AKs receive a very nice aesthetic/cosmetic result in most every case. We have also learned that the original drug incubation time, which was 14-18 hours with 20% ALA, is not needed in most cases. Clinical studies have shown that short-contact ALA drug incubation—from one to three hours—works with the same efficacy as the longer drug incubation time periods.

It’s also important to note that with proper documentation, PDT treatments are covered by most insurance plans. One must accurately document where the AKs are located and how many are being treated. But with that proper documentation, we can now see adequate insurance coverage reimbursement for these lesions.

Outside the US, there is a 16% methyl-aminolevulinic (MAL) cream available to treat AKs and also NMSC. Based on numerous published manuscripts, we know MAL works extremely well in treating NMSC after lesion preparation and three-hour occluded drug incubation and illumination with a red-light source. Superficial basal cell carcinomas (BCCs) and squamous cell carcinomas (SCC) have also been shown to respond well. Recurrences at up to five years have been comparable to surgical procedures. MAL has documented efficacy in treating AKs as well.

So it is interesting that we do not have MAL in the US market. An attempt was made to bring MAL to the US...
approximately 10 years ago. When it came to the US, it received an indication only to treat AKs and not BCCs or SCCs. The main indication for MAL outside the US is for NMSC and this would have been the ideal indication for MAL here in the US, too. Without an FDA approval, MAL did not do well here for AKs and the drug was pulled from the market several years later.

In 2016, a new ALA compound, a 10% ALA nanoemulsified gel, entered the US market, with the approval of a needed drug incubation of three hours, and the use of a red light source to activate the drug. The approval and the clinical trials to gain approval were performed on AKs over time. In clinical experience, shorter drug incubations, up to one hour, and the use of either red or blue light was used. Once again, the efficacy of the 10% ALA gel showed an acceptable response rate in the treatment of AKs, and cosmetic improvements were also seen in most patients who were treated with this treatment modality.

In Europe, the 10% ALA gel is approved for the treatment of BCCs. This is significant because it has paved the way for its potential approval in the US for this indication. Clinical trials for the use of the 10% ALA gel in the treatment for BCCs are to begin in the second half of 2018 and once the results are known, we may have another important option to offer patients with BCCs that come to our clinics.

SUPERFICIAL RADIATION THERAPY

SRT is the use of fractionated superficial radiation therapy to treat NMSCs, and for those who perform this treatment in their clinics, this has become a game changer for many patients. SRT is FDA approved for the treatment of NMSC and for the treatment of keloids. While we will not discuss the treatment of keloids in this manuscript, once again, for many, this treatment has been an amazing addition to our treatment armamentarium. Recurrence rates with surgery and SRT in the treatment of keloids has shown, thus far, that at one-year post excision and SRT the recurrence rate for keloids may be less than 10 percent.

SRT for NMSC is also an important addition to what is available for our patients who suffer from these cancers. We know that surgical excision, electrodessication and curettage, and Moh’s Surgery are true-and-tried modalities to treat these lesions. However, we all have patients who have NMSC on the scalp, ears, nose, and face, along with NMSC lesions on the leg. For many who are not ade-
nable to surgery or who may not be a good candidate for a surgical procedure or for those patients who have what has been coined “Surgical Fatigue”—where after so many surgical procedures, the patient just does not want surgery anymore—this is where SRT fits in and where many use SRT the most. Even Mohs surgeons who have incorporated SRT into their practices are finding it useful in many of these patients.

SRT allows for the precise application of an exact amount of radiation delivered to the NMSC areas. By fractionating the total dose to be given, over time, we can successfully treat and clear NMSC lesions. Most commonly, our patients are coming to the office two to three times per week for their SRT treatments, which are short and painless, and have the ability to function normally as the radiation therapy yields its effects on the skin cancers. We do 15-17 treatments on these patients, to an acceptable total radiation dose, and there is no further surgical procedure needed. Clinical studies evaluating SRT cure rates have shown very acceptable cure rates, and the cosmetic appearance following SRT is very acceptable in most every case, as well.

In my clinical practice, when we have a patient with a NMSC on the scalp, on the ears, on the nose, or on the legs, they are given the option to have SRT performed. We perform the consultation addressing what the best treatment modalities are for these skin cancers. Elderly patients, in particular, are ideal candidates for SRT, especially those who have had numerous skin cancers cut out in the past. We have had extremely happy patients, as a result of being able to offer SRT in addition to the more traditional surgical procedures.

**ADDING SRT TO YOUR OFFICE**

So how does one start the process of offering SRT to patients? It is not a simple undertaking but with what is now in place, it is seamless for most every office. You will need to dedicate one of your treatment rooms to be your “SRT Room.” You need this, as the company (Sensus Healthcare) will come to your office, usually on a weekend, and lead-line it and set it up with appropriate outside-the-room monitoring so that the care team can see inside the room and monitor patients during the SRT procedure itself. You also need to register with your state that you are doing this and be prepared for yearly inspections, as is done in all environments where radiation therapy is performed.

You will be provided with all the materials and training that you and your staff need to assure that everyone who will be working with SRT is very comfortable in performing this therapy. It has been an amazing addition to the practice, and again, we have had lots of very happy patients who have benefitted from SRT.

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As important as with PDT, SRT is fully covered by most US insurance companies and the reimbursement is very acceptable in today’s healthcare market and environment. We do pre-determinations on all of our patients and recommend other practices do the same, but we have found that most every patient is covered when we perform SRT.

A clinical example of a patient before and after treatment with SRT is shown in Figure 1.

**PDT AND SRT: TWO EFFICACIOUS OPTIONS**

PDT and SRT are two procedures we offer to our patients. At this time PDT is used primarily for the treatment of numerous AKs on the face, scalp, and extremities. We are hopeful that we can see in the near future a NMSC indication for the 10% ALA gel. We do use SRT for many who suffer from NMSC who are not candidates for surgery, who have surgical fatigue, or who have NMSC lesions on the scalp, ears, nose, and legs where we think that we can achieve a positive and acceptable cure rate.

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