

Assessment of Functionality in Elderly Patients When Determining Appropriate Treatment for Nonmelanoma Skin Cancers

MICHAEL A. RENZI JR., MD,* MATTHEW BELCHER, MD,[†] BRUCE BROD, MD,[‡]
PRESTON W. CHADWICK, MD,[§] ASHLEY DECKER, MD,* CYNTHIA A. DOLAN, MD,^{||}
ERUM N. ILYAS, MD,[¶] ANNA M. MAGEE, MD,** ELIZABETH I. MCBURNEY, MD,^{††}
THOMAS D. REGAN, MD,^{‡‡} ROY S. SEIDENBERG, MD,^{§§} ALLY-KHAN SOMANI, MD, PHD,^{|||}
LACY L. SOMMER, MD,* DIVYA SRIVASTAVA, MD,^{¶¶} AND NAOMI LAWRENCE, MD*

BACKGROUND The treatment of nonmelanoma skin cancer (NMSC) in the elderly population is a source of significant debate. Mohs micrographic surgery (MMS) is a highly effective treatment option yet not every patient with a cutaneous malignancy that meets appropriate use criteria (AUC) should be treated with surgery.

OBJECTIVE The purpose of this study was to use the Karnofsky Performance Status (KPS) scale to categorize the functional status of patients aged 75 years and older who required treatment of NMSC. The authors wanted to see whether functionality played a role on the treatment selection.

METHODS Patients aged 75 years and older presenting for biopsy of a suspected NMSC that met AUC for MMS were included in the study. Trained medical assistants used the KPS scale to assess patient functionality. Treatment modality was recorded once the biopsy confirmed the NMSC.

RESULTS A cohort of 203 subjects met inclusion criteria for the study. There was a statistically significant difference in utilization of surgical treatments between high and low functionality patients ($p = .03$).

CONCLUSION Dermatologists consider patient functionality when selecting a treatment for NMSC and use less invasive modalities for patients with poor functional status, even when the tumor meets AUC.

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The reasonable approach to treating nonmelanoma skin cancers (NMSCs) in the elderly population has become a subject of debate in the current medical environment in which the use of resources is carefully scrutinized. According to current data, approximately 1 in 5 Americans will be diagnosed with NMSC in their lifetime.^{1,2} Approximately 5,400,000 Americans are diagnosed with NMSC annually, leading to an average of

\$4.2 billion in annual cost for treatment in the United States.³ Most of these NMSCs are found among America's elderly population, a demographic that has continued to grow over the last decade. As the average lifespan in the United States continues to increase, the total number of patients over the age of 75 will rise, resulting in a continually increasing population of patients with NMSC.

*Division of Dermatology, Cooper Medical School of Rowan University, Camden, New Jersey; [†]Department of Dermatology, Augusta University, Augusta, Georgia; [‡]Department of Dermatology, University of Pennsylvania Perelman School of Medicine, Philadelphia, Pennsylvania; [§]Salem Dermatology Clinic, PC, Salem, Oregon; ^{||}North Georgia Dermatology, Lawrenceville, Georgia; [¶]Montgomery Dermatology, LLC, King of Prussia, Pennsylvania; **Charlottesville Dermatology, Charlottesville, Virginia; ^{††}Sanova Dermatology, Slidell, Louisiana; ^{‡‡}Pennsylvania Centre for Dermatology, Philadelphia, Pennsylvania; ^{§§}Laser Skin and Surgery Center of New York, New York, New York; ^{|||}Indiana University School of Medicine, Indianapolis, Indiana; ^{¶¶}University of Texas Southwestern, Dallas, Texas

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With the rising incidence of NMSCs, there has been a noticeable increase in available treatment options. Over the past several years, topical therapies such as 5-fluorouracil and imiquimod have become more commonly used in the treatment of NMSC. In addition, an oral therapy, vismodegib, has also been introduced to the market for advanced basal cell carcinomas; however, its use is limited by its price (\$45,000 for a 6-month course), side-effect profile, and high rate of recurrence of the cancer once the medication is discontinued.⁴ Mohs micrographic surgery (MMS) is the gold standard modality with documented cure rates of 99% for basal cell carcinomas and 97% for squamous cell carcinomas.⁵ However, simple elliptical excisions, as well as destruction through electrodesiccation and curettage, remain viable treatment methods. Excision is the most common procedure used to treat low-risk tumors due to its low cost and acceptable cure rates.⁶ Electrodesiccation and curettage is used to treat superficial NMSC and has recurrence rates based on the location of the tumor. High-risk locations have a recurrence rate of 4.5% to 17.6%, while low-risk sites have a decreased recurrence rate of only 3.3%.^{5,6} Recurrence rates increase for recurrent tumors treated with ED&C, with studies demonstrating 33.3% recurrence of basal cell carcinomas short term (less than 5 years) and 40% at 5 years.⁷

In 2012, the American Academy of Dermatology in collaboration with the American College of Mohs Surgery, the American Society for Dermatologic Surgery Association, and the American Society for Mohs Surgery set forth Appropriate Use Criteria (AUC) for evaluating tumor characteristics to determine whether MMS is an acceptable treatment choice for NMSC.⁸ The criterion is based on tumor type, location, size, pathology, and the immune status of the patient. Based on these factors, the tumor is rated on a scale of 1 to 9. A score of 7, 8, or 9 is designated as appropriate for MMS while a score of 4, 5, or 6 marks uncertainty, and a score of 1, 2, or 3 is considered inappropriate. However, even with such criteria, the debate surrounding all the treatment modalities is largely centered on whether to treat skin cancer at all in older Americans with NMSC.

Some argue that most NMSCs should be treated, though primarily with minimally invasive methods such as topical therapies. This position assumes that

patients consider topical therapy to be less “invasive” than surgical treatments. Recent research has demonstrated that while topical therapies have low recurrence rates of 5% for superficial basal cell carcinoma and squamous cell carcinoma in situ, patient satisfaction and cure rates are higher with MMS.³ With the cost of health care increasing, the debate originates from the question of how limited and costly resources should be allocated to patients of advanced age. This fact, combined with the new focus on quality measures in treatment, makes it essential to establish a guideline for how elderly patients with non-life-threatening skin cancers should be treated during their final years of life.

Within the past few years, *JAMA Internal Medicine* published a study exploring how patients with nonfatal conditions were treated at the end of life.² More specifically, patients with NMSCs were evaluated using the Charlson Comorbidity Index (CCI). This index considers age and comorbid conditions when predicting 10-year survival of patients. The CCI scores were then compared with the method of treatment for NMSCs. The authors concluded that most NMSCs were treated, the majority with a surgical modality, Mohs or simple excision, regardless of whether or not the patient had a limited life expectancy. Unfortunately, the CCI is a poor choice to evaluate appropriateness of treatment for a low morbidity procedure performed with local anesthesia. The true utility of the CCI is in predicting how chronic or underlying conditions affect the outcomes of invasive surgical procedures necessitating general anesthesia as opposed to in-office procedures under local anesthesia.^{9–11} The CCI falls short in that it fails to consider the overall health status of the patient. For example, based on the CCI, both a 70-year-old patient without comorbid medical conditions and a 60-year-old diabetic well controlled on oral medication would be considered limited life expectancy. The benefit of functional status is that it allows the physician to assess a patient’s independence and ability to perform daily activities. Without an assessment of functionality, it is impossible to definitively determine how NMSC will impact a patient’s life.

The Karnofsky Performance Status (KPS) scale is a reliable and valid method to assess physical performance, symptom burden, and therefore, the extent

of medical disease.¹² The KPS uses 11 descriptions to rate the functionality of the patient on a scale from 0 to 100 in increments of 10 (Table 1). Limited survival time is predicted in patients who score less than 50.¹³ The KPS is used across multiple disciplines, including oncology and geriatric medicine, to determine the appropriateness of interventions in elderly patients.^{13–16} It also has proven utility in the dermatology setting when considering treatment of advanced squamous cell carcinoma of the head and neck, as well as advanced melanoma.^{17–23}

When deciding upon the treatment method for NMSC, the functional status of the patient must be considered. Currently, there are no formal functionality criteria in place, but it is the authors' belief that dermatologists are already considering patient functionality when selecting a treatment modality. The purpose of this study is to categorize the functionality, using the KPS scale, of all patients aged 75 years and older who present for treatment of NMSC to determine its effect on treatment selection.

Patients/Methods

Setting and Patients

The authors conducted a prospective cohort study of consecutive patients, performed at 12 geographically diverse locations, including both private and academic institutions, across the United States (Table 2). The institutional review board at each participating academic institution approved the study.

Participating practices were selected from multiple states to ensure varied patient populations and dermatologists of differing training backgrounds. The goal sample size for this study was 200 subjects to achieve statistical significance. This was based on the assumption of 80% power, 5% alpha error, and a small to medium effect size between the proportion of different treatment modalities used between the KPS ≥ 60 group and the KPS < 60 group. A statistician at Cooper Medical School of Rowan University completed all sample size calculations and data analysis. Overall, 276 patients were eligible for the study. All subjects were recruited consecutively as they presented to the office to prevent selection bias for higher functionality patients. For patients with multiple NMSCs, the largest lesion was selected for data analysis. Patients aged 75 years or older were recruited when they presented with a potential NMSC. Eligible patients were biopsied and then included if their histopathology revealed a NMSC that met AUC for Mohs. Ultimately, the final cohort comprised 203 patients.

Data Collection

Eligible patients who presented for examination of a potential NMSC were approached by an investigator for potential enrollment in the study. After consenting to participate, the patient's functionality was evaluated by a medical assistant using the KPS scale. This assessment was conducted without the dermatologist present to ensure that the physician was blind to the patient's KPS score. Before initiation of enrollment, all medical assistants involved with patient recruitment underwent brief training to

TABLE 1. The Karnofsky Performance Status (KPS) Scale

100	Normal; no complaints; no evidence of disease
90	Able to carry out normal activity; minor signs or symptoms of disease
80	Normal activity with effort; some signs or symptoms of disease
70	Cares for self; unable to carry on normal activity or to do active work
60	Requires occasional assistance but is able to care for most personal needs
50	Requires considerable assistance and frequent medical care
40	Disabled; requires special care and assistance
30	Severely disabled; hospitalization is indicated although death is not imminent
20	Very sick; hospitalization necessary and active support treatment is necessary
10	Moribund; fatal processes
0	Dead

TABLE 2. Characteristics of Participating Practices

<i>Practice</i>	<i>Region</i>	<i>Academic vs Private Institution</i>	<i>Mohs Surgeon on Site</i>	<i>Low Functionality Subjects Recruited</i>
A	Northeast	Academic	Yes	No
B	South	Private	No	Yes
C	South	Private	No	No
D	South	Private	Yes	No
E	South	Private	Yes	No
F	Northeast	Private	No	No
G	Northeast	Private	Yes	No
H	Northeast	Private	No	No
I	West	Private	Yes	No
J	Northeast	Private	Yes	No
K	Midwest	Academic	Yes	No
L	South	Academic	Yes	Yes

decrease variability between scorers. After the functionality assessment, the patient was asked 7 questions to determine the impact of the NMSC on the patient's overall quality of life (Table 3). A caregiver was permitted to answer the questions in the event that the patient was unable to respond. The authors used the same questionnaire created by Regula and colleagues for a previously published study assessing the functionality of patients presenting for MMS.²⁴

Before the tumor was biopsied, structured data collection sheets were used to record demographic information including the patient's age and sex. In addition, information pertinent to determining AUC such as location of the tumor, type, size, pathologic characteristics, immune status, and whether the tumor was primary or recurrent was also recorded.

Upon return of the biopsy results and patient follow-up, the investigator recorded the tumor type and treatment modality selected. Possible treatment types included MMS, simple excision, electrodesiccation and curettage, other (including cryotherapy and curettage, cryotherapy alone, external radiation therapy [XRT], or topical therapy), and no treatment.

Outcome Measure and Analysis

The primary outcome of interest was treatment selected in relation with KPS score. A reference threshold of 60 was selected because, according to the

KPS scale, patients below a threshold of 60 require considerable assistance to perform normal daily functions and activities. The authors sought to measure which treatments were selected for patients above and below the reference threshold. Once the KPS scores were dichotomized according to the threshold, a chi-square test was performed to evaluate differences in treatment selection between groups. An independent *t*-test was used to determine differences in patient and tumor size between functionality groups.

Results

A total of 203 patients met criteria and completed the study. The mean age of the cohort was 83.6 years, and

TABLE 3. Questionnaire Assessing Impact of NMSC on Quality of Life

1. Are you having discomfort at the site of your lesion?
2. Is your lesion hurting, throbbing, stinging, or sensitive in some other way?
3. Is your lesion making you unhappy, depressed, or worried?
4. Is your lesion making it hard to do daily activities? That is, wearing glasses, combing your hair, wearing clothes
5. Has your lesion bled or is it messy in some other way?
6. Is it difficult to keep clean?
7. Does your lesion make you avoid others or socializing because you think others find it unattractive?

NMSC, nonmelanoma skin cancer.

TABLE 4. Results of Chi-Square Test to Determine Differences in Treatment Utilization Between Functionality Groups

Treatment	KPS <60			KPS GE 60			p
	N	n	Percent (%)	N	n	Percent (%)	
Surgery (Mohs and simple exc)	5	1	20.0	198	139	70.2	0.033
Mohs surgery	5	1	20.0	198	111	56.1	0.176
Simple excision	5	0	0.0	198	28	14.1	1.000
ED&C	5	4	80.0	198	53	26.8	0.023
Other procedure	5	0	0.0	198	4	2.00	1.000

ED&C, electrodesiccation and curettage; KPS, Karnofsky Performance Status.

67.0% were men. The mean KPS score for the cohort was 86.9. There were 5 patients with KPS scores less than 60, categorizing them as low functionality. All 5 of these patients were male, received KPS scores of 50, and had an average age of 77.2 years. The low functionality group had a nonsignificant difference in mean tumor diameter of 12.4 mm, compared with the 10.3 mm of the high functionality group.

Of the cohort, 97.5% had a KPS score of 60 or greater. Data analysis revealed that 68.9% of tumors were treated surgically with 55.1% undergoing MMS and 13.7% receiving simple excision. There was a statistically significant difference ($p = .033$) in the utilization of surgical treatment between the 2 functionality groups (Table 4). The average KPS score for patients treated with a surgical modality was 88.3 (Table 5). Of the tumors treated surgically, 50% were located on the face and 84.3% were located above the shoulders. Electrodesiccation and curettage (ED&C) was the

second most common treatment and was used for 28.1% of tumors. Eighty percent of the low functionality patients were treated with ED&C. A single low functionality patient was treated with MMS.

“Other procedures” were used for 2% of the high functionality group. Of these 4 subjects, 2 were treated with XRT, 1 was treated with cryotherapy and curettage, and 1 with cryotherapy alone. No topical therapies were used. In addition, 2 subjects categorized as high functionality refused to have their NMSC treated.

Discussion

The results of this study demonstrate that surgical treatment modalities for NMSC that meet AUC are used less frequently in low functionality patients 75 years of age or older. The majority of the cohort was treated surgically with 55.1% undergoing MMS and

TABLE 5. KPS Scores Stratified by Treatment

KPS	Full Sample	Mohs and Simple					Other Treatment
		Mohs Surgery	Simple Excision	Excision Combined	ED&C		
N	203	112	28	140	57	4	
Mean	87	89.91	82.14	88.36	83.33	85	
SD	13.29	12.04	11.66	12.33	14.80	17.32	
Minimum	50	50	60	50	50	60	
Maximum	100	100	100	100	100	100	
25th percentile	80	80	70	80	75	67.5	
Median	90	90	80	90	90	90	
75th percentile	100	100	90	100	100	97.5	

ED&C, electrodesiccation and curettage; KPS, Karnofsky Performance Status.

13.7% undergoing simple excision. This supports a 2012 study assessing adherence to AUC in the treatment of NMSC at a single academic institution. The authors identified 1,026 cases of NMSC, of which 710 met AUC. Of these, 339 were treated with MMS giving a utilization percentage of 46.6% at that institution.²⁴ These results demonstrate that while most NMSCs that are treated with Mohs meet AUC, many eligible lesions are treated with other modalities. In addition, while over half of the current study's cohort was treated with a surgical modality, 50% of the tumors were located on the face and 84.3% were above the shoulders. These results indicate that surgical intervention was largely reserved for lesions located in visible locations. Histologic subtype likely also factored into treatment selection as 82.8% of aggressive NMSCs were treated surgically (Table 6). Squamous cell carcinoma in situ was the subtype most frequently treated with ED&C.

Only 2.5% of the cohort was categorized as low functionality based on KPS score. Of the low functionality patients, 80% had their NMSC treated with ED&C. A single patient with a functionality score less than 60 was treated with a surgical modality, in this case MMS. All the tumors in the low functioning patients were located on the head, including the cheek, temple, and forehead. Despite these visible tumor

locations and qualification for MMS in accordance with AUC, only one patient was treated with MMS. The notable difference between the patient treated with MMS and the other low functionality patients was impact on quality of life. Unlike the others, the surgically treated patient answered, "yes" to 4 of the 8 quality of life questions. Therefore, surgery was only used for a low functionality patient when the NMSC was bleeding and causing significant discomfort.

The predominance of high functioning patients in the outpatient dermatology environment was unexpected but certainly significant. The skew is possibly due to either self-selection or the priorities in the primary care setting. It is not by chance that 97.5% of the cohort from geographically diverse environments was found to have a KPS score of 60 or greater, indicating that the patients are able to perform normal daily functions with minimal assistance. Only 5 patients in the cohort were found to be low functioning. On the KPS scale, low functionality patients are characterized by symptoms and disability caused by chronic conditions. Such debilitating conditions typically require significant, time-consuming management.

Another recent study measured patient functionality in those presenting solely in the MMS environment. That study used a KPS score of 70 as the threshold and

TABLE 6. Histologic Subtype of NMSCs Stratified by Treatment Method

Histologic Subtype	Treatment							
	Mohs		Simple Excision		ED&C		Other (Cryotherapy and XRT)	
	n	%	n	%	n	%	n	%
203 lesions								
Basal Cell Carcinoma								
Aggressive	12	5.9	1	0.5	2	0.9	0	0
Nodular	40	19.7	7	3.4	9	4.4	1	0.5
Superficial	7	3.4	1	0.5	5	2.5	0	0
Squamous Cell Carcinoma								
Aggressive	10	4.9	6	2.9	5	2.5	1	0.5
Keratoacanthoma type	5	2.5	4	1.9	5	2.5	0	0
In situ/Bowen disease	20	9.9	6	2.9	23	11.3	2	0.9
Verrucous	1	0.5	1	0.5	0	0	0	0
Without aggressive histological features	17	8.4	2	0.9	8	3.9	0	0

ED&C, electrodesiccation and curettage; NMSC, nonmelanoma skin cancer; XRT, external radiation therapy.

found that 92.8% of the patients presenting for MMS were high functioning.²⁵ Therefore, it is likely that low functionality patients simply do not prioritize the treatment of skin disease and present infrequently to outpatient dermatologists. Although the investigators were not expecting such a low number of low functionality patients, the geographical and environmental diversity of the study group protects against a biased sample.

One potential limitation to study is that the participating physicians were aware that the study was occurring. Although all participating dermatologists were blinded to the formal functional assessment, it is possible that knowing the study was taking place may have biased participants toward less invasive treatment modalities. However, the purpose of the study was to ascertain whether dermatologists consider patient functionality when selecting treatment for NMSC; therefore, there should be no incentive for the clinicians to decrease their utilization of surgical modalities.

It is the authors' conclusion that dermatologists consider functionality when determining whether to proceed with surgical treatment for NMSC. The results of this study indicate that most patients presenting to the dermatologist are high functioning. The KPS score provides a more comprehensive assessment of the overall health of the patient. Therefore, functionality should be the preferred metric over tools based solely on age and comorbid conditions. It is important to remember that while most of the patients in this study were treated surgically, all the patients met AUC for MMS. However, it is also common for physicians to use less invasive treatment methods when appropriate, even when a lesion meets AUC for MMS. Highly functioning elderly patients should continue to be offered the option of gold standard treatments with low morbidity, including MMS, for their NMSCs.

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Address correspondence and reprint requests to: Michael A. Renzi Jr., MD, PGY-2 Resident, Cooper Medical School of Rowan University, 3 Cooper Plaza, Suite 504, Camden, NJ 08103, or e-mail: Renzi-michael1@cooperhealth.edu