Now there is hope

Visudyne™ therapy for predominantly classic CNV secondary to AMD allows you to help slow down the inevitable progression towards the loss of central vision in a broad number of patients.

- **Visudyne Reduces The Risk of Vision Loss**

  59% of Visudyne patients lost less than 3 lines of vision over 24 months (vs 31% of placebo patients, $P<0.001$)

- **Visudyne Helps Maintain Visual Acuity Over 24 Months**

  19% of Visudyne patients experienced no change in visual acuity[1]

  13% of Visudyne patients experienced an improvement of ≥1 line in visual acuity

- **Visudyne Restricts The Growth Of Lesions**

  55% of Visudyne patients vs 25% of placebo patients maintained ≤6 Macular Photocoagulation Study (MPS) disc areas (DA) at 24 months

- **Visudyne Offers A Favorable Safety Profile**

  Proven safety of 2240 treatment courses over 24 months[1]

  1.9% of Visudyne patients discontinued treatment due to adverse events[1]

  Treatment rate was an average of 3.7 courses of therapy over year one and 2.1 courses over year two[1]

Reference:
1. Data on file, CIBA Vision Corporation.

Presentation: Powder for solution for infusion. Each vial contains 15 mg verteporfin and the excipients dimyristoyl phosphatidylcholine, egg phosphatidylglycerol, ascorbyl palmitate, butylated hydroxytol and lactose. Packs: 1 vial per package

Indication: Visudyne is indicated for the treatment of age-related macular degeneration in patients with predominantly classic subfoveal neovascularization.

Dosage:
Step 1: Infusion of 6 mg verteporfin per m^2 body surface dissolved in 30 mL 5% glucose for injection over a period of 10 minutes.
Step 2: 15 minutes after the start of the infusion, exposure of 50 J/m^2 of red light (689 nm) onto the choroidal neovasculature over a period of 83 seconds with an appropriate laser device.

Treatment should be repeated every 3 months if CNV recurs.

Contraindications: Known hypersensitivity to verteporfin or to any component of the formulation. In patients with severe hepatic impairment.

Precautions/Warnings: Patients must avoid direct exposure to direct sunlight or bright indoor light for 48 hours after the treatment.
Visudyne therapy should be considered carefully in patients with moderate hepatic impairment and biliary obstruction.
Patients who experience a severe decrease of vision (4 lines or more) within one week should not be retreated until their vision completely recovers to pre-treatment level.
If extravasation occurs, infusion should be stopped immediately. The affected area must be thoroughly protected from direct light until swelling and discoloration have disappeared. Cold compresses should be placed on the injection site and analgesics may be given if necessary.
Visudyne therapy under general anesthesia should be considered with caution.
Interactions: Concomitant treatment with other photosensitizing agents may increase photosensitivity reactions.
Undesirable effects (0.5% and higher):
Ocular side effects: Abnormal vision such as blurry, hazy, fuzzy vision or flashes of light, decreased vision, visual field defect such as grey or dark haloes, scotoma and black spots, lacrimation disorder, subretinal hemorrhage, vitrous hemorrhage.
Injection site side effects: Pain, edema, extravasation, inflammation, hemorrhage, hypersensitivity.
Systemic side effects: Nausea, photosensitivity reactions, back pain during infusion, asthenia, pruritus, hypercholesteraemia, increased creatinine.
Note: Before prescribing consult full Prescribing Information.

Visudyne™
verteporfin

Changing perceptions of neovascular AMD

To order Visudyne contact your local sales representative
For additional information visit
www.visudyne.com

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CLINICAL CASE STUDY

Treatment of macular degeneration (A controlled case)

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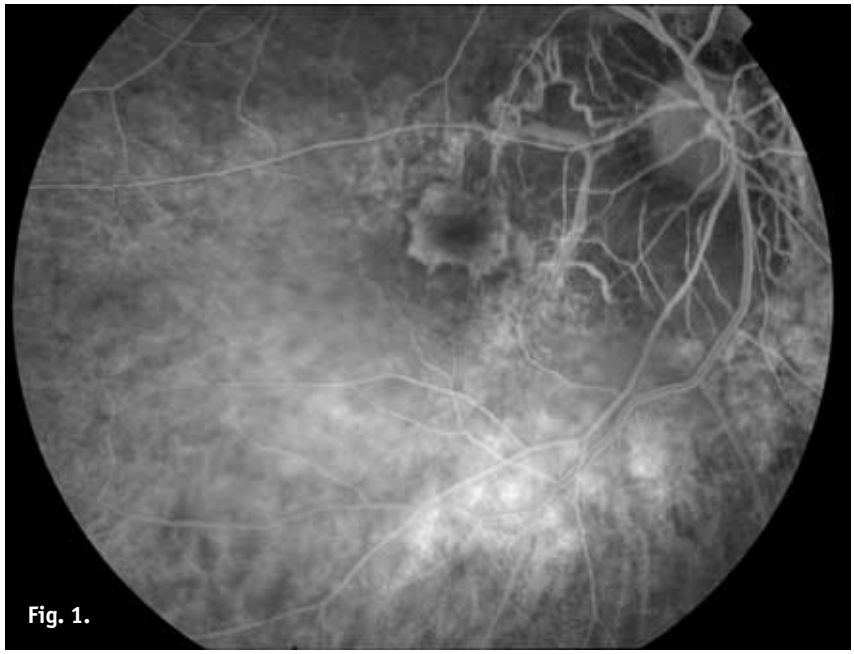
Abstract

Our controlled case describes the drug possibility to stabilize the exudative form of Age-related Macular Degeneration. The new approach of selective destruction of choroidal neovascularization (CNV) can be applied in patients with subfoveal lesions. Photodynamic therapy (PDT) is based on the reaction of photoactivable drug with the light of low-energy laser beam. So far only verteporfin [Visudyne, Novartis] as sensitizer is marketed and laser with wavelength of 689 nm is used. But it is questionable whether to apply this very costly treatment to extremely old people. An example of treatment of 90–year old woman with AMD with classic form of CNV is presented. Her BCVA was 0.05 OD. She underwent four session of PDT. At the last visit (eighteen months after initial and ten months after last session of PDT) the BCVA remained 0.05 OD. The patient is using a special magnifying lens for reading achieving near vision of 0.32.
The presented example indicates the necessity of detailed study of every case to promote the therapeutic decisions for the benefit of progress in the field.



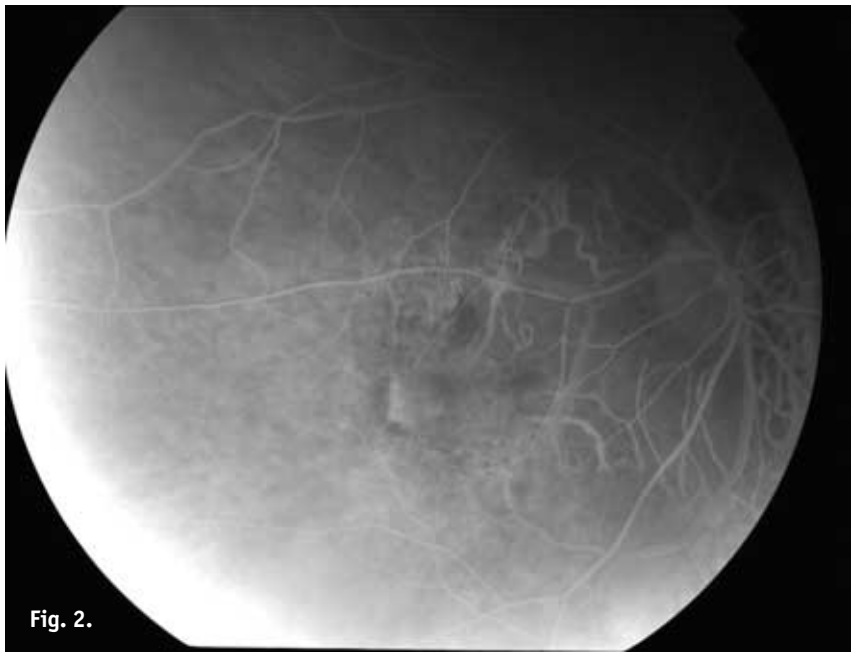


Figure 1. Subfoveal CNV on the fluorescein angiography before treatment.
Figure 2. More than 50% of classic CNV closed without leakage on fluorescein angiography after four sessions of treatment.

In developed countries the Age-related Macular Degeneration (AMD) is the most frequent cause of severe central visual loss among people older than 65 years (1). There are two forms of AMD: the dry and the wet. The slowly progressive dry (non-vascular) form accounts for about 90% of all cases. It is characterized by abnormalities of the retinal pigment epithelium (drusen, atrophy, hypopigmentation or hyperpigmentation). The wet or neovascular AMD (about 10% of all cases) is characterized by choroidal neovascularisation (CNV) (1). New vessels from the choriocapillaris proliferate through breaks in Bruch's membrane under the retinal pigment epithelium and further grow into the subretinal space. This process can lead to subretinal hemorrhage, detachment of the retinal pigment epithelium and the neurosensory retina. The formation of a fibrovascular scar follows. The wet form is frequently devastating and in some cases vision may be lost within a few weeks.

So far there is no treatment possibility for patients with the dry form of AMD. For patients with the wet form there are two possibilities: photocoagulation or photodynamic therapy (PDT).

Laser photocoagulation of CNV causes nonselective thermal tissue destruction. It destroys not only surrounding choriocapillaris, but also retinal pigment epithelium and adjacent photoreceptors. This leads to an absolute scotoma at the area of treatment. Thus only extrafoveal CNV can be treated by this method (2).

The new approach of selective destruction of CNV can be applied in patients with subfoveal lesions. This treatment is based on the reaction of photoactivable drug with the light of low-energy laser beam (3). The method used in PDT is as follows. The first step is the intravenous administration of a senzitizer. It distributes throughout the choroid with preferential accumulation in CNV. The second step is its activation by non-thermal laser. Exposure to light induces generation of singlet oxygen, free radicals and other cytotoxic species. This leads to the damage of endothelial cells followed by platelet adhesion and degranulation and finally to thrombosis of the CNV selectively within the treated area.

So far only verteporfin [Visudyne, Novartis] as sensitizer is marketed and laser with wavelength of 689 nm is used. Patients with subfoveal predominantly classic lesion on fluorescein angiography (FA) and vision better than 0.1 are indicated for PDT with verteporfin (3). After several sessions (6 in two years in average) vision can be stabilized and leakage from CNV diminished as show our own results (4). But it is questionable whether to apply this very costly treatment to extremely old people.

A 90–year old woman with AMD was presented with decline of vision. An ophthalmologic evaluation elsewhere revealed the best-corrected visual acuity (BCVA) of 0.4 OD due to AMD and the BCVA of 0.01 OS due to amblyopia. Two months later BCVA worsened to 0.2 OD. After next 2 months the patient was examined in our department. The BCVA was 0.05 OD. There was bilateral nuclear sclerosis. Fundus examination revealed peripapillary atrophy of retinal pigment epithelium. Subretinal tissue in the center of macula corresponded with findings on FA, where subfoveal CNV was found, with 80% of classic component, *Figure 1*. The patient underwent first session of PDT.

Three months later leakage from CNV was found on FA. We performed retreatment at this time, 4 and 8 months later. On the last FA more than 50% of classic CNV was closed without leakage, *Figure 2*. At the last visit (eighteen months after initial and ten months after last session) the BCVA was 0.05 OD. Thickness of neuroretina on Optical Coherence Tomography was 133–250 ∝m, *Figure 3*. The patient is using a special magnifying lens for reading (Coil 6) achieving near vision of 0.32. The patient was able to read through the TVi Zoom device even before PDT and is able to do so today.

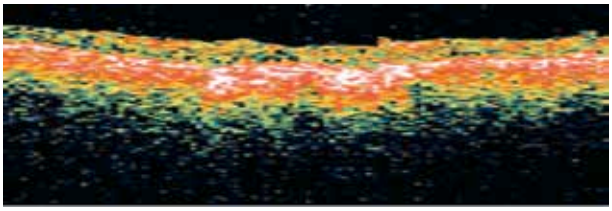


Figure 3. Thickness of the neuroretina on Optical Coherence Tomography at the last visit.

The presented example indicates the necessity of detailed study of every case to promote the therapeutic decisions for the benefit of progress in the field.

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