Transpupillary Thermotherapy as Primary Treatment for Small Choroidal Melanomas

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Objective: To report the short-term follow-up results of eyes containing small choroidal melanomas that were treated with transpupillary thermotherapy.

Methods: Twenty eyes with suspected small choroidal melanomas were treated with transpupillary thermotherapy using infrared light delivered from the diode laser.

Results: The age of the patients ranged from 26 to 82 years. In 14 patients, there was documented growth of the melanoma before transpupillary thermotherapy. The tumor thickness ranged from less than 1.0 to 3.2 mm. Seven tumors were treated more than once. Follow-up ranged from 6 months to more than 3 years. Following treatment, the tumor thickness decreased in all cases, usually within 2 months. Progressive atrophy of tumor mass and loss of pigmentation within the tumor continued beyond 1 year of follow-up in some eyes. Complications included field defects, vascular changes, and macular abnormalities.

Conclusions: Transpupillary thermotherapy of small choroidal melanomas is usually followed by early tumor shrinkage but is complicated by dense scotomas, nerve fiber bundle defects, and, occasionally, macular abnormalities. The short-term follow-up results suggest that transpupillary thermotherapy may arrest the growth of selected small melanomas.


REVAILING contemporary treatments for choroidal melanomas include enucleation and radiation therapy (teletherapy with proton beam or helium ions or brachytherapy with iodine 125, cobalt 60, ruthenium 106, and palladium 103).

Recently, investigators from the Netherlands have reported success in treating choroidal melanoma with transpupillary thermotherapy (TTT). With this technique, near-infrared radiation therapy (810 nm) from a diode laser is delivered to the tumor through a dilated pupil. Experiments with a hamster melanoma model demonstrated that the temperature of the tumor could be increased to 60°C with an exposure of approximately 1 minute. Such an exposure was found to induce extensive necrosis of the experimental melanoma. Additional studies with human melanoma have described tumor necrosis to a depth of more than 3 mm following TTT. The first clinical study reporting the use of TTT in the management of melanoma was published by Oosterhuis et al in 1995. Shields et al subsequently published their preliminary observations with TTT in the management of choroidal melanoma. We began investigating the use of TTT in the management of suspected small choroidal melanomas in 1996. This article reports our experience with the use of TTT as a primary treatment for small choroidal melanomas. We will emphasize some new observations.

RESULTS

Twenty patients, ranging in age from 26 to 82 years, were treated for what was presumed to be a small choroidal melanoma (Table). The maximum basal diameter of the tumors ranged from 4.0 to 12.0 mm, and the thickness ranged from less than 1.0 to 3.2 mm. The treatment usually consisted of multiple 60-second applications using the 3-mm-diameter beam with energies of 600 mW or more. Follow-up ranged from 6 months to more than 3 years. Following treatment, we were unable to recognize any inflammation in the anterior segment or injuries to the cornea, the iris, or the lens. Inflammation in the vitreous cavity was minimal. In most eyes, no cells were seen in the vitreous cav-
MATERIALS AND METHODS

In accordance with an investigational protocol approved by the Institutional Review Board of the Mayo Clinic, Rochester, Minn, men and women aged 18 years or older with suspected small choroidal melanoma (<3.5 mm in thickness) that either had been observed to grow or was within 3 mm of the optic nerve or the fovea were considered for primary treatment with TTT. Exclusion criteria included eyes with a maximum pupillary diameter of less than 6 mm; eyes with choroidal lesions in the midperipheral fundus, where delivery of TTT was difficult and the risk of iris injury high; eyes with media opacities precluding a clear view of the tumor; eyes with confounding fundus disorders; and patients who were unable to give informed consent. Patients giving informed consent agreed to return for scheduled follow-up examinations, including fluorescein angiography and ultrasonography. Before treatment, a complete ophthalmic examination was performed. The diagnosis of suspected choroidal melanoma was based on results of the clinical examination, which included ophthalmoscopy, slit-lamp biomicroscopy, and indirect ophthalmoscopy. The characteristics of the tumor were documented with color fundus photographs and fluorescein angiography. The basal dimensions of the tumor were estimated, and the thickness was measured with ultrasonography. Baseline and 1-month follow-up corneal endothelial studies were determined in both eyes of 12 patients. These studies included the determination of endothelial cell densities, coefficient of variation of cell size, the percentage of hexagonal cells, and the percentage of cell loss.

Treatment was delivered after maximally dilating the pupils with 2% cyclopentolate hydrochloride and 10% phenylephrine hydrochloride. Retrobulbar anesthesia with 4 mL of 2% lidocaine hydrochloride was induced for pain control. The diode laser (wavelength, 810 nm) was modified to deliver a large-beam diameter (≥3 mm) through a slitlamp adapter. A contact lens was placed on the cornea to view the fundus and focus the laser beam. Treatment was initiated using a 60-second exposure and a low energy level of 350 mW using the 3-mm aperture on the slitlamp adapter. The beam was directed to the tumor while titrating the energy from low to higher levels. The energy was raised stepwise by 50 to 100 mW until the surface of the tumor developed a grayish color during the second half of the 1-minute exposure. An attempt was made to avoid high-energy levels that produced an early white coagulation effect within the first 20 to 30 seconds of exposure. If a gray color change became visible during the first 20 to 30 seconds of exposure, the intensity was reduced by 50 to 100 mW. A desired response was achieved when the treated tissue became gray to white during the last 15 to 20 seconds of exposure. The treatment applications were repeated to cover the entire surface of the tumor confluent. The 3-mm aperture provided a beam that translated to an exposure on the retina approximately 1.5 mm in diameter. A smaller beam diameter was sometimes used when treating near the macula or when the desired reaction could not be achieved with the 3-mm aperture.

Twenty-four to 48 hours following the examination, the patients’ eyes were studied for evidence of protein and cellular reaction in the anterior chamber and vitreous cavity; evidence of injury to the cornea, iris, and lens; and any alterations in subretinal fluid that may have accompanied the tumor before the treatment. The patients were reevaluated 2 to 6 weeks after treatment, at which time ultrasonograms, endothelial cell counts, and fundus photographs were obtained. Additional follow-up at 6-month intervals included ultrasonography, fundus photography, and usually visual field examination performed with either the tangent screen or the Goldmann perimeter. Systemic evaluation conducted in advance of treatment included determining serum liver function enzyme levels and obtaining a chest x-ray film. According to the study protocol, these evaluations were repeated annually after the treatment.

ity following treatment. During application of the infrared light, the tumor tissue and the overlying retinal pigment epithelium turned gray. The gray color change involving the surface of the tumor was usually clearly demarcated from normal-appearing retina and choroid around the tumor base that was included in the overlapping treatments. In 7 eyes, a serous retinal detachment that accompanied the choroidal tumor before treatment was observed to increase within 48 hours of the TTT. In each of these eyes, the serous detachment had resolved by the 6-week follow-up visit. In 1 of the cases, the detachment became serosanguineous. In 1 eye, dense accumulation of retinal axoplasmic debris was observed near the perimeter of the TTT applications. Dense scotomata were experienced by all patients, reflecting the destruction of the retina overlying the tumor. In addition, nerve fiber bundle field defects were demonstrated in all but 1 patient. These were generally in the form of a wedge-shaped field defect. Retinal veins overlying the tumor often were closed during the treatment, and small, focal, retinal hemorrhages were commonly seen overlying the tumor at the early follow-up visits. Transient venous occlusive changes developed in the retina peripheral to the treatment in 5 eyes. Permanent arteriolar occlusions were induced over the tumor in 9 eyes. Arteriolar narrowing and sheathing were also commonly seen following TTT.

In 1 eye (case 10), a frond of intravitreal neovascularization developed 1 year after the second treatment with TTT. Fluorescein angiography defined a chorioretinal arterial anastomosis over the treatment site near the localized neovascularization. Additional TTT was administered with sector panretinal photocoagulation, resulting in regression of the neovascularization.

Delayed development of transient cystoid macular edema was noted in 3 eyes, 1 of which also developed a mild epiretinal membrane. An epiretinal membrane developed in another eye (case 14), sufficiently dense to compromise vision and require surgical removal.

The tumor thickness decreased in all cases and was usually evident at the 6-week visit. In most instances, the tumor thickness was reduced to a nonmeasurable scar within 3 months. Although the tumors showed a reduction in thickness, the ophthalmoscopic appearance often did not change greatly during the first 3 months after TTT. However, tumor tissue and choroidal pigmentation progressively decreased well beyond 1 year.
Seven eyes developed dark pigmentation in the inner retina at the periphery of the treatment site. This pigmentation appeared to increase beyond 1 year of follow-up in 3 eyes.

Seven tumors were treated more than once. In 2 cases (cases 3 and 10), re-treatment was deemed necessary when review of the photographs at follow-up indicated that part of the tumor had not been included in the initial treatment. In 4 cases, a second application was given to the tumor because of perceived inadequate initial treatment (1 case was re-treated 14 months after the initial treatment) or incomplete response (3 cases, re-treated 1, 2, and 8 months later). One eye (case 1) was re-treated 14 months after the initial treatment for what was believed to be an edge recurrence. When a tumor was treated a second time, it was usually difficult to make the tumor tissue turn gray, despite the presence of pigmentation within the tumor and despite increasing the laser energy.

The endothelial cell densities, coefficient of variation of cell size, percentage of hexagonal cells, and percentage of cell loss between the baseline study and the study 1 month following TTT (12 patients) were not statistically different from the findings in the control eyes using a paired t test (2-tailed) and the Wilcoxon analysis.

The Table summarizes details of the 20 cases. Three cases have been selected to describe characteristic findings.

**CASE 1**

A 72-year-old man was initially seen with a pigmented choroidal tumor located temporal to the left fovea. The tumor had been observed to grow during the previous 4 years, and enucleation had been recommended. The patient's visual acuity was 20/25 OS. The tumor had a base dimension of 7.5 × 6.0 mm (Figure 1, A) and a thickness of 2.4 mm, as measured with B-scan ultrasonography. It was located approximately 1000 µm temporal to the fovea; a sensory retinal detachment overlying the tumor spared the fovea. Lipofuscin was present on the tumor surface.

The tumor was treated with TTT. The gray appearance of the tumor 24 hours after treatment is shown in Figure 1, A. At the 3-month follow-up visit, a grayish plaquelike discoloration of the surface of the tumor and a small amount of atrophy around the superior temporal perimeter had developed (Figure 1, C). Four months later, there was progressive atrophy of the pigment within the tumor, which had completely flattened by ultrasonography. One year following therapy, there was further loss of pigment within the tumor (Figure 1, D). An area suggestive of persistent tumor at the superonasal boundary of the lesion was treated with additional TTT 14 months after the initial treatment (Figure 1, E). Two years after the initial treatment, there was further loss of pigment from the tumor and atrophy at the site of the treated recurrence. Dark intraretinal proliferations of pigment that became visible near the perimeter of the applications of the TTT during the first year became more prominent at the second year, but changed little between the second and third years of follow-up (Figure 1, F). B-scan ultrasonograms demonstrate the pretreatment and posttreatment thickness of the tumor (Figure 1, G). The patient experienced a dense scotoma corresponding to the treated site and a wedge-shaped nasal...
field defect (Figure 1, H) from nerve fiber damage. The central visual acuity has been maintained at 20/25 OS for the 3 years of follow-up.

CASE 6

A 56-year-old man with a visual acuity of 20/25 OD was initially seen with a pigmented choroidal tumor located superior-temporal to the right fovea (Figure 2, A). Tumor growth had been documented over 4 years. The tumor had a base dimension of 7.5 × 5.5 mm and an ultrasonographic thickness of 1.4 mm. There was lipofuscin over the surface of the tumor and a secondary serous detachment that extended inferior to the tumor. The most posterior extent of the tumor was approximately 1000 µm from the center of the fovea.

The tumor was treated with TTT, resulting in a gray tissue reaction involving the site of the tumor and, to a lesser degree, the tissue surrounding the tumor (Figure 2, B). The tumor was reduced to a flat scar at the 2-month follow-up visit. Progressive loss of pigment continued even beyond the follow-up visit at 14 months. Progressive intraretinal proliferations of pigment have developed near the periphery of the treatment site (Figure 2, C and D). The B-scan ultrasonograms show the pretreatment and posttreatment appearance of the tumor (Figure 2, E). The dense wedge-shaped defect in the peripheral visual field observed after treatment has remained unchanged (Figure 2, F). The patient remains healthy, and the eye maintains a central visual acuity of 20/25 OD 2 years following TTT.

CASE 7

A 59-year-old man was observed to have a growing lesion in the superior-temporal fundus of the right eye. The base dimensions of the tumor originally measured 6.0 × 12.0 mm, and the thickness was 1.7 mm. The visual acuity at the time of the initial presentation was 20/20 OD. After 2 years of observation, the temporal portion of the tumor was observed to expand (Figure 3, A and B). The tumor was treated with TTT. Twenty-four hours following the treatment, the visual acuity remained 20/20 OD (Figure 3, C). Six weeks following treatment, the patient returned with blurred vision from cystoid macular edema. The cystoid macular edema spontaneously resolved and central visual acuity returned to 20/20 OD over a 6-week period (Figure 3, D). Atrophy of the pigment within the tumor tissue initially noted at the 3-month follow-up visit became more evident 6 months following treatment (Figure 3, D and E). Progressive pigment atrophy was observed at the 12- and the 23-month follow-up visits (Figure 3, F and G). Intraretinal pigment proliferation at the margin of the treatment site was present at the 12- and the 23-month follow-up visits. The visual acuity remains 20/20 OD, and there is no elevation detectable by B-scan ultrasonography. A wedge-shaped peripheral field defect was present (Figure 3, H).

COMMENT

The decision to treat a small melanoma has been the subject of considerable controversy. However, there is general agreement that the low metastatic disease rate from a small melanoma increases with growth of the tumor to medium size. There are recognized features that identify those small melanomas with a high risk for growth (primarily the presence of lipofuscin, greater tumor thickness, and subretinal fluid). Observing a growing small melanoma until it reaches medium size ($≥3$ mm in thickness) may not be appropriate. If we knew which small tumors would grow to medium size, most of us would consider treating the tumor when it was still small, pro-

<table>
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<tr>
<th>Interval Between First Rx and Re-Rx</th>
<th>FU Thickness</th>
<th>Last VA</th>
<th>Loss of Vision, No. of Lines</th>
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<tr>
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vided the treatment was efficacious and the incidence of complications was low and acceptable.

Transpupillary thermotherapy is a relatively new therapeutic alternative for the management of choroidal melanoma. A comprehensive review of this subject in the form of a thesis was published in the spring of 1998 by Journee-de Korver. This alternative clearly is capable of causing tumor necrosis and shrinkage of choroidal melanoma. Transpupillary thermotherapy can be administered as an outpatient office procedure; it does not require incisional surgery and thus avoids some of the complications inherent with surgery and some of the manipulations that have been thought by some to encourage dissemination of tumor cells. The impressive histopathologic demonstration by Journee-de Korver et al of extensive tumor necrosis to 3.5 mm in human choroidal melanoma after TTT prompted our interest in the use of TTT in the management of selected small choroidal melanomas in 1996.

We chose to investigate the use of TTT as an alternative to brachytherapy with the hope of avoiding some of the long-term complications commonly observed after radiation therapy. We concluded that TTT was not likely to be associated with local complications not already known to be caused by radiation therapy (cata- ract; hemorrhage; neovascularizations; radiation retinopathy and neuropathy; uveitis; vitritis; intravitreal pigment dispersion, including melanoma cells; retinal detachment; and failure of local tumor control). Specifically, complications resulting from ionizing radiation therapy would not be encountered with TTT.

Most tumors in this present series were growing tumors that had high-risk characteristics for continued growth. The 2 cases in which the thickness of the lesions was less than 1 mm deserve comment. Case 12 was that of a 67-year-old woman known to have a growing pigmented lesion involving the papillomacular bundle. The lesion was contiguous with the optic nerve approxi-
mately 180°, and serous fluid extended into the fovea. Lipofuscin was visible at the surface of the lesion, and the fluorescein angiogram showed pinpoint areas of hyperfluorescence overlying the tumor. These 4 high-risk features—observed growth, lipofuscin, pinpoint areas of hyperfluorescence, and subretinal fluid—argued for treatment despite the small size of the tumor and the knowledge that the central acuity would be impaired.

Case 16 was that of a 63-year-old man who had a recognized growing pigmented lesion with lipofuscin on the surface. The lesion progressively expanded to within 0.5 disc diameters of the fovea and optic nerve. Because of the growth, it was believed to have malignant potential, and because of the location, it was still favorable for central vision-sparing treatment; therefore, TTT was offered. Thus far, there has not been a decline in the central visual acuity. While these growing lesions may still have been nevi, we elected to include them in this series.

In our series of 20 small pigmented choroidal tumors, we observed that the tumor thickness decreased in all cases, usually within 2 to 3 months. In most instances, the tumor was reduced to a flat scar. Although 7 tumors were treated more than once, we have learned that second treatments may have been prematurely given in some cases, as we have observed progressive atrophy of tumor tissue and progressive loss of pigment from the tumor site that has continued beyond 1 year of follow-up after a single treatment with TTT in other cases.

The treatment causes damage to the retina, the retinal pigment epithelium, and the retinal vasculature overlying the tumor. Retinal veins often closed during the treatment, and localized perivascular intraretinal hemorrhages developed. Retinal arterial sheathing, narrowing, and sometimes occlusion was observed. In 1 eye (case 10), intravitreal neovascularizations developed, requiring photocoagulation. In this same eye, a chorioretinal arterial anastomosis over the tumor was confirmed by fluorescein angiography. Occasionally, a serous detachment that accompanied the tumor was observed to increase after TTT. It resolved within 6 weeks in each case. Following treatment, the anterior chamber has been free of inflammation and the vitreous cavity has also been remarkably free of inflammation.

All patients treated with TTT experienced dense scotomas associated with destruction of the retina overlying the tumor. In addition, nerve fiber bundle defects usually in the form of wedge-shaped field defects have been demonstrated in all but 1 eye. This observation has not been reported by others. Three eyes developed transient cystoid macular edema. Four eyes developed an epiretinal membrane that in 1 eye caused marked visual loss.

Intraretinal dark pigment proliferation has been seen near the periphery of the treatment site in 7 eyes. This pigment proliferation has progressed in some eyes for more than 1 year. Such pigmentation has not been reported by others. Although we believe this pigment derives from proliferating retinal pigment epithelium cells and not from tumor cells, careful monitoring of these areas is advisable.

Excluding the 2 lesions less than 1 mm thick, the mean size of the tumors in this series was 7.0 mm in larg-
est base diameter and 1.9 mm in thickness. These tumors are somewhat smaller in size than those reported by Shields et al, who obtained regression to a flat scar after TTT in 94.0% of the tumors treated. In their 100 cases, 4 tumors recurred. In our series, 18 (90%) of the 20 tumors were reduced to a flat scar. One edge recurrence was observed, which has been controlled for 2 years with additional TTT.

We continue to evaluate TTT cautiously. We remain concerned about the possibilities that melanoma cells that have invaded the sclera may not be destroyed by TTT. For example, intrascleral invasion of melanoma cells has been observed in more than 50% of eyes with medium and large tumors. Furthermore, Journee-de Korver et al reported viable-appearing tumor cells in the sclera of eyes in which tumor necrosis up to the inner scleral surface had been induced by TTT. The single case in which histologically viable tumor cells were recognized in the sclera following TTT is disconcerting, but perhaps no more so than the common identification of viable-appearing tumor cells seen in enucleated eyes following radiation therapy. Nevertheless, this observation prompted investigators from the Netherlands to suggest that TTT be combined with brachytherapy to eradicate tumor cells that may have invaded the sclera. While this might seem to be a reasonable approach in the management of some melanomas, the additional complications we have observed with TTT need to be considered before these complications are added to those already known to occur with brachytherapy. For example, it is important to know that dense scotomata and often nerve fiber bundle defects occur immediately after TTT, while loss of visual acuity and visual field usually are late occurrences following radiation therapy.

From past studies using photocoagulation to treat melanomas, we have learned that early satisfactory tumor regressions may be followed by recurrences that may not become apparent until years after treatment. Shields et al.
comparing xenon and argon laser photocoagulation in the treatment of choroidal melanomas (22 eyes treated with xenon arc and 16 treated with argon laser photocoagulation), reported a recurrence rate of 14% after xenon arc photocoagulation and 64% after argon laser photocoagulation. Recurrences were observed on an average of 2½ years after treatment with argon laser photocoagulation and 6 years after treatment with xenon arc photocoagulation. These relatively high rates of recurrence and the relatively late detection must be taken into account when investigating a new therapeutic modality like TTT. We continue to perform careful evaluations with ophthalmoscopy and ultrasonography every 4 to 6 months after TTT. Even if the tumor has been replaced by a flat scar, regularly performed imaging with ultrasonography, looking for evidence of tumor growth posterior to the globe, is advisable.

Although the concept of TTT appears to be sound, we believe TTT remains an investigational procedure. Short-term follow-up results suggest that TTT can promote local control of small choroidal melanomas while preserving central visual acuity, even when tumors are within 1000 μm of the fovea. Long-term follow-up is important to observe for recurrences and other complications.

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REFERENCES