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Clinical research on one-third dose verteporfin photodynamic therapy in the treatment of chronic central serous chorioretinopathy

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Abstract. – OBJECTIVE: To observe the curative effect and safety of one-third dose Verteporfin photodynamic therapy (PDT) in the treatment of chronic central serous chorioretinopathy (CSC).

PATIENTS AND METHODS: A total of 60 patients (68 eyes) treated in our hospital from January 2016 to December 2016 were selected in this study, and they were diagnosed with chronic CSC via fluorescein fundus angiography (FFA), indocyanine green angiography (ICGA) and optical coherence tomography (OCT). Besides, patients were treated with one-third conventional dose Verteporfin PDT. The subfoveal choroidal thickness (SFCT), superior, inferior, nasal and temporal choroidal thickness at 1.5 mm away from macula central fovea, central choroidal capillary layer thickness, photoreceptor layer thickness, best corrected visual acuity (BCVA), subretinal fluid absorption, FFA and ICGA manifestations and complications of patients were observed and recorded before treatment and at 1, 3 and 6 months after treatment.

RESULTS: After PDT via one-third conventional dose of Verteporfin, patients were followed up for 1 month, 3 months, and 6 months. The SFCT of affected eyes was changed from (381.23 ± 83.29) μm before treatment to (385.31 ± 90.89) μm, (369.59 ± 75.60) μm and (374.08 ± 102.81) μm successively, and the differences were statistically significant ($p < 0.001$). Central choroidal capillary layer thickness and superior, inferior, nasal and temporal choroidal thickness at 1.5 mm away from macula central fovea ($SCT_{1.5mm}$, $ICT_{1.5mm}$, NCT1.5mm and $TCT_{1.5mm}$) were significantly decreased at 1 month, 3 months and 6 months after treatment compared with those before treatment ($p < 0.001$). With the passage of time after treatment, the photoreceptor layer thickness of affected eyes was increased gradually, and the difference was statistically significant ($F = 268.8$, $p < 0.0001$). After PDT, BCVA had a statistically significant difference compared with that before treatment ($p = 36.16$, $p < 0.001$); BCVA at 3 months after treatment had no statistically significant difference compared with that at 6 months after treatment ($p > 0.05$). At 6 months after treatment, the subretinal fluid in 63 eyes (92.6%) completely subsided, and a little subretinal fluid was retained in 5 eyes (7.4%). FFA and ICGA showed the choroidal vessel dilatation in affected eyes after treatment and significantly improved moderate-advanced high fluorescein leakage compared with that before treatment. There were no obvious complications in the body and fundus during the follow-up period.

CONCLUSIONS: One-third dose Verteporfin PDT can improve BCVA, stop or reduce the choroidal vasodilatation and leakage, accelerate the absorption of serous subretinal fluid, and help the recovery of photoreceptor layer of patients with chronic CSC, which is safe and reliable.

Key Words:
Central serous chorioretinopathy, Photodynamic therapy, One-third dose, Verteporfin.

Introduction

Central serous chorioretinopathy (CSC) is a kind of common fundus disease, which occurs in young males, and binocular incidence is often common in the elderly. The symptoms of pa-

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tients mainly include blurred vision, preocular shadow, metamorphopsia, micropsia accompanied with changes in color vision and vision loss in different degrees; sometimes, hypermetropic refractive changes also occur in the early stage. The typical fundus manifestations are 1-3DD limited discoid retinal detachment in macular region, subretinal yellowish white spot effusion, and disappearance of macula central reflection, accompanied with serous pigment epithelium detachment (PED)[1,2]. With the development of fundus fluorescein angiography (FFA) and indocyanine green angiography (ICGA), people have gradually recognized that in CSC, the effusion in choroidal capillaries in lesion area enters the retinal sensory layer through the damage area of retinal pigment epithelial layer, resulting in retinal neuroepithelial serous detachment. Due to the self-limitation of CSC, conservative treatment was dominated in the past, but the disease relapses easily with a recurrence rate of 40-50%, which repeatedly occurs in some patients and often develops into chronic CSC[3,4]. In recent years, photodynamic therapy (PDT) has been widely used in the treatment of choroidal neovascularization (CNV), achieving good clinical effects. PDT can block CNV, especially lesions in macular central fovea, without damage to the normal retinal tissues[5]. In the treatment of CSC with PDT, a kind of photosensitizer (Verteporfin) is injected into the vein, which will automatically accumulate in the receptor tissues and cells in 8-15 min; under the guidance of ICGA, the special non-thermal laser (cool laser) is used to treat the abnormal choroidal vessels in the leakage area shown in ICGA. With increasingly wider application, the potential side effects of standard PDT in the treatment of pigment epithelial atrophy, choroidal ischemia and CNV in chronic CSC have gradually attracted attention. In recent years, in order to improve the safety factor of PDT in the treatment of chronic CSC, the energy or dose of PDT is set as one half or even lower. Moreover, it is reported that the half-dose PDT can effectively seal the leakage point in the treatment of CSC, while avoiding the occurrence of serious complications[6-8]. This provides a new safe and effective way for CSC patients with a longer course and delayed healing, especially those whose leakage point is in macula center. This study aimed to observe the curative effect and safety of one-third dose Verteporfin PDT in the treatment of chronic CSC.

Patients and Methods

Patients

A total of 60 patients (68 eyes) diagnosed with chronic CSC via medical history, fundus examination, optical coherence tomography (OCT), FFA and ICGA in the Bayi Hospital Affiliated Nanjing University of Chinese Medicine from January 2016 to December 2016 were selected in this study, including 52 males (58 eyes) and 8 females (10 eyes) with a male/female ratio of about 6.5:1. They were aged 28-65 years old with an average of (41.6 ± 5.6) years old. All patients signed the informed consent. This study was approved by the Ethics Committee of The Bayi Hospital Affiliated Nanjing University of Chinese Medicine.

Inclusion criteria: patients with loss of vision, central scotoma, micropsia or metamorphopsia for more than 6 months; OCT showed retinal neuroepithelial serous detachment, FFA or ICGA showed the fluorescein leakage point below or near the macula central fovea, showing diffuse leakage (> 5 leakage points), focal leakage (≤ 5 leakage points) or lack of clear leakage point; with macular choroidal vasodilatation and increased vascular permeability. Exclusion criteria: patients with macular neuroepithelial serous detachment caused by CNV, polypoidal choroidal vasculopathy, optic pit, uveomeningoencephalitic syndrome, etc.; patients with a medication history of glucocorticoids; patients with a history of laser photocoagulation or intraocular medication (anti-vascular endothelial growth factor antibody); patients with poor general physical conditions, or a history of hypertension, diabetes mellitus and kidney disease.

Routine Examinations of Eyes

The visual acuity and best-corrected visual acuity (BCVA) were detected using the international standard logarithmic visual acuity chart; after pupillary dilation with 0.5% tropicamide, the anterior segment and fundus were detected using the slit-lamp ophthalmoscope.

OCT

All patients underwent the OCT (Heidelberg Engineering, Heidelberg, Germany) in affected eyes using the enhanced depth imaging (EDI) technique. Before PDT via one-third dose of Verteporfin and at 1, 3, and 6 months after treatment, the choroidal thickness, subfoveal choroidal thickness (SFCT), superior, inferior, nasal

and temporal choroidal thickness at 1.5 mm away from macula central fovea ($SCT_{1.5mm}$, $ICT_{1.5mm}$, $NCT_{1.5mm}$ and $TCT_{1.5mm}$), central choroidal capillary layer thickness, photoreceptor layer thickness were measured. All measurements were performed independently by two experienced physicians for three times, and the averages were taken.

FFA and ICGA

The allergic history, cardiovascular and cerebrovascular disease history and liver and kidney disease history were asked in detail. Patients were informed of relevant matters to the radiography, and signed the informed consent. Skin allergy test: the diluted fluorescein sodium and indocyanine green were subcutaneously injected, and the skin was observed after 15 min; no swelling, rash, pruritus, general malaise, etc., indicated the negative. Negative patients received FFA and ICGA; first they underwent the infrared and autofluorescence photography, intravenous injection of mixture of 5 mL 10.0% fluorescein sodium (Alcon, TX, USA) and 2 mL 12.5% indocyanine green (Dandong Yichuang Pharmaceutical, Liaoning, China), as well as FFA and ICGA synchronously. After the contrast medium injection, the vessels were immediately photographed usually for 30 min. All patients received FFA and ICGA before treatment and at 3 months after treatment, and the angiography results were interpreted by experienced experts in fundus disease.

PDT

One-third dose (2 mg/m^2 body surface area) of Verteporfin (Novartis, Basel, Switzerland) was injected via elbow vein within 8 min. At 10 min after injection, the semiconductor laser (Opal Photoactivator, Lumenis, CA, USA) with a wavelength of 689 nm, light energy density of 50 J/cm^2 and power density of 600 mW/cm^2 was used for continuous irradiation for 83 s. Laser irradiation ranges included the fluorescein leakage area related to retinal neuroepithelial detachment, choroidal vasodilatation and increased vascular permeability areas, and retinal pigment epithelial detachment area. The spot diameter was 1300-5600 μm. After treatment, patients were asked to wear protective glasses to keep out of the sun for 72 h.

Statistical Analysis

Statistical Product and Service Solutions 19.0 (SPSS, Inc., Armonk, NY, USA) software was used for statistical treatment. The general data of subjects and the detection indexes were presented as mean ± standard deviation ($\bar{x} \pm s$). One-way repeated measures analysis of variance was used for the data comparison of subjects before and after treatment, and least significant difference (LSD)-*t* test was used for pairwise comparison. The paired-samples *t*-test was used for the comparison of two sample means. $p < 0.05$ suggested that the difference was statistically significant.

Results

Comparison of Choroidal Thickness Before and After Treatment

After PDT, 60 patients (68 eyes) were followed up for 6-9 months with the median time of 8 months. The SFCT of 68 affected eyes was 245-687 μm with an average of (451.23 ± 83.29) μm before treatment. At 1, 3 and 6 months after PDT via one-third dose of Verteporfin, the SFCT was 196-578 μm, 163-546 μm and 177-560 μm, respectively. Compared with that before treatment, the SFCT at each time point after PDT was significantly decreased ($F = 12.50$, $p < 0.001$). The SFCT was decreased significantly at 3 months after PDT compared with that at 1 month after PDT, and the difference was statistically significant (LSD-*t* test: $p = 0.002$). The average SFCT at 6 months after PDT was (374.08 ± 102.81) μm, which was slightly increased compared with that at 3 months after treatment [(369.59 ± 75.60) μm]; the difference was not statistically significant (LSD-*t* test: $p = 0.139$). The choroidal capillary layer thickness was (127.32 ± 28.51) μm before treatment, and it was decreased at 1, 3 and 6 months after treatment ($F = 16.33$, $p < 0.001$). $SCT_{1.5mm}$, $ICT_{1.5mm}$, $NCT_{1.5mm}$ and $TCT_{1.5mm}$ at 1, 3 and 6 months after treatment had statistically significant differences compared with those before treatment (Table I).

BCVA Before and After Treatment

BCVA at 1, 3 and 6 months after treatment had a statistically significant difference compared with that before treatment, respectively ($p = 36.16$, $p < 0.001$); BCVA at 3 months after treatment had no statistically significant difference compared with that at 6 months after treatment ($p > 0.05$). Compared with that before treatment, BCVA of 49 out of 68 eyes (72.0%) was improved, and the remaining 19 eyes (28.0%) remained unchanged; there were no eyes with loss of vision (Table II).

Table I. The comparison of choroidal thickness and choroidal capillary thickness at posterior pole of chronic CSC patients before and after PDT treatment (μm).

Time	SFCT	SFCCT	$SCT_{1.5mm}$	$ICT_{1.5mm}$	$NCT_{1.5mm}$	$TCT_{1.5mm}$
Before PDT	451.23 ± 83.29	127.32 ± 28.51	412.55 ± 47.35	360.30 ± 55.51	362.66 ± 61.79	412.19 ± 59.05
1 month after PDT	385.31 ± 90.89	111.89 ± 22.07	350.12 ± 41.57	311.91 ± 60.78	307.19 ± 66.76	329.43 ± 69.33
3 months after PDT	369.59 ± 75.60	101.31 ± 24.81	323.49 ± 39.60	290.86 ± 65.91	261.44 ± 58.22	301.02 ± 51.44
6 months after PDT	374.08 ± 102.81	103.09 ± 20.90	336.52 ± 38.72	298.63 ± 75.11	270.38 ± 55.91	310.80 ± 52.68
F value	12.50	16.33	60.14	15.75	38.87	50.80
p value	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

Notes: CSC: central serous chorioretinopathy; PDT: photodynamic therapy; SFCT: subfoveal choroidal thickness; SFCCT: subfoveal choroidal capillary thickness; $SCT_{1.5mm}$: choroidal thickness 1.5 mm superior to subfoveal; $ICT_{1.5mm}$: choroidal thickness 1.5 mm inferior to subfoveal; $NCT_{1.5mm}$: choroidal thickness 1.5 mm nasal to subfoveal; $TCT_{1.5mm}$: choroidal thickness 1.5 mm temporal to subfoveal.

Photoreceptor Layer Thickness

The comparisons of photoreceptor layer thickness at 1, 3 and 6 months after treatment with that before treatment showed that it was slightly decreased in the affected eyes at 1 month after treatment, and the difference was not statistically significant ($p > 0.05$). With the passage of time after treatment, the photoreceptor layer thickness of affected eyes was increased gradually; one-way analysis of variance revealed that and the difference was statistically significant ($F = 213.6$, $p < 0.0001$), proving the significant therapeutic effect after treatment (Table III).

Subretinal Fluid Absorption

OCT showed that at 1 month after PDT, the subretinal fluid in 31 eyes (45.6%) completely subsided, and a little subretinal fluid was retained in 37 eyes (54.4%); at 3 months after treatment, the subretinal fluid in 49 eyes (72.1%) completely subsided, and a little subretinal fluid was retained in 19 eyes (27.9%); at 6 months after treatment, the subretinal fluid in 63 eyes (92.6%) completely subsided, and a little subretinal fluid was retained in 5 eyes (7.4%) (Table IV).

FFA and ICGA Manifestations

FFA: Before treatment, there was focal fluorescein leakage (≤ 5 leakage points) in 52 eyes (76.5%), and diffuse fluorescein leakage (> 5 leakage points) in 12 eyes (17.6%); 4 eyes (5.9%) had no clear fluorescein leakage points. At 3 months after PDT, there was no fluorescein leakage in 61 eyes (89.7%), and the diffuse leakage was converted into slight leakage in 7 eyes (10.3%).

ICGA: Before treatment, 55 eyes (80.9%) had choroidal vasodilatation and moderate-advanced high fluorescein leakage, and 13 eyes (19.1%) had no vasodilatation. At 3 months after treatment, 51 eyes (75.0%) had choroidal vasodilatation, among which 48 eyes had no moderate-advanced high fluorescein leakage, and 3 eyes had leakage; the choroidal vasodilatation was improved compared with that before treatment in 46 eyes (90.2%), and similar to that before treatment in 5 eyes (9.8%). The comparisons of FFA and OCT of typical cases before PDT and at 3 months after PDT are shown in Figure 1.

Table II. The comparison of BCVA of chronic CSC patients before and after PDT treatment.

Time	BCVA (Log MAR)
Before PDT	0.62 ± 0.22
1 month after PDT	0.34 ± 0.29
3 months after PDT	0.19 ± 0.30
6 months after PDT	0.21 ± 0.27
F-value	36.16
p-value	< 0.001

Notes: BCVA: best corrected visual acuity; CSC: central serous chorioretinopathy; PDT: photodynamic therapy.

Table III. The comparison of photoreceptor thickness at posterior pole of chronic CSC patients before and after PDT treatment (μm).

Time	Photoreceptor thickness (μm)
Before PDT	30.93 ± 8.01
1 month after PDT	29.06 ± 6.61
3 months after PDT	41.75 ± 7.39
6 months after PDT	62.45 ± 11.69
F-value	213.6
p-value	< 0.001

Notes: CSC: central serous chorioretinopathy; PDT: photodynamic therapy.

Table IV. The comparison of SRF outcome in chronic CSC patients before and after PDT treatment.

Time	Completely absorbed (n, %)	Incompletely absorbed (n, %)
Before PDT		
1 month after PDT	31 (45.6%)	37 (54.4%)
3 months after PDT	49 (72.1%)	19 (27.9%)
6 months after PDT	63 (92.6%)	5 (7.4%)
χ^2-value	36.109	
p-value	< 0.001	

Notes: CSC: central serous chorioretinopathy; PDT: photodynamic therapy; SRF: subretinal fluid.

Complications

No systemic complications occurred in patients, and no complications, such as CNV and pigment epithelial atrophy, were found in all patients during follow-up period.

Discussion

CSC is a kind of common fundus disease, which has its own limitations; but due to the delayed healing of preocular shadow or metamorphopsia in patients, retinal neuroepithelium and RPE are damaged, leading to the permanent loss of vision. The improvement in FFA, ICGA, OCT and other means of inspection helps people have a better understanding of the cause and pathogenesis of CSC. The update of treatment means makes the active treatment of CSC advocated by more and more clinicians. In recent years, PDT has been widely used in the treatment of CNV. A number of studies have shown that the application of half-dose Verteporfin PDT in the treatment of chronic CSC can achieve good effects with fewer adverse reactions[9-12].

It is reported that pigment epithelial atrophy, incomplete photoreceptor function, choroidal

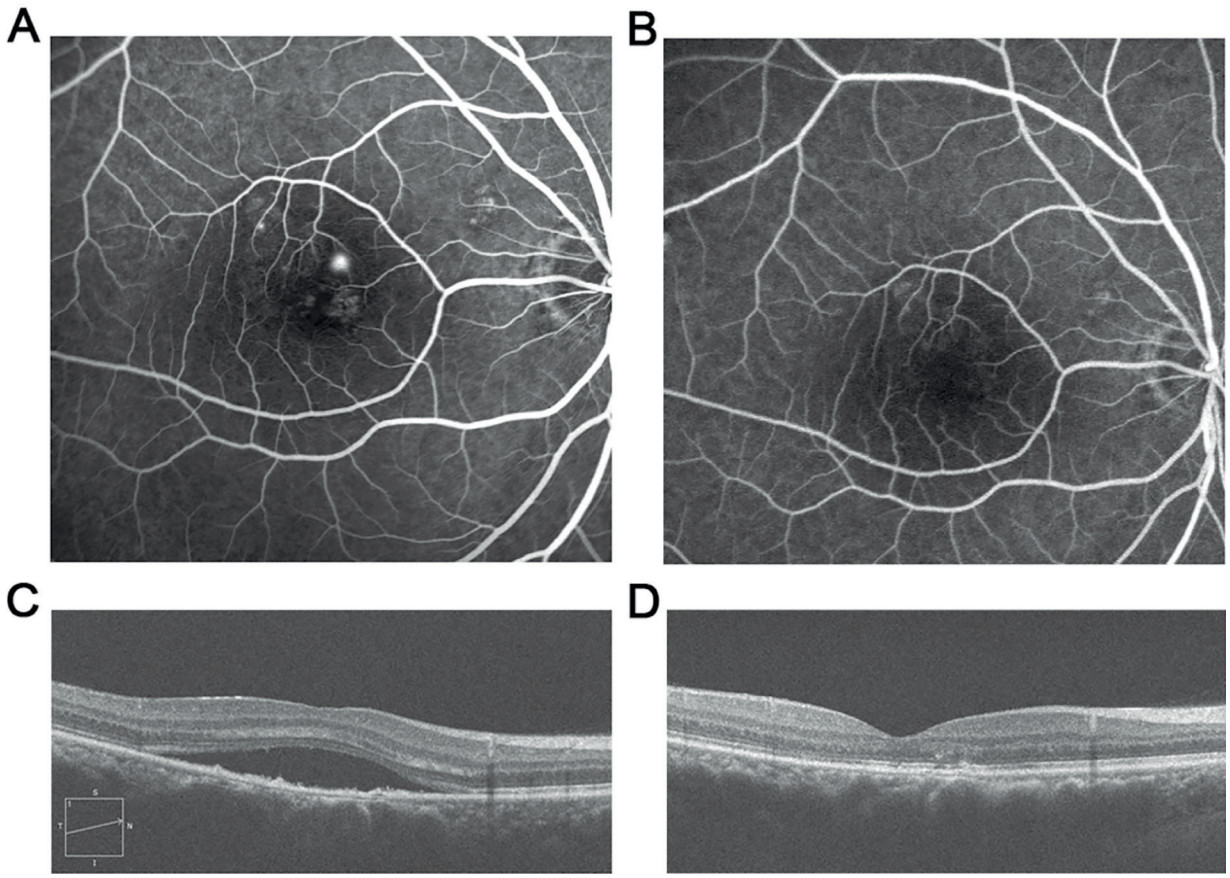

Figure 1. Images of a 41-year-old man with chronic central serous chorioretinopathy treated with one-third-dose verteporfin photodynamic therapy (PDT). ***A,*** Fundus fluorescein angiography image before PDT showed characteristic leakage at central macula and near macula. ***B,*** Fundus fluorescein angiography image 3 months after PDT indicated the leakage almost absorbed. ***C,*** OCT image before PDT showed typical neuroepithelium detachment at central macula. ***D,*** OCT image indicated retinal fluid disappeared 3 months after PDT.

ischemia and CNV will occur in the treatment of CSC with Visudyne (6 mg/m^2) according to the Age-related Macular Degeneration (AMD) Treatment Guidelines[9,10,13,14]. The impact of PDT on normal choroidal vessels has a dose-effect manner, and it was reported in 2016 that the treatment of chronic CSC with half-dose Visudyne (3 mg/m^2) could avoid serious complications with a similar curative effect to full dose[15,16]. Zhao et al[17] in Peking University People's Hospital performed a study on the treatment of acute CSC with PDT via 70%, 60%, 50%, 40%, 30%, 20%, 10% conventional-dose Visudyne, and the results showed that 30% conventional dose was safe and effective in the treatment of acute CSC. Application of small-dose Verteporfin PDT in the treatment of CSC, especially the leakage in macular central fovea, can effectively achieve the treatment goal, lower the treatment cost, and reduce the damaged to normal structure compared with traditional laser treatment. In this study, chronic CSC was treated with one-third dose of Verteporfin, and changes in SFCT, and $SCT_{1.5mm}$, $ICT_{1.5mm}$, $NCT_{1.5mm}$ and $TCT_{1.5mm}$ within 6 months after treatment were observed. The results showed that the choroidal thickness was reduced after treatment of chronic CSC with one-third dose Verteporfin PDT, and it was the smallest at 3 months after treatment, which was consistent with previous studies[18-21]. Choroidal capillary layer thickness was significantly decreased after treatment compared with that before treatment, and both FFA and ICGA showed that the disease in most affected eyes was relieved, accompanied with subretinal fluid absorption. These results suggested that one-third dose Verteporfin PDT can relieve the entire posterior choroidal hyperperfusion of patients with chronic CSC, reduce the choroidal blood flow, alleviate the leakage, and block the subretinal fluid source, which is effective in the treatment of chronic CSC. Choroidal thickness may rebound at 6 months after treatment, possibly due to the recovery of perfusion state of choroidal blood vessels over time, which may be associated with the recurrence of CSC in some patients after PDT, so CSC cannot be treated via one-time PDT once and for all. In this study, there was no recurrence in 60 patients (68 eyes) during follow up for 6 months. It is hypothesized that there is a lag effect between choroidal thickness rebound and choroidal hyperperfusion or CSC recurrence, so patients should be closely observed and the follow up should be enhanced at 6 months after treatment.

In OCT, the external border of photoreceptor in the normal macular central fovea was longer and thinner than that of photoreceptor in other regions, making the low reflection band in this region more obvious in OCT. It was found that the low reflection band almost disappeared in CSC patients with serous detachment in one-third dose PDT and after serous detachment completely disappeared, and the band was gradually recovered after 3 months [the photoreceptor thickness of affected eyes was changed from (30.93 ± 8.01) μm before treatment to (41.75 ± 7.39) μm], and basically returned to normal after 6 months [the photoreceptor thickness of affected eyes was changed from (30.93 ± 8.01) μm before treatment to (62.45 ± 11.69) μm], indicating that the photoreceptor is gradually recovered after 3 months and the photoreceptor metabolism basically returns to normal after 6 months, which further accounts for the favorable prognosis of CSC patients after PDT via one-third dose of Verteporfin.

Although most CSC patients can heal spontaneously, central vision can be partially recovered in some patients with a longer course of disease after subretinal fluid absorption, and determining the appropriate treatment opportunity requires further theoretical support and clinical observation. This study preliminarily showed that the treatment of CSC with one-third dose Verteporfin PDT can improve and stabilize the vision, stop or reduce the choroidal vasodilatation and leakage, speed up the absorption of serous subretinal fluid and help the photoreceptor layer recovery, which is safe and reliable. However, the number of cases in this study was small, but the observation time was long enough; more reasonable treatment plan, specific changing trend, and speed of choroidal thickness after PDT and the root cause of choroidal hypertransfusion (recurrence), still need further large-sample and multi-center studies.

Conclusions

PDT via one-third dose of Verteporfin can improve and stabilize the vision, stop or reduce the choroidal vasodilatation and leakage, accelerate the absorption of serous subretinal fluid, and help the recovery of photoreceptor layer of patients with chronic CSC, which is safe and reliable.

Conflict of Interest

The Authors declare that they have no conflict of interests.

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