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Surgical versus medical treatment for ocular surface squamous neoplasia: A quality of life comparison

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Abstract

Purpose: To characterize vision-related and psychosocial quality of life (QoL) parameters in medically and surgically treated patients with OSSN.

Methods: Forty-one patients with OSSN treated with medical therapy consisting of interferon alpha 2b drops 1 MIU/ml (n=22) or who underwent surgical excision (n=19) were contacted. All subjects answered a quality of life assessment with an original questionnaire in which they were asked about a range of parameters. Overall satisfaction and motivating factors for treatment were also reviewed.

Results: The mean age at the time of the survey was 64.6 and 51% were male with similar demographics between groups. Based on the previous cohort, rates of tumor resolution and recurrences were comparable in the two groups. Reasons for choosing a particular treatment varied between the groups. Forty percent of individuals in the medical group reported a fear of surgery (p=0.03) and often made the decision after personal research (p=0.008). Thirty-two percent of patients in the surgical group chose surgery due to fear of decreased vision due to lesion growth, therefore wanting immediate resolution (p=0.09). Drops precipitated more ocular symptoms such as tearing and itchiness, on the other hand, patients who had surgery reported having more pain.

Conclusion: Quality of life considerations before, during, and after OSSN treatment is an important yet understudied topic. Our study is the first to look at QoL parameters in OSSN treatment and we found that patients in both medically and surgically treated groups had similar QoL metric but were driven to choose chemotherapy due to fear of surgery and/or prior literature review.

Ocular surface squamous neoplasia (OSSN) is a collective term referring to dysplastic and cancerous lesions of the corneal, limbal, or conjunctival epithelium.(1–3) OSSN tends to be

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slow growing and low-grade, but lack of appropriate diagnosis and treatment can lead to local invasion but rarely metastasis.(2, 4) Unlike conjunctival melanomas, whose mainstay of treatment is wide local excision(5), OSSN can be managed with a variety of approaches including medical treatment with interferon- α 2b (IFN), 5-fluorouracil (5-FU), and mitomycin C (MMC) and wide-surgical excision.(6) We previously demonstrated that primary treatment with interferon had equivalent long-term recurrence outcomes when compared to primary surgical excision.(3) In this case-control study comparing topical interferon eye drops versus surgery, outcomes were similar. Recurrence rates were 3% in the interferon group, and 5% in the surgery group 1 year out of treatment.(3) Many have found similar success in both medically and surgically treated patients.(7)

In terms of cost, we previously found the surgical group overall had more expenses covered. (8) At that time, the cost of interferon drops at our institution was \$240 for a 4 week supply. As a compounded medication, the patient typically pays out of pocket for each bottle. In terms of time, patients had a mean of two extra follow up visits over a one year period in the medical group compared to the surgically treated group.(8)

While efficacy and cost issues have been compared and studied in medically and surgically treated OSSN, what is missing is quality of life information on the impact of OSSN and its subsequent treatment. As above, both treatments have enjoyed similar results, but their effect on a patient's pre- and post-treatment emotional health, and functionality have never been studied.

Health-related quality of life (QoL) measures have become increasingly important in measuring patient outcomes, particularly for neoplastic conditions. Quality of life can be defined as measures distinct from classical treatment outcomes, such as survival or remission, and can involve physical, social, psychological, and emotional functioning.(9, 10) As novel therapies become standard practice and existing ones improve, patients' quality of life depends on tolerance to the various treatment options, which are often comparable in efficacy.(11–13)

To bridge the knowledge gap concerning quality of life in OSSN, the purpose of this study was to compare quality of life metrics in an OSSN cohort in which we previously reported similar treatment efficacy(3) and cost(8) between those treated medically with interferon eye drops versus those who underwent surgical excision.

Methods

The study was based on a cohort of 98 patients with OSSN treated medically with interferon or surgically with excisional removal of tumor.(3, 8) All patients in this cohort who were seen at Bascom Palmer between 1997 and 2012 were given the questionnaire to assess quality of life metrics. Of the 98 original patients, 10 passed away due to unrelated causes, 47 elected not to participate, leaving 41 individuals with QoL data available. University of Miami Institutional Review Board review and approval was obtained to retrospectively review the data. This endeavor was initiated as a quality assurance project and all individuals

treated at our institution for OSSN were contacted and asked to complete the survey. IRB approval was later obtained to retrospectively review and analyze the results.

The study was conducted in accordance with the principles of the Declaration of Helsinki.

Quality of life metrics:

The goal was to evaluate the impact of OSSN and its treatment on emotional health, perceptions of visual function, and performance of activities of daily living (ADLs). To compare two ophthalmic cancer treatments, it was necessary to evaluate parameters that measured visual function and ability as well as overall personal changes involved in cancer diagnosis and treatment. These included subjective visual improvement, functional status (such as activities of daily living and occupational ability), well-being, treatment course (perceptions, side effects, and satisfaction), and affordability.

We selected questions that reflected the patients' perception of the treatment they chose, such as whether it affected their emotional health or lifestyle. As such, validated QoL questionnaires were reviewed: Short Form-36 (SF-36)(14), Comparison of Ophthalmic Medications for Tolerability (COMTOL)(15), Spiritual Well-being while dealing with cancer (FACIT-Sp-Ex)(16), Treatment Satisfaction for cancer patients (FACIT-TS-PS)¹⁶, anxiety related to diagnosis of cancer (CaNDI)(17) and patient decision-making given a choice between medical therapy versus surgical therapy for prostate cancer(18). As no ideal survey instrument exactly fit our study, we used 32 relevant questions from 6 previously validated questionnaires. Our questionnaire consisted of five different sections divided chronologically to obtain patients' retrospective perceptions before, at the time of, and after OSSN diagnosis, reasons for choosing a certain treatment, and overall experience after treatment.

Statistical analysis:

Patient responses on all questions ranged from 1 to 5 (1= not at all, 2= a little bit, 3= moderately, 4= quite a bit, 5= extremely). Statistical analysis was performed using Microsoft Excel 2011 and IBM SPSS Statistics 22. Descriptive statistics were used to summarize patient information. Independent t-test methodology was used to compare differences in means between responses in the two groups. For purposes of statistical analysis, groups were additionally divided as 1–2 and 3–5 for a categorical comparison, a technique utilized in other QoL comparisons.(19–23) The former was considered a negatory response and the latter an affirmative response. Chi square statistics were used to compare frequencies of responses between groups.

Results

Study demographics:

Our study population consisted of 41 patients who answered the questionnaire, from which 22 used IFN eye drops and 19 have undergone surgery. The average age of our study population at the time of survey was 64.6 years (medical: 64.7, SD 14.4, surgical: 64.3, SD 11.9). Almost half of the patients were male (n=21) and the majority were white (58%,

n=24) (Table 1). As previously reported(3, 8), there were no statistically significant differences in age, gender, race, tumor area, clinical American Joint Committee on Cancer (AJCC) stage, or history of prior OSSN between the interferon and surgical groups.

There was no significant difference in time from treatment completion to survey acquisition. Questionnaires were administered at a mean of 7.2 years after completion of treatment standard deviation (SD) 3.09. On average, the interferon group answered the questionnaires 6.8 years after completion of treatment vs. 5 years in the surgical group. (SD: 3.5 vs. 2.5 respectively, $p=0.49$)

Self-reported status prior to and at time of diagnosis:

Prior to the diagnosis of OSSN, a similar number of patients in each group (Table 2) reported anxiety and depressive symptoms. At the time of diagnosis, however, a lower frequency of patients in the medical group reported anxiety (50% $n=11$) and depressive (23%, $n=5$) symptoms compared to patients who chose surgical treatment (58% $n=11$ and 32%, $n=6$, respectively) but this difference was not statistically significant, $p=0.61$ and 0.52 , respectively. Most patients (73%, $n=31$) reported that they were healthy before being diagnosed with OSSN; and a minority of patients recalled having a comorbidity or taking systemic medications at the time of diagnosis. (Table 2)

Treatment decision:

In all cases, both medical and surgical options were given to the patient. Forty percent of those in the medical group reported a fear of surgery compared to 11% in surgical group, $p=0.03$. Interestingly, patients who preferred medical therapy had often performed internet research of medical treatments before making a decision (20% vs 0% in surgical group, $p=0.008$), reassuring them of its safety and efficacy. The surgical group reported being more fearful of decrease in visual function (32% $n=6$) compared to the medical group (10% $n=2$), however, this was not significant. Two patients preferred surgical treatment due to the out of pocket costs for medical treatment. There were no differences in terms of convenience, and 92% of the patients did not feel time constraints were an important factor in deciding treatment. (Table 2)

Treatment experience:

Only a small number of individuals ($n=3$) reported feeling depressed because of treatment, of which two belonged to the surgical group. ADL-related functioning between both groups was similar, and the majority of patients (98%, $n=40$) did not report problems performing recreational and occupational activities. Regarding symptoms such as redness, tearing, and itchiness during treatment, there was not a significant difference comparing medicine versus surgery, but there was a tendency for patients who had surgery to report more pain after the procedure (20% medical vs 37% surgical, $p=0.24$). (Table 2)

Cost and time impressions:

In terms of costs, 33% of the patients on medical therapy felt this option was difficult to afford, compared to 21% in the surgical group, but this difference was not significant ($p=$

0.44). Cost was not a significant factor in treatment selection ($p=.54$). Time commitment perceptions were similar. Table 2

Considerations after treatment:

After completing treatment, the majority of patients in both groups expressed satisfaction with the chosen treatment, and all asserted they would recommend it to someone with the same diagnosis. All patients regained visual function and the ability to perform occupational and recreational activities. (Table 2)

Discussion:

A diagnosis of cancer can be overwhelming to some individuals and can lead to anxiety and depression. Mitchell and associates(18) concluded in a study that patients in cancer settings should be screened for distress and depression. Clinician's interpersonal skills, effectiveness of offered treatment and ability to reduce problems associated with treatment, are special needs that the patients require to trust their physician. Greater contact during the treatment, as well as screening after completion, can improve patients' care and quality of life.

Post-treatment quality of life has been studied in different oncologic scenarios(24, 25) but never for the treatment of ocular surface squamous neoplasia. In this study, we used a cohort of patients with medical and surgical treatment, of which both groups had similar clinical outcomes, proving medical and surgical therapy are good first-line options in treating OSSN(3, 8). We found that both treatment modalities had similar quality of life implications on patients, learning that even though management was very different, patients who underwent surgery did not perceive their pathology as a more serious condition; furthermore, we reported a minority of patients feeling depression and anxiety due to either therapy. The majority of patients were able to continue ADL, work, and hobbies, which means quality of life outcomes, are very satisfactory. In fact, the majority of patients in each group were overall happy with their chosen treatment.

All patients in this study reported being satisfied with the explanation of the diagnosis and treatment options, which made it easier for them to cope with this disease and make a decision about the different treatment options. They also felt satisfied with their treatment modality and reported that they would recommend it to other patients.

While OSSN is rarely a life-threatening cancer, it can instill a fear of impending disaster and potentially compromise visual function. Fear of visual loss is a potential component to any ocular condition, whether real or perceived. Preservation of visual function is an important and unique concern in the treatment of OSSN. If the lesion grows significantly it can obscure the visual axis, impede ocular motility, or invade ocular structures(26). In our study, the AJCC classification was similar in both groups, but the surgical group demonstrated a higher tendency of fear for decreased vision ($p=0.09$) compared to the medical group, perhaps making them more likely to choose a surgery as a faster method of eradicating the cancer.

In the twenty first century, having internet as an accessible and powerful research tool, has changed the way patients receive and understand their diagnosis, and how they make a decision on their treatment. The opportunity to search medication side effects and efficacy versus other options given may have a major influence in what treatment patients decide to pursue. In this case, patients were offered surgery and chemotherapy, the options not only included IFN, but also a less expensive alternative, 5FU, that is known to have more side effects. We found that patients who did literature research tended to choose medical therapy with IFN ($p=0.008$).

It is also understandable that surgery and the risks that come with it make many patients anxious. A group of endocrinologists and bariatric surgeons in Germany studied the reasons why obese patients chose conservative treatment such as dieting, instead of bariatric surgery. They found that among factors like higher body mass index (BMI) and greater prevalence of comorbidities, fear of surgery was a major key to determine their treatment modality.(27) In our study, those most fearful of a procedure chose to be in the medically treated group ($p=0.03$). Interferon treatment requires compliance due to its dosing and need of refrigeration. Surprisingly, patients who had IFN did not have any significant differing opinions about time or commitment needed to follow their therapy, in comparison with the surgical group. Additionally, cost is often a factor in decisions. Evaluating treatment cost issues can be complicated. Medical therapy has out of pocket costs for the patient, and surgical therapy has costs which can vary depending on the patient's coverage.(8) While 2 patients in our study chose surgical therapy due to cost concerns, overall, our study found no significant difference in perceived cost burden between the two modalities ($p= 0.44$).

Our findings must be considered within the limitations of our study, which include its retrospective nature and limited number of patients. Using a well-studied cohort of surgical and medically treated groups with similar outcomes and recurrences allowed us to more fairly evaluate the QoL responses. As described, both groups were overall content with their treatment methodology. Our long follow up time was an advantage in many respects, including sufficient time for patients to reflect on their treatment experience, functional and cosmetic results, and any persistent symptoms. We acknowledge, however, that administering the questionnaire long after completion of treatment, might have resulted in recall bias with a dissipation of strong feelings regarding treatment modality.

Future prospective studies should look at QoL factors at multiple times points (e.g. immediately after treatment, 1, 4, and 7 years after treatment), as well as individuals treated with other medical modalities, such as mitomycin and 5-fluorouracil and comparing these results to those treated with interferon and surgery. Other factors not evaluated were the duration between tumor diagnosis and presentation to our center and whether prior advice was received from the referring physician. A delay in receiving care or specific preferences of the referring physician may have affected our patients' thoughts on the proposed treatments. This information would be important to evaluate in a future QoL study on this topic.

Our study is the first to evaluate QoL parameters in OSSN. In this cohort of patients who had similar clinical outcomes, our study concludes that treatment satisfaction with either

topical interferon or surgical therapy are both high. Overall parameters between groups were similar. Of note was that patients with a fear of surgery and whom had performed more literature research tended to choose the medical modality and those with a fear of visual loss tended to choose surgery. As such, with a thorough explanation from the physician, the patient can choose the therapy that meets their expectations and best fits their budget and lifestyle.

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Table 1.

Demographic features of the studied population by treatment group.

	Medical	Surgical	p-value
Age *, years, mean (SD)	64.7 (22)	64.3 (19)	
Gender, % (n) male	45% (10)	58% (11)	0.42
Race, % (n) White	64% (14)	53% (10)	0.77
Ethnicity, % (n) Hispanic	32% (7)	42% (8)	
Education, % (n) HS or less	27% (6)	42% (8)	0.58
% (n) Some or all college	22% (5)	21% (4)	
% (n) Postgraduate	50% (11)	36% (7)	

SD=standard deviation, HS=high school

*
age at time of survey

Table 2.

Comparison of responses between the two groups.

	Medical	Surgical	
	% with response 3, 4, or 5* (n)	% with response 3, 4, or 5* (n)	P value
Pre-diagnosis			
Are you often depressed?	9% (2)	21% (4)	0.28
How anxious of a person are you?	9% (2)	21% (4)	0.28
Do you feel that your health is good?	68% (15)	84% (16)	0.23
Do you think that medicine is helpful?	95% (21)	100% (19)	0.34
When first diagnosed			
How anxious were you at the time of diagnosis?	50% (11)	58% (11)	0.61
How depressed were you at the time of diagnosis?	23% (5)	32% (6)	0.52
Did you have many comorbidities at the time of diagnose?	27% (6)	26% (5)	0.94
Did you use many other medications at the time of diagnose?	27% (6)	32% (6)	0.73
Did you feel your doctor explained the treatment options adequately?	100% (22)	100% (19)	1
In choosing treatment modality			
Was your choice motivated by time constraints?	5% (1)	11% (2)	0.54
Was your choice motivated by cost/insurance coverage?	5% (1)	11% (2)	0.54
Was your choice motivated by convenience?	37% (7)	21% (4)	0.28
Was your choice motivated by fear of your visual function decreasing?	10% (2)	32% (6)	0.09
Was your choice motivated by fear of surgery?	40% (8)	11% (2)	0.03
Was your choice motivated by literature review?	27% (6)	0% (0)	0.008
During treatment			
Did you experience pain?	20% (4)	37% (7)	0.24
Did you experience visual symptoms?	9% (2)	11% (2)	0.91
Did you have difficulty with activities of daily living (eating, bathing, ect.)?	95% (21)	100% (19)	1
Did you have difficulty with work activities?	5% (1)	0% (0)	0.34
Did you have difficulty with social activities (hobbies or sports)?	5% (1)	0% (0)	0.34
Did you feel depressed about your treatment?	5% (1)	11% (2)	0.46
Was the treatment difficult to afford financially?	33% (7)	21% (4)	0.44
Did you feel the treatment took too long?	0% (0)	5% (1)	0.26
1 year after treatment			
Did your vision return to its original state?	100% (22)	95% (18)	0.27
Did activities of daily living return to original state?	100% (22)	100% (19)	1

	Medical	Surgical	P value
	% with response 3, 4, or 5* (n)	% with response 3, 4, or 5* (n)	
Did work abilities return to original state?	100% (22)	100% (19)	1
Did social activity abilities return to original state?	100% (22)	100% (19)	1
How satisfied are you with the treatment?	100% (22)	100% (19)	1
Did you feel the treatment cost too much?	32% (7)	21% (4)	0.43
Did the treatment require too much of a time commitment?	23% (5)	26% (5)	0.79
Would you recommend your treatment to another patient?	93% (22)	95% (18)	0.27

* Patient responses on all questions ranged from 1 to 5 (1= not at all, 2= a little bit, 3= moderately, 4= quite a bit, 5= extremely). Responses were additionally divided as 1–2 and 3–5 for a categorical comparison, the latter was considered as an affirmative response.