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Gene Therapy for nAMD: Focus on Future Readiness

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Dr. Regillo:
I'm Carl Regillo. Here with me today is Dr. Lejla Vajzovic. It's an exciting time in retina with multiple gene therapies and development for retinal diseases. What are some of the clinical pearls that retina specialists should be aware of should these treatments be approved, Lejla?

Dr. Vajzovic:
Thank you, Carl. It is exciting time in retina indeed. I think it's exciting to be talking about biofactory approach, anti-VEGF biofactory or gene therapy delivery for retinal diseases. We gave a overview earlier about ixo-vec, sura-vec, and 4D-150 really having 2 options as intravitreal approaches with really aflibercept and 4D-150, aflibercept, VEGF-C RNAi, and in sura-vec being subretinal approach, which is ranibizumab-like with anti-VEGF Fab. All of these programs now are in phase 3 programs, and we most certainly will be hearing exciting reports starting next year for all of those. What we do know so far in terms of durability signal for these programs, and this data is really coming from earlier phase trial, phase 2 trials, which, by the way, enrolled, especially in ixo-vec and sura-vec programs, enrolled really high treatment burden patients, those who received an annually almost 10 injections before being enrolled, so are frequent injection-needing patients. And as we enrolled in these trials, we saw significant reduction in treatment burden or need for recurrent injections ranging from 65% to 88% in those programs. And in 4D-150 trial, or at least the programs thus far, have had a benefit of hearing the learnings from the earlier phases and enroll not only previously treated but almost treatment-naive patients that responded to anti-VEGF. So those did not have as high treatment burden, and sequentially we do see similarly excellent burden reduction in reports of theoretical reports of 78% in those program. I think these are some of differentiators in terms of populations that enrolled. But what else can we really compare?

And I think delivery and safety is very important with all of these. We talked about in-office versus vitrectomy in the operating room. We talk about needing topical steroid therapy and not just for shorter, like kind of post-op duration, but needing it for 3, 4 months in duration and a long taper period.

We've learned that topical steroid prophylaxis is the key, and topical alone is needed for these intravitreal, but really sustained longer prophylaxis is necessary. While subretinal approach, which does require a trip to the OR and complexity related to that, does not require any steroid prophylaxis.

These eyes do not require it. We have also learned that, yes, without topical steroid prophylaxis, inflammation may be an issue, although in these well-prophylaxed patients in clinical trials, we did not really see IOI events or any recurrence inflammation in them. And then we do see pigmentary changes about 70% of patients as the drug is delivered inferiorly, and that has been kind of the nuanced learning from the earlier phase trials to deliver the therapy subretinally inferiorly.

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I think nuances in terms of procedural, we're all super familiar with intravitreal injection. That is really standard practice for all of us. I think subretinal gene therapy delivery, while we may—it may sound exotic—it most certainly is not. We all do vitrectomy, plus the subretinal step is very much what we're used to and, I think, familiar with. Really, I wouldn't say it a big deal in terms of procedural step. We did learn that, again, we need to deliver the product inferiorly to mitigate pigmentary changes in that area in the future. And in suprachoroidal approach, we have gotten familiar with that approach with some approved therapies that we inject in that space.

But still, there's a learning curve with that. It is definitely hypothetical space, and there are nuances to really stay perpendicular, place pressure as you inject in that area, to really allow for the expansion of that space. So definitely some learnings with that, but nonetheless, something that can very much be accomplished in clinic.

So in terms of clinical integration, I think there will be some logistical holes to integrate gene therapy into our practice to logistically understand where exactly it will be stored and how to make it to our clinic for injection. But nonetheless, all of us had been very much participating in clinical trials and have mastered this process.

Dr. Regillo:
That was a fantastic summary. We really have learned a lot about gene therapies, the different ways to administer them, nuances with techniques, ways to make sure we minimize adverse events. There's pros and cons to all the approaches, but they all look very promising.

This has really been a great discussion. Thank you so much, Lejla, for being here, and thank you to our audience for joining us.

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