

PREDICTIVE FACTORS FOR COMPLICATIONS IN ELDERLY PATIENTS WHO UNDERWENT HEAD AND NECK ONCOLOGIC SURGERY

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Abstract: *Background.* Postoperative complications are relevant outcomes in patients with head and neck tumor who have undergone surgery. Few trials have assessed predictive factors in older patients. We assessed the predictive effect of preoperative clinical factors on postoperative complications.

Methods. We conducted a cohort study with 242 patients older than 70 years with head and neck cancer who underwent surgery. Logistic regression identified predictive factors for postoperative complications. Significant variables were used to build a predictive index.

Results. Comorbidities were present in 87.6% of patients, and 56.6% had some type of complication (44.6% local and 28.5% systemic). Male sex, bilateral neck dissection, presence of 2 or more comorbidities, reconstruction, and clinical stage IV were associated with postoperative complications. The predictive index showed a receiver operating characteristics curve (ROC) area of 0.69.

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Conclusion. It is possible to predict postoperative complications in older patients with head and neck tumors who underwent oncologic surgery using clinical preoperative variables.

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Keywords: aged; head and neck neoplasms; comorbidity; prognosis; postoperative complications

Head and neck cancer is the eighth cause of cancer mortality in the world.¹ In the United States, 39,000 new cases and 12,000 deaths were registered in 2004.² It is widely accepted that head and neck cancer has a higher incidence in people older than 50 years, primarily due to its relationship with chronic exposure to tobacco smoking and alcohol drinking.³ Besides cancer, these exposures also determine the appearance of other significant systemic comorbidities, such as pulmonary, cardiovascular, and hepatic, which can modify tolerance to the treatment and influence short-term prognosis.

As the world population becomes older, the number of patients with head and neck cancer surpassing the artificial limit of 70 years of age is increasing. Since surgery is the main therapeutic

procedure for most head and neck cancers and because the risk of postoperative complications is high in older patients, surgeons have to make therapeutic decisions based on expected oncologic results and the subjective assessment of complication development.

The main predictive factor for postoperative complications is comorbidity.⁴ Studies have assessed the effect of comorbidities on postoperative complications and overall survival and shown that comorbidities increase the frequency of postoperative complications and decrease the overall survival in different populations of patients, with or without cancer.^{5,6} Various instruments have been developed to measure comorbidities. Both the early Charlson Comorbidity Index⁷ and the new Washington University Head and Neck Comorbidity Index⁸ try to quantify the comorbidities and their effect on patient outcome. However, the use of these indices needs training and the reliable completion of these instruments from clinical charts could be compromised when structured and active search for comorbidities is not performed. It seems obvious that the presence of comorbidity could modify treatment approach and prognosis, but it also seems logical that a well-controlled comorbidity does not have the same weight as an uncontrolled comorbidity.⁸ Moreover, the prognostic effect of comorbidity on postoperative complications has been assessed in general populations with small sample sizes of patients older than 70 years. The effect of comorbidity on this specific population with an intrinsic survival bias is unknown.

Because postoperative complications are very important outcomes that modify prognosis⁹ and resource consumption and because a higher risk of complications could modify the adjuvant treatment and postoperative care of elderly patients, we decided to assess the predictive effect of major comorbidities and other clinical variables in postoperative complications on elderly patients who underwent head and neck oncologic surgery and to develop a simple predictive index that could better predict these outcomes in a clinical setting with the available preoperative clinical information alone.

MATERIALS AND METHODS

The medical records of all patients with head and neck cancer admitted to the Centro de Tratamento e Pesquisa Hospital do Cancer A. C. Camargo, São Paulo, Brazil, between January 1, 1980, and December 31, 2000, were reviewed. The following

criteria were used for inclusion in the study: age older than 70 years, a histologically confirmed diagnosis of malignant disease, no past history of other tumor, absence of previous oncologic treatment for this primary tumor, no distant metastasis, and surgical treatment with a curative purpose, exclusive or as part of a multidisciplinary approach. Patients with surgery for thyroid or benign conditions and minor surgical procedures were excluded.

Data collection from the medical records was performed using a specially designed form. These data included demographic information, TNM staging (Union Internationale Contre le Cancer or American Joint Committee on Cancer classification), tumor site, surgical risk according to the American Society of Anesthesiologists (ASA), type of surgery and neck dissection, type of reconstruction, blood transfusion, comorbidities, and perioperative complications. The assessed comorbidities were diabetes mellitus, hypertension, chronic obstructive pulmonary disease, cardiac disease (including chronic heart failure, arrhythmia and coronary artery disease), and cerebrovascular event sequelae. Outcome measures included the development of complications (local or systemic) in the immediate postoperative period (30 days) extracted from medical charts. Wound infection was recorded only for patients with suppurative drainage and those who developed a salivary fistula. Wounds noted to have erythema were considered infected in the presence of fever based on an evaluation performed by the surgeon.

The information from the forms was entered into a database (Excel for Windows). For the statistical analysis, commercially available software (Stata 8.0, Stata Corporation, TX) was used. Descriptive statistics were used to show the distribution of variables in population. Univariate analysis was conducted to explore the relation between baseline variables and outcome events, and results were reported using relative risk (RR) with 95% confidence interval (95% CI). The *t* test and Mann-Whitney test were used to compare means according to its distribution, and the chi-square test to compare categorical variables.

Continuous and discrete variables were categorized to facilitate data analysis and presentation. In case of ordinal variables, a dummy variable was created for each level for use in the logistic regression analysis.

Logistic regression was used to identify independent risk factors for postoperative complications (either present or absent, independently if

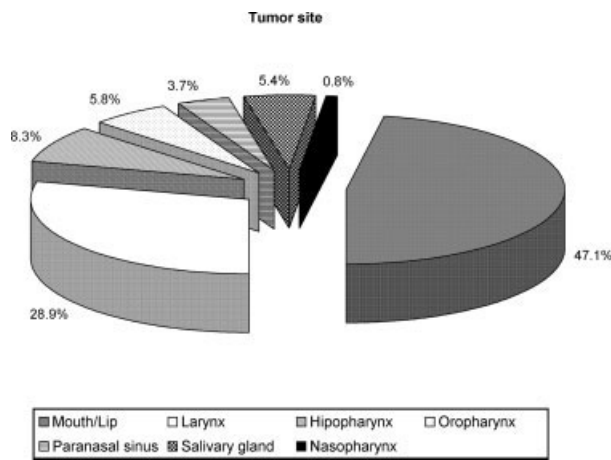


FIGURE 1. Localization of primary tumor.

local or systemic). A selection of variables to include at the full model was made using results of univariate analysis and clinical criteria. Before performing the logistic regression, a colinearity analysis of included variables was performed, selecting those to be used. A backward stepwise logistic regression was then carried out to prove the independent contribution of variables to the final model, using a $p = 0.2$ for entry into the model. For statistically significant variables, odds ratio (OR) with 95% CI was reported. Regression diagnostic techniques as residuals and leverage analysis were applied for the final model to build the best predictive model. Hosmer-Lemeshow goodness-of-fit values and operative characteristics (sensitivity and specificity) were reported for models at a discriminative value of 50%. Receiver operating characteristics (ROC) curve area was also reported.

A final predictive scale for complications was built using OR values rounded to the next superior unit for each statistically significant variable. The operative characteristics of these scales were also reported. Validity of this scale was assessed using a random sample approach by testing the scale developed with the full sample in 10 different random samples of the main database. For all statistical tests, $p < 0.05$ was considered statistically significant.

RESULTS

Clinical charts for 306 patients older than 70 years were taken from the Hospital Medical Archives. Only 242 patients fulfilled inclusion and exclusion criteria. The mean age was 74.6 ± 4.5 years (range, 70–95; median, 73.5 years). A total of 33 patients (13.6%) were older than 80 years. A total

Table 1. Distribution of patients by clinical stage.

T Classification	No. of patients by N classification						Total
	N0	N1	N2a	N2b	N2c	N3	
T1	29	0	0	0	0	1	30
T2	53	12	2	2	0	0	69
T3	52	17	3	3	4	0	79
T4	40	11	3	1	3	2	60
Total	174	40	8	6	7	3	238

of 180 patients were men (74.4%), and 216 (89.3%) of the total patients were white.

Primary tumor localization is shown in Figure 1. Distribution by T and N classification is shown in Table 1. In 4 patients, it was not possible to establish the clinical stage because of the Tx or Nx classification.

Two hundred twelve (87.6%) patients had at least 1 comorbidity: diabetes mellitus in 27 (11.1%), hypertension in 112 (46.3%), chronic obstructive pulmonary disease (COPD) in 150 (62.0%), cardiac disease in 107 (44.2%), and sequelae resulting from cerebrovascular events in 8 (3.3%). Distribution of patients by number of comorbidities was: 0 in 30 (12.4%) patients, 1 in 81 (33.5%) patients, 2 in 78 (32.2%) patients, and 3 or more in 53 (21.9%). Distribution by the American Society of Anesthesiologists (ASA) index was ASA I, 3 (1.3%) patients; ASA II, 108 (44.6%); ASA III, 127 (52.3%), and ASA IV, 4 (1.8%) patients.

Table 2. Local and systemic complications.

Complications	No. of events (%)
Local complications	35 (26.5)
Surgical site infection	35 (26.5)
Local necrosis	23 (17.4)
Salivary fistula	20 (15.2)
Seroma	14 (10.6)
Hematoma	12 (9.1)
Chylous fistula	5 (3.8)
Vessels rupture	2 (1.5)
Other local complications*	21 (15.9)
Total	108
Systemic complications	
Pneumonia	24 (28.9)
Cerebrovascular event	8 (9.6)
Abdominal complications	6 (7.2)
Urinary tract infection	6 (7.2)
Sepsis	5 (6.0)
Pulmonary thromboembolism/ deep vein thrombosis	2 (2.4)
Other systemic complications†	32 (38.7)
Total	83

*Include erythema nondefined as surgical site infection and dehiscence of surgical wound.

†Include postoperative fever, phlebitis, hyperglycemia, delirium, and urinary retention.

Table 3. Univariate analysis for factors predictive of occurrence of postoperative complication.

Variable	Without complications (n = 105)	With complications (n = 137)	RR (95% CI)	p value
Age, y				
70–79	89 (42.6%)	120 (57.4%)	0.89 (0.63–1.27)	.52
≥80	16 (48.5%)	17 (51.5%)		
Sex				
Female	36 (58.1%)	26 (41.9%)	1.47 (1.07–2.01)	.005
Male	69 (38.3%)	111 (61.7%)		
Comorbidity				
No	18 (60.0%)	12 (40.0%)	1.47 (0.93–2.31)	.03
Yes	87 (41.0%)	125 (59.0%)		
Diabetes				
No	93 (43.3%)	122 (56.7%)	0.97(0.68–1.39)	.53
Yes	12 (44.4%)	15 (55.6%)		
Hypertension				
No	61 (46.9%)	69 (53.1%)	1.14(0.91–1.42)	.14
Yes	44 (39.3%)	68 (60.7%)		
COPD				
No	47 (51.1%)	45 (48.9%)	1.25 (0.98–1.60)	.03
Yes	58 (38.7%)	92 (61.3%)		
Cardiac disease				
No	64 (47.4%)	71 (52.6%)	1.17(0.94–1.45)	.09
Yes	41 (38.3%)	66 (61.7%)		
Cerebrovascular event sequel				
No	103 (44.0%)	131 (56.0%)	1.33(0.88–2.03)	.24
Yes	2 (25%)	6 (75%)		
No. of comorbidities				
0	18 (60%)	12 (40%)	1	
1	37 (45.7%)	44 (54.3%)	1.47 (0.93–2.31)	.29
2	32 (41.0%)	46 (59.0%)	1.22 (0.97–1.53)	
3	16 (34.8%)	30 (65.2%)	1.22 (0.96–1.54)	
≥4	2 (28.6%)	5 (71.4%)	1.27 (0.78–2.05)	
ASA classification				
1–2	52 (50%)	52 (50%)	1	.03
3–4	43 (35.8%)	77 (64.2%)	1.28 (1.01–1.62)	
Tumor site				
Lip/mouth	58 (50.9%)	56 (49.1%)	0.77 (0.61–0.97)	.02
Oro/hypopharynx	11 (32.4%)	23 (67.6%)	1.23(0.94–1.60)	
Larynx	27 (38.6%)	43 (61.4%)	0.77 (0.61–0.97)	
Clinical stage				
I	19 (61.3%)	12 (38.7%)	1	.005
II	26 (50.0%)	26 (50.0%)	1.52 (0.96–2.40)	
III	38 (47.5%)	42 (52.5%)	1.35 (1.03–1.76)	
IV	21 (28.0%)	54 (72.0%)	1.46 (1.18–1.81)	
Bilateral neck dissection				
No	91 (49.2%)	94 (50.8%)	1.48 (1.20–1.82)	.001
Yes	14 (24.6%)	43 (75.4%)		
Reconstruction				
No	73 (48.3%)	78 (51.7%)	1.25 (1.01–1.55)	.04
Yes	32 (35.2%)	59 (64.8%)		
ICU transfer				
No	76 (48.4%)	81 (51.6%)	1.27 (1.02–1.58)	.03
Yes	29 (34.1%)	56 (65.9%)		
Blood transfusion				
No	94 (47.0%)	106 (53%)	1.39 (1.11–1.73)	.01
Yes	11 (26.2%)	31 (73.8%)		

Abbreviations: RR, relative risk; CI, confidence interval; COPD, chronic obstructive pulmonary disease; ASA, American Society of Anesthesiologists; ICU, intensive care unit.

The most common surgical procedures for primary tumors were partial glossectomy with/without floor of mouth resection and/or mandibulec-

tomy in 77 patients (31.8%), laryngectomy with/without pharyngectomy in 72 patients (29.8%), oropharyngeal resection in 32 patients (13.2%)

Table 4. Index for predicting complications in elderly patients.

Variable	Value
Male sex	2
Two or more comorbidities*	2
Reconstruction during primary surgery	2
Bilateral neck dissection	2
Tumor clinical stage IV	3

Total value is obtained by adding variable values. 0 value is classified as low risk, 2–4 values are classified as intermediate risk, 5–11 values are classified as high risk.

*Comorbidities considered were: diabetes mellitus, arterial hypertension, chronic obstructive pulmonary disease, cardiac disease, and cerebrovascular event sequelae.

and commando operation in 22 patients (9.1%). Ipsilateral neck dissection was performed on 169 (69.8%) patients, and bilateral neck dissection was performed on 57 (23.6%) patients. Reconstruction of any type was done on 91 (37.6%) patients. Forty-two (17.4%) patients received blood transfusion, and 85 (35.1%) patients were transferred to the ICU postoperatively. One hundred thirty-three (54.9%) patients received postoperative radiotherapy, and 8 (3.3%) patients received chemotherapy as part of their cancer treatment. Twenty-six (10.7%) patients had positive surgical margins in the definitive pathology report.

One hundred thirty-seven (56.6%) patients had some type of complication. Of these, 24 patients had more than 1 complication (local or systemic). Local and systemic complications occurred in 108 (44.6%) and 69 (28.5%) patients, respectively. The distribution of complications is shown in Table 2. The results of univariate analysis for complications are shown in Table 3.

Eleven (4.6%) patients died postoperatively. The causes of death were sepsis ($n = 2$), cardiac failure ($n = 2$), acute myocardial infarct ($n = 1$), renal failure ($n = 1$), cerebrovascular event ($n = 1$), cervical vessels rupture ($n = 1$), and multiple

Table 5. Frequency of complications by predicted index.

Cut point	No. of patients	No. of complications (%)		
		Total	Local	Systemic
0	13	1 (7.7)	1 (7.7)	0 (0)
2	45	18 (40.0)	14 (31.1)	10 (22.2)
3	2	1 (50.0)	1 (50.0)	0 (0)
4	71	36 (50.7)	29 (40.8)	14 (19.7)
5	17	11 (64.7)	8 (47.1)	7 (41.2)
6	29	21 (72.4)	17 (58.6)	8 (27.6)
7	29	20 (68.9)	17 (58.6)	10 (34.5)
8	5	4 (80.0)	4 (80.0)	2 (40.0)
9	25	20 (80.0)	12 (48.0)	17 (68.0)
11	2	2 (100.0)	2 (100.0)	1 (50.0)

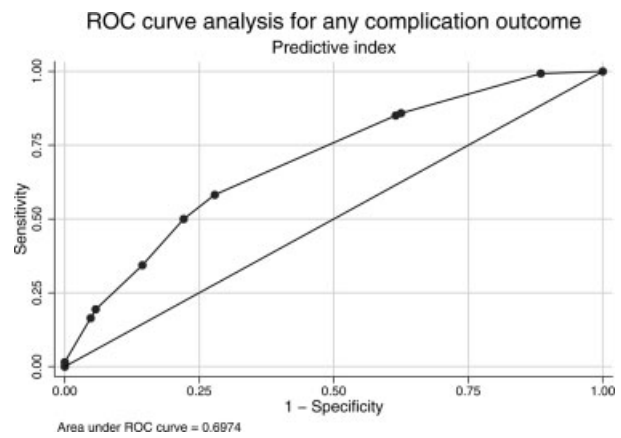


FIGURE 2. Receiver operating characteristics (ROC) curve analysis for any complication outcome using the predictive index.

organ failure ($n = 3$). Eight of the patients who died had 2 or more comorbidities.

Complications and death rates between younger patients and patients aged 80 years or older were not statistically different (57.4% vs 51.5% for any complication and 5.2% vs 0% for postoperative death).

Complications Predictive Model. The final model for prediction of complications retained 5 variables: bilateral neck dissection (OR 2.13; 95% CI 1.01–4.47; $p = .04$), 2 or more comorbidities (OR 2.21; 95% CI 1.20–4.06; $p = .01$), reconstruction (OR 2.23; 95% CI 1.17–4.24; $p = .01$), male sex (OR 1.89; 95% CI 0.96–3.73; $p = .06$), and clinical stage IV (OR 2.85; 95% CI 1.42–5.70; $p = .003$) Hosmer-Lemeshow goodness-of-fit probability was 0.25. Model sensitivity was 84.4% and specificity was 41.1% with a rate of 66.5% correctly classified data. The area under ROC curve for this model was 0.72.

With these variables, a predictive index was built (Table 4). Risk of complications and operative characteristics of this model are shown in Table 5 and Figure 2, respectively. Values of this index can be 0 or go from 2 to 11. Value 1 does not exist because of the numerical values assigned to each item in the index. After testing various levels to set a cutoff point, we decided to divide the scale into an ordinal scale by grade of risk: low risk, with a value of 0 and probability of complications of 7.6% (local 7.6%, systemic 0%); intermediate risk, with a value between 2 and 4 and a probability of complications of 46.6% (range, 40% to 50%; local 31.1% to 50%, systemic 19.7% to 22.2%), and high risk, with a value of 5 to 11 and a proba-

bility of complications of 72.8% (range, 64% to 100%; local 47% to 100%, systemic 27.6% to 50%). A random-sample approach to validate the index showed ROC curve areas from 0.647 (95% CI, 0.55–0.74) in the worst case to 0.74 (95% CI, 0.65–0.83) in the best case.

DISCUSSION

Progressive aging of the population has modified the way surgeons treat patients.¹⁰ It is hard to define the age limit for an aged person. The American Geriatrics Society considers all people older than 65 years “aged.”¹¹ However, some authors have suggested that 70 years could be a good chronological threshold.^{12,13} Unfortunately, this group of patients is not well represented in most oncologic studies,¹⁴ and many clinical decisions applied to them are derived from results of trials with younger patients. Furthermore, there is a tendency to consider the old patient less compliant and with a lower expected treatment tolerance.¹⁵ Head and neck surgery is an area in which aging is a determining feature, because patients usually develop cancer after a long time of exposure to predisposing factors such as tobacco and alcohol.

The contribution of age for cancer prognosis is made mainly through comorbidities. It has been demonstrated that comorbidity is a risk factor that could modify short- and long-term prognosis. More specific studies performed in head and neck cancer populations have consistently demonstrated the deleterious effect of comorbidity in overall survival.^{4,5,8,16} However, those studies had involved low numbers of elderly patients, and their conclusions could be different in selected older populations because of the expected effect of survival bias. If a patient can reach a longer age, it could be suggested that he surpassed the risks predicted to modify prognosis when he was younger, and in this case other different prognostic factors could appear, or established risk factors for younger people could have a lower weight in these older groups.

One of the main outcomes associated with head and neck surgery is postoperative complications. As it is a risk factor for death,⁹ surgical therapy, commonly suggested for a younger patient, could not be considered a good option for an older patient because of the expected risk of developing complications, especially associated with anesthetic risks. Moreover, postoperative complications have been closely related with comorbidity

in other studies,^{4,5,8,17,18} and even more, it has been suggested that its presence could modify the type of surgical treatment leading to the choice of less complex and time-consuming procedures.^{15,19} Consequently, exploration of the effect of comorbidity on these outcomes in an older population could help understand its prognostic importance.

The presence and number of comorbidities was high compared with studies that included younger patients.^{6,17,20} In this study, more than 85% of the patients had chronic impairments, such as cardiovascular or pulmonary diseases, and the proportion of patients with more than 2 comorbidities was close to 50%. However, the incidence of complications was 56%, which was similar to the rates reported in other studies with a less selected population, and postoperative deaths occurred in 4.6% of patients, a slightly higher rate than those reported by other authors in more healthy populations.^{21–25}

In addition to the presence of comorbidity, a severity measure of comorbidity must be included to predict short-term prognosis. Over 50% of the patients had some grade of systemic compromise associated with chronic disease, as shown by a high number of ASA III patients. As we could not capture information related with severity of comorbidities in this study, we used ASA classification as an easy proxy for disease severity, since some authors suggested its value as a comorbidity prognostic marker and because older clinical charts provided more elements for a reliable ASA classification than for other more complex indexes.^{26,27} However, we could not prove the prognostic influence of ASA in this study. The predictive power of indices that include severity of comorbidity as ACE-27 and Washington University Head and Neck Comorbidity Index has been demonstrated.^{5,8,16} However, the implementation of these instruments in clinical services requires training and calculating its reliably from clinical charts with nonstandardized primary compilation of information is challenging, as occurred with older charts reviewed in this study.

Local and systemic complications were high in this group of patients but are within the range found by other authors, and the distribution of complications was not different from other studies. Infection and serous collection were the most frequent local complications, and pneumonia was the most frequent systemic complication.^{21–25} Risk factors associated with postoperative complications in univariate analysis were male sex, presence of comorbidity, presence of COPD, tumor site

other than the lip and mouth, neck dissection and bilateral neck dissection, reconstruction, trans-fusion, and ICU transfer. As the presence of comorbidity and number of comorbidities were highly colinear in the initial model, we decided to include the last one in the regression analysis, because it offers more information than the categorical variable. When a regression analysis including all the clinical relevant variables was conducted, the presence of more than 2 comorbidities adjusted by site, TNM clinical stage, sex, neck dissection, and measures of surgical procedure complexity as reconstruction, trans-fusion and ICU transfer, showed an independent effect.

The measures of predictive ability of the resulting model were acceptable (sensitivity of 84%). The index developed and assessed included significant variables and patient sex, because of its important weight in the prediction of the selected outcome and showed an acceptable ROC curve area that assesses discrimination capacity. Also, it is easy to calculate in a clinical setting and the cutoff points markedly differentiate the risk for complication. The index allows predicting the risk of complications of an old patient without making any preoperative exam and only using the proposed surgical treatment.

It is important to remind that retrospective studies are vulnerable to bias, and conclusions of this type of predictive scales must be validated in other geographical and temporal settings to prove its reliability. More studies are necessary to assess the predictive effect of geriatric measures of functional status adjusted by known prognostic variables, such as clinical stage and number of comorbidities. Even more, it is important to bear in mind that patients included in this study are those who were in satisfactory preoperative states and could not reflect outcomes of all head and neck cancer patients older than 70 years. However, it also shows that aged patients who are candidates for surgery have similar outcomes as younger patients. Another weakness of the study is related to the impossibility of capturing information concerning severity of comorbidities, although we used ASA classification as a proxy variable to compensate for this weakness. Comparison with a series of patients younger than 70 years could have offered a strong conclusion. However, we believe that this series shows that adequately selected older patients are good candidates for standard surgical procedures and they do not present dramatic differences in complica-

tions and mortality with younger patients, as is commonly proposed.

In conclusion, this study shows the importance of comorbidity as a predictive factor for postoperative complications in patients older than 70 years who underwent head and neck oncologic surgery and proposes a simple index to predict the occurrence of postoperative complications using simple clinical variables.

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