Quality of Life in Croatian Metastatic Melanoma Patients

Iva Dumbović Dubravčić[1], Jasmina Marić Brozić[3], Ana Aljinović[2] and Joško Sindik[1]

[1] Institute for Anthropological Research, Zagreb, Croatia

[2] University of Zagreb, School of Medicine, University Hospital Centre Zagreb, Department of Orthopaedic Surgery, Zagreb, Croatia

[3] University of Zagreb, »Sestre Milosrdnice« University Hospital Centre, University Department of Oncology and Nuclear Medicine, Zagreb, Croatia

ABSTRACT

The aim of this study was to examine the quality of life (QoL) in 40 Croatian metastatic melanoma patients who had completed at least first-line treatment and to see if there was a correlation between QoL parameters and serum lactate dehydrogenase (LDH). LDH levels were measured and all patients clinically examined between April and September 2013. Two QoL questionnaires were used for patient self-evaluation: the European Organization for Research and Treatment of Cancer Quality of life Questionnaire (EORTC QLQ-C30) and the Dartmouth Primary Care Cooperative Research Network and the World Organization of National Colleges, Academies, and Academic Associations of General Practitioners/Family Physicians (COOP/WONCA) charts. The average EORTC QLQ-C30 score for global health status (GHS) was 41.204. The average scores for functional scales were high, with the exception of emotional functioning (65.02). Blood LDH levels positively correlated with the Eastern Cooperative Oncology Group (ECOG) status (r=0.415; p<0.01) and pain (r=0.345; p<0.05), but not with any functional or COOP/WONCA scores. Global health status (GHS) positively correlated with patient age at the time of evaluation (r=0.386; p<0.05) and age at the time when metastatic disease had been diagnosed (r=0.366; p<0.05). Quality of life for the studied group of metastatic melanoma patients in Croatia can be considered generally good, with the exception of emotional functioning and symptoms of fatigue, dispnoea, insomnia, and financial difficulties.

Key words: Quality of Life, Metastasis, Melanoma, Croatian, LDH

Introduction

In oncology patients, quality of life (QoL) is often affected as soon as patients become aware of their disease and of the limited therapeutic resources at hand, and yet QoL in these patients is understudied, especially in metastatic melanoma patients. It is only over the last ten years that therapy research has included QoL for patients with cancer at an advanced stage, including melanoma[1–5], most often using standardised and sometimes disease-specific questionnaires[6].

Regardless of greater awareness about the risk factors and new therapy options, melanoma incidence and mortality has been rising worldwide. In Croatia, total melanoma incidence has increased 149% in men and 130% in women from 1998 to 2008, whereas mortality has increased 45% in men and 50% in women[7].

For more than a decade, dacarbazine (DTIC) and temozolomide had been the only approved metastatic melanoma therapies, with limited effects on disease control. Current chemotherapy of metastatic melanoma may also include vinca alkaloids, nitrosourea, platinum-based compounds, and taxanes alone or more often in combination with DTIC or temozolomide. Over the last ten years, clinical trials have focused on immunomodulators such as interleukin 2 (IL-2) and interferon alpha (IFN α), but the greatest breakthrough in treating metastatic melanoma has come with targeted biological therapy, above all with BRAF and MEK inhibitors and then with anti CTLA-4 and PD-1/PD-L1 monoclonal antibodies[8–11]. These new therapies have increased the survival in metastatic melanoma patients but have also affected their

QoL, as they are associated with a number of adverse effects that interfere with everyday patient activities[9,11]. In addition, these new therapies are very expensive and none has been included in the list of medicinal products for the treatment of metastatic melanoma that are covered by the Croatian Health Insurance Fund (CHIF)[12–14]. Considering the current state of Croatian economy, average income, and the unemployment rate, a large number of metastatic melanoma patients cannot afford this kind of treatment[15,16].

As the disease progresses the tumour becomes larger, and its vessels become insufficient to supply the tumour with blood. This leads to necrosis within the tumour and the levels of blood lactate dehydrogenase (LDH) rise[17,18]. The aim of this study was to establish QoL in Croatian metastatic melanoma patients who had completed first-line therapy and to test our assumption that high LDH levels as an indicator of advanced disease should inversely correlate with QoL. We also wanted to see if serum LDH correlated with any of the functional scales and global health status (GHS) and whether QoL differed between genders and therapies received so far.

Patients and methods

This study was approved by the Ethics Committee of the Clinical Hospital »Sestre milosrdnice«, and all patients gave their informed consent before entering the study. The study included 40 adult patients treated at the Oncology and Nuclear Medicine Clinic of the Clinical Hospital »Sestre milosrdnice« from April to September 2013. All patients had previously been diagnosed metastatic melanoma according to the American Joint Committee on Cancer (AJCC) melanoma staging guidelines[19], had received at least one treatment cycle, and had regularly been followed up.

Another inclusion criterion was the Eastern Cooperative Oncology Group (ECOG) Performance Status between 0 and 2, where grade »0« stands for a fully active patient who is able to carry out all daily activities as before the disease developed and grade »2« for an ambulatory patient, who is up and about more than 50% of the waking time and capable of all self-care, but unable to perform work activities[20]. We opted for this inclusion criterion to be able to compare our findings with most QoL studies in oncology patients published so far[4,5].

For correlation analysis we took serum LDH values from the most recent measurements.

Of the 40 study patients, 15 were men and 25 women. Table 1 shows patient demographics. Twenty-five had the ECOG grade 0, thirteen grade 1, and two grade 2. At diagnosis, their mean age was 50.67±15.70 years, ranging from 21 to 76 years. On study enrolment, their mean age was 58.03±14.27 years, ranging from 26 to 79 years. Average time between the first diagnosis of metastatic melanoma and study enrolment/QoL measurement was 8.62 years.

For QoL evaluation the patients were asked to complete two self-administered questionnaires: the translated Croatian version 3.0 of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30 (EORTC QLQ-C30)[6,21–24] and the Dartmouth Primary Care Cooperative Research Network and the World Organization of National Colleges, Academies, and Academic Associations of General Practitioners/Family Physicians (COOP/WONCA) questionnaire[25–27]. The EORTC QLQ-C30 consisted of five functional scales (physical, role, cognitive, emotional, and social) in which higher score indicates higher functionality, three symptom scales (nausea/vomiting, pain, and fatigue) and six single items (dyspnoea, insomnia, appetite loss, constipation, diarrhoea, and financial difficulties) in which higher score indicates serious symptoms, and finally a global health status (GHS)/QoL scale, in which higher score indicates better quality of life[6,21–24]. The COOP/WONCA questionnaire consisted of six charts, five of which served to evaluate patient's state, including physical fitness, feelings (which include fear, anxiety and pain), daily activities, social activities, and overall health, whereas the sixth chart evaluated change in health. Items were scored on a five-point Likert scale, where »1« indicated no impairment and »5« the worst impairment. All score descriptors were accompanied by illustrations[25–27]. The use of the two questionnaires was approved by respective copyright owners.

The questionnaires were distributed to patients by study doctors during scheduled visits and were completed before diagnostic or therapeutic procedures and counselling about disease progress and further therapy.

To the best of our knowledge, this study is the first to combine the two questionnaires to evaluate QoL in patients with metastatic melanoma.

Statistical analysis

All data were analysed using the SPSS package version 18.0. Due to a small sample, non-normal distribution of data, and a great number of ordinal-type variables (all COOP/WONCA scales and the EORTC QLQ-C30 symptom scales), we used medians and the non-parametric Mann-Whitney U test for differences between two independent samples, Kruskal-Wallis test for differences between several independent samples, and Spearman's rank correlation coefficient. Statistical significance was set at $p < 0.05$ and $p < 0.01$ for all tests.

Results

Most (28) patients received DTIC, whereas seven patients received Vemurafenib and five other treatment (Table 1).

Mean serum LDH was 293.27±172.49 U/L (at 37 °C), ranging from 130 to 1003 U/L (at 37 °C), whereas the normal range for adults over 20 years of age is<241 U/L (37 °C). High serum LDH was found in 15 patients.

TABLE 1
PATIENT DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

	Patiens (n)
Sex	
Men	15
Women	25
Total	40
ECOG status	
0	25
1	13
2	2
Primary tumour site	
head	6
neck	2
torso	19
arms	6
legs	7
Total	40
Secondary tumour site	
brain	5
lungs	13
skin	6
bones	2
liver	14
Total	40
Previous therapy	
DTIC	28
Vemurafenib	7
Other	5
Total	40

TABLE 2
EORTC QLQ C30 FINDINGS BY SCALES

	Q1	Median	Q3
GHS	21.528	41.204	56.250
Functional scales			
Physical	68.333	86.667	93.333
Role	66.667	71.272	100.000
Emotional	43.750	65.019	83.333
Cognitive	66.667	83.333	100.000
Social	66.667	83.333	100.000
Symptom scales			
Fatigue	22.222	33.333	61.111
Nausea/vomiting	0.000	0.000	16.667
Pain	0.000	16.667	33.333
Dyspnoea	0.000	33.333	33.333
Insomnia	0.000	31.624	66.667
Loss of appetite	0.000	0.000	33.333
Constipation	0.000	0.000	33.333
Diarrhoea	0.000	0.000	8.333
Financial difficulties	0.000	26.852	58.333

GHS – global health status

The scores on the symptom scales suggest good control over the symptoms usually associated with metastatic diseases; only fatigue, dyspnoea, and insomnia affected patient performance to a higher degree, whereas pain affected it moderately.

Financial difficulties also seem to have significantly affected patient performance (Table 2).

On the scale between 1 (very poor) and 7 (excellent), the patients rated their GHS with the median score 4. On the same scale range from 1 to 7, the median score for QoL was 4, which was also the most common score among the patients (mode). These results indicate that the patients' quality of life and health status had diminished.

The correlations between functional scales (Table 3) show significantly inverse correlation between GHS and feelings, cognitive, social, physical, and role function.

Of the 40 patients in the study, 37 completed the EORTC QLQ-C30 questionnaire, whereas three failed to answer at least one question. The questionnaires of these three patients were included in the final data analysis. In most functional scales the patients showed high scores, except for the feelings, which points to a higher degree of tension and worry among them (Table 2).

TABLE 3
CORRELATIONS BETWEEN FUNCTIONAL SCALES (EORTC QLQ C-30)

	GHS	FF	FU	EF	KF	SF
GHS	1.000	−0.468**	−0.450**	−0.371**	−0.448**	−0.382*
Physical		1.000	0.651**	0.432*	0.471**	0.689**
Role			1.000	0.675*	0.518**	0.701**
Emotional				1.000	0.695**	0.606**
Cognitive					1.000	0.524**
Social						1.000

*$p < 0.05$ (two-way), ** $p < 0.01$ (two-way); GHS – global health status

The correlation between other functions was positive and significant.

We also observed a significant correlation between patient age at questionnaire completion and GHS and a significant inverse correlation between age and physical function. In other words, the patients found that their health status improved, yet their perception of their physical condition got worse with age. Furthermore, patients who had longer been diagnosed metastatic melanoma found their health status better than those who had learned of their diagnoses more recently.

Looking at the symptoms, older patients reported fatigue and constipation more often, whereas high blood LDH was associated with more frequent nausea and vomiting.

Patients with higher ECOG grade rated their physical and role function lower, reported nausea/vomiting, insomnia, and loss of appetite more often, and had higher blood LDH (Table 4).

Greater fatigue correlated with most of the reported symptoms (nausea/vomiting, pain, dyspnoea, insomnia, loss of appetite, constipation) but not with diarrhoea and financial difficulties (Table 5).

TABLE 4
CORRELATIONS BETWEEN CLINICAL DATA, DEMOGRAPHICS, FUNCTIONAL SCALES, AND SYMPTOMS (EORTC QLQ C-30)

	Age at diagnosis of metastatic melanoma	ECOG status	Age at evaluation	Last measured blood LDH (U/L)
GHS	0.366*	0.207	0.386*	0.245
Physical	–0.202	–0.354*	–0.346*	–0.100
Role	–0.243	–0.363*	–0.273	–0.259
Emotional	–0.080	–0.214	–0.065	–0.207
Cognitive	0.012	–0.185	–0.132	0.108
Social	–0.158	–0.309	–0.19	–0.307
Fatigue	0.197	0.414**	0.368*	0.207
Nausea/vomiting	–0.01	0.319*	–0.07	0.47**
Pain	0.069	0.234	0.177	0.225
Dyspnoea	0.189	0.286	0.3	0.165
Insomnia	0.081	0.468*	0.222	0.03
Loss of appetite	0.168	0.532**	0.189	0.282
Constipation	0.159	0.079	0.325*	0.210
Diarrhoea	–0.071	–0.109	–0.021	–0.035
Financial difficulties	0.065	0.181	0.075	0.035
Last measured blood LDH (U/L)	0.148	0.415**	0.035	1

*p<0.05 (two-way), ** p<0.01 (two-way)

TABLE 5
CORRELATIONS BETWEEN SYMPTOMS AND GLOBAL HEALTH STATUS (EORTC QLQ-30)

	Fatigue	Nausea/ vomiting	Pain	Dyspnoea	Insomnia	Loss of appetite	Constipation	Diarrhoea	Financial difficulties
Fatigue	1								
Nausea/vomiting	0.424**	1							
Pain	0.596**	0.396*	1						
Dyspnoea	0.642**	0.147	0.566**	1					
Insomnia	0.573**	0.397*	0.411**	0.374*	1				
Loss of appetite	0.466**	0.622**	0.446**	0.221	0.293	1			
Constipation	0.281	0.016	0.39*	0.05	0.202	0.043	1		
Diarrhoea	0.296	0.031	0.233	0.249	0.163	–0.055	0.238	1	
Financial difficulties	0.287	–0.040	0.550**	0.566**	0.271	0.154	0.166	0.151	1
GHS	0.572**	0.265*	0.353*	0.362*	0.416**	0.138	0.444**	0.190	0.233

*p<0.05 (two-way), ** p<0.01 (two-way)
GHS – global health status

TABLE 6
COEFFICIENTS OF CORRELATION BETWEEN COOP/WONCA SCALES, PATIENT DEMOGRAPHICS, AND CLINICAL DATA

	Physical fitness	Feelings	Daily activities	Social activities	Pain	Overall health	Change in health
Age at diagnosis	–0.073	0.069	0.175	0.248	0.129	0.221	0.226
ECOG status	0.050	0.018	0.247	0.371*	0.190	0.243	0.020
Age at evaluation	0.034	0.079	0.215	0.270	0.018	0.345*	0.232
Last measured blood LDH (U/L)	0.011	–0.087	0.218	0.248	0.356*	0.155	0.180
Physical fitness	1.000	–0.087	–0.088	0.089	0.023	–0.011	0.255
Feelings		1.000	0.757**	0.650**	0.469**	0.563**	0.261
Daily activities			1.000	0.768**	0.579**	0.556**	0.010
Social activities				1.000	0.532**	0.698**	0.175
Pain					1.000	0.425**	–0.001
Overall health						1.000	0.339*
Change in health							1.000

*p<0.05 (two-way), **p<0.01 (two-way)

Greater pain was also significantly associated with other symptoms (except for diarrhoea).

Interestingly, dyspnoea was most often reported by patients who rated high their financial difficulties, as well as by patients reporting fatigue and diarrhoea.

Low rating of GHS was significantly associated with higher scores for fatigue, pain, dyspnoea, insomnia, and constipation (Table 5).

Similar to the EORTC QLQ-C30 findings, the analysis of the COOP/WONCA charts shows a significant correlation between the intensity of pain and LDH levels.

The patients reported better health status as the pain, anxiety and fear lessened, and their social activities intensified. The same is true if their rating of the change in health was lower.

The charts have also confirmed the significant association between patient age and health status rating established by the EORTC QLQ-C30. Good health status was also associated with lower ECOG grade and higher rating of social activity. Patients who reported intense feelings of anxiety, fear, and uncertainty also reported increased pain and lower social and daily activity. Daily activity significantly correlated with social activity and dropped with the rating of pain (Table 6).

We did not establish any differences in any of the QoL variables between genders or treatment groups regardless of the questionnaire (data not shown).

Discussion and conclusion

Our study has confirmed earlier findings that QoL diminishes in patients with metastatic melanoma. In our patient group, this was most prominent in the emotional aspect, which does not come as a surprise, considering that Croatian hospitals have not developed a system of psychological support for their oncology patients. Kasparian[28] reported that 30% of melanoma patients suffered from one or other form of psychological disorder that required psychological support and treatment. Cornish et al.[29] found that, similar to our study, psychological disorders were common in patients in the follow-up stage, whereas patients receiving chemotherapy and/or intereferon reported lower role, emotional, social, and cognitive function and poorer GHS.

In our study, better general health score was associated with older age. Blood LDH did not seem to affect it, but higher ECOG grade and the intensity of pain did. LDH showed a strong correlation with nausea/vomiting, pain, and ECOG grade. Our findings are in line with what has already been reported on QoL in patients with metastatic melanoma[30] and call for setting up systematic psychological/psychiatric support for oncology patients, melanoma patients in particular[1–4,28]. We also believe that our findings may provide some direction for supportive and paliative therapy. This primarily refers to pain relief in the form of pharmacological and radiotherapy as well as acupuncture[31–34]. Improvements are also possible in the treatment and prevention of nausea and vomiting with a variety of medicinal products available to that end.

We also believe that new therapy options such as BRAF and MEK inhibitors and monoclonal antibodies may improve patient QoL, but in Croatia right now the number of patients receiving this novel type of treatment is quite limited, and only future studies will be able to compare current and novel treatment and investigate how financial status affects QoL in patients with metastatic melanoma in this country.

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A. Aljinović

University of Zagreb, School of Medicine, University Hospital Centre Zagreb, Department of Orthopaedic Surgery, Šalata 6, 10000 Zagreb, Croatia
e-mail: ana.aljinovic@gmail.com

KVALITETA ŽIVOTA BOLESNIKA SA METASTATSKIM MELANOMOM U HRVATSKOJ

SAŽETAK

Cilj ovoga istraživanja je bio ispitati kvalitetu života i njenu povezanost sa razinama laktat dehidrogenaze (LDH) u krvi bolesnika te utvrditi povezanost vrijednosti LDH i pojedinih skala upitnika kvalitete života. U razdoblju od travnja do rujna 2013. u ovo istraživanje je uključeno četrdeset bolesnika sa ranije dijagnosticiranim metastatskim melanomom koji su završili barem jednu liniju liječenja i nalaze se u periodu praćenja bolesti. Svi su bolesnici klinički pregledani i svoma su izmjerene vrijednosti LDH u krvi. Za samoprocjenu kvalitete života bolesnika su korištena dva upitnika: European Organization for Research and Treatment of Cancer Quality of life Questionnaire (EORTC QLQ-C30) i Dart-mouth Primary Care Cooperative Research Network (COOP) and the World Organization of National Colleges, Acade-mies, and Academic Associations of General Practitioners/Family Physicians (WONCA) score (COOP/WONCA). Re-zultat ukupne procjene zdravstvenog stanja (GHS) EORTC QLQ-C30 upitnika je 41,203, rezultati funkcionalnih ljest-vica su bili visoki uz isuzetak emotvne skale funkcionalnosti (65,02). Razine LDH u krvi su povezane sa ECOG (Eastern Cooperative Oncology Group) statusom bolesnika (r=0,415 p<0,01) i jačinom boli (r=0,345; p<0,05), no nema poveza-nosti sa niti jednom skalom funkcionalnosti COOP WONCA upitnika. Bolesnici svoje zdravlje procjenjuju boljim sa većom dobi kod postavljanja dijagnoze metastatskog melanoma i ispunjavanja upitnika. (r=0,366; p<0,05). Kvaliteta života ispitivane skupine bolesnika sa metastatskim melanomom je smanjena a posebno je sniženja emotivna funk-cionalnost te su jače izraženi simptomi umora, zaduhe, nesanice i financijske poteškoće.