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Quality of life in patients with malignant choroidal melanoma after radiotherapy

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Abstract *Background:* Patient-oriented endpoints have attracted little attention in patients with malignant choroidal melanoma. This study was conducted to explore the long-term effects of malignant choroidal melanoma and radiotherapy on QOL by means of a differentiated and modular QOL approach, including global QOL, social support, and mental health, in comparison with sociodemographically matched healthy controls. *Methods:* A random sample of 100 outpatients treated by radiotherapy were asked by mail to take part in a psychodiagnostic study [instruments: Short-Form 36 Health-Survey (SF-36), Symptom Checklist-90-Revised, German Social Support Questionnaire]. The same instruments were applied to a healthy control group, which was matched to patients with regard to age, gender, and vocational situation. *Results:* 93 patients (average age 61.2 years) responded at an average of 5.5 years

(± 3.7) after diagnosis. Visual acuity in the affected eye decreased considerably from diagnosis (0.49 ± 0.30) to participation in the study (0.09 ± 0.21). Compared with healthy controls, patients reported on average statistically significantly lower global QOL (SF-36), whereas social support and mental distress did not differ. Frequencies of clinically relevant mental distress were significantly higher in patients than in controls (35.5% vs. 16.1%). Mental distress was associated with poorer visual acuity, but not with the extent of loss of visual acuity or number of follow-up treatments. *Conclusion:* Patients with choroidal melanoma suffer from low long-term global QOL, and every third patient suffers from relevant mental distress. Regular screening for mental distress should be implemented along with psychological counseling. Additional follow-up treatment does not seem to induce mental distress.

Introduction

Malignant choroidal melanoma is the most common primary intraocular malignancy, with a 5-year melanoma-related mortality rate of 20% [6, 33]. Due to the neoplasm, visual acuity is substantially decreased, even if an eye-preserving treatment approach like radiotherapy is performed [5]. In ophthalmology restoring or preserving vision serves as a major clinical endpoint, and in oncology treatment strategies are traditionally evaluated by survival [1, 20]. Consideration of the mentioned endpoints

only neglects the patient's perspective, as these parameters do not reflect the impact of an illness on functioning or on the social and psychological domains. This gap has been filled by the concept of quality of life (QOL), which is defined as the subjective assessment of the impact of disease and treatment across the physical, psychological, social and somatic domains of functioning and well-being [30].

Oncologists were one of the first physicians to implement QOL measurement into practice, as the side effects of chemotherapy raised the question of the extent

to which quantity of life was gained at the expense of quality of life [1]. Prevalence studies suggest that one of every three newly diagnosed cancer patients will suffer from clinically relevant distress, with numbers decreasing over time, and that patients may benefit from social work, psychological or psychiatric intervention [9, 10, 13, 18, 34, 40]. In the long term, it appears that cancer patients adapt as well as patients with other chronic conditions (e.g., arthritis, end-stage renal disease) and do not suffer from greater mental distress than the general population [4]. In ophthalmology, there is a lack of exploration of patients' QOL compared with QOL of sociodemographically matched healthy controls. Only few studies have compared QOL of patients with ocular conditions with a normative sample, and reduced QOL in patients has been both asserted [38] and denied [19, 36]. In patients with malignant choroidal melanoma treated by either radiotherapy or enucleation, a 1-year follow-up showed impaired global QOL compared with healthy controls in four out of five cases [2], whilst a 5-year follow-up found global QOL in patients comparable with global QOL of healthy people as well as with global QOL of patients with other chronic conditions (myocardial infarction, hypertension) [7]. Regarding correlations between visual acuity and QOL as measured by the Short Form 36 Health Survey (SF-36), low positive correlations have been described [e.g. 11, 15, 28, 32], in one study, however, there was no correlation [23]. Low to moderate correlations were found for mental distress and visual acuity [39]. Compared with other health-problems, including hypertension, type II diabetes, history of myocardial infarction, and headache, visual impairment has been reported to have a greater impact on general functional status and well-being [24]. In detail, functional status is more closely correlated to the functioning of the better eye [11, 25, 32, 39].

As patients with malignant choroidal melanoma suffer from both cancer and a chronic ocular condition, clinical end-points of both medical disciplines should be integrated; they comprise survival, visual acuity, and QOL. This study was conducted to assess comprehensively the long-term effects of malignant choroidal melanoma and radiotherapy on QOL, using a differentiated and modular QOL approach including global QOL, social support, and mental health, in comparison with sociodemographically matched healthy controls [30]. Furthermore, correlations between parameters of QOL and visual acuity were to be evaluated. The hypotheses were: (a) long-term global QOL is not impaired in patients compared with healthy controls [7], (b) frequencies of clinically relevant mental distress are not increased in patients compared with controls [18, 34, 40], (c) global QOL is positively and mental distress is negatively correlated to visual acuity of the fellow eye [11, 25, 32, 39].

Methods

Data collection

The inquiry was carried out among outpatients of the Center for Ophthalmology, University of Essen, Germany. Criteria for inclusion in the study were (a) diagnosis of primary malignant choroidal melanoma at least 1 year before participation in the study; and (b) treatment by radiotherapy. One hundred randomly chosen patients were asked by mail to take part in this study, with 93 patients responding. Written informed consent was obtained from each patient, in adherence with the Declaration of Helsinki. Telephone interview revealed that of the seven missing patients three had died, one was too ill to answer and three had changed address and could not be contacted. Clinical data were gathered from the patients' records on the day psychodiagnostic inventories were mailed. The maximum time gap between mailing and clinical examination was 1 month.

A healthy control group was established by an accumulative process starting from members of the University Hospital Essen. Data gathered in controls comprised sociodemographic characteristics; additionally, the same psychodiagnostic inventories as in patients were administered. In a second step, patients and controls were matched according to age, gender, and vocational situation. A variance of ± 2 years in age between groups was allowed. The total sample of controls comprised 638 persons; after excluding those with a self-description of having a severe acute or chronic disease (especially with regard to cancer or ophthalmologic conditions), the sample consisted of 575 persons. This group was named "healthy controls", bearing in mind the problems of defining normality and abnormality or health and illness. The findings of Glasgow and Hampson [17], who demonstrated that recruitment of controls (elderly subjects) either through community volunteers (as done in the presented study) or through their doctor's office resulted in participants who were very similar on QOL variables, supported the chosen method to gather control persons.

QOL Assessment

Consistent with the multidimensional definition of QOL, a modular and comprehensive psychodiagnostic approach was chosen to ensure a balanced evaluation of distinct areas of functioning and well-being and to comply with international recommendations [30]. To meet these criteria, a global QOL measure (SF-36) was combined with two questionnaires exploring distinct areas of QOL (Symptom Checklist 90 Revised, SCL-90-R, and the Short Form of the Questionnaire for Social Support, K-22, German) [8, 13, 14, 15, 16, 30].

Global QOL was measured by the SF-36, which has been widely applied in patients with visual disabilities, cancer patients and especially in patients with malignant choroidal melanoma [7, 19, 24, 25, 26, 36, 38]. The SF-36 comprises 36 items, which constitute eight subscales and two sum scores. The subscales comprise (1) "Physical functioning", (2) "Role physical", (3) "Bodily pain", (4) "General health", (5) "Vitality", (6) "Social functioning", (7) "Role emotional" and (8) "Mental health". Scales 1-4 contribute to the scoring of the "Physical component summary," whereas scales 5 and 6 contribute to the scoring of the "Mental component summary". Psychometric properties of the SF-36 in German samples met the standard requirements in terms of internal consistency, convergent and discriminant validity, and sensitivity. In a German norm population ($n=2914$), Cronbach's α was between 0.74 and 0.94; in different patient groups ($n=1312$), Cronbach's α was between 0.57 and 0.93, with 4 coefficients out of 48 not reaching 0.7 [3].

Special attention was drawn to the detection of mental distress and social support, using the Symptom Checklist 90 Revised

(SCL-90-R) and the Short Form of the Questionnaire for Social Support (K-22, German; [8, 13, 16]). The SCL-90-R contains 90 items, which constitute nine subscales and three global scores. The subscales include "Somatization", "Obsessive-compulsive", "Interpersonal sensitivity", "Depression", "Anxiety", "Anger/hostility", "Phobic anxiety", "Paranoid ideation" and "Psychoticism". The three global indices reflect various aspects of overall mental distress; GSI (Global Severity Index), PSDI (Positive Symptom Distress Index), and PST (Positive Symptom Total). Psychometric properties of the SCL-90-R have proven to be adequate in terms of convergent and discriminant validity, sensitivity and reliability: in a German norm population ($n=2141$), Cronbach's α was between 0.75 and 0.97, while in a group of psychotherapy patients ($n=5057$), Cronbach's α was between 0.74 and 0.97. The SCL-90-R has previously shown cancer patients to be at high risk for the development of mental distress. Clinically relevant mental distress is diagnosed if the criteria of the "case-definition" (Global Severity Index and/or two subscales with a T-score ≥ 63) are met [9, 13, 40]. The K-22 comprises 22 items and assesses social support in five dimensions: "Emotional support", "Practical support", "Social integration", "Confidants", and "Satisfaction with social support". The "Global Index of Social Support" reflects social support by consideration of all items. Psychometric properties of the instrument are adequate in terms of internal consistency—in medical students ($n=91$), student nurses ($n=98$), and patients with an immunodeficiency syndrome ($n=79$) Cronbach's α was between 0.64 (in only 18 individuals under 0.7) and 0.97—convergent and discriminant validity, and sensitivity [12]. Social support is acknowledged to facilitate adjustment to cancer [21]. The K-22 is an economic German inventory to measure social support.

Visual acuity assessment

The eye examination consisted of an assessment of corrected visual acuity for distance in each eye separately. Subjects were positioned 5 m from the E chart. The test was administered in a "forced-choice" manner, and the identification of the correct position of at least four of five Es was necessary to indicate sufficient visual acuity for each given line [29].

Statistical analysis

Analysis of parameters in two groups was performed with Student's t -test, and analysis of parameters in three groups was performed by means of analysis of variance (ANOVA) with post-hoc Scheffé tests. Evaluation of frequencies in patients and controls as to the "case definition" and as to mental distress due to follow-up treatment was done using the chi-square test. Testing was performed according to the guidelines for multiple testing. Statistical analyses were performed with the SPSS computer package.

Results

Sociodemographic data

The patient sample and the control sample consisted of 93 persons each. In both samples there were 44 men (47.3%) and 49 women (52.7%). The average age in patients was 61.2 years (± 11.9), in controls it was 60.1 years (± 11.2 ; difference statistically not significant). In both samples, half of the members were retired, 20% were employed, and 14% described themselves as housewife / househusband (Table 1).

Medical-ophthalmologic data

Time of participation in the study (t_1) was on average 5.5 years (± 3.7) after diagnosis of the choroidal melanoma (t_0). At t_0 , visual acuity was already impaired in the affected eye (average visual acuity 0.49; ± 0.29), while the

Table 1 Sociodemographic characteristics of patients (data on age, gender and vocational situation were matched between patients and controls)

Age	61.2 years (± 11.9)
Gender	
Male	44 (47.3%)
Female	49 (52.7%)
Living condition	
With spouse / friend	68 (73.1%)
Alone	20 (21.5%)
Other	5 (5.4%)
Education	
8 years	61 (65.6%)
10 years	21 (22.6%)
>10 years	11 (11.8%)
Vocational situation	
Retired	47 (50.5%)
Full-time	14 (15.1%)
Part-time	8 (8.6%)
Unemployed	8 (8.6%)
Housewife/househusband	13 (14.0%)
Other	3 (3.2%)

Table 2 Visual acuity before (t_0) and after (t_1) radiotherapy

	Affected eye		Fellow eye	
	t_0	t_1	t_0	t_1
Average visual acuity	0.49 (± 0.30)	0.09 (± 0.17)	0.89 (± 0.23)	0.88 (± 0.23)
Average loss of visual acuity	0.40 (± 0.31)	0.01 (± 0.14)		
Level of visual impairment ^a				
Normal (≥ 0.30 and above)	75.3%	8.6%	95.6%	95.6%
Impaired (< 0.30)	21.5%	32.3%	–	–
Severely impaired (< 0.05)	1.1%	26.9%	2.2%	2.2%
Blind (< 0.02)	2.2%	32.3%	2.2%	2.2%
Cumulative visual impairment	24.8%	91.5%	4.4%	4.4%

^a Numbers in parentheses refer to visual acuity

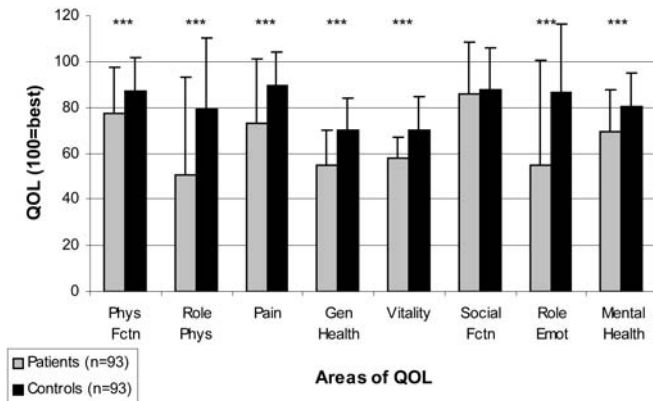


Fig. 1 Quality of life (SF-36) in patients with malignant choroidal melanoma compared to sociodemographically matched healthy controls. *** $P < 0.0001$ (t -test), Bonferroni α -adjustment $P < 0.00625$

visual acuity of the fellow eye can be described as normal for age ($0.89; \pm 0.23$). From t_0 to t_1 , patients suffered from a substantial decrease in visual acuity in the affected eye, on average $0.40 (\pm 0.31)$. In detail, mean visual acuity in the affected eye was $0.09 (\pm 0.17)$ at t_1 , and consequently four out of five patients had to be classified as visually impaired with respect to this eye (Table 2). Visual acuity in the fellow eye remained stable (average at t_1 : $0.88; \pm 0.23$). Reasons for visual impairment in the fellow eye included enucleation in one case and macular degeneration in three cases. The tumor thickness shrank from an average of $4.5 \text{ mm} (\pm 2.0; t_0)$ to $1.6 \text{ mm} (\pm 1.4; t_1)$. To assure tumor control, one additional radiotherapy during follow-up was performed in 14 patients (15%) and one additional laser therapy was conducted in 27 patients (29%). A second additional treatment was not required in any of the patients.

Psychodiagnostic results

Patients and controls differed neither as to the “Global Index of Social Support” (K-22) nor as to the three global indices and nine subscales of the SCL-90-R (i.e., mental distress). As to the subscales of the K-22, patients reported statistically significantly ($P < 0.001$) better emotional support as well as statistically significantly ($P < 0.001$) better support by confidants than controls. On the other hand, satisfaction with social support was significantly ($P < 0.007$) lower in patients than in controls. These results remain statistically significant even after Bonferroni α -adjustment ($P < 0.0083$). Patients reported statistically significant poorer global QOL (SF-36) than controls in both sum scores (“Physical Component Summary”, “Mental Component Summary”) and in all but one (“Social functioning”) subscales (Fig. 1).

Statistically significant differences in terms of the frequency of clinically relevant distress between patients

Table 3 Quality of life in mentally distressed patients, in mentally non-distressed patients, and in controls. Numbers in parentheses represent the standard deviation; analysis computed by ANOVA and post-hoc Scheffé test; statistically significant results after consideration of Bonferroni α -adjustment ($P < 0.0020833$) underlined

	(1) Mentally distressed patients ($n=33$)	(2) Non-distressed patients ($n=60$)	(3) Controls ($n=93$)	ANOVA (F, P)	Explanation of variance	1 vs 2 (F, P)	1 vs 3 (F, P)	2 vs 3 (F, P)
PCS	43.43 (8.09)	46.08 (8.14)	50.98 (6.39)	16.24 $P < 0.0001$	15.1%	ns	-7.55 $P < 0.0001$	-4.90 $P < 0.0001$
MCS	42.22 (9.50)	49.86 (7.80)	52.91 (9.05)	18.17 $P < 0.0001$	16.6%	7.63 $P < 0.0001$	-10.69 $P < 0.0001$	ns
Physical function	72.63 (18.08)	80.28 (20.07)	87.17 (14.54)	9.44 $P < 0.0001$	9.4%	ns	-14.54 $P < 0.0001$	ns
Role physical	39.39 (45.08)	56.25 (40.55)	79.03 (31.34)	16.14 $P < 0.0001$	15.0%	ns	-39.64 $P < 0.0001$	-22.78 $P < 0.0001$
Pain	60.61 (28.61)	79.67 (26.23)	89.36 (14.88)	21.34 $P < 0.0001$	18.9%	19.06 $P < 0.0001$	-28.75 $P < 0.0001$	-9.69 $P < 0.05$
General health	51.82 (14.02)	56.83 (15.35)	69.96 (14.15)	25.78 $P < 0.0001$	22.0%	ns	-18.15 $P < 0.0001$	-13.13 $P < 0.0001$
Vitality	56.94 (11.25)	58.47 (7.90)	69.89 (14.80)	22.01 $P < 0.0001$	19.4%	ns	-12.95 $P < 0.0001$	-11.42 $P < 0.0001$
Social function	78.18 (27.09)	90.33 (18.59)	87.42 (18.76)	3.88 $P < 0.05$	4.0%	12.15 $P < 0.05$	ns	ns
Role emotional	37.37 (45.46)	64.45 (42.90)	86.74 (29.55)	22.57 $P < 0.0001$	19.8%	27.07 $P < 0.01$	-49.37 $P < 0.0001$	-22.29 $P < 0.01$
Mental health	58.59 (18.75)	75.83 (14.36)	80.32 (14.46)	24.82 $P < 0.0001$	21.3%	17.25 $P < 0.0001$	-21.74 $P < 0.0001$	ns

Table 4 Ophthalmological differences between mentally distressed and non-distressed patients

	Mentally distressed patients (n=33)	Non-distressed patients (n=60)	
Affected eye			
Visual acuity (t ₀)	0.49 (±0.30)	0.49 (±0.29)	ns
Visual acuity (t ₁)	0.05 (±0.09)	0.12 (±0.20)	t=2.2, P<0.05
Average loss of visual acuity	0.45 (±0.32)	0.38 (±0.31)	ns
Fellow eye			
Visual acuity (t ₀)	0.82 (±0.28)	0.92 (±0.18)	t=2.0, P<0.05
Visual acuity (t ₁)	0.78 (±0.28)	0.94 (±0.19)	t=3.2, P<0.01
Average loss of visual acuity	0.04 (±0.18)	-0.01 (±0.11)	ns
Follow-up treatment			
Additional radiotherapy required	4	10	
Additional radiotherapy not required	29	50	ns
Additional laser therapy required	8	19	
Additional laser therapy not required	25	41	ns

Differences of visual acuity computed by the student t test
Differences of follow-up treatment computed by the Chi-Square test
ns=not significant

and controls are found when applying the “case-definition”. Thirty-three patients (35.5%) meet the criteria of the case-definition compared with 15 controls (16.1%; chi-square test, $F=8.01$; $P<0.005$). Subscales with scores ≥ 63 in distressed patients include “Somatization”, “Anxiety”, and “Phobic anxiety” as well as the global scores “Global Severity Index” and “Positive Symptom Distress Index”. Within an in-depth analysis, global QOL in mentally distressed and mentally non-distressed patients as well as in controls was explored. Mentally distressed patients suffered statistically significantly more from “Bodily Pain” and from statistically significantly poorer “Mental Health” both on the sum score level and on the subscale level compared with mentally non-distressed patients. Mentally distressed patients suffer from statistically significant poorer global QOL (all subscales except for “Social functioning”, and both global scores) than controls. Mentally non-distressed patients show statistically significantly worse overall global physical QOL (“Physical Component Summary”) as well as significantly poorer global QOL as to the subscales “Role physical”, “General health” and “Vitality” than controls (Table 3).

Regarding the association of psychodiagnostic and ophthalmological parameters, mentally distressed patients showed poorer visual acuity in the affected eye at t₁ ($P<0.05$) as well as poorer visual acuity in the fellow eye at t₀ ($P<0.05$) and t₁ ($P<0.01$) than non-distressed patients. There were no statistically significant differences between distressed and non-distressed patients with regard to average loss of visual acuity between t₀ and t₁ and to number and/or kind of follow-up treatments (Table 4). Correlations of ophthalmological (visual acuity and average loss of visual acuity between t₀ and t₁ in either the affected or the fellow eye) and psychodiagnostic parameters (“Physical Component Score” and “Mental Component Score”, both SF-36; “Global Severity Index”, SCL-90-R; “Global Index of Social Support”, K-22) did not remain statistically significant after Bon-

ferroni α -adjustment, except for the “Global Index of Social Support” and visual acuity of the fellow eye at t₁.

Discussion

The integration of QOL as clinical endpoint has been discussed and in part been implemented in oncology and is gaining increasing importance in ophthalmology. This study was undertaken to improve the knowledge about long-term outcomes in patients with malignant choroidal melanoma after radiotherapy in terms of global QOL, mental distress, and social support.

In contrast to most previous studies, correlations between visual acuity and global QOL (SF-36) and / or mental distress (SCL-90-R) were lacking in the presented study [19, 22, 23, 28, 32]. The data of the presented study support the assumption that the SF-36 represents a tool too global to establish (stronger) correlations with visual acuity [15, 27]. Lack of correlations between visual acuity and mental distress—as clearly seen in patients shortly after an acute macular hemorrhage [39]—might be due to the lack of production of acute distress due to the relatively chronic and slow decrease of visual acuity in patients with choroidal melanoma. From a methodological point of view, a “ceiling effect” regarding the visual acuity of the fellow eye and a “bottom effect” in the affected eye in patients with choroidal melanoma serves as limiting factor for the establishment of correlations.

Patients described their global QOL in both sum scores and in all SF-36 subscales but one (“Social function”) as significantly worse than the matched healthy controls. Corresponding to the SF-36, comparable social support of patients and controls was shown on the global index level of the K-22. In contrast to the statistically significantly impaired mental health scores in patients as measured by the SF-36, mental health as measured by the SCL-90-R was comparable in patients and controls. It seems that the

severity of mental health problems produces impairment in terms of global QOL (SF-36), but on average does not lead to psychopathologic ratings (SCL-90-R). The latter result is in accordance with the findings of Cassileth et al. [4], who found that the mental health (Mental Health Index) of cancer patients a median time of 2 years after diagnosis was comparable with that of the general population. Long-term global QOL impairment is surprising, as previously only short-term (1 year) impairments in global QOL after diagnosis and treatment for malignant choroidal melanoma have been described [2], whilst long-term impairments (5–6 years) have been denied [7]. Lack of global QOL impairment in the latter study might be attributed to the patient selection process, which may have tended to exclude patients with more severe disease.

Whereas clinically relevant mental distress was not found regarding average scores of the entire patient group, analysis on an individual level by application of the “case-definition”, proved that more than twice as many patients as controls are affected (35.5% vs 16.1%; $P < 0.005$). Distressed patients suffer from (phobic) anxiety and increased global distress. This result is surprising, as a rate of around 33% of mental distress in cancer patients was previously described only for the period shortly after diagnosis [40], with frequency decreasing over time [18, 34]. Exploration of global QOL within the three groups of distressed patients, non-distressed patients and controls reveals that global QOL is also impaired in non-distressed patients, especially with regard to the physical domains, whereas distressed patients compared with non-distressed patients are especially characterized by lower

scores in the mental health domain. In the clinical context it should be considered that impaired global physical QOL should be expected in long-term survivors of malignant choroidal melanoma. Every third long-term survivor may require psychosocial counseling; issues may be related especially to feelings of anxiety and / or subjective dissatisfaction with social support [10].

For clinical decision making, it is important to consider that in this study neither the extent of loss of visual acuity between diagnosis and follow-up 5 years later nor the number and / or nature of follow-up treatments was associated with increased mental distress.

In conclusion, patients with choroidal melanoma suffer from low long-term global QOL, but not from noteworthy mental distress in general or decreased social support. Good social integration in this patient group may prevent the occurrence of general mental distress [21]. Furthermore, a surprisingly high proportion (one out of three patients) constitute a vulnerable group that is characterized by clinically relevant mental distress, particularly impairment in terms of global mental QOL, and low visual acuity either at the time of diagnosis and / or at long-term follow-up. High frequency of mental distress in this patient group might be due to the double threat to both life and vision.

It is therefore suggested that a longitudinal study be carried out to carefully and differentially monitor QOL in patients with choroidal melanoma over at least 5 years and to screen for mental distress at yearly intervals with special focus on the vulnerable patient group with low visual acuity. Multimodal psychosocial interventions should be provided for distressed patients.

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