

A new horizon in Stargardt's disease: a comprehensive rapid review of interventional therapies

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ABSTRACT

This rapid synthesis comprised seven studies on inherited macular dystrophy, known as Stargardt disease, which primarily affects children and young adults and is caused by the breakdown of a particular type of light-sensing cell in the eye called ABCA4. One database was selected, and search was carried out using the keywords Stargardt disease and interventional techniques by the application of the appropriate inclusion and exclusion criteria. Most studies were randomized controlled trials, and other systematic reviews and meta-analyses were included, which provided information about the study's methodology and results. The interventional therapies used in this review, including the use of saffron, docosahexaenoic acid, emuxistat hydrochloride, and biofeedback therapy, had a positive effect on Stargardt disease. Therefore, additional studies and syntheses, including controlled trials, case series, adequate sample sizes, and multiple centers, are needed in the future.

Keywords: Stargardt disease, Rapid synthesis, Emuxistat, Docosahexaenoic acid, Saffron, review

INTRODUCTION

Stargardt's disease (STGD) was expressed by Karl Stargardt in 1909, and an inherited condition, which means that parents pass it on to their offspring. It is frequently referred to as juvenile macular dystrophy, which causes children and young adults to lose eye vision. Due to the death of specific light-sensing cells in the macula, known as photoreceptors, individuals with Stargardt disease experience blurred or darkened central vision. It could also be challenging to discern colors clearly. STGD symptoms

can include difficulty in seeing colors and hazy, distorted, or black areas. The disease begins slowly before accelerating and leveling out.¹ A defective gene (ABCA4) is a causative factor inherited from both parents for the classic Stargardt illness to manifest symptoms. A person with the Stargardt disease gene from just one parent will be a carrier of the condition but will not exhibit any signs or symptoms. Other types of Stargardt illness, which are extremely uncommon, require a gene from just one parent to manifest symptoms. At approximately 20/40 vision, an individual can see at 20 feet compared to a normal person

with normal vision who sees at 40 feet.^{1,2} Fluorescein angiography and genetic testing can be used to diagnose STGD. Currently; there is no known cure for Stargardt's disease. However, scientists are currently investigating pharmacological and gene therapies.² This review aimed to examine the most recent studies that determined the advancement of STGD treatment options.

METHODOLOGY

Rapid reviews are a type of evidence synthesis that works effectively for analyzing the existing body of knowledge about a particular policy, any intervention and systematic review. They used a streamlined review procedure to generate information because they were completed quickly and usually was conducted by Preferred Reporting Items for Systematic review and meta-analysis (PRISMA) guidelines.^{3,4} The three stages of the search procedure were as follows: A search for the terms "Stargardt Disease" in databases like PubMed and the Cochrane library, a search for Stargardt disease, randomized controlled trial (RCTs), systematic reviews, and meta-analyses that were released within the last five years, and a search for the most recent review that contained only information about Stargardt disease and were in English-language articles. Articles published between 2017 and 2022, with free full-text access, free access to open individual articles, and unlocked articles met the inclusion criteria. The exclusion criteria, such as research conducted prior to 2017, papers that were locked or written in a language other than English, and incomplete articles about Stargardt disease, were not taken into consideration. Only PubMed database was considered as it coherent with the all-inclusion list.

RESULTS

Only seven of the 1417 items from the databases were included in this rapid evaluation because they met all the inclusion requirements. The randomized controlled trial included were N=3, systematic review and meta-analysis was N=4. The databases that included the number of publications with the term 'Stargardt Disease' and the type of study are displayed in (Table 1). The information from the included articles, including the author's name, type of study, method, and results, is reported in (Table 2).

DISCUSSION

There is no established treatment for STGD because it is a genetic illness that causes macular degeneration, which typically affects young people. Hypotheses have emerged concerning the subjects' participation in clinical trials, and various new therapeutic approaches have come to the surface.¹² This synthesis focused on new regimes for Stargardt's disease. A hereditary disorder called Fundus flavimaculatus (FFM) is regarded as one of the two extremes of a disease characterized by the appearance of retinal flecks, and consequence of ABCA4 and PRPH2 genes, as well as the overproduction of vitamin A, that have been related to the beginning of the condition.

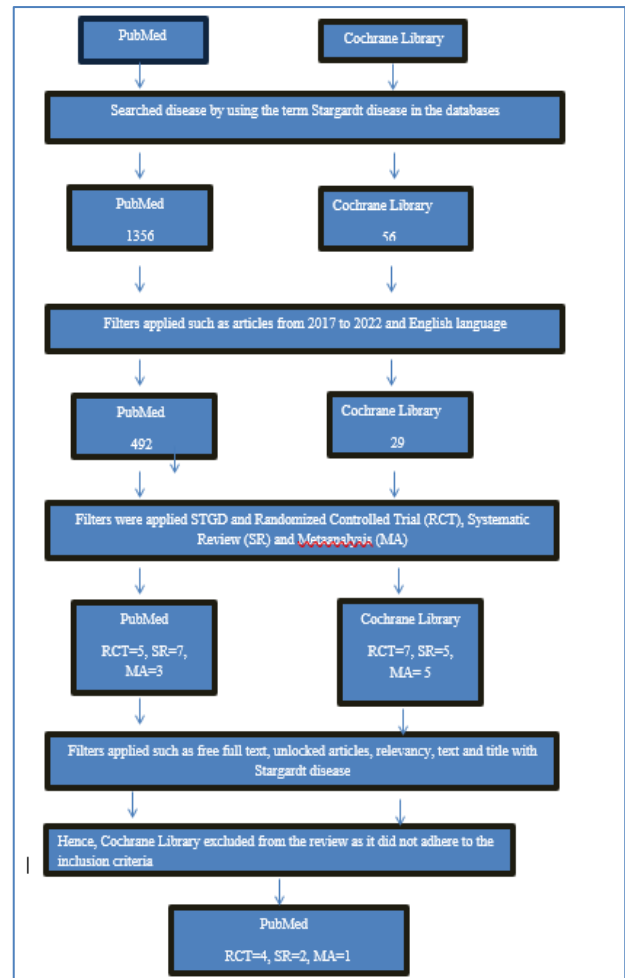


Figure 1: Systematic representation of the search from the databases.

However, it tends to have a slower pace of advancement and later onset than the others. The sickness that strikes toward the close of the second or third decade is referred to as FFM. Visual acuity is adversely affected during the first two decades of STGD. This pilot study evaluated fERG amplitude (in V), phase (in degrees), and visual acuity in STG/FF patients with the ABCA4 mutation to assess central retinal function after saffron administration.¹²⁻¹⁴ Saffron, which is generated from the pistils of *Crocus sativus*, may protect against oxidative damage. The researchers demonstrated that lutein supplementation raised macular pigment optical density levels but had little to no effect on foveal-macular sensitivity. Intriguingly, when compared to age-matched controls, patients with ABCA4 mutations who were not treated demonstrated a decline in macular pigment optical density, suggesting that ABCA4 dysfunction may be partially correlated with the generation and effectiveness of macular pigment and study did not shown any negative outcomes.¹⁰

Basically, biofeedback (BF) rehabilitation are employed to take control of uncontrollable functions. These techniques, used in a variety of medical specialties, teach patients how

to control various bodily functions automatically through practise, even in the unavailability of a return signal. Through a device that measures and translates them in audio and/or visual signals, the patient first begins to comprehend the fluctuations of a physical function.¹⁵ Hence, cited study aimed to evaluate BF rehabilitation in patients with Stargardt's illness caused by ABCA4 gene mutations in visual function and primary visual cortex (PVC) activity of STGD1 patient.

Table 1: The data related to the number of the articles and databases.

Database	Searches	Articles
PubMed	Stargardt disease	1321
PubMed	Stargardt disease from 2017- 2022	492
PubMed	Stargardt disease and Meta-analysis	4
PubMed	Stargardt disease and Systematic Review	8
PubMed	Stargardt disease and Randomised Controlled Trial	7
Cochrane Library	Stargardt disease	56
Cochrane Library	Stargardt disease and Systematic Review	5
Cochrane Library	Stargardt disease and Metanalysis	5
Cochrane Library	Stargardt disease and Randomised Controlled Trial	4

A preferred retinal locus (PRL) is a distinct retinal region containing the center of the target image for 20% of the fixation interval. This study examined sizable sample of STGD1 patients who had been treated with MP1-BF and compared it to a control group (CG) of STGD1 patients. According to the study findings, the treatment significantly improved patients' reading abilities, as seen by a large reduction in the print character size that they could read and an increase in their reading speed. Additionally, best-corrected visual acuity (BCVA) significantly improved and, compared to control group (CG) patients undergoing rehabilitation, showed considerable improvement in retinal sensitivity and fixation stability. This study has several limitations because subjects assigned to the treatment group (TG) had higher expectancies than those randomized to the CG; it was impossible to ignore the so-called placebo-expectancy effects owing to the lack of a control task in the CG.⁹ Additionally, other studies that evaluated the effectiveness of rehabilitation with MP1-BF over the course of 10 sessions, each lasting 10 minutes, in five patients with diverse macular disorders (only one patient had STGD1). The patients with nonhomogeneous macular degeneration and the absence of a CG were the study's principal limitations, even if the authors discovered a considerable refinement in the visual function metrics at the end of the treatment.¹⁶ Similar study with the eight

sessions that lasted for 10 min shown significant improvement in fixation stability, BCVA and RS.¹⁷

Thus, emixustat hydrochloride may offer protection against STGD-induced retinal damage caused by STGD. It is an orally accessible small drug that inhibits the formation of the visual chromophore (11-cis-retinal) in a dose-reliant and adjustable manner by targeting the retinal pigment epithelium-specific 65 kDa protein (RPE65).¹⁸ The study was conducted to describe the pharmacodynamic effects of emixustat on electroretinography (ERG) in patients with secondary STGD-related macular atrophy (MA) after oral administration of the medication for one month. The ERG's rod b-wave amplitude is regarded as an accurate indicator of the degree of rhodopsin regeneration and signal processing in the retina.¹⁹ Hence, emixustat inhibited RPE65 in this population in a dose-dependent manner. The single-flash cone response and 31 Hz flicker cone response did not show any significant differences. The modest sample size and the intrinsic, sizable inter- and intra-subject variability observed in ERGs are two limitations of this study, which made it difficult to generalize the findings of this investigation to the entire STGD community, in addition to the large genetic and phenotypic heterogeneity within the STGD population. However, the outcomes of this trial showed distinct variations between the dosing groups.⁵ The specific retinal effects of docosahexaenoic acid (DHA) include increased retinal pigment epithelium (RPE) acid lipase activity, increased mitochondrial activity, and antioxidative, antiproliferative, and antiapoptotic effect.²⁰ In this study, serum levels increased throughout the period of DHA supplementation and then decreased when switching to a placebo. The average change in peak amplitude and phase angle of the flicker ERG remained consistent across all visits, whereas none of the subjects exhibited a change in the multifocal electroretinogram (mfERG) greater than 20% from baseline values during periods of DHA supplementation or placebo. No discernible differences were observed in any of the subsidiary outcome indicators. Around eight negative outcomes were reported, however, it was determined that they were not caused by the medication.¹¹ In another research, the dimension of central atrophy did not change in any way, and none of the 20 patients developed choroidal neovascularization (CNV) by the end of the six-month period. The lack of ELOVL4 gene mutations in all patients was discovered by molecular biology analysis of the ELOVL4 gene, which was made to develop predictive variables for the effectiveness of DHA treatment. Hence DHA showed influence on functional parameters in the patient with STGD.²¹ The prevalent neuronal-ceroid-lipofuscinosis is known as CLN3 illness and also called as juvenile-neuronal-ceroid-lipofuscinosis or Batten's disease (NCLs). The intra-cellular collection of autofluorescence archived material in most tissues unites these genetically and clinically diverse degenerative illnesses of the brain and, in the retina, and collectively represent a significant contributor to childhood neurodegeneration.^{22,23}

Table 2: The information related to the study's author name, methodology, outcome and type of article.

Authors name	Article type	Method	Conclusion
Kubota et al.⁵	Randomized Controlled Trial	23 patients with secondary Stargardt disease macular atrophy were randomly assigned to receive one of three daily emixustat doses (2.5, 5, or 10 mg) for a month.	The biological action of emixustat in patients with Stargardt's disease was confirmed by this investigation, which showed a dose-dependent decrease in rod b-wave amplitude recovery following photo-bleaching.
Shen et al.⁶	Meta-analysis and Systematic Review	Seven of the 3158 articles that were screened fit combined study- and individual-level datasets along a straight line in the RLM after involving horizontal translation factors to adjust for various entrance duration.	Both the study and individual data showed that STGD1 lesions developed in a manner that mirrored the RLM. A good outcome metric for tracking STGD1 progression could be the effective radial growth rate of atrophic lesions..
Waugh et al.⁷	Systematic Review	The titles and abstracts of 7948 papers were scrutinized for inclusion. For additional reference verification and screening, the complete texts of 398 articles were collected and 112 articles were included in the final report. We searched for research on vision preservation or restoration therapies for STGD or dry AMD (age-related macular degeneration) patients	Visual acuity (VA), contrast sensitivity, reading speed, driving ability, side effects of treatment, quality of life, disease progression, and patient choice are among the most crucial outcomes. Potential research areas include pharmacological therapies, stem cells, novel laser therapies, and implantable intraocular lens telescopes were seen in this review.
William et al.⁸	Meta-analysis	36 publications were found in the literature search that was appropriate for inclusion, describing 104 patients with classical and 14 individuals with prolonged CLN3 disease.	Around the time of diagnosis, cognitive dysfunction is apparent in all cases of classic CLN3 illnesses
Melillo et al.⁹	Randomized controlled trial	24 STGD1 patients were allocated randomly to one of two groups: the treatment group (TG), which underwent BF therapy, and the control group (CG). Each eye underwent a 10-min course of BF therapy once a week for 12 weeks. The individuals completed baseline and three-month follow-up examinations, including functional magnetic resonance imaging (fMRI), microperimetry, and best-corrected visual acuity (BCVA) testing (fMRI).	The research revealed that STGD1 patients who underwent biofeedback rehabilitation (BF) for visual rehabilitation utilized their remaining visual function more effectively.
Marrco et al.¹⁰	Randomized controlled trial	After receiving oral saffron (20 mg) or a placebo for six months, 31 patients with ABCA4-related STG/FF (Fundus flavimaculatus) and a visual acuity greater than 0.25 switched to P or S for another six months. Over six months of either with saffron or placebo, complete ocular exams and central 18° focal electroretinogram (fERG) recordings were made. Fourier analysis was used to separate the fundamental harmonic components of the fERG.	Saffron intake for a brief period of time was well sustained and did not have negative effects on electroretinographic reactions or visual acuity of the central retina.

Continued.

Authors name	Article type	Method	Conclusion
MacDonald et al.¹¹	Randomized controlled trial	A placebo-controlled trial with a crossover design involving 11 patients with Stargardt disease (2 males and 9 females). Six subjects were randomly assigned to two cycles of docosahexaenoic acid (DHA) supplementation (2000 mg/day) for three months, followed by three months of placebo. Five individuals were randomly assigned to an alternative order. A thorough eye examination, a food frequency, an NEI-VF25 questionnaire, multifocal electroretinography (ERG, primary outcome), a 30-Hz flicker ERG, a Humphrey 10-2 visual field, a D15 color test, and a blood lipid analysis were all used to examine each participant.	In a small group of Stargardt patients who adhered to the treatment, no apparent impact of DHA supplementation on macular function was noticed as measured by changes in serum DHA levels.

In the study, it was determined whether patients with CLN3 frequently experienced cognitive decline. The impact of diagnosis on neurocognitive functioning was investigated in a referral centre cohort of patients with CLN3 disease, and another cohort of patients with Stargardt disease was created to control for the potential effects of rapid early vision loss on neurocognitive functioning. Results from the 36 studies' intelligent quotient (IQ) tests used for data analysis revealed that cognitive reduction began at a average age of 6.8 years and that between the ages of 6 and 9 years, IQ scores dropped due to the CLN3 disease. A more conclusive result was not obtained because of the smaller population and a larger amount of missing data.⁸

The usual cause for loss of vision in elderly persons is age-related-macular-degeneration (AMD), an eye anomaly that could lead to blurred central vision but does not result in total blindness. However, decreasing central vision can make it more difficult to read, drive, recognize faces, or perform close-up tasks such as cooking or home maintenance. 112 articles were included in the review, some trials have reported useful outcomes, especially in STGD, including those of sufficient size and duration. The fundamental constraint in AMD is often a low caliber of the evidence. Despite insufficient time to observe changes, many studies have employed visual acuity (VA) as their primary endpoint. Little research has been conducted on STGD therapies. Most studies examined therapies without using a control group; they lasted for far too little time, and several of them were of low quality.⁷ Basic treatment involved lifestyle modifications, including vitamin supplements, smoking, and regular exercise. Eylea injection for macular degeneration is the most widely considered treatment. The other types of anti-VEGF injections include ranibizumab and bevacizumab. Each of these substances inhibits the formation of blood vessels in

a distinct way.^{25, 26} Metformin, a medication presently used to treat diabetes, is being investigated by researchers as a potential pharmacological therapy to halt the advancement of Stargardt illness. Researchers anticipate that metformin will help some cells, especially retinal cells, function better. Other studies have focused on inducing the maturation of retinal pigment epithelium from embryonic stem cells, which could be utilized to restore eyesight.²⁷ Autologous bone marrow-derived stem cells (BMSC), as offered in SCOTS, may be effective and impactful for patients with Stargardt's disease. The vast majority of reported patients' vision was found to improve or stabilize, and these outcomes were highly statistically significant.²⁸

ALK-001 is a counterfeit vitamin A oral tablet that prevents the development of harmful vitamin A dimers in the eye. Usually, this type of vitamin A takes longer to convert to lipofuscin, which could delay eyesight loss by delaying its deposition. Other vitamin A variations have been investigated and are currently undergoing testing in Phase II multicenter clinical research.^{29,30} Tinlarebant, from a phase 2 trial, has previously been designated as an orphan drug in the United States and Europe, and a rare pediatric disease in the United States. It functions by halting the accumulation of toxins in the eye, leading to Stargardt's disease and dry age-related macular degeneration.³¹ Other therapies, such as avacincaptad pegol and lentivirus vectors, prevent MAC formation.³² Although there is no capitalistically accessible management for STGD1, a number of therapy categories are being researched to address this unmet need. Prospects for patients with this illness are positive thanks to ongoing rapid therapeutic innovation. As a result, this review attempted to analyze the data and their results to assess therapeutic modalities. Administration of DHA, emixustat hydrochloride, and saffron demonstrated positive short-term effects. This study also examined how visual and

cognitive problems affect STGD in AMD and CLN3 patients. A limitation of this study was the inclusion of fewer publications; therefore, it did not reflect the actual effective care of STGD and on other similar illnesses. This bias is predictable because the included RCTs had a smaller sample size. As it was known, that STGD does not have any treatment options, hence the study on novel treatment negative outcomes was not recorded properly. More data were not analyzed due to the time constraint, as it used only 5-year articles; therefore, the constructive outcome was not concluded.

CONCLUSION

Emuxistat hydrochloride, MP1-BF, saffron injection, and DHA were interventions that had a positive influence on patients. Additional research is needed to study and maximize the effects based on the frequency and timing of sessions and to examine the stability of the effects over time, particularly in relation to the deterioration of visual function caused by the advancement of the disease. Furthermore, there is a need for more beneficial interventional research that uses RCTs, case studies, and case presentations to thoroughly examine the effects of treatment. There is a requirement for the participation of a sizeable population and numerous centers to lessen the likelihood of bias in the outcomes.

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