9:10 AM

Assessing the Level of Evidence for Commercially Available “Cell Therapy” Treatments for Retinal Diseases at U.S. “Cell Therapy” Clinics

- Daniel Simhaee, MD
- Rajinder S Nirwan, MD, BSc
- Thomas A. Albini, MD
- Jayanth Sridhar, MD
- Harry W. Flynn, MD
- Ajay E Kuriyan, MD, MS

OBJECTIVE To identify what the level of evidence is for commercially available "cell therapy" treatments for retinal diseases at U.S. "cell therapy" clinics.

PURPOSE Interest in cell therapy for retinal diseases is high due to promising results from scientific clinical trials. Although cell therapies studied in those trials are not commercially available, “cell therapies” are commercially available at U.S. “cell therapy” clinics. Therefore we assessed the level of evidence for commercially available treatments at these U.S. “cell therapy” clinics.

METHODS A systematic review of scientific literature was performed using PubMed to identify the levels of evidence for commercially available “cell therapy” treatments for retinal diseases at U.S. “cell therapy” clinics, using the Oxford Centre levels of evidence scheme. Due to the paucity of scientific publications on commercially available “cell therapy” treatments for retinal diseases, a systematic review of evidence presented on U.S. “cell therapy” clinic websites was performed.

RESULTS No Level 1, 2, 3 or 4 evidence for “cell therapy” treatments of retinal diseases at U.S. “cell therapy” clinics were found. One level 5 case report reported a positive

outcome. However, there was 1 case series with Level 4 evidence and 3 case reports with Level 5 evidence of complications of commercially available “cell therapy” treatments. Evaluation of U.S. “cell therapy” clinic websites found that there are 23 that treat retina conditions and of those 10 (43%) reported clinically significant benefits and 5 (22%) made vague claims about very positive possible outcomes. Only 7 (30%) described a range of possible outcomes from the treatment and 3 (13%) acknowledged that the treatment is “not a cure” and that the benefits “are not guaranteed.” Ten (43%) did not mention any potential risks or side effects while 5 (21.7%) claimed “only minor risks.” Six (26%) claimed there have been no adverse effects or events among their patient base.

CONCLUSION There are more published reports of complications after commercially available “cell therapy” treatments for retinal diseases at U.S. “cell therapy” clinics than positive outcomes. “Cell therapy” clinic websites appear to overemphasize potential benefits and underemphasize potential risks. It is important to educate patients about the potential risks of treatments at these “cell therapy” clinics.

9:13 AM

Nd:YAG Capsulotomy Is Associated With Sustained IOP Elevation in Patients Treated With Anti-VEGF Injections

- Assaf Dotan, MD
- Amir Sternfeld, MD

OBJECTIVE The effect of lens status and Nd:YAG capsulotomy on sustained intraocular pressure (IOP) elevation in patients treated with anti-VEGF injections.

PURPOSE To assess the effect of lens status on sustained IOP elevation in patients treated intravitreally with anti-VEGF agents.

METHODS Data were retrospectively collected for all patients treated with intravitreal injections of anti-VEGF medication at a tertiary medical center in July 2015. Findings were analyzed by lens status during 6 months' follow-up. The main outcome measure was a sustained increase in IOP (IOP ≥21 mmHg or change of ≥6 mmHg from baseline on >2 consecutive visits, or addition of a new IOP- lowering medication during follow-up).

RESULTS A total of 119 eyes of 100 patients met the study criteria: 40 phakic, 40 pseudophakic, and 39 pseudophakic after Nd:YAG capsulotomy. The rate of sustained IOP elevation was significantly higher in the post-capsulotomy group (23.1%) than in the phakic/pseudophakic groups (8.1%) (p=0.032), with no statistically significant differences among the 3 groups in mean number of injections, either total (p=0.82) or

by type of anti-VEGF mediation (bevacizumab: p=0.19; ranibizumab: p=0.13), or mean follow-up time (p=0.70).

CONCLUSION The present study suggests that Nd:YAG capsulotomy is a risk factor for sustained IOP elevation in patients treated with anti-VEGF injections. This finding could be crucial due to the increasing use of anti-VEGF injections nowadays along with the potential irreversible damage caused by the elevated IOP. This study did not identify other major risk factors for sustained IOP elevation.

Criterion	Phakic eyes	Pseudophakic eyes	Post capsulotomy eyes	p value
≥6 mmHg increase on 2 consecutive visits	3 (7.5%)	3 (7.5%)	5 (12.8%)	0.64
	6 (7.5%)		5 (12.8%)	0.35
≥21 mmHg on 2 consecutive visits	0 (0%)	0 (0%)	0 (0%)	
New IOP lowering medication	0 (0%)	2 (5%)	4 (10.3%)	0.11
	2 (2.5%)		4 (10.3%)	0.09
Total	3 (7.5%)	4 (10%)	9 (23.1%)	0.09
	7 (8.8%)		9 (23.1%)	0.03*

9:16 AM

Complications Following Laser Vitreolysis for Symptomatic Floaters

- Paul Hahn, MD, PhD
- Homayoun Tabandeh, MD
- Robert W. Wong, MD
- Eric W Schneider, MD
- Jennifer I. Lim, MD
- Geoffrey G. Emerson, MD, PhD

OBJECTIVE To assess the spectrum of real-world complications associated with laser vitreolysis for symptomatic floaters.

PURPOSE To evaluate complications following laser vitreolysis as reported to the American Society of Retina Specialists Research and Safety in Therapeutics (ASRS ReST) Committee by the ASRS members.

METHODS Retrospective study including all cases of complications following laser vitreolysis that were voluntarily reported by vitreoretinal specialists throughout the United States to the ASRS ReST Committee from September 2016 through March 2017.

RESULTS Seven vitreoretinal specialists reported a total of 16 complications in 15 patients following laser vitreolysis. Complications included prolonged elevation of intraocular pressure (5) with 2 cases progressing to secondary glaucoma requiring surgical intervention, focal cataract (5) including 2 with posterior capsule defect, retinal hemorrhages (2), retinal tear (1), retinal detachment (2), and increased floaters (1). Two eyes required subsequent cataract surgery.

CONCLUSION A spectrum of complications ranging from lenticular to retinal following laser vitreolysis has been reported to the ASRS ReST Committee. The complications rate

cannot be determined, as the number of performed procedures is unknown and there is certainly under-reporting. Awareness of potential complications is an important aspect of informed consent and managing patient expectations.

HUMAN RESEARCH This study involves human research.
IRB Approval Status: Exempt from approval

9:19 AM

Aflibercept-Related Sterile Intraocular Inflammation

- Philip J. Ferrone, MD
- Jonathan P Greenberg, MD
- Peter J Belin, MD

OBJECTIVE To describe recent reports of Aflibercept-related sterile intraocular inflammation and their outcomes.

PURPOSE There has been a recent increase in the number of cases of sterile intraocular inflammation following Aflibercept Injection reported to The American Society of Retina Specialists (ASRS) Research and Safety in Therapeutics Committee. We report this increase in incidence and describe the characteristics and outcomes of these cases.

METHODS A retrospective review of 78 eyes of 74 patients that were voluntarily reported by 15 practices throughout the United States from 1/7/17 to 1/19/18 (76/78 eyes reported after 9/1/17). An additional 43 eyes of 42 patients have been reported and are pending data collection. Diagnosis of sterile intraocular inflammation was at the discretion of each physician. Data Analysis included baseline and demographic information, presenting signs and symptoms, changes in visual acuity (VA), injection characteristics and management details. 26 lot numbers were implicated. The most frequently involved lot number was responsible for 21% and the 3 most frequent lot numbers for 50% of cases.

RESULTS Mean time to symptom onset was 2.4 days (range 0-15 days). Presenting symptoms included blurry vision (95%), floaters (62%), pain (42%) and photophobia (19%). Mean pre-injection and presenting VA were 20/44 and 20/109, respectively. Signs included conjunctival injection (15%), corneal edema (10%), anterior chamber reaction (76%), vitritis (83%) and hypopyon (8%). Four patients were affected bilaterally. Treatment included steroids (92%), antibiotic injection (19%) and vitrectomy

(3%). Samples were obtained in 21% of eyes - 1 grew staph epidermidis; the rest were negative. Inflammation was resolved in 72% of eyes (mean time to resolution 34 days, range 1-123 days, 50% [39/78] resolved by 1 month). Of resolved eyes, 16% lost ≥2 lines at final VA. Further VA loss after initial presentation was associated with worse visual outcome (p=0.005). Shorter time to symptom onset (p=0.08), presence of pain (p=0.053), photophobia (p=0.10) and hypopyon (p=0.055) trended towards worse visual outcomes.

CONCLUSION This is the largest report, to our knowledge, of Aflibercept-related sterile intraocular inflammation. Several lot numbers were associated with a large proportion of events. Most cases presented with initial vision loss and intraocular inflammation without severe pain, prominent injection, or hypopyon. Vision remained significantly decreased in a minority of patients at last follow-up.

HUMAN RESEARCH This study involves human research.
IRB Approval Status: Exempt from approval