JOJ Ophthalmology
ISSN: 2473-5477

Juniper Publishers
key to the Researchers

Research Article
Volume 12 Issue 3 - March 2025
DOI: 10.19080/JOJO.2025.12.555837

JOJ Ophthalmol

Effectiveness of Adjuvant Interferon Therapy (Alpha-2b Interferon) in Organ-Preserving (Photodestruction, Brachytherapy) Treatment of Uveal Melanoma

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Submission: February 26, 2025; **Published:** March 05, 2025

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Abstract

Purpose: Consider the effectiveness of adjuvant interferonotherapy (IFT) in patients with choroidal melanoma (CM) in combination with xenon photocoagulation (XP), transpupillary thermotherapy (TTT), brachytherapy (BT).

Methods: The analysis was carried out in 702 patients with MS (men - 317 (51.7±0.15) patients, women - 385 (53.1±0.13), who underwent treatment with XP, TTT, BT and IFTin various combinations.

Results: It has been shown that IFT leads to a positive result in small swellings in 88.7%, in medium ones in 90.7%, in the control group in 64.0% and 76.2%, similar. There was no significant difference in the effectiveness of IFT with TTT or combined with BT. It was noted that in patients with partial tumor regression on the fourteenth day, with monitoring for 3 months. up to 3.5 years, the tumor regression was more active in the equal group, indicating an increase or stabilization of the tumor.

Conclusions:

The effectiveness of XP, TTT and their combination with BT in patients with ocular uveal melanoma (UM) in the significant world indicated by the clinical parameters of the tumor.

The inclusion of interferon in the complex of XP and its combination with BT the process of tumor regression and improves the result for small tumor up to 88.7%, with average tumor up to 90.7%, in the control group 64.0% and 76.2%, similar.

Depending on the clinical reaction of CM (resorption, stabilization, increase) on the 14th day after treatment, the sensitivity of tumor to treatment factors can be predicted and the result of outcome.

Keywords: Choroidal Melanoma, Xenon Photocoagulation, Transpupillary Thermotherapy, Brachytherapy, Interferotherapy

Abbreviations: BT: Brachytherapy; IFT: Interferonotherapy; CM: Choroidal Melanoma; XP: Xenon Photocoagulation; TTT: Transpupillary Thermotherapy; UM: Uveal Melanoma; IF: Interferon

Introduction

Uveal melanoma (UM) poses a threat not only to the organ of vision, but also to the patient's life. Thus, 50% of patients at different times, regardless of the method of treatment of the primary tumor, develop a metastatic disease. Factors of unfavorable prognosis in UM include: age of patients, size of primary tumor, cell composition (epithelioid or mixed histological type of cells), extra-ocular growth, chromosomal changes (monosomy of chromosome 3 and/or amplification of chromosome 8). The average European rate of UM is in the range of 5 to 8 per 1 million population. Among malignant tumors of the eye, melanoma is the most common. About 95% of all eye melanomas occur in the vascular (uveal) tract of the eye (anterior - iris and posterior - ciliary body and choroid), and 5% are divided between melanomas of the conjunctiva, orbit, and eyelids. At present, two main directions in the approaches to the therapy of UM of the eye are clearly defined, i.e., enucleation of the eye and organ-preserving treatment. A great achievement in the organ-preserving treatment of UM are methods using light energy -

xenon photocoagulation (XP) and laser radiation. The ease of their use, high efficiency in small tumors, the "exquisite" effect allows avoiding serious complications, in addition, the possibility of repeated exposure is the basis for photo- and laser coagulation and TTT to take a strong place not only in ophthalmology, but also in general oncology. However, as noted by a number of authors, with the help of XP, laser coagulation and TTT, it is possible to destroy a melanoma with a protrusion of no more than 3.0 mm, and the number of cases of intra-ocular melanoma with such a protrusion is only 20-25%. In order to expand the organ-preserving treatment of UM, we previously proposed the simultaneous use of XP and BT, which allowed us to achieve a clinical result in UM with a prominence of up to 8.0 mm 6, while BT alone was effective in UM with a prominence of only up to 5.0 mm. A significant point in conducting organ-preserving treatment of patients with UM is that in 41-52% of cases it is possible to preserve visual functions, which is very important in the presence of a tumor in one eye. To increase the efficiency of photo destruction, various approaches are presented, including the use of biological response modifiers that strengthen the state of tumor cells and activate the body's anti-tumor resistance function [1-4].

Such modifiers of biological responses include cytokines (interferons, interleukins, tumor necrosis factors, etc.), the inclusion of which in the complex of organ-preserving treatment (light coagulation and BT) of UM made it possible to expand the effectiveness of treatment of intra-ocular tumors. In order to increase the sensitivity of MC to light energy and BT, our attention was drawn to recombinant alpha-2b-interferon (IF). We conducted preliminary studies of the effectiveness of interferon therapy in combination with xenon photocoagulation on 16 patients and its combination with BT on 43 patients showed that the activity tumor regression occurred more actively in comparison with patients who were not administered interferon. There are no studies on the combination of IFT and TTT, as well as its combination with TTT and BT. We also find it interesting to conduct a comparative analysis of the effectiveness of IFT in combination with XP and BT and TTT with BT. Thus, we believe that studying the role of adjuvant interferon therapy (IFT) in combination with XP, TTT, as well as in the complex of XP with BT and TTT with BT can be of both scientific and practical interest.

Purpose

To study the effectiveness of adjuvant IFT during organ-preserving therapy (XP, XP + IFT, TTT + IFT, XP, BT and IFT and TTT, BT and IFT) in patients with CM.

Methods

The analysis was carried out on 702 patients who were treated at the Institute of Eye Diseases and Tissue Therapy named after V.P. Filatov, National Academy of Sciences. By gender and age, the patients were divided as follows: men - 317, age - (51.7±0.15) years, women - 385, age - (53.1±0.13) y.o. who underwent photo destruction as an organ-preserving treatment (XP, TTT), BT and IFT. Frequency of intra-ocular melanoma in relation to the eye: right eye - 362 (51.7%), left - 340 (48.3%) [5-8].

The distribution of patients with MC depending on its degree of pigmentation is as follows: non-pigmented in 115 (16.4%) cases, weakly pigmented in 413 (58.8%) and intensely pigmented in 174 (24.8%). Taking into account the fact that various approaches to the treatment of patients with UM were used during organ-preserving therapy, we present the analysis in the following groups (Table 1). XP was performed after drug-induced mydriasis was achieved (Sol. Atropini sulfuriti 1%), epibulbar anesthesia was performed on the affected eye (Sol. Dicaini 0.5%). CF was performed transpupillary using a xenon lamp with an incandescent current of 90-120 A, a spot diameter of 6 mm, 15-45 pulses per session. The course of treatment consisted of 2-3 sessions with an interval of 2-4 days. Photo destruction was carried out on a xenon photocoagulator of the company "Opton". TTT was performed after drug-induced mydriasis was achieved (Sol. Atropini sulfuriti 1%) and epibulbar anesthesia (Sol. Dicaini 0.5%) was performed on the affected eye and was carried out using a diode laser (810 nm) in continuous mode with an exposure of 60-90 seconds, with a power of 200-1200 mW and a light spot diameter of 1.5-7 mm. The number of sessions per course is up to 4, with an interval of 3-4 months between courses. TTT was performed on a diode laser manufactured by Quantel Medical. BT -After general anesthesia, a beta-applicator (strontium-90 + yttrium-90) was sewn to the sclera at the base of the tumor. The diameter of the beta applicator was selected so as to completely cover the base of the tumor, as well as the surrounding healthy tissue of the tumor with a width of 2 mm. The duration of radiation therapy was from 3 to 10 days and depended on the size of the tumor and the type of beta-applicator. The total radiation doses were on average (2295±240 Gy). The method of administration of alpha-2b-interferon to patients with MC of the eye was carried out according to the method previously developed by us.

Table 1: Distribution of patients according to the nature of organ-preserving therapy in patients with MC.

№	The nature of the treatment	Number of patients	The size of the tumour M ± m (mm)
1	XP of a tumor	50	3,5±0.19
2	XP + IFT	53	2,9±0.15
3	TTT with iIFT	22	2,2±0.18
4	XP and BT	147	6,0±0.2
5	XP, BT and IFT	225	6,43±0.11

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6	TTT, BT and IFT	205	6,49±0.14
TOTAL:		702	

Note: XP – xenon photocoagulation; IFT - interferon therapy; TTT-transpupillary thermotherapy; BT- brachytherapy is the number of patients

The evaluation of the effectiveness of the treatment was carried out after the start of the treatment. Complete, partial regression and stabilization of tumor growth was evaluated as a positive result, and continued tumor growth - the absence of a clinical effect. On the 14th day, the previous response of the tumor to the therapeutic effect (larger, no change and reduction of the tumor) was evaluated to predict the future clinical outcome and tumor regression activity. Methods of statistical processing of material. To assess the statistical significance of differences between comparative clinical groups, parametric t-Student tests and Fisher's F- test were used at the confidence level of $p<0.05$. This study was performed in line with the principles of the Declaration of Helsinki.

Research Results

At the first stage, we considered it expedient to conduct a comparative analysis of the regression of small-sized MC during organ-preserving therapy with the use of XP of the tumor in 50 patients (3.5+0.19) mm and its combination with IFT in 53 patients (2.9 + 0.15) mm. Analysis of the dynamics of tumor regression during XP and its combination with IFT over a five-year period is presented in (Figure 1). Analyzing the nature of the curves in Figure 1, it can be noted that in patients who underwent XP in combination with IAT, the activity of tumor regression occurred sooner, especially in the first 6 months (after 3 months, and h/z 6 - $p = 0.032$), 1 .5 years ($p < 0.02$). After 3 years $p = 0.48$, 3.5 - $p = 0.003$, 4 - $p = 0.001$ and after 5 years $p = 0.017$. In addition, 1.5 years after the start of treatment (photocoagulation), progression of tumor growth was noted in the control group of patients. The analysis of the obtained research results allows us to conclude that tumor regression occurs more pronouncedly in patients with MC of the eye when using XP in combination with IFT. It should be noted that the following types of clinical reaction of the tumor to the therapeutic effect were noted in the process of XP on the background of IFT in patients with UM of the eye (Table 1, 2).

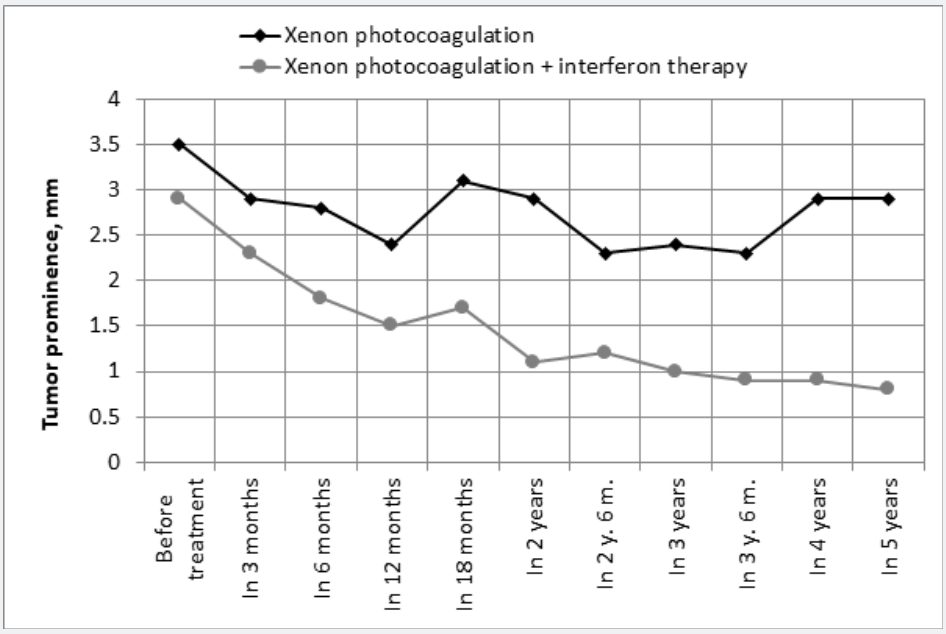

Figure 1: Analysis of the dynamics of tumour regression in patients with choroidal melanoma after organ-preserving treatment in the following groups: xenon photocoagulation and xenon photocoagulation + interferon therapy at a 5-year follow-up period.

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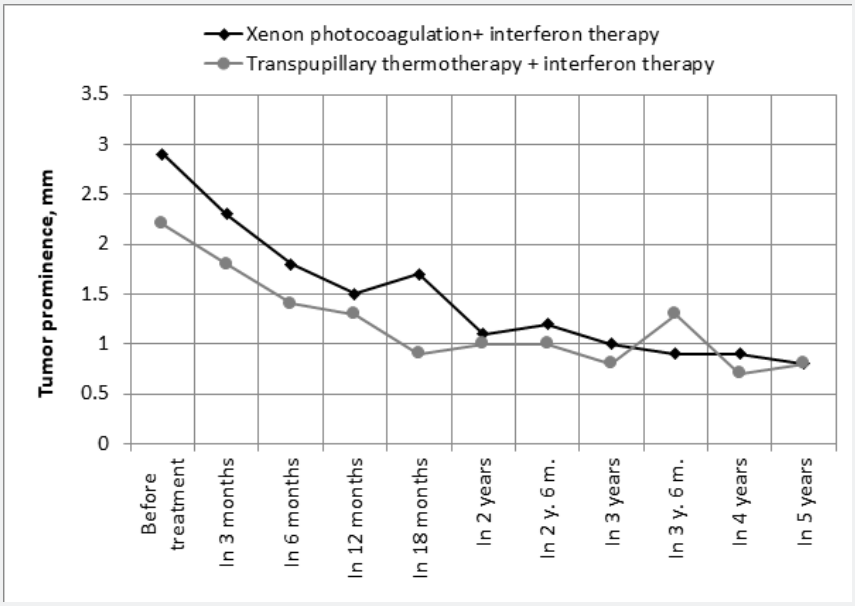

Figure 2: Analysis of tumor regression in patients with choroidal melanoma during organ-preserving treatment in the following groups: xenon photocoagulation + interferon therapy and transpupillary thermotherapy + interferon therapy at a 5-year follow-up period.

Table 2: Distribution of patients with choroidal melanoma undergoing organ-sparing treatment (XP and XP with IFT) depending on the nature of the tumour's clinical response to treatment.

Treatment	The nature of the Clinical Reaction of the Tumour for Treatment, n (%)			
	Full Regression	Partial Regression	Stabilization of Growth	Continuation of Growth
XP with IFT, n = 53	22 (41,5%)	22(41,5%)	3 (5,7%)	6 (11,3%).
XP, n = 50	3 (6,0%)	15 (33,0%)	14 (28,0%)	18 (36,0%)

Note: XP – xenon photocoagulation; IFT - interferon therapy; n - is the number of patients

According to the data shown in Table 2, it can be seen that the positive clinical result (complete, partial resorption and stabilization of tumor growth) when using a combination of XP with IFT was the highest and amounted to 88,7%, while in the group of patients who underwent only in XP it was the smallest and amounted to only 64,0%. A comparative analysis of the dynamics of CM regression was performed in the group in which XP and IFT were performed and with the group of patients who underwent TTT and IFT. Analysis of the dynamics of tumor regression during XP in combination with IFT and TTT with IFT over a five-year observation period is presented in Figure 2.

Analysis of the graphic images presented in Figure 2 allowed us to note that there was no significant difference in the dynamics of tumor regression in the studied groups of patients who underwent TTT and IFT, compared to those patients who underwent XP and IFT, despite the fact that in the group of patients who underwent TTT and IFT, the initial parameters of tumor prominence were significantly lower (p = 0,01). It should also be noted that in the course of conducting TTT on the background of IFT in patients with eye MC, the following types of clinical reaction of the tumor to the therapeutic effect were noted (Table 3) [9-14].

Table 3: Distribution of patients with CM undergoing organ-sparing treatment (XP + IFT and TTT in combination with IFT) depending on the nature of the tumor's clinical response to treatment.

Treatment	The Nature of the Clinical Response of the Tumor to Treatment, n (%)			
	Full Regression	Partial Regression	Stabilization of Growth	Continued Growth
XP + IFT n = 53	22 (41,5%)	22 (41,5%)	3 (5,7%)	6 (11,3%)
TTT with IFT n = 22	8 (36,4%)	7 (31,8%)	3 (13,6%)	4 (18,2%)

Note: XP - xenon photocoagulation; TTT- Transpupillary Thermotherapy; IFT - interferon therapy; n - is the number of patients

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According to the data presented in Table 3, it can be noted that the combination of IFT with XP allows to achieve a clinical result (full, partial regression and stabilization of growth) in 86,8%, while with TTT + IFT - in 81,8%. It should be noted that complete and partial regression of the tumor in patients who underwent XP in combination with IFT was 83,0%, while in patients after TTT and IFT - 68,2%. It is known that some authors attribute the stabilization of tumor growth to a negative clinical result 13. This is dictated by the fact that the stabilization of tumor growth is often the cause of continued tumor growth after two years from the start of treatment. Given the positive clinical result of XP and IFT in small CM (Table 3), we thought it would be appropriate to study the role of IFT in combination with XP and BT in medium-sized intraocular melanomas. The analysis presents two research groups. The first group consisted of 225 patients who underwent XP, BT and IFT as organ-preserving treatment, and the second - control group - consisted of 147 patients who underwent XP of tumor and BT.

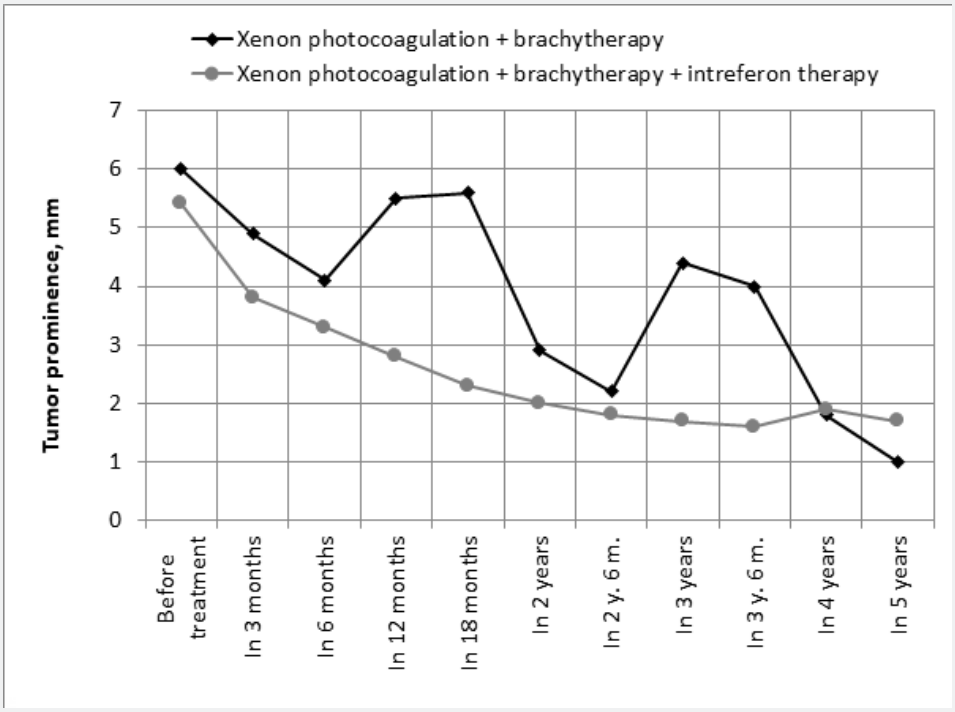

Figure 3: Analysis of tumour regression in patients with choroidal melanoma after organ-preserving treatment in the following groups: xenon photocoagulation + brachytherapy and interferon therapy combined with xenon photocoagulation and brachytherapy with a 5-year follow-up period.

A five-year analysis of tumor regression in the above two groups is presented in Figure 3. According to the data presented in Figure 3, it can be noted that the combination of alpha-2b-interferon in a complex with XP and BT significantly activates the process of regression of intraocular melanoma, especially a significant difference was noted in the period from 3 months to two years (after 3 months p = 0,0001, after 6 - p = 0,006, after12 and 18 months p = 0,0001, over two years - p = 0,004), as well as from 3 to 3.5 years (p = 0,0001). It should be noted that in the process of performing photocoagulation against the background of BT and their combination with IFT in patients with MC of the eye, the following types of clinical reaction of the tumor to the therapeutic effect were noted (Table 4). According to the data presented in Table 4, it can be noted that the clinical result (complete, partial and stabilization of tumor growth) of organ-preserving treatment of MC in combination with XP, BT and IFT was significantly higher and amounted to 90,7%, compared to without IFT - it was 76,19% [15,16].

The data presented in Table 4 allow us to conclude that IFT in combination with XP and BT activates the process of regression of UM and allows obtaining a higher clinical result. We thought it appropriate to conduct a comparative analysis of the dynamics of CM regression in the following clinical groups. The first group - 225 patients who underwent IFT with XP and BT and the second - 205 patients who underwent TTT, BT and IFT. Analysis of the effectiveness of IFT in combination with XP and BT, as well as with a group of patients with CM who underwent IFT in combination with TTT and BT are presented in figure 4.

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Table 4: Distribution of patients with CM undergoing organ-sparing treatment (XP + BT and their combination with IFT) depending on the nature of the tumour's clinical response to treatment.

Treatment	The Nature of the Clinical Reaction of the Tumor for Treatment, n (%)			
	Full Regression	Partial Regression	Stabilization of Growth	Continued Growth
XP + BT, n = 147	22 (14,96%)	62 (42,17%)	28 (19,0%)	35(23,8%)
XP, BT and IFT, n = 225	58 (25,7%)	137 (60,9%)	9 (4,0%)	21 (9,3%)

Note: XP - xenon photocoagulation; BT- Brachytherapy; IFT - interferon therapy; n - is the number of patients

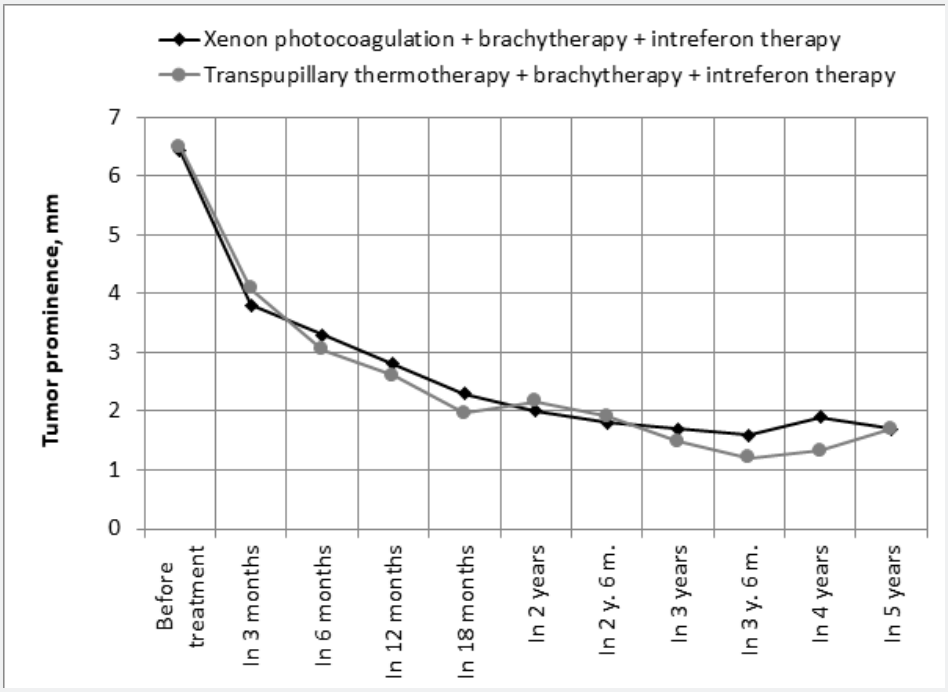

Figure 4: Analysis of tumour regression in patients with choroidal melanoma after organ-preserving treatment in the following groups: xenon photocoagulation + brachytherapy + interferon therapy, as well as transpupillary thermotherapy, brachytherapy with interferon therapy at a 5-year follow-up period.

It is important to note that the dynamics of CM regression in the comparison groups did not differ significantly. We thought it would be appropriate to follow the nature of the clinical reaction of the tumor in the above-mentioned groups (Table 5). According to the data presented in Table 5, it can be noted that the clinical result (complete, partial and stabilization of tumor growth) of organ-preserving treatment of MC during TTT, BT with IFT was 90,7%, and in the group of patients who underwent XP, BT and IFT - 90,6%. The obtained data indicate that the clinical response of CM after two years was the same. As we noted in our research and a number of other authors, intra-ocular melanoma is differently sensitive to photo destruction and local radiation therapy (brachytherapy). In order to possibly predict the results of TTT, BT and IFT, we decided to determine the reaction of the tumor (reduction, no changes and its increase) on the 14th day after the treatment. The analysis was carried out on 85 patients who underwent TTT, BT and IFT and were divided into two groups. The first group consisted of 63 patients in whom, on the 14th day after treatment, there was a decrease in tumor protrusion from 0,1 to 3,0 mm, and the second group (22 patients), in whom, on the 14th day after treatment, the absence of or an increase in tumor protrusion from 0,0 to 2,85 mm. The dynamics of tumor regression in these groups is presented in Figure 5.

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Table 5: Distribution of patients with CM undergoing organ-sparing treatment (XP, BT, IFT and TTT, BT and IFT) depending on the nature of the tumor's clinical response to treatment.

Treatment	The Nature of the Clinical Reaction of the Tumor for Treatment (amount and %)			
	Full Regression	Partial Regression	Stabilization of Growth	Continued Growth
TTT, BT, IFT n = 205	53 (25,8%)	124 (60,5%)	9 (4,4%)	19 (9,3%)
XP, BT and IFT n = 225	58 (25,7%)	137 (60,9%)	9 (4,0%)	21 (9,3%)

Note: XP - xenon photocoagulation; TTT - transpupillary thermotherapy; BT - brachytherapy; IFT - interferon therapy; n is the number of patients.

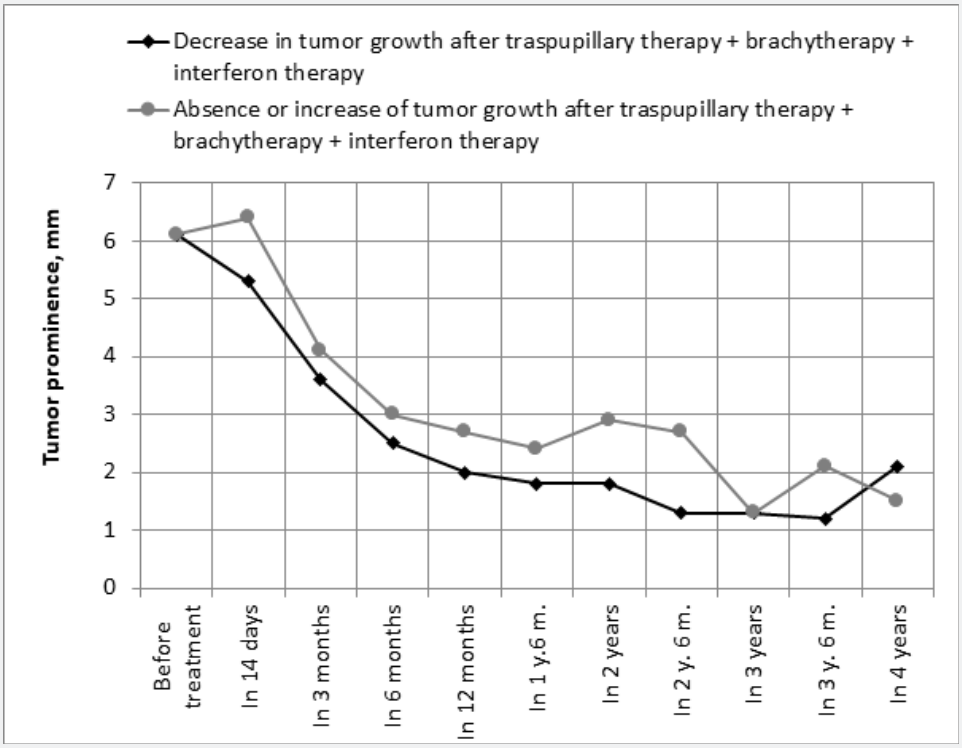

Figure 5: Analysis of the dynamics of choroidal melanoma regression in patients undergoing transpupillary thermotherapy, brachytherapy, and interferon therapy, depending on the reaction of the tumour 14 days after the treatment.

According to the data presented in Figure 5, it can be noted that the dynamics of tumor regression after the performed TTT, BT and IFT was more active in the group of patients in whom tumor reduction was noted on the 14th day from the start of treatment, while in the group of patients, in which tumor growth was observed, tumor regression took place less intensively. We did not find a significant difference between the studied groups. We believe that according to the reaction of the tumor in the early stages (on the 14th day), we can talk about the possible activity of tumor regression after the combined organ-sparing treatment (TTT, BT and IFT).

In order to determine the influence of IFT on the prognosis for the life of patients with UM, a comparison was made between the survival of 225 patients with a tumor prominence of 6,43 + 0,1 mm who underwent XP, BT and IFT with the survival of 147 patients (6,0 + 0,2 mm.) of the control group, which was conducted only XP and BT. The analysis of the results of the study showed that the survival rate in the period from 30 to 60 months was higher (0,94 ± 0,03 - 0,86 ± 0,05) in patients who received IFT XP in combination with BT than in the group patients who were not administered interferon - 0,89 ± 0,03 - 0,79 ± 0,05 (Cox.F-Test = 1,53, p = 0,17).

Discussion

In recent decades, photo destruction (XP, laser coagulation, and TTT) has been used as an organ-preserving treatment method for UM. However, the above methods can destroy intra-ocular tumors with a protrusion no higher than 2,5-3,5 mm, and their prevalence is 20-25% of all tumors. The simultaneous application

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of photo destruction and BT made it possible to achieve a clinical result in UM with a prominence of up to 8,0 mm, while BT alone - only up to 5,0 mm. In order to expand the indicators for organ-preserving treatment, UM can follow the method of increased sensitivity of tumors cells to therapeutic factors (XP and BT) by including recombinant alpha-2b-interferon (IF) in the treatment complex. Our preliminary studies of the effectiveness of IFT in combination with XP on 16 patients and its combination with BT on 43 patients showed that the activity of tumor regression occurred more actively compared to patients who were not administered interferon [17].

As we and a number of other authors noted in our research, intra-ocular melanoma is differently sensitive to photo destruction and local radiation therapy (BT). In order to possibly predict the results of TTT, BT and IFT, we decided to determine the reaction of the tumor on the 14th day after the treatment. The analysis of the research results, which were conducted on 702 patients with MC, allows us to conclude that the effectiveness of combined organ-preserving treatment depends on the initial growth of the tumor and the individual sensitivity of MC to treatment factors. Thus, the analysis of clinical studies in the combination of XP with IFT in the presence of a tumor of 2,9+0.15 mm made it possible to achieve a clinical result (complete, partial regression and stabilization of growth) in 88.7%, while in the control group 64,0% (table 2), and with TTT + IFT (tumor prominence 2,2 + 0.18 mm) the positive clinical result was 81,8% (Table 3).

It should be noted that the complete and partial regression of the tumor in patients who underwent XP combined with IFT amounted to 83,0%, patients after TTT and IFT - 68,2%. It is known that some authors attribute the stabilization of tumor growth to a negative clinical result, as this group of patients is often the cause of continued tumor growth after two years from the start of treatment. Having received the positive clinical result of XP and IFT in small MCs (Tables 2,3), we thought it appropriate to study the role of IFT in combination with XP and BT, as well as with TTT and BT in medium-sized intraocular melanomas. Thus, the results of clinical studies allow us to note that the inclusion of recombinant alpha-2b interferon in the complex of organ-preserving treatment of MC in a complex with XP and BT, as well as with TTT and BT allows to achieve a higher positive clinical result with an average of 90,7%, then as in the control group, 64,0% and 76,2% (Table 5), respectively. Analyzing the dynamics of UM regression and the clinical outcome in patients who underwent organ-sparing treatment, it is possible to draw a conclusion about different photo- and radiosensitivity of the tumor to therapeutic factors. Evidence of this can be our studies of tumor response on the fourteenth day of treatment (TTT, BT and IFT) and their dynamics of regression over four years (Figure 5), which allows us to conclude that in those patients in whom partial regression of the tumor was observed on the fourteenth day in subsequent periods, tumor regression took place more actively in comparison with the group of patients in whom tumor growth was observed during the study period. Thus, a comprehensive approach to conducting organ-preserving treatment of patients with eye MC, taking into account clinical criteria, as well as the inclusion of alpha-2b-interferon in the complex of organ-preserving therapy of intraocular melanoma allows to achieve a higher clinical result.

Conclusions

1. The effectiveness of combined organ-sparing treatment (XP, TTT, and BT) in patients with MC of the eye is largely determined by the clinical parameters of the tumor.

2. The inclusion of alpha-2b-interferon in the complex of organ-preserving treatment (XP and its combination with BT) in patients with MC activates the process of tumor regression and increases the clinical result in small tumors up to 88,7%, and in medium - 90,7%, while in the control group - 64,0% and 76,2%, respectively.

3. Depending on the clinical reaction of the MC (decrease, unchanged and increase) on the 14th day from the start of treatment, it is possible to predict the sensitivity of the tumor to treatment factors and the result of treatment.

Disclosures

Author Statement: The author confirms sole responsibility for the following: conception and design of the study, collection of data, analysis and interpretation of the results, and preparation of the manuscript.

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How to cite this article: Anatoliy M. Effectiveness of Adjuvant Interferon Therapy (Alpha-2b Interferon) in Organ-Preserving (Photodestruction, Brachytherapy) Treatment of Uveal Melanoma. JOJ Ophthalmol. 2025; 12(3): 555837. DOI: 10.19080/JOJO.2025.12.555837

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DOI: 10.19080/JOJO.2025.12.555837

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