EXTENDED REPORT

Combined photodynamic therapy and intravitreal triamcinolone injection for the treatment of choroidal neovascularisation secondary to pathological myopia: a pilot study

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Background: To assess the efficacy and safety of combined intravitreal triamcinolone (IVTA) and photodynamic therapy (PDT) with verteporfin in the treatment of choroidal neovascularisation (CNV) secondary to pathological myopia.

Methods: 22 eyes of 22 patients with subfoveal or juxtafoveal CNV due to pathological myopia were prospectively recruited for combined PDT with IVTA. The treatment outcomes at 1 year were compared with those in a control group of 22 eyes that received PDT monotherapy.

Results: At 1 year, the logMAR best-corrected visual acuity (BCVA) for the combined PDT with IVTA group changed from 0.62 to 0.61 ($p=0.74$), whereas that for the monotherapy group changed from 0.61 to 0.67 ($p=0.33$). The mean logMAR BCVA and proportions of patients without losing ≥ 3 lines at 1 year were similar between the two groups ($p=0.68$ and 0.74 , respectively). Subgroup analyses showed that eyes with baseline logMAR BCVA worse than 0.6 (Snellen equivalent 20/80) or CNV with greatest linear dimension ≥ 750 μm which received combined therapy had better mean logMAR BCVA at 1 year ($p=0.023$ and 0.041 , respectively), with a higher proportion of eyes gaining ≥ 2 lines of BCVA ($p=0.027$ and 0.017 , respectively) compared with PDT monotherapy.

Conclusions: Combined PDT with IVTA did not seem to result in significantly better visual outcome compared with PDT monotherapy. However, combined therapy might result in better visual outcome in selected patients with worse initial visual acuity or larger myopic CNV. Further studies are warranted to investigate the role of combined PDT with IVTA in the treatment of myopic CNV, especially in patients with worse prognostic factors.

Choroidal neovascularisation (CNV) is one of the most sight-threatening complications in pathological myopia, and develops in around 5–10% of highly myopic eyes.^{1–3} Based on the natural history of myopic CNV, the visual prognosis is generally poor.^{2 4–7} Treatment should therefore be considered, especially in patients with worse prognostic factors.^{8 9} Photodynamic therapy (PDT) with verteporfin is the main treatment modality for myopic CNV, and various studies have shown its efficacy.^{8–17} However, PDT is not without limitations as choriocapillaris hypoperfusion and retinal pigment epithelium (RPE) atrophy have been reported after PDT.^{18–20} PDT is also associated with high retreatment rates and around 25% of patients with myopic CNV continued to develop moderate visual loss 1 year after PDT.^{12 17} Therefore, it will be beneficial to identify agents which can optimise the efficacy of PDT for myopic CNV.

Recently, studies have shown that combined PDT with IVTA injection might improve the visual outcome and reduce the retreatment rate in patients with subfoveal CNV due to age-related macular degeneration (AMD).^{21–27} The rationale of combined PDT with IVTA is due to the antiangiogenic and anti-inflammatory properties of triamcinolone on CNV.^{28–30} Case reports have also reported the beneficial effects of combined PDT with IVTA in patients with myopic CNV.^{31 32} In view of these results, we investigated the use of combined PDT with IVTA in patients with myopic CNV, and compared the outcome with that in a control group that received PDT monotherapy.

METHODS

Patient recruitment

This was a non-randomised comparative study in which consecutive patients who received combined PDT with IVTA for myopic CNV were prospectively recruited from May 2003. Inclusion criteria included: (1) spherical equivalent ≥ -6.0 D; (2) subfoveal or juxtafoveal CNV; (3) best-corrected visual acuity (BCVA) of 20/400 or better; (4) leakage within the CNV on fluorescein angiography; and (5) greatest linear dimension (GLD) < 5400 μm . Exclusion criteria included: (1) CNV secondary to causes other than pathological myopia; (2) prior PDT, laser or submacular surgery; and (3) history of glaucoma. The combined treatment group was compared with a non-concurrent control group that received PDT monotherapy matched by baseline vision and CNV characteristics. The group included historical controls and patients who declined IVTA injection. The research protocol was approved by an ethics committee and informed consent was obtained from all patients.

At baseline and post-treatment visits, BCVA was measured by certified optometrists with ETDRS logMAR chart at 4 m or Snellen chart at 6 m being converted to logMAR equivalent for analysis.³³ Slit-lamp examination, dilated fundus examination,

Abbreviations: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; CNV, choroidal neovascularisation; GLD, greatest linear dimension; IOP, intraocular pressure; IVTA, intravitreal triamcinolone; PDT, photodynamic therapy; RPE, retinal pigment epithelium

Table 1 Baseline demographics of 44 patients who had combined photodynamic therapy (PDT) with intravitreal triamcinolone or PDT monotherapy for myopic choroidal neovascularisation

	All eyes (n = 44)	Combined PDT+IVTA (n = 22)	PDT monotherapy (n = 22)	p Value
Age, mean (SD) (years)	53.1 (15.8)	52.8 (16.2)	53.3 (15.7)	0.91*
Sex				
Male	18	10	8	0.54†
Female	26	12	14	
Lens status				
Phakic	32	15	17	0.50†
Pseudophakic	12	7	5	
Mean (SD) spherical equivalent refractive error (D)	-11.3 (3.7)	-11.6 (3.9)	-11.0 (3.6)	0.60*
Mean duration of symptoms (months)	3.1	3.2	3.1	0.80*
Location of CNV				
Subfoveal	21	11	10	0.76†
Juxtafoveal	23	11	12	
Location of retinal haemorrhage				
None	10	4	6	0.37†
Subfoveal	11	7	4	
Juxtafoveal	16	6	10	
Mean (SD) baseline CNV with greatest linear dimension (µm)	910 (450)	920 (420)	890 (480)	0.82*
Mean baseline logMAR BCVA (Snellen equivalent)	0.61 (20/81)	0.62 (20/83)	0.61 (20/81)	0.63‡
Mean (SD) baseline IOP (mm Hg)	14.8 (3.6)	14.8 (3.2)	14.8 (4.1)	1.00*

BCVA, best-corrected visual acuity; CNV, choroidal neovascularisation; IOP, intraocular pressure; IVTA, intravitreal triamcinolone; PDT, photodynamic therapy.

*Two-tailed t test.

† χ^2 test.

‡Mann-Whitney U test.

fundus photography and fluorescein angiography were performed. Fluorescein angiography was assessed by two unblinded ophthalmologists (TYYL and ALW) with measurements made using a digital imaging system and disagreement was settled by consensus.

PDT and IVTA injection

PDT with verteporfin was administered according to the TAP (treatment of age-related macular degeneration with photodynamic therapy) and VIP (verteporfin in photodynamic therapy) studies.^{10–11, 34} For the combined group, 4 mg triamcinolone acetonide (40 mg/ml Kenacort-A, Bristol-Myers-Squibb, Italy) in 0.1 ml was injected 4 mm post-limbus using a 27-gauge needle 5 min after PDT under aseptic techniques. Indirect ophthalmoscopy and non-contact tonometry were carried out after the procedure. In eyes with sustained post-injection intraocular pressure (IOP) >30 mm Hg, anterior chamber paracentesis was performed. Patients were asked to avoid bright light for 3 days, and were given topical levofloxacin 0.5% four times daily (Cravit, Santen, Japan) for 2 weeks.

Follow-up visits

Follow-up visits were arranged every 3 months, with BCVA testing, tonometry, slit-lamp examination, fundus examination and fluorescein angiography being performed. Additional visits at 1 week and 1 month were carried out in the combined group for monitoring of IOP and complications. Glaucoma eye drops were used temporarily in patients with IOP ≥21 mm Hg. In cases with leakage in follow-up fluorescein angiography, repeat PDT with IVTA injection was administered in the combined group if IOP was <21 mm Hg, and PDT alone in the

monotherapy group using identical retreatment criteria. Further IVTA injections were performed if IOP returned to <21 mm Hg after cessation of glaucoma drops at the time of retreatment.

Statistical analysis

The main outcome measures included logMAR BCVA, changes in number of lines, proportion of eyes that lost ≤3 lines or gained ≥2 lines, and the mean number of treatments during the first year. Statistical analysis was carried out using SPSS V.11.5. Continuous variables were compared using the two-tailed t test and the Mann-Whitney U test, and serial comparisons using Wilcoxon signed ranks test. χ^2 and Fisher's exact tests were used to compare categorical variables. Subgroup analyses were performed to evaluate the treatment outcomes in patients with worse prognostic factors.^{8, 9} These included baseline logMAR BCVA worse than 0.6 (Snellen equivalent 20/80), CNV with GLD ≥750 µm, subfoveal CNV and age ≥50 years. These values were chosen to approximate the median of values of the patients.

RESULTS

Patients' demographics

Twenty two eyes of 22 patients in each of the combined and monotherapy groups were analysed. The mean (standard deviation (SD)) age was 53.1 (15.8) years (range 23–83 years), and the mean (SD) spherical equivalent refractive error was -11.3 (3.7) D (range -6.0 to -20.0 D). All eyes had predominately classic CNV. Analyses showed that all major baseline characteristics were comparable between the two groups ($p>0.3$; table 1).

Table 2 Treatment outcomes of 44 eyes that received combined photodynamic therapy (PDT) with intravitreal triamcinolone or PDT monotherapy

	Combined PDT+IVTA (n = 22)	PDT monotherapy (n = 22)	p Value
Mean baseline logMAR BCVA (Snellen equivalent)	0.62 (20/83)	0.61 (20/81)	0.83*
Mean logMAR BCVA at 12 months (Snellen equivalent)	0.61 (20/81)	0.67 (20/94)	0.68*
No of eyes without losing ≥ 3 lines (%)	16 (73%)	15 (68%)	0.74†
No of eyes improved by ≥ 2 lines (%)	10 (46%)	5 (23%)	0.11†
Mean number of treatments	1.9	1.9	0.95*

BCVA, best-corrected visual acuity; IVTA, intravitreal triamcinolone; PDT, photodynamic therapy.

*Mann-Whitney U -test.

† χ^2 test.**Treatment outcomes of all eyes**

For the combined PDT with IVTA group (table 2), the mean logMAR BCVA changed from 0.62 (Snellen equivalent 20/83) at baseline to 0.61 (Snellen equivalent 20/81) at 1 year, whereas for the monotherapy group, it changed from 0.61 (Snellen equivalent 20/81) to 0.67 (Snellen equivalent 20/94). The changes in logMAR BCVA for both groups were not significant ($p = 0.74$ and 0.33 , respectively). No significant difference in the mean logMAR BCVA at 1 year was observed between the combined and PDT monotherapy groups ($p = 0.68$).

The mean number of lines reduced at 1 year for the combined and monotherapy groups were 0.1 and 0.6, respectively ($p = 0.32$). The proportions of patients without moderate

visual loss (< 3 lines) were also similar between the two groups ($p = 0.74$). In all, 10 (46%) eyes in the combined treatment group had improvement of ≥ 2 lines compared with 5 (23%) eyes, but the difference did not reach significance ($p = 0.11$).

The mean number of treatments within the first year was 1.9 for both groups ($p = 0.95$), and 12 (50%) eyes in each group required retreatment. In all, 8 (67%) of the 12 eyes in the combined group had repeat PDT with IVTA, and four had PDT alone due to persistent IOP elevation. No significant differences were observed in the final logMAR BCVA and lines changed between patients with or without repeat injections ($p > 0.5$). Altogether, 5 (23%) eyes in the combined treatment group compared with 2 (9%) eyes in the monotherapy group had

Table 3 Subgroup analyses of eyes that received combined photodynamic therapy (PDT) with intravitreal triamcinolone or PDT monotherapy

	Combined PDT+IVTA	PDT monotherapy	p Value
Eyes with logMAR BCVA worse than 0.6 (20/80) (n = 23)			
No of eyes	11	12	
Age, mean (SD) (years)	56.6 (19.9)	60.9 (15.0)	0.57*
Mean baseline logMAR BCVA (Snellen equivalent)	0.87 (20/148)	0.85 (20/142)	0.34†
Mean logMAR BCVA at 12 months (Snellen equivalent)	0.70 (20/100)	1.04 (20/217)	0.023†
No of eyes without losing ≥ 3 lines (%)	9 (81%)	5 (42%)	0.089‡
No of eyes that improved by ≥ 2 lines (%)	6 (55%)	1 (8%)	0.027‡
Eyes with CNV with greatest linear dimension $\geq 750 \mu\text{m}$ (n = 26)			
No of eyes	14	12	
Age, mean (SD) (years)	53.0 (17.1)	59.6 (15.8)	0.32*
Mean baseline logMAR BCVA (Snellen equivalent)	0.69 (20/98)	0.78 (20/121)	0.74†
Mean logMAR BCVA at 12 months (Snellen equivalent)	0.67 (20/94)	1.03 (20/214)	0.041†
No of eyes without losing ≥ 3 lines (%)	10 (71%)	5 (42%)	0.23‡
No of eyes that improved by ≥ 2 lines (%)	6 (43%)	0 (0%)	0.017‡
Eyes with subfoveal CNV (n = 21)			
No of eyes	11	10	
Age, mean (SD) (years)	58.4 (17.0)	59.7 (16.9)	0.86*
Mean baseline logMAR BCVA (Snellen equivalent)	0.77 (20/118)	0.76 (20/115)	0.70†
Mean logMAR BCVA at 12 months (Snellen equivalent)	0.86 (20/145)	0.85 (20/142)	0.83†
No of eyes without losing ≥ 3 lines (%)	7 (64%)	7 (70%)	1.00‡
No of eyes that improved by ≥ 2 lines (%)	4 (36%)	2 (20%)	0.64‡
Age ≥ 50 years (n = 25)			
No of eyes	12	13	
Age, mean (SD) (years)	65.1 (9.4)	63.9 (10.3)	0.77*
Mean baseline logMAR BCVA (Snellen equivalent)	0.69 (20/98)	0.77 (20/118)	0.62†
Mean logMAR BCVA at 12 months (Snellen equivalent)	0.91 (20/163)	0.87 (20/148)	0.70†
No of eyes without losing ≥ 3 lines (%)	7 (58%)	8 (62%)	1.00‡
No of eyes that improved by ≥ 2 lines (%)	3 (25%)	2 (15%)	0.65‡

BCVA, best-corrected visual acuity; CNV, choroidal neovascularisation; IVTA, intravitreal triamcinolone; PDT, photodynamic therapy.

*Two-tailed t test.

†Mann-Whitney U test.

‡Fisher exact test.

persistent leakage from the CNV and required retreatment ($p = 0.41$).

At baseline, 6 (27%) eyes had RPE atrophy in the combined group compared with 5 (23%) eyes in the monotherapy group. At 12 months, 7 (32%) eyes in the combined group compared with 8 (36%) eyes in the monotherapy group had RPE atrophy. The differences in RPE atrophy between the two groups were not significant ($p = 0.75$).

Subgroup analysis of eyes with worse prognostic factors

Subgroup analysis was performed to compare the effects of combined therapy versus monotherapy in eyes with worse prognostic factors (table 3). For the 23 eyes with baseline logMAR BCVA worse than 0.6, 11 eyes which received combined therapy had improvement of logMAR BCVA from 0.87 to 0.70, whereas the logMAR BCVA for the 12 eyes treated with monotherapy was reduced from 0.85 to 1.04. The logMAR BCVA at 1 year was also significantly better in eyes with baseline logMAR BCVA worse than 0.6 treated with combined therapy compared with monotherapy ($p = 0.023$). In all, 6 (55%) of the 11 eyes which received combined therapy gained ≥ 2 lines compared with only 1 (8%) in the monotherapy group ($p = 0.027$). Also, 9 (81%) eyes in the combined group compared with 5 (42%) eyes in the monotherapy group lost < 3 lines of vision, but the difference was not significant ($p = 0.089$).

For the subgroup of 26 eyes with CNV GLD $\geq 750 \mu\text{m}$, the 14 eyes that received combined therapy had significantly better logMAR BCVA at 12 months compared with the 12 eyes that had monotherapy (0.67 and 1.03, respectively, $p = 0.041$). In the combined therapy group, 6 (43%) eyes gained ≥ 2 lines of BCVA at 12 months, whereas in the monotherapy group, none gained ≥ 2 lines ($p = 0.017$).

Further, subgroup analyses of patients aged ≥ 50 years and subfoveal location of CNV showed no significant difference in visual outcomes between the combined and monotherapy groups. Six eyes received repeat PDT with IVTA injection in each of the subgroups, except the subgroup of subfoveal CNV, in which five eyes received repeat PDT with IVTA.

Complications

None of the patients developed ocular or systemic complications related to PDT. In the combined group, 10 (46%) eyes developed IOP increase of ≥ 21 mm Hg after IVTA injection. All were successfully managed with glaucoma eye drops. In all, 6 of the 10 eyes required subsequent PDT, of which two had repeat PDT with IVTA after cessation of glaucoma eye drops and four had subsequent PDT without IVTA owing to continued use of glaucoma eye drops. Of the 15 patients with phakia in the combined therapy group, 3 (20%) patients developed an increase in cataracts, but none required cataract surgery. No serious complications such as endophthalmitis or retinal detachment developed after IVTA injection.

DISCUSSION

As the action of PDT with verteporfin on CNV is usually transient, combined PDT with IVTA may improve the treatment outcome by allowing longer-lasting and synergistic effects.²¹ Previously, studies have shown that combined PDT with IVTA might be beneficial in CNV due to AMD.^{21–27} Theoretically, combined PDT with IVTA should also be useful in myopic CNV, but there were only two cases reported in the literature.^{31–32} Potter *et al*³¹ described the use of combined therapy in a teenager with myopic CNV, and vision improved from 20/80 to 20/25 after treatment.²⁸ Degenring and Jonas³² reported the use of combined therapy in a patient with recurrent myopic CNV

despite receiving PDT five times previously, and no subsequent retreatment was required after combined therapy.

In this pilot study, our results did not show a significant visual benefit in using combined PDT with IVTA over monotherapy when all eyes were analysed. Visual outcomes in terms of logMAR BCVA and proportion of patients without moderate visual loss at 1 year were similar between the two groups. This might be due to the relatively small sample size in the study. Nonetheless, statistical analysis showed that our sample size had a 70% power to detect a two line difference in BCVA between the two groups. Another reason for the lack of significant benefit in using combined therapy might be the differences in the underlying histopathology between myopic CNV and CNV secondary to AMD. Previous histopathological studies of CNV specimens obtained after PDT in neovascular AMD have shown the presence of inflammatory cells in most specimens.^{18–35–36} However, there was a lack of inflammatory reaction observed within myopic CNV specimens.³⁷ As suggested by Grossniklaus and Green,³⁸ CNV may occur as a continuum according to the associated inflammatory reaction. On one end of the continuum, CNV may be associated with marked inflammatory responses such as those secondary to choroiditis, whereas at the other end, CNV secondary to pathological myopia or angioid streaks may have little or no inflammatory response; CNV secondary to AMD may lie somewhere in the middle.³⁸ Therefore, the anti-inflammatory role of IVTA in combination with PDT for myopic CNV might be less compared with that for CNV due to AMD. This might also account for the similar retreatment rates in the two groups as observed in our study. Laboratory studies have suggested that IVTA may result in RPE toxicity, and this might lead to the absence of benefit as observed in our study.^{39–40} In addition to RPE toxicity due to IVTA, PDT might also result in visual deterioration as closure of the choroidal vasculature or choroidal infarction has been described after PDT in AMD and pathological myopia.^{41–43} Patients with myopic CNV might be particularly prone to these PDT-related side effects due to diffuse atrophy of the choriocapillaris. The less healthy RPE in eyes with pathological myopia might be excessively damaged by PDT and may result in a reduction in final vision. Another reason for the lack of effect of combined therapy for myopic CNV might be the insufficient dosage of IVTA given in our patients. Previous studies on combined therapy for CNV in AMD have used IVTA ranging from 4 to 25 mg.^{21–27} Owing to axial elongation, the vitreous volume is greater in highly myopic eyes, and therefore a larger dose of IVTA might be required to produce a sufficient treatment effect. Lastly, 3 of the 15 patients with phakia who received combined therapy developed cataracts, and this might also have limited the visual benefit.

We performed subgroup analyses to determine whether combined therapy would be more effective in patients with worse prognostic factors. Our results showed that eyes with baseline logMAR BCVA worse than 0.6 (Snellen equivalent 20/80) or CNV with GLD $\geq 750 \mu\text{m}$ which received combined therapy had significantly better BCVA at 1 year and were more likely to have gained ≥ 2 lines compared with monotherapy. This result was consistent with a previous study of IVTA for AMD CNV, as patients with worse baseline vision were found to have greater visual improvement after treatment.⁴⁴ Further studies on the use of combined PDT with IVTA may therefore consider recruiting patients with poorer prognostic factors. Subgroup analyses of other prognostic factors such as older age and subfoveal CNV, however, did not show significant differences in treatment outcome between the two groups. The exact cause is uncertain, but might be related to more severe irreversible damage such as RPE atrophy in these patients.

In terms of side effects after combined therapy, IOP elevation and cataract progression occurred in 45% and 20% of eyes, respectively. Although the rate of cataract progression seemed similar to those in previous studies on combined PDT with IVTA, the rate of IOP increase seemed to be higher.^{24–27} This might be due to younger age in patients with myopic CNV as young age is a known predictor for IOP increase after IVTA.⁴⁵ Therefore, IOP should be monitored carefully in patients who undergo combined therapy for myopic CNV. Fortunately, the IOP was controlled by glaucoma drops in all patients, and none required glaucoma surgery.

In conclusion, our pilot study showed that there seemed to be no significant benefit in using combined PDT with IVTA over monotherapy in myopic CNV. Nonetheless, combined therapy might be beneficial in patients with myopic CNV having worse visual acuity or with larger CNV on initial presentation, as combined therapy resulted in better final vision, with a higher proportion of eyes having visual gain compared with monotherapy. The main limitation of our study was the small number of patients, especially in the subgroup analyses. Another shortcoming was the lack of randomisation and the use of a non-concurrent control group for comparison. Despite these limitations, our pilot study provided the first comparative trial in the literature assessing the efficacy of combined PDT with IVTA versus PDT monotherapy for myopic CNV. Based on our findings, further randomised controlled trials might be justified to determine the role of combined PDT with IVTA for myopic CNV, especially in patients with worse prognostic factors.

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