A 50% vs 30% Dose of Verteporfin (Photodynamic Therapy) for Acute Central Serous Chorioretinopathy One-Year Results of a Randomized Clinical Trial

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IMPORTANCE A randomized clinical trial is needed to evaluate what is the best photodynamic therapy (PDT) protocol to use for acute central serous chorioretinopathy.

OBJECTIVE To compare the efficacy and safety of a 50% dose of verteporfin (a method of PDT) with the efficacy and safety of a 30% dose for acute central serous chorioretinopathy.

DESIGN, SETTING, AND PARTICIPANTS A multicenter, noninferiority, double-masked, randomized, controlled, clinical trial in which 131 patients (131 eyes) with acute central serous chorioretinopathy for less than 6 months were recruited with a follow-up of 12 months from university-based ophthalmology practices.

INTERVENTIONS Patients were randomly assigned to either a 50% dose of verteporfin (the 50%-dose PDT group) or a 30% dose (the 30%-dose PDT group).

MAIN OUTCOMES AND MEASURES The 2 primary outcome measures were the proportion of eyes with complete absorption of subretinal fluid and the proportion of eyes with complete disappearance of fluorescein leakage at 6 and 12 months. The secondary outcome measures included the subretinal fluid recurrent rate, the fluorescein leakage recurrent rate at 12 months, the mean best-corrected visual acuity, the retinal thickness of the foveal center, and the maximum retinal thickness at each scheduled visit.

RESULTS The noninferiority of the 30%-dose PDT compared with the 50%-dose PDT for the primary outcomes was not demonstrated. The optical coherence tomography-based improvement rate in the 30%-dose PDT group was less than that in the 50%-dose PDT group both at 6 months (73.8% vs 92.9%; α = 0.0125, P = .006) and at 12 months (75.4% vs 94.6%; α = 0.0125, P = .004). The fluorescein angiography-based improvement rate in the 30%-dose PDT group was less than that in the 50%-dose PDT group both at 6 months (68.9% vs 91.1%; α = 0.0125, P = .003) and at 12 months (68.9% vs 92.9%; α = 0.0125, P = .001). The subretinal fluid recurrence rate in the 30%-dose PDT group was greater than that in the 50%-dose PDT group (24.0% vs 5.7% at 12 months; P = .010, determined by use of the log-rank test). The fluorescein leakage recurrence rate in the 30%-dose PDT group was significantly higher than that in the 50%-dose PDT group (16.7% vs 3.8% at 12 months; P = .03, determined by use of the log-rank test). No ocular adverse event was encountered in the study.

CONCLUSIONS AND RELEVANCE A 50% dose of verteporfin may be more effective at resolving subretinal fluid and fluorescein leakage, and with better visual outcomes, than a 30% dose for acute central serous chorioretinopathy.

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Central serous chorioretinopathy (CSC) is characterized by serous detachment of the neurosensory retina with or without serous detachment of the retinal pigment epithelium (RPE) at the posterior pole caused by increased permeability of the choroidal vessels.1-6 Although acute CSC usually resolves spontaneously within months,7 some patients may lose contrast sensitivity; 30% to 50% of patients may experience recurrence within the first year; and 5% of patients may develop chronic CSC,8-18 which can result in damage to the RPE and progressive decline in visual acuity. Furthermore, chronic CSC is more likely to be complicated by choroidal neovascularization (CNV).14-17 Nonsubfoveal focal leakage can be treated with laser photocoagulation, but it has the disadvantage of causing RPE atrophy, scotoma, or secondary CNV.14-17 Recently, photodynamic therapy (PDT) has been shown to be effective against both acute and chronic CSC.11-12,18-22 Although this type of therapy yielded favorable results, post-PDT complications such as RPE atrophy, RPE tear, secondary CNV, and choriocapillaris ischemia have been reported.23-25 Many modified PDT protocols for CSC involve lowering verteporfin doses, decreasing laser treatment times, decreasing laser power, or the 30%-dose PDT group at a ratio of 1:1. The randomization sequence was generated using a computerized randomization table, and the group allocation was performed before PDT. All patients, examiners, investigators, and research assistants at the reading centers were masked to the treatment allocation group.

Methods

Design

Our study was a multicenter, noninferiority, double-masked, randomized, controlled, clinical trial of 2 different doses of verteporfin (ie, 2 different PDT methods) for the treatment of acute CSC. The study patients were recruited from 4 different eye centers in China between March 2011 and February 2012. All study sites obtained institutional review board approval before initiation of the study. Written informed consent was obtained from all enrolled patients. All data were collected by the reading center and analyzed by the statistics center. This clinical trial registration was made publicly available.

Inclusion Criteria

The patients were consecutively enrolled in our study when the following inclusion criteria were fulfilled: (1) symptoms occurred for the first time, as an episode duration of less than 6 months, or there was a medical record that could prove the presence of subretinal fluid (SRF) for less than 6 months if the patient was asymptomatic; (2) patient was between 18 and 50 years of age; (3) the presence of SRF involving the macula and detected by use of optical coherence tomography (OCT); and (4) active fluorescein leakage during fluorescein angiography (FA) and abnormal dilated choroidal vasculature detected by use of indocyanine green angiography (ICGA).

Exclusion Criteria

The exclusion criteria were as follows: (1) previous PDT, focal photocoagulation, intravitreal injections of anti–vascular endothelial growth factor, or ocular surgery; (2) other macular abnormalities such as CNV or polypoidal choroidal vasculopathy; (3) choroidopathy that may affect choroidal thickness; (4) any retinal vascular disease that may have fluorescein leakage during FA; (5) history of porphyria or photosensitivity; (6) severe impaired kidney or liver function and/or unstable heart condition; (7) pregnancy; (8) inability to obtain photographs or to perform FA or ICGA; and (9) use of steroid systemically or topically in the last 6 months.

Randomization and Masking

Patients were randomly assigned to the 50%-dose PDT group or the 30%-dose PDT group at a ratio of 1:1. The randomization sequence was generated using a computerized randomization table, and the group allocation was performed before PDT. All patients, examiners, investigators, and research assistants at the reading centers were masked to the treatment allocation group.

Photodynamic Therapy

The area of choroidal hyperperfusion (detected by use of ICGA) that was connected to the area of serous macular detachment and that corresponded to the hyperfluorescence (detected by use of FA) was measured before PDT with the built-in measurement software. The research assistants who were assigned to perform the randomization at each study site prepared the wrapped syringes (ensuring that the appropriate dose was placed in the syringe) and assigned them to the appropriate patients: 3 mg/m² of verteporfin and 1.8 mg/m² of verteporfin were infused for 10 minutes for the 50%-dose PDT group and the 30%-dose PDT group, respectively. After infusion, patients were instructed to avoid strong light for 48 hours.

Baseline and Follow-up Examinations

Patients were assessed at baseline and followed up at 2 weeks, 1 month, 3 months, 6 months, and 12 months after PDT. At baseline, all patients underwent a complete eye examination, which included an assessment of best-corrected visual acuity (BCVA), a measurement of refraction, a measurement of intraocular pressure, a slitlamp examination, a funduscopy examination after pupil dilation, OCT, FA, and ICGA. The patients’ BCVA and
intraocular pressure were measured at each visit. Optical coherence tomography was performed at baseline, 2 weeks, 1 month, 3 months, 6 months, and 12 months. Fluorescein angiography was performed at baseline, 2 weeks, 6 months, and 12 months.

The greatest linear diameter of the choroidal hyperperfusion area was measured based on ICGA images at baseline. The BCVA letter score was measured by certified optometrists using the Early Treatment Diabetic Retinopathy Study (ETDRS) chart at 4 m. Optical coherence tomographic images were obtained using spectral-domain OCT and were used to measure the retinal thickness. Volume scans were taken through the fovea and the area to be treated. The central foveal thickness (CFT) and the maximum retinal thickness (MRT) were measured manually and were defined as the distance between the inner surface of the choroid and the inner surface of the neurosensory retina at the fovea center and as the maximum retinal thickness within the neurosensory area of the detached retina, respectively. At post-PDT visits, OCT was performed at the same locations as at baseline.

Outcome
The 2 primary outcome measures were the OCT-based improvement rate (defined as the proportion of eyes with complete absorption of SRF on OCT images) and the FA-based improvement rate (defined as the complete disappearance of leakage on FA images) at 6 and 12 months. The secondary outcome measures included the OCT-based recurrent rate, the FA-based recurrent rate at 12 months, and the BCVA (ETDRS letter score), CFT, and MRT at each scheduled visit. The OCT-based recurrent rate was defined as the number of eyes with reappearance of SRF after previous complete absorption of SRF divided by the number of eyes with complete absorption of SRF during the follow-up. The FA-based recurrent rate was defined as the number of eyes with reappearance of leakage after previous total disappearance of leakage divided by the number of eyes with total disappearance of leakage during the follow-up. The key safety assessments were the incidence and severity of ocular and nonocular adverse events related to verteporfin.

Statistics
The sample size was calculated based on the following assumptions for the primary efficacy end point: a 2-sided significance level of 5%, a power of 80%, a noninferiority margin of 15%, and an expected success rate of PDT for the 2 treatment groups of 90%. Under these assumptions, the estimated required sample size should be 56 patients in each group. To account for attrition and protocol noncompliance, an estimated 65 participants should be enrolled in each treatment group.

Comparisons of baseline demographics and clinical data were made between the 2 treatment groups using the 2-tailed t test and the Wilcoxon signed rank test for continuous variables and the Pearson χ² test and the Fisher exact test for binary variables. A noninferiority test based on the Wald method was applied to compare the OCT- and FA-based improvement rates at 6 and 12 months between the 2 groups with a noninferiority margin of 15%. The χ² test was supplemented to test for superiority when noninferiority was not demonstrated.

Kaplan-Meier survival analysis with a log-rank test was used to compare the SRF and leakage recurrence rates between the 2 groups. The mixed models regression was applied to assess the overall difference in mean BCVA (ETDRS letter score), CFT, and MRT at each scheduled visit between the 2 treatment groups. The tests were based on the SP(POW) covariance model and account for the unequally spaced measurements.

A descriptive analysis of the safety end points included patients with at least 1 adverse event related to verteporfin and any abnormal changes assessed during an eye examination. For the principal analysis of the primary outcomes comparison, α = 0.0125 was established as the threshold for statistical significance considering that the OCT- and FA-based improvement rates at 6 and 12 months are of equal importance. For other analyses, P = .05 was considered to be statistically significant. Statistical analyses were performed on the full analysis set.

Figure 1. Patient Flowchart

131 Patients assessed for eligibility (131 eyes)

129 Randomized (129 eyes)

65 Randomized to receive 30% dose of verteporfin

64 Randomized to receive 50% dose of verteporfin

4 Lost to follow-up

61 Analyzed

8 Lost to follow-up

56 Analyzed
Results

Baseline Demographic and Clinical Data

A total of 121 eyes from 121 patients with acute CSC were considered, of which 64 eyes were randomized to 50%-dose PDT and 65 eyes were randomized to 30%-dose PDT (ie, a total of 129 eyes from 129 patients). At 12 months, 12 of the 129 patients were lost to follow-up, and the remaining 117 patients (90.7%) were included in the data analysis: 61 patients were in the 30%-dose PDT group, and 56 patients were in the 50%-dose PDT group (Figure 1).

The baseline demographic and clinical data of the 2 treatment groups are summarized in Table 1. No differences between the 2 groups were identified with respect to the mean age, sex, mean duration of symptoms, history of systemic steroid use, history of other systemic disease, history of CSC, mean BCVA, mean IOP, mean greatest linear diameter of the choriocapillaris vascular abnormal area, mean CFT, mean MRT, presence of pigment epithelial detachment, and involvement of the foveal center in the area to be treated.

Resolution of SRF

In the 30%-dose PDT group, the SRF detected on OCT images disappeared in 45 eyes (73.8%) within 6 months and in 46 eyes (75.4%) within 12 months (Table 2). Subretinal fluid reappeared in 7 of 45 eyes (15.6%) within 6 months and in 11 of 46 eyes (24.0%) within 12 months.

In the 50%-dose PDT group, the SRF detected on OCT images disappeared in 52 eyes (92.9%) within 6 months and in 53 eyes (94.6%) within 12 months (Table 2). Subretinal fluid reappeared in 3 of 52 eyes (5.8%) within 6 months and in 3 of 53 eyes (5.7%) within 12 months.

The mean difference in the OCT-based improvement rates between the 2 treatment groups (30%-dose PDT group − 50%-dose PDT group) was −19.1% (95% CI, −32.0% to −6.2%; P = .004) at 6 months and −19.2% (95% CI, −31.5% to −6.9%; P = .006) at 12 months. The Pearson χ² test was supplemented to test for noninferiority of 30%-dose PDT to 50%-dose PDT for the OCT-based improvement rate was not demonstrated (eFigure 1 in the Supplement). The Pearson χ² test was supplemented to test for superiority and demonstrated that the OCT-based improvement rate in the 30%-dose PDT group was significantly less than that in the 50%-dose PDT group both at 6 months (73.8% vs 92.9%; d = 0.0125, P = .006) and at 12 months (75.4% vs 94.6%; d = 0.0125, P = .004) (Table 2).

Thirty-five eyes (57.4%) in the 30%-dose PDT group and 50 eyes (89.3%) in 50%-dose PDT group had complete absorption of SRF without recurrence during the 1-year follow-up. The log-rank test demonstrated that the SRF recurrence rate at 12 months was higher in the 30%-dose PDT group than in the 50%-dose PDT group (24.0% vs 5.7%; P = .010) (Figure 2).

Resolution of Fluorescein Leakage

In the 30%-dose PDT group, the fluorescein leakage detected on FA images disappeared in 42 eyes (68.9%) within 6 and 12 months (Table 2). Of these 42 eyes, 5 (11.9%) had a reappearance of leakage detected on FA images within 6 months, and 7 (16.7%) had a reappearance of leakage detected on FA images within 12 months.

In the 50%-dose PDT group, the leakage detected on FA images disappeared in 51 eyes (91.1%) within 6 months and in 52 eyes (92.9%) within 12 months.
### Table 2. Resolution of SRF and Fluorescein Leakage in the 2 Treatment Groups

<table>
<thead>
<tr>
<th>Outcome, End Point</th>
<th>30%-Dose PDT Group (n = 61)</th>
<th>50%-Dose PDT Group (n = 56)</th>
<th>Difference Between 2 Groups, % (95% CI)</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>SRF detected on OCT images, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 6 mo</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not present</td>
<td>45 (73.8)</td>
<td>52 (92.9)</td>
<td>−19.1 (−32.0 to −6.2)</td>
<td>.006</td>
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<tr>
<td>Present</td>
<td>16 (26.2)</td>
<td>4 (7.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 12 mo</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not present</td>
<td>46 (75.4)</td>
<td>53 (94.6)</td>
<td>−19.2 (−31.5 to −6.9)</td>
<td>.004</td>
</tr>
<tr>
<td>Present</td>
<td>15 (24.6)</td>
<td>3 (5.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluorescein leakage detected on FA images, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 6 mo</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not present</td>
<td>42 (68.9)</td>
<td>51 (91.1)</td>
<td>−22.2 (−36.0 to −8.4)</td>
<td>.003</td>
</tr>
<tr>
<td>Present</td>
<td>19 (31.1)</td>
<td>5 (8.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 12 mo</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not present</td>
<td>42 (68.9)</td>
<td>52 (92.9)</td>
<td>−24.0 (−37.4 to −10.6)</td>
<td>.001</td>
</tr>
<tr>
<td>Present</td>
<td>19 (31.1)</td>
<td>4 (7.1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: FA, fluorescein angiographic; OCT, optical coherence tomographic; PDT, photodynamic therapy; SRF, subretinal fluid.

*a Determined by use of the Pearson χ² test.

### Figure 2. Kaplan-Meier Plot for SRF and Fluorescein Leakage Recurrent Rates of the 2 Treatment Groups

The log-rank test revealed that the subretinal fluid (SRF) and fluorescein leakage recurrent rates of the 30%-dose photodynamic therapy (PDT) group are significantly higher than those of the 50%-dose PDT group at 12 months. The small vertical ticks indicate censored events.
52 eyes (92.9%) within 12 months (Table 2). The leakage detected on FA images reappeared in 3 of 51 eyes (5.9%) within 6 months and in 2 of 52 eyes (3.9%) within 12 months.

The mean difference in the FA-based improvement rates between the 2 treatment groups (30%-dose PDT group − 50%-dose PDT group) was −22.2% (95% CI, −36.0% to −8.4%; P = .85, determined by use of the asymptotic Wald test) at 6 months and −24.0% (95% CI, −37.4% to −10.6%; P = .75, determined by use of the asymptotic Wald test) at 12 months. The noninferiority of 30%-dose PDT to 50%-dose PDT for the FA-based improvement rate was not demonstrated (eFigure 2 in the Supplement). The Pearson χ² test was supplemented to test for superiority and demonstrated that the FA-based improvement rate in the 30%-dose PDT group was significantly less than that in the 50%-dose PDT group both at 6 months (68.9% vs 91.1%; α = 0.0125, P = .003) and at 12 months (68.9% vs 92.9%; α = 0.0125, P = .001) (Table 2).

Thirty-five eyes (57.4%) in the 30%-dose PDT group and 50 eyes (89.3%) in 50%-dose PDT group had complete disappearance of fluorescein leakage without recurrence during the 1-year follow-up. The log-rank test demonstrated that the leakage recurrent rate at 12 months was significantly higher in the 30%-dose PDT group than in the 50%-dose PDT group (16.7% vs 3.8%; P = .03) (Figure 2).

**Changes in Retinal Thickness**

At 2 weeks after PDT, both groups showed a significant decrease in CFT and MRT (P < .001). This trend continued until the last visit (P < .001; eTable 1 in the Supplement and Figure 3). In the 30%-dose group, the mean (SD) CFT decreased from 384.6 (117.4) μm at baseline to 195.9 (73.6) μm at 12 months, and the mean (SD) MRT decreased from 427.8 (124.4) μm at baseline to 235.3 (92.4) μm at 12 months. In the 50%-dose group, the mean (SD) CFT decreased from 410.5 (150.0) μm at baseline to 195.9 (73.6) μm at 12 months, and the mean (SD) MRT decreased from 427.8 (124.4) μm at baseline to 235.3 (92.4) μm at 12 months. The mixed-effects model revealed that the 50%-dose PDT group had greater reductions of CFT (P < .001) and MRT (P = .01) than the 30%-dose PDT group (eTable 2 in the Supplement).

**Changes in Visual Acuity**

In eTables 1 and 3 in the Supplement and in Figure 4, serial changes in BCVA and visual gain vs baseline BCVA were compared between the 2 groups. At 2 weeks after PDT, both groups showed significant improvement in BCVA (P < .01) compared with baseline BCVA up until the last follow-up (P < .01). The mean (SD) BCVA increased from an ETDRS letter score of 75.0 (12.9) (Snellen equivalent, 20/32) at baseline to 83.0 (13.5) (Snellen equivalent, 20/20) at 12 months in the 30%-dose group and from an ETDRS letter score of 75.3 (9.8) (Snellen equivalent, 20/32) at baseline to 84.7 (9.2) (Snellen equivalent, 20/20) at 12 months in the 50%-dose group. There were no significant differences between the 2 groups in terms of BCVA gain at the last visit (P = .27, determined by use of the paired t test). Compared with the baseline BCVA, in the 30%-dose PDT group, 4 eyes (6.6%) lost 5 or more letters, 18 eyes (29.5%) gained 5 to 9 letters, and 20 eyes (32.8%) gained 10 or more letters at 12 months, whereas in the 50%-dose group, 0 eyes (0.0%) lost 5
or more letters, 15 eyes (26.8%) gained 5 to 9 letters, and 28 eyes (50.0%) gained 10 or more letters (eTable 3 in the Supplement; $P = .008$, determined by use of the Fisher exact test). The mixed-effects model reveals that BCVA improvement in the 30%-dose PDT group was less than that in the 50%-dose PDT group and that the effect of the treatment on BCVA was marginally significant ($P = .05$) (eTable 2 in the Supplement).

**Safety**

Among all patients, only 1 in the 30%-dose PDT group developed slight nausea because of an allergic reaction to verteporfin. No ocular adverse effects, including development of CNV, were seen in any cases throughout the follow-up period.

**Discussion**

Many studies have shown that PDT with a conventional dose of verteporfin is useful in the treatment of both acute and chronic CSC. But the post-PDT complications may be important drawbacks restricting the use of full-dose PDT for acute CSC because patients with this type of CSC generally have better vision. Although many studies on half-dose PDT have resulted in favorable outcomes with less risk of complications, there was only 1 randomized clinical trial about PDT for acute CSC. Furthermore, the authors of that randomized clinical trial simultaneously changed 3 treatment parameters (verteporfin dose, infusion time, and interval between injection and laser treatment), which complicates the evaluation of each parameter for efficacy and safety of the modified PDT protocol.

In the present study, we found that a 50% dose of verteporfin was more effective than a 30% dose in the resolution of SRF and fluorescence leakage in acute CSC. The anatomic and vision outcomes in our 30%-dose PDT group for acute CSC were better than those for the chronic CSC reported by Uetani. In chronic CSC, the barrier and pump functions of RPE may be weaker, and a stronger suppression of the choroidal vessels may be necessary for the resolution of SRF in chronic CSC than in acute CSC.

Central serous chorioretinopathy is associated with a thickened choroid and choroidal hyperpermeability. The thickness of the choroid and the thickness of the cross-sectional area of the large choroidal vein have been reported to significantly decrease in patients with chronic CSC who received 50%-dose PDT but not in patients with chronic CSC who received 30%-dose PDT. This decrease may also explain the better response to 50%-dose PDT than to 30%-dose PDT in acute CSC. One of the limitations of our study is the lack of a comparison of choroidal thickness between the 2 treatment groups because of equipment limitations.

**Conclusions**

In summary, these results suggest that 50%-dose PDT may be more effective in the resolution of SRF and fluorescence leakage, and with better visual outcomes, than 30%-dose PDT for acute CSC. Additional studies that confirm or refute these findings would be helpful to guide physicians in the use of PDT for acute CSC.

**ARTICLE INFORMATION**

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Author Contributions: Dr Zhao had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Drs Zhao, F. Zhang, Chen, Dai, and Qu contributed equally to this work.

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