SPEAKER: Choosing the patients with scleroderma to treat with ECP, you need to really have a systemic, standardized approach to therapy. Now, it's not really going to be your primary therapy for people with skin disease, We'll try, like we do here, most of the time it's going to be with mycophenolate mofetil. But in a patient who has progressive skin hardening despite a first line therapy, the addition of ECP can really help them.

So to select the right patient for treatment with ECP, typically we look at whether they've failed a first line immunosuppresive therapy, such as mycophenolate mofetil, with progression of skin disease. And now we use, in terms of how often we use ECP, we really look back to that clinical trial data, where they tested a monthly frequency of the procedure. and what happens is, every month, they come in for treatment, and then that treatment is repeated the following day.

And this is really identical to the frequency of treatment that was originally discovered for cutaneous T-cell lymphoma by Dr. Edelson, who is the chair of dermatology at Yale University. And so this frequency has really continued to work in these other disease types. And so then how do we know how long how long to treat for improvement? So if you really look at, yet again, we're going back to the clinical trial data, you really want to test six months to a year to know whether or not ECP is helping with the disease or not.

And the measurements are primarily going to be the same endpoints of a skin severity score, such as the modified Rodnan skin score, or oral aperture and a hand grip. And so if we get improvement in any of those scores, that would support continuing therapy with ECP. Now, ECP is relatively well tolerated in most circumstances. During the procedure, there is a small loss of blood volume in their latest machines about 240 milliliters. So this blood loss is really small, and the vast majority of patients tolerate it absolutely fine. But a patient who's in severe duress and is hypotensive, this is somebody you're not going to agree with ECP, but otherwise most people do fine.

Returning to that question of the frequency of treatment, the other question is, in a patient who's not responding to ECP, is there anything more aggressive to do. And so in patients with graft versus host disease or heart or lung transplant rejection, then those patients are treated with a higher frequency of ECP. And so to translate the data for scleroderma, it suggests that we might get a better result with potentially every two weeks or even weekly treatments. And so we may try that change in that increased frequency if we're not getting where we need to be with the monthly treatment plan.