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External Validation of an Extended Prognostic Assessment Model in Patients With Brain Metastases from Small-cell Lung Cancer

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Abstract

Background/Aim: Recently, the small-cell lung cancer (SCLC) grade model for patients with brain metastases was developed by a Japanese group. It includes sex, performance status, number of brain metastases, primary tumor control and presence of extracranial metastases. The aim of the present study was to validate this prognostic score in a European cohort of patients.

Patients and Methods: The retrospective validation study included 189 patients from two centers in Germany and Norway. Survival according to the SCLC grade score was evaluated. Additional prognostic factors were analyzed.

Results: Median survival was 7.5 months. The 3-tiered SCLC grade score based on the sum of adverse prognostic features was significantly associated with survival (p<0.001): A higher point sum resulted in shorter survival. However, in our validation cohort, age affected survival to the same degree as several parameters that were part of the score.

Conclusion: This validation study supports the international applicability of the SCLC grade model. Age, which has also been identified as a relevant prognostic factor in other previous studies (including the SCLC Graded Prognostic Assessment), may deserve consideration when trying to optimize survival prediction. Given that different studies identified different age limits, *e.g.*, 70 or 75 years, merged databases are needed to provide definitive conclusions.

Keywords: Radiation therapy, stereotactic radiotherapy, brain metastases, prognostic factors, small cell lung cancer.

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Introduction

Additional treatment options such as immune checkpoint inhibitors (ICI) have contributed to prolonged survival of patients with small-cell lung cancer (SCLC) (1, 2). This tumor type has long been known for a particular propensity towards early and widespread dissemination, often involving the brain (3, 4). Different scenarios of brain metastasis diagnosis exist, *e.g.*, few, small, asymptomatic lesions detected on initial staging magnetic resonance imaging (MRI) of the brain, miliary/diffuse spread with 50 lesions or more, metachronous asymptomatic spread detected on surveillance MRI in patients who did not receive prophylactic cranial irradiation (PCI), or metachronous symptomatic metastases in patients with up-front extensive disease outside the brain whose options for systemic treatment have been exhausted, to name some examples. This heterogeneity in disease extent, timing and other baseline parameters makes it challenging to choose the preferred treatment approach (5).

In the present era of increasing acceptance of stereotactic radiosurgery (SRS) in SCLC with brain metastases (6, 7), options include systemic therapy alone, SRS, whole-brain radiotherapy (WBRT), and, in very select cases, surgical resection, *e.g.*, if a large-volume lesion is difficult to control with radiation alone. Often, more than one approach may be appropriate, resulting in inter-physician and inter-institutional differences in preferences. One of the guiding principles in the decision-making process is to assess each patient's survival prognosis in order to avoid grave mismatch between treatment intensity and achievable outcome (8, 9). Survival prediction models provide useful, although imperfect, information, and their evolution is ongoing. Sperduto *et al.* introduced graded prognostic assessment (GPA) for SCLC in a multi-institutional study of 570 patients treated between 2015 and 2020 in the USA, Canada and Japan (10). Predominantly (n=314), treatment consisted of WBRT, while 108 patients were selected for SRS. In just 30 cases was neurosurgical resection a component of care. It was common that patients also had systemic chemotherapy (before local treatment: 331, afterwards: 170). The study identified the following prognostic factors for survival: Age, Karnofsky performance status (KPS), extracranial metastases and number of brain metastases. Sex, race and ethnicity were not significant.

This 4-tiered GPA was then studied by our own group in a smaller cohort of European patients (11). The latter effort confirmed the significant prognostic impact of the GPA point sum. Group-by-group comparison of the resulting survival curves showed significant differences in most instances. However, similar survival curves were found for the two groups with better prognoses. We were unable to confirm the appropriateness of the GPA stratification by number of brain metastases (namely 1-3, 4-7, and ≥8). On the other hand, age, KPS and extracranial metastases were associated with survival. Based on the results of our study, we proposed modification of the classification criteria that lead to assignment to the poor prognosis group and to the best one. However, we felt that the study size of 180 patients did not justify a definitive recommendation.

More recently, a Japanese study also found that the GPA did not precisely reflect the survival differences (12). Instead, a quite different model was proposed, named the SCLC grade. Their study included a test cohort (340 patients) and a validation group (168 patients). All had received gamma-knife SRS between 1998 and 2018. The overall median survival after SRS was 7.7 [95% confidence interval (CI)=6.5-8.5] months. Sex (female *vs.* male), KPS (80 or better *vs.* 70 or worse), lesion number (single *vs.* multiple), primary tumor status (controlled *vs.* not controlled) and extracerebral metastases (no *vs.* yes) were the factors influencing the SCLC grade assignment (Table I). The aim of our present study was to validate this new 3-tiered survival prediction model.

Patients and Methods

Patients. We adhered to the design and methods that were utilized in comparable, older validation studies by our

Table I. *Calculation of the point sum determining a patient's prognostic group by Graded Prognostic Assessment (GPA) and its modification, small-cell lung cancer (SCLC) grade.*

		Score, points					Prognostic class, sum			
Prognosis by	Baseline parameter	0	0.5	1	1.5	2	Unfavorable	Intermediate		Favorable
GPA	KPS	≤60	70	80	90	100	0-1	1.5-2	2.5-3	3.5-4
	Number of BM	≥8	4-7	1-3	–	–				
	Extracranial metastases*	Present	Absent	–	–	–				
	Age*	≥75	<75 Years	–	–	–				
SCLC grade	Male	–	–	Yes	–	–	>3	2-3	0-1	
	KPS	–	–	<80	–	–				
	Number of BM	–	–	>1	–	–				
	Extracranial metastases*	–	–	Yes	–	–				
	Primary cancer controlled	–	–	No	–	–				

BM: Brain metastasis; KPS: Karnofsky performance score. *At diagnosis of BM.

group (11, 13, 14). Patients with brain metastases from SCLC were identified from the Institutional Review Board-approved databases at Nordland Hospital Trust Bodø, Norway, and University Hospital Freiburg, Germany. The following inclusion criteria were required: Treatment in the time period 2006-2023, parenchymal brain metastases from histologically verified extracranial primary SCLC managed with WBRT, SRS, surgery or upfront chemotherapy/chemotherapy plus ICI followed by salvage radiotherapy. Completion of radiation treatment was not required. In this real-world cohort, treatment sequence and radiotherapy prescription were individualized, as was further treatment for new or recurrent brain metastases. Systemic treatment was continued or initiated as judged appropriate by the multidisciplinary lung cancer tumor boards and physicians in charge at the study sites. The prevailing WBRT dose-fractionation regimen was 30 Gy in 10 fractions. A minority of patients received 20 Gy in 5 fractions or WBRT plus boost (often simultaneously integrated).

Methods. Extracranial staging consisted of computed tomography. When clinically relevant, further modalities were added to clarify computed tomography findings, *e.g.* isotope bone scan, ultrasound, positron-emission tomography. The number of brain metastases was derived from MRI reports. Overall survival (time to death) from radiological diagnosis of brain metastases was calculated employing the Kaplan–Meier method, and different groups were compared using the log-rank test (SPSS 29.0.1.0; IBM Corp., Armonk, NY, USA). Six out of 189 patients were censored after a minimum of 9 months of follow-up. Date of death was known for all other patients. For continuous variables, such as age, univariate Cox regression was employed. A multivariate forward conditional Cox regression analysis was also performed. The SCLC grade was calculated as proposed by Yamamoto *et al.* (one point each for male sex, KPS <80, more than one brain metastasis, uncontrolled primary tumor, presence of extracranial metastases) resulting in three tiers for prognosis (point sum of 0-1, 2-3 or >3; Table I). A *p*-value of less than 0.05 was considered statistically significant.

Results

This study cohort included 189 patients, largely managed with WBRT (7% resection or SRS). The median age was 65 years. Table II provides further baseline characteristics. The median overall survival was 7.5 months (95% CI=6.2-8.8 months). For the complete cohort, survival after 1, 2 and 5 years reached 26%, 8% and 2%, respectively. All five parameters needed to assign the SCLC grade (sex, KPS,

Table II. *Characteristics of study patients (n=189).*

Baseline parameter	Value
Sex, n (%)	
Female	75 (40)
Male	114 (60)
KPS, n (%)	
≤60	46 (24)
70	53 (28)
80	38 (20)
90	32 (17)
100	20 (11)
Extracranial metastases, n (%)	
None	56 (30)
≥1	133 (70)
Primary tumor, n (%)	
Controlled	127 (67)
Uncontrolled	55 (29)
Not recorded	7 (4)
Brain metastasis, n (%)	
Single	42 (22)
Multiple	147 (78)
Timing of brain metastasis, n (%)	
Synchronous	91 (48)
Metachronous	88 (47)
Not recorded	10 (5)
Age, n (%)	
<70 Years	132 (70)
≥70 Years	57 (30)
Neurosurgical resection, n (%)	
Yes	6 (3)
Primary SRS/focal radiotherapy, n (%)	
Yes	7 (4)
Chemotherapy, n (%)	
Naïve	52 (28)
Before local therapy of brain metastases	137 (72)
Age, years	
Mean±SD	64±10
Median (range)	65 (35-88)

KPS: Karnofsky performance score; SRS: stereotactic radiosurgery.

single brain metastasis, primary control, extracranial metastases) were significantly associated with survival in univariate analyses ($p<0.05$). Age was significant in univariate Cox regression (shorter survival in older patients); when the cohort was dichotomized, a cut-off of 65 years was not predictive of survival, whereas 70 years was statistically significant ($p<0.001$). Finally, synchronous brain metastases were associated with longer survival, with a median of 9 months *vs.* 5 months when metachronous ($p=0.016$). With regard to treatment, survival was significantly longer in patients who had received systemic therapy after diagnosis of brain metastases (median=9 months) *vs.* those who had not (median=3 months), $p<0.001$.

The 3-tiered SCLC grade was significantly associated with survival. Median values were 11, 10 and 5 months for groups with 0-1 (n=19), 2-3 (n=80) and >3 (n=83) point sums, respectively. The Kaplan–Meier curves are shown in Figure 1. In the multivariate Cox regression analysis of prognostic factors for survival, KPS emerged as the central parameter [hazard ratio (HR) of 0.52 for those with better KPS, 95% CI=0.41-0.63; $p<0.001$]. It was followed by extracranial metastases (HR=1.75, 95% CI=1.50-2.00; $p=0.003$), primary tumor control (HR=0.65, 95% CI=0.40-0.90; $p=0.01$), female sex (HR=0.71, 95% CI=0.48-0.94; $p=0.04$), and single brain metastasis ($p=0.16$, not significant). In a separate model where age <70 years and synchronous presentation were also included, results changed. KPS, primary tumor control and age <70 years all achieved *p*-values of less than 0.001, whereas extracranial metastases had $p=0.008$. Neither synchronous presentation nor single brain metastasis or sex remained significantly associated with survival.

Discussion

The purpose of this study was to provide external validation of the SCLC grade survival prediction model. As displayed in Figure 1, the performance of the model was satisfactory. The original Japanese study reported a median survival of 7.7 (95% CI=6.5-8.5) months in patients managed exclusively with SRS (12). Our study reported a median survival of 7.5 (95% CI=6.2-8.8) months, but treatment was largely based on WBRT. Group-wise inter-study comparison showed medians 15.3 months in Japanese patients treated with SRS with favorable prognosis *vs.* 11.0 months in the present study. The intermediate groups had median times of 7.9 and 10.0 months, and the unfavorable groups 3.2 and 5.0 months, respectively. These differences may be related to variation in prescription and timing of systemic therapy, a factor with major impact on survival in our study, which

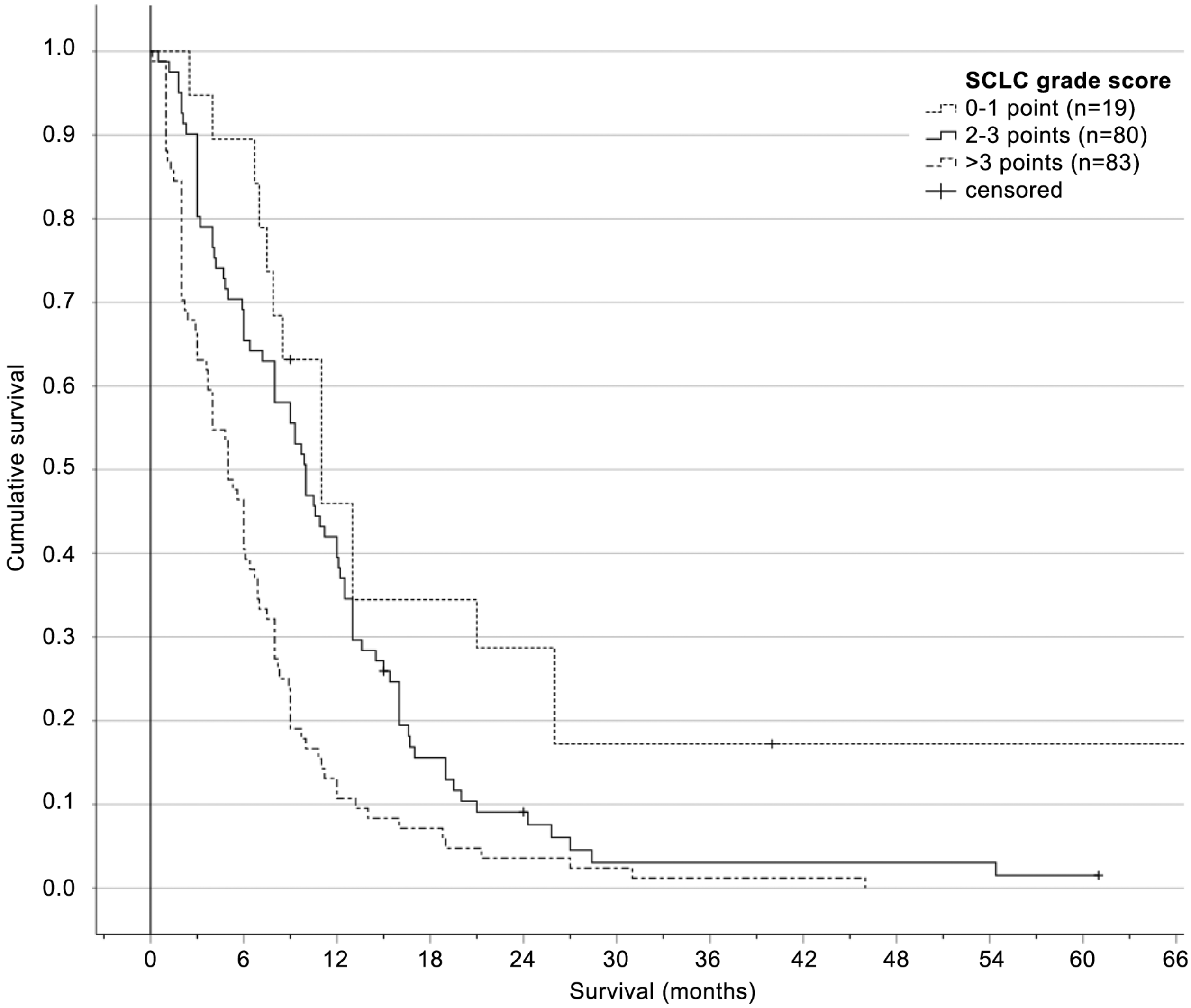

Figure 1. *Actuarial overall survival (Kaplan–Meier curves, log-rank test pooled over all strata: p<0.001). The remaining patients had incomplete baseline data. In pairwise comparison, all survival differences reached statistical significance. The favorable group had a maximum of one adverse prognostic factor.*

was not reported in sufficient detail in the Japanese cohort. Furthermore, the Japanese patients were treated before 2019, *i.e.*, before life-prolonging ICI therapy became commonplace, while our inclusion period ended in 2023. Hypothetically, better systemic therapy may have improved survival in the unfavorable and intermediate groups. The favorable group was small in our study, which may be a reason for the unexpectedly short median survival. The long-term survival plateaued at 17% in our favorable subgroup, a figure very similar to the Japanese results in both development and validation cohort.

Slight differences in stratified survival outcomes between both studies may also result from the fact that only four out of five prognostic factors actually predicted survival in our study (presence of a single brain metastasis was not significant in the multivariate model). Our results also suggest that SCLC grade may benefit from the addition of age (highly significantly predictive of survival in our cohort).

In the Japanese study, age was also a significant factor (with a cut-off of 65 years in contrast to 70 years for our dataset), but based on the lower hazard ratio, the authors decided to exclude it from the final predictive model. Limitations of our study include low patient numbers and size of subgroups impacting statistical power, as well as temporal changes in preferred treatment approaches.

It is also important to discuss the well-known GPA study (10). Median survival was 10 months (9 after WBRT) in that study. Stratified by groups of deteriorating prognoses, the respective values were 23, 13, 8 and 4 months. In principle, expansion to four strata may provide useful additional information. On the other hand, clinicians may be most concerned about the best and worst groups, if they are trying to avoid undertreatment of patients who can benefit most and overtreatment of patients who have little, if anything, to gain. Given that both external validation studies (11, 12) discovered some weaknesses of the original GPA, development of an internationally applicable, harmonized model should continue. All three studies suggest that KPS and extracranial metastases should remain central components. Discrepancy exists regarding the number of brain metastases, age, sex and primary tumor control. Some additional parameters such as nutrition/weight loss/cachexia remain to be explored in patients with brain metastases (15).

Rades *et al.* studied 157 patients treated with WBRT (30 Gy in 10 fractions) (16). The prognostic factors idealized were identical to those in the GPA publication (age, performance status, number of brain metastases, extracranial metastases). Hou *et al.* studied four older scores including the diagnosis-specific GPA (17) in 451 patients treated with WBRT and eventually proposed an alternative model (18). The latter also included KPS, number of brain metastases, extracranial metastases, and (the only difference to the new GPA and SCLC grade) whether treatment had been received before diagnosis of brain metastases. A large Canadian study included 8,705 patients whose median age at diagnosis was 68 years (19). Median survival was 7.5 (95% CI=7.2-7.7) months. A total of 4%, 62% and 35% received SRS, WBRT or no treatment, respectively. In propensity score-matched analyses, survival was non-inferior between SRS- and WBRT-treated cohorts among patients who did not receive PCI, and in favor of SRS for those who received PCI prior to brain metastasis development (hazard ratio=0.47, 95% CI=0.3-0.7; p=0.004).

In a study of 107 patients with synchronous brain metastases treated at a single institution, the median survival was 9 months (20) (identical to the result of our study). An increased number of brain lesions was significantly associated with reduced survival. Patients who received both chemotherapy and WBRT had improved survival compared to those who had either chemotherapy or WBRT alone. There was no significant difference in outcome depending on the sequence of therapy or the dose of WBRT.

In summary, several groups from different countries have so far reported comparable survival outcomes and developed 3- or 4-tiered scores predicting survival. In the light of newly introduced combined ICI/chemotherapy approaches and diminishing administration of PCI, despite availability of hippocampus-sparing techniques that may preserve neurocognitive functions (21, 22), it will be important to examine their applicability and performance in sufficiently large contemporary patient cohorts, stratified for synchronous *vs.* metachronous setting.

Conclusion

This validation study supports the international applicability of the SCLC grade model. Age, which has also been identified as a relevant prognostic factor in previous other studies (including the SCLC GPA), may deserve consideration when trying to optimize survival prediction. Given that different studies identified different age limits, namely 70 or 75 years, merged databases are needed to provide definitive conclusions.

Conflicts of Interest

The Authors declare that they have no conflicts of interest in relation to this study.

Authors' Contributions

CN participated in the design of the study and performed the statistical analysis. CN, IP and ALG conceived the study and drafted the article. All Authors read and approved the final article.

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