



化疗引起的周围神经病变患者生活质量 影响因素调查及预测模型构建*

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【摘要】 目的 探讨化疗引起的周围神经病变(chemotherapy-induced peripheral neuropathy, CIPN)患者生活质量的影响因素,并构建风险预测模型。**方法** 选取2022年1月-2024年12月我院收治的CIPN患者作为研究对象。依据癌症治疗功能评价系统量表(Functional Assessment of Cancer Therapy-General, FACT-G)得分的平均值,将262例患者分为生活质量良好组与不良组。比较两组临床资料,采用二元logistic回归分析生活质量的影响因素,并构建列线图预测模型。通过受试者工作特征(receiver operating characteristic, ROC)曲线、校准曲线、Hosmer-Lemeshow拟合优度检验及决策曲线评估模型预测效能。**结果** 262例患者FACT-G平均得分为(84.65±13.65)分,其中良好组135例,不良组127例。多因素分析显示,婚姻状况[比值比(odds ratio, OR)=2.317, 95%置信区间(confidence interval, CI): 1.037~5.176]、肾功能异常(OR=2.635, 95%CI: 1.197~5.801)、肿瘤TNM分期T2(OR=2.744, 95%CI: 1.095~6.878)、T3(OR=0.301, 95%CI: 0.110~0.828)、焦虑(OR=2.763, 95%CI: 1.260~6.060)、疼痛(OR=4.651, 95%CI: 1.998~10.828)、呕吐(OR=3.459, 95%CI: 1.567~7.637)、失眠(OR=5.215, 95%CI: 1.789~15.197)、嗜睡(OR=3.870, 95%CI: 1.387~10.795)是CIPN患者生活质量的独立影响因素($P<0.05$)。基于上述因素构建的列线图预测模型在建模组中ROC曲线下面积(area under the curve, AUC)为0.864(95%CI: 0.813~0.915),其ROC曲线最佳截断值对应的特异度为0.827(0.752~0.901)、灵敏度为0.741(0.648~0.834);在验证组中AUC为0.803(95%CI: 0.707~0.900),最佳截断值对应的特异度为0.703(0.555~0.850)、灵敏度为0.738(0.605~0.871),提示模型诊断效能良好。理想曲线与校准曲线拟合良好, Hosmer-Lemeshow检验示模型校准度良好。决策曲线显示模型在0.5~1.0范围内具有较高的净收益。**结论** 婚姻状况、肾功能异常、肿瘤TNM分期、焦虑、疼痛、呕吐、失眠、嗜睡是CIPN患者生活质量较差的独立影响因素;基于这些因素构建的预测模型具有良好的区分度与校准度,可用于临床评估CIPN患者的生活质量。

【关键词】 化疗 周围神经病变 生活质量 预测模型

Investigation of Factors Influencing the Quality of Life in Patients With Chemotherapy-Induced Peripheral Neuropathy and Construction of a Prediction Model

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The study was supported by the Jiangsu Provincial Social Development General Project (No. BE2019693).

【Abstract】 Objective To investigate the factors influencing quality of life in patients with chemotherapy-induced peripheral neuropathy (CIPN) and to construct a risk prediction model. **Methods** Patients with CIPN admitted to our hospital from January 2022 to December 2024 were selected. Based on the mean score of the Functional Assessment of Cancer Therapy-General (FACT-G) scale, 262 patients were divided into good quality of life group and poor quality of life group. Clinical data were compared between the two groups. Binary logistic regression was used to identify factors influencing quality of life, and a nomogram prediction model was constructed. The predictive performance of the model was evaluated using receiver operating characteristic (ROC) curve, calibration curve, Hosmer-Lemeshow goodness-of-fit test, and decision curve analysis. **Results** The 262 patients were divided into a good group (135 cases) and a poor group (127 cases) based on the mean FACT-G score of 84.65 ± 13.65 . Multivariate analysis showed that marital status (odds ratio [OR] = 2.317, 95% CI: 1.037-5.176), renal dysfunction (OR = 2.635, 95% CI: 1.197-5.801), tumor TNM stage T2 (OR =

* 江苏省社会发展面上项目(No. BE2019693)资助

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出版日期: 2026-05-20

2.744, 95% CI: 1.095-6.878), stage T3 (OR = 0.301, 95% CI: 0.110-0.828), anxiety (OR = 2.763, 95% CI: 1.260-6.060), pain (OR = 4.651, 95% CI: 1.998-10.828), vomiting (OR = 3.459, 95% CI: 1.567-7.637), insomnia (OR = 5.215, 95% CI: 1.789-15.197), and somnolence (OR = 3.870, 95% CI: 1.387-10.795) were independent influencing factors for quality of life in CIPN patients (all $P < 0.05$). The nomogram prediction model was established based on the above factors. In the training cohort, the AUC of the ROC curve was 0.864 (95% CI: 0.813-0.915). The specificity and sensitivity corresponding to the optimal cut-off value were 0.827 (95% CI: 0.752-0.901) and 0.741 (95% CI: 0.648-0.834), respectively. In the validation cohort, the AUC was 0.803 (95% CI: 0.707-0.900), with a specificity of 0.703 (95% CI: 0.555-0.850) and a sensitivity of 0.738 (95% CI: 0.605-0.871) at the optimal cut-off value, suggesting good diagnostic efficacy of the model. The ideal curve aligns well with the calibration curve, and the Hosmer-Lemeshow test indicates that the model is well calibrated. Decision curve analysis demonstrated a high net benefit of the model within the range of 0.5 to 1.0. **Conclusion** Marital status, renal dysfunction, tumor TNM staging, anxiety, pain, vomiting, insomnia, and somnolence are factors associated with a lower quality of life in patients with CIPN. The prediction model constructed based on these factors exhibits good discrimination and calibration, which can facilitate clinical assessment of quality of life in CIPN patients.

[Key words] Chemotherapy Peripheral neuropathy Quality of life Prediction model

癌症是严重危害人民群众生命健康的重大疾病,其治疗手段主要包括手术、放疗、化疗、靶向治疗及免疫治疗等,其中化疗仍是常用方法^[1]。研究显示,中国所有癌症的年龄标准化5年相对生存率稳步上升,2019-2021年期间已提高至43.7%^[2]。随着医疗技术的不断进步,癌症患者的总生存期逐渐延长,化疗所致周围神经病变(chemotherapy-induced peripheral neuropathy, CIPN)的发病率也随之上升。CIPN以四肢神经损伤或功能障碍为特征,可引起肢体远端感觉异常(如手足麻木、刺痛、触觉改变)及运动异常(如无力、步态不稳等),是与抗肿瘤药物相关的常见临床并发症^[3]。约50%~90%的恶性肿瘤患者在化疗后会发生CIPN,其中约30%~40%的患者进一步发展为慢性神经病变;多数患者仅能部分恢复,症状长期持续。该并发症不仅导致患者身体不适,还显著影响其长期生活质量和预后,给患者带来沉重的生活负担^[4-5]。本研究通过探究CIPN患者生活质量的预测因子并构建风险预测列线图模型,旨在为CIPN患者制定更个性化的治疗方案及护理计划,为提高化疗患者的生活质量和幸福感提供参考依据。

1 资料与方法

1.1 研究对象

本研究经连云港市第一人民医院医学伦理委员会批准(批准号: LW-20250605001-01)。回顾性选取2022年1月-2024年12月我院收治的262例CIPN患者作为研究对象,按7:3的比例分为建模组(183例)和验证组(79例)。纳入标准:①年龄 ≥ 18 岁;②符合美国国家癌症研究所常见不良事件评价标准(Common Terminology Criteria for Adverse Events, CTCAE) 5.0版^[6]中CIPN的诊断标准;③术后随访时间 ≥ 1 个月;④已告知患者本研究内容并取得知

情同意。排除标准:①合并瘫痪、肌无力等导致肢体运动功能障碍的疾病;②临床资料不完整。

1.2 方法

1.2.1 资料收集

通过医院电子病历系统收集患者的临床资料,包括:①一般信息:性别、年龄、体质量指数(body mass index, BMI)、婚姻状况、文化程度、癌症家族史、合并症(高血压、糖尿病、甲状腺功能异常、肝功能异常、肾功能异常);②病情资料:肿瘤TNM分期、远处转移情况、化疗周期、是否合并营养不良;心理状态(焦虑、抑郁);并发症(癌因性疲乏、疼痛、呕吐、失眠、嗜睡)。

1.2.2 诊断标准及工具

Piper疲乏修订量表(the revised Piper Fatigue Scale, PFS-R)^[7]是我国临床上常用的癌症相关性疲乏(cancer-related fatigue, CRF)多维度评估量表。该量表从行为、情感、感觉及认知4个维度进行评估,共22个条目,总分为0~220分,平均分值为总分除以22所得的数值,得分越高表示疲乏越重。

失眠严重程度指数(Insomnia Severity Index, ISI)^[8]是一种专门用于评估失眠严重程度的自评量表,包含7个条目,总分为0~28分,得分越高表示失眠越严重。

汉密尔顿焦虑量表(Hamilton Anxiety Scale, HAMA)^[9]在临床上常用于焦虑症的诊断及严重程度划分,包含14个条目,总分为0~56分,得分越高表示焦虑程度越严重。

汉密尔顿抑郁量表(Hamilton Depression Scale, HAMD)^[10]是临床上评定抑郁状态时应用最为普遍的量表。该量表包含24个条目,总分 < 8 分正常,8~20分可能有抑郁症,21~35分可确诊抑郁症, > 35 分严重抑郁症。

Epworth嗜睡量表(Epworth Sleepiness Scale, ESS)^[11]被用于评估个体在日常生活中不同场景下的嗜睡倾向。该

量表包含8个条目,总分0~24分,1~6分正常,7~8分一般嗜睡,9~24分异常嗜睡(可能是病理性的)。

1.2.3 癌症治疗功能评价系统量表

癌症治疗功能评价系统量表(Functional Assessment of Cancer Therapy-General, FACT-G)^[12]广泛应用于所有癌症患者的生命质量评估。该量表包含身体、社交、情感和功能健康4个维度共27个条目,总分0~108分,分数越高表示生活质量越好。研究显示中文版FACT-G在肿瘤患者生命质量评价中的适用性较高,量表Cronbach's α 系数为0.907。根据所有患者该量表得分的平均值将262例患者分为生活质量良好组与不良组。

1.3 统计学方法

采用SPSS 26.0处理及分析数据。采用Shapiro-Wilk检验计量数据正态性,符合正态分布以 $\bar{x} \pm s$ 表示,采用独立样本 t 检验;计数资料以例数(%)表示,采用卡方检验。根据容忍度及方差膨胀因子(variance inflation factor, VIF)判断自变量间的共线性,容忍度 <0.1 且 $VIF>5$ 则认为自变量间存在共线性。生活质量的影响因素分析采用二元logistic回归分析(双向逐步回归),根据回归分析结果构建风险预测列线图模型。采用受试者工作特征(receiver operating characteristic, ROC)曲线下面积(area under the curve, AUC)评价模型区分度;采用校准曲线和Hosmer-Lemeshow检验中 $P>0.05$ 提示模型校准度良好。采用决策曲线(decision curve analysis, DCA)评价模型的临床应用价值。检验水准设定为 $\alpha=0.05$,双侧检验;除文中特别说明外,以 $P<0.05$ 为差异具有统计学意义。

2 结果

2.1 CIPN患者的生活质量分析

在262例患者中,FACT-G的平均分为(84.65 $\pm$ 13.65)分,最低分为60分,最高分为107分;其中FACT-G $\geq$ 84.65分有135例,纳入良好组,FACT-G $<$ 84.65分有127例,纳入不良组。

2.2 建模组患者临床资料比较

建模组患者生活质量良好组和不良组在性别、年龄、BMI、婚姻状况、文化程度、癌症家族史、高血压、糖尿病、甲状腺功能异常、肝功能异常、远处转移、化疗周期、营养不良、癌因性疲乏方面差异无统计学意义($P>0.05$),在肾功能异常、肿瘤TNM分期、焦虑、抑郁、疼痛、呕吐、失眠、嗜睡方面差异具有统计学意义($P<0.05$),见表1。

2.3 CIPN患者生活质量的多因素logistic分析

将上述单因素分析具有统计学意义的变量进行共线

性分析,结果显示各变量容差在0.551~0.963之间,VIF在1.038~1.815之间,各变量之间不存在共线性。将上述所有变量作自变量,生活质量(良好=0,不好=1)作为因变量,进行多因素logistic分析(双向逐步法)。结果表明,婚姻状况[比值比(odds ratio, OR)=2.317]、肾功能异常(OR=2.635)、肿瘤TNM分期T2(OR=2.744)、T3(OR=0.301)、焦虑(OR=2.763)、疼痛(OR=4.651)、呕吐(OR=3.459)、失眠(OR=5.215)、嗜睡(OR=3.870)是CIPN患者生活质量的独立影响因素($P<0.05$),见表2。

2.4 CIPN患者生活质量的风险预测列线图模型构建

在多因素logistic回归分析结果的基础上,进一步构建CIPN患者生活质量的风险预测列线图模型,对各风险因素赋值,见图1。

2.5 对CIPN患者生活质量的诊断价值

列线图预测模型建模组AUC为0.864(0.813~0.915),其ROC曲线最佳截断值对应的特异度为0.827(0.752~0.901)、灵敏度为0.741(0.648~0.834),验证组AUC为0.803(0.707~0.900),最佳截断值对应的特异度为0.703(0.555~0.850)、灵敏度为0.738(0.605~0.871),模型诊断效能良好,见图2。校准曲线显示建模组与验证组的校准曲线均贴近理想45°线,直观提示拟合良好,见图3。Hosmer-Lemeshow检验显示建模组 $\chi^2=5.7033$,验证组 $\chi^2=4.7684$, $df=8$, P 均 >0.05 ,模型校准度良好。决策曲线显示:建模组(图4A)与验证组(图4B)的模型曲线,在阈值概率0.5~1.0区间内均高于“全部干预”与“无干预”参考线,具有较高的净收益。

3 讨论

与CIPN密切相关的药物包括紫杉烷类(如紫杉醇)、铂类(如顺铂、卡铂)、长春花生物碱(如长春新碱)、蛋白酶体抑制剂(如硼替佐米)和免疫调节剂(如沙利度胺)^[13]。其中紫杉烷类诱导的CIPN是最常见的非血液学不良事件^[14]。CIPN多呈剂量依赖型特征,目前可用且有效的临床治疗策略非常有限,通常通过减少或停用诱发神经不良反应的化疗药物以缓解患者的症状,但部分患者在停止药物治疗后CIPN症状仍会加重或出现新的变化,这可能与化疗药物对周围神经的长期毒性作用以及个体神经修复能力的差异有关^[15]。

CIPN是生活质量的负向预测因子,CIPN症状越严重,患者生活质量水平越低,癌症患者生活质量与预后死亡风险密切相关,生活质量良好者死亡风险较低^[16-17]。因此生活质量已成为医护人员评估癌症患者预后的理想指标。本研究262例患者FACT-G的平均分为(84.65 $\pm$ 13.65)

表 1 CIPN患者生活质量的单因素分析
Table 1 Univariate analysis of quality of life in CIPN patients

Characteristic	Total (n = 183)	Poor quality of life group (n = 85)	Good quality of life group (n= 98)	t/χ^2	P
Sex/case (%)				0.656	0.418
Female	91 (49.73)	45 (52.94)	46 (46.94)		
Male	92 (50.27)	40 (47.06)	52 (53.06)		
Age/yr.	49.61 ± 14.53	48.39 ± 15.14	50.67 ± 13.97	-1.062	0.290
Body mass index/case (%)				0.452	0.501
< 25 kg/m ²	91 (49.73)	40 (47.06)	51 (52.04)		
≥ 25 kg/m ²	92 (50.27)	45 (52.94)	47 (47.96)		
Marital status/case (%)				1.954	0.162
Married	109 (59.56)	46 (54.12)	63 (64.29)		
Unmarried or other	74 (40.44)	39 (45.88)	35 (35.71)		
Level of education/case (%)				2.931	0.231
Junior high school and below	46 (25.14)	19 (22.35)	27 (27.55)		
High school or technical college	91 (49.73)	48 (56.47)	43 (43.88)		
College degree or above	46 (25.14)	18 (21.18)	28 (28.57)		
Family history of cancer/case (%)				0.386	0.535
No	136 (74.32)	65 (76.47)	71 (72.45)		
Yes	47 (25.68)	20 (23.53)	27 (27.55)		
Comorbidity/case (%)					
Hypertension	81 (44.26)	33 (38.82)	48 (48.98)	1.903	0.168
Diabetes	142 (77.60)	66 (77.65)	76 (77.55)	0.000	0.988
Thyroid dysfunction	85 (46.45)	45 (52.94)	40 (40.82)	2.690	0.101
Liver dysfunction	87 (47.54)	43 (50.59)	44 (44.90)	0.591	0.442
Renal dysfunction	86 (46.99)	48 (56.47)	38 (38.78)	5.722	0.017
TNM staging of tumors/case (%)				17.415	< 0.001
T1	67 (36.61)	33 (38.82)	34 (34.69)		
T2	67 (36.61)	41 (48.24)	26 (26.53)		
T3	49 (26.78)	11 (12.94)	38 (38.78)		
Distant metastasis/case (%)				2.368	0.124
No	139 (75.96)	69 (81.18)	70 (71.43)		
Yes	44 (24.04)	16 (18.82)	28 (28.57)		
Chemotherapeutic cycle/cycle, $\bar{x} \pm s$	3.46 ± 1.05	3.54 ± 1.04	3.39 ± 1.05	0.989	0.324
Malnutrition/case (%)				0.623	0.430
No	94 (51.37)	41 (48.24)	53 (54.08)		
Yes	89 (48.63)	44 (51.76)	45 (45.92)		
Anxiety/case (%)				6.597	0.01
No	94 (51.37)	35 (41.18)	59 (60.20)		
Yes	89 (48.63)	50 (58.82)	39 (39.80)		
Depression/case (%)				9.812	0.002
No	74 (40.44)	24 (28.24)	50 (51.02)		
Yes	109 (59.56)	61 (71.76)	48 (48.98)		
Cancer-related fatigue/case (%)				2.578	0.108
No	87 (47.54)	35 (41.18)	52 (53.06)		
Yes	96 (52.46)	50 (58.82)	46 (46.94)		
Pain/case (%)				23.183	< 0.001
No	73 (39.89)	18 (21.18)	55 (56.12)		
Yes	110 (60.11)	67 (78.82)	43 (43.88)		
Vomit/case (%)				23.661	< 0.001
No	78 (42.62)	20 (23.53)	58 (59.18)		
Yes	105 (57.38)	65 (76.47)	40 (40.82)		
Insomnia/case (%)				5.297	0.021
No	54 (29.51)	18 (21.18)	36 (36.73)		
Yes	129 (70.49)	67 (78.82)	62 (63.27)		
Drowsiness/case (%)				8.788	0.003
No	75 (40.98)	25 (29.41)	50 (51.02)		
Yes	108 (59.02)	60 (70.59)	48 (48.98)		

分,与一项针对宫颈癌前病变患者的研究中FACT-G的平均分89.50分相似^[18]。最低分60分和最高分107分显示患者之间的生活质量存在较大的差异,这可能是患者的病情、治疗阶段、个人应对能力等多种因素导致的,对于得分较低的患者可以加强心理干预、提供疼痛管理或康复

指导等。

未婚状态成为CIPN患者生活质量的独立影响因素,可能是由社交支持不足、经济压力较大、心理状态欠佳、生活方式与健康管理差异以及应对疾病策略不同等多方面因素共同作用导致的,未婚患者可能在这些方面相对

表 2 CIPN患者生活质量的多因素logistic分析

Table 2 Multivariate logistic analysis of quality of life in CIPN patients

Characteristic	B	SE	Wald χ^2	P	OR	95% CI
Marital status (With married as a reference)	0.840	0.410	4.198	0.040	2.317	1.037-5.176
Renal dysfunction	0.969	0.403	5.794	0.016	2.635	1.197-5.801
TNM staging of tumors (With T1 as a reference)						
T2	1.009	0.469	4.635	0.031	2.744	1.095-6.878
T3	-1.199	0.515	5.415	0.020	0.301	0.110-0.828
Anxiety	1.016	0.401	6.431	0.011	2.763	1.260-6.060
Pain	1.537	0.431	12.709	< 0.001	4.651	1.998-10.828
Vomit	1.241	0.404	9.431	0.002	3.459	1.567-7.637
Insomnia	1.652	0.546	9.157	0.002	5.215	1.789-15.197
Drowsiness	1.353	0.523	6.687	0.010	3.870	1.387-10.795
Intercept	-5.141	0.910	31.911	< 0.001		

B: partial regression coefficient; SE: standard error; OR: odds ratio.

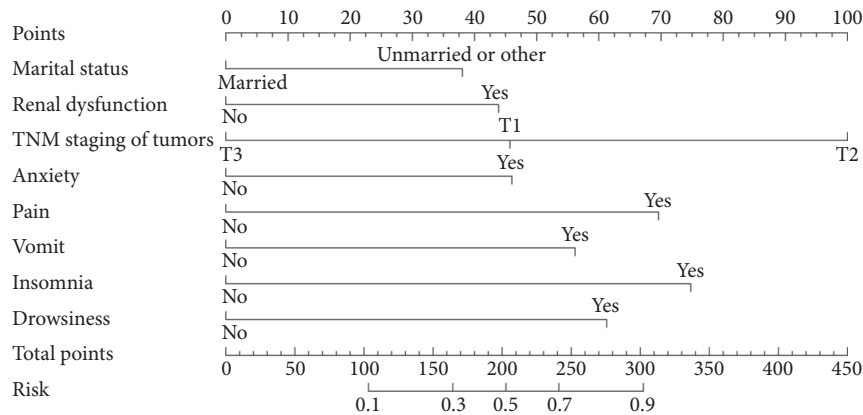


图 1 CIPN患者生活质量的预测列线图模型

Fig 1 Nomogram model for predicting the quality of life in patients with CIPN

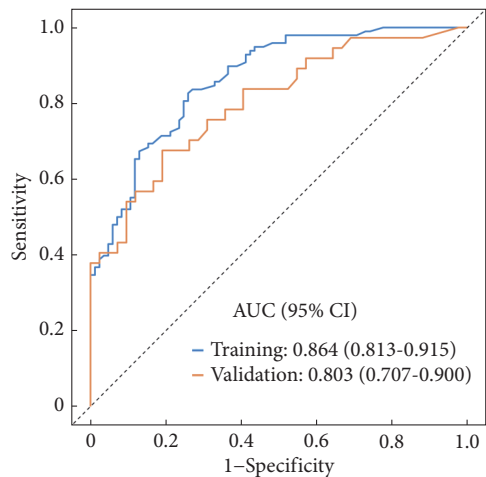


图 2 ROC曲线分析模型对CIPN患者生活质量的诊断价值

Fig 2 Diagnostic value of the ROC curve analysis model for the quality of life in patients with CIPN

劣势。肾功能异常与CIPN相互作用,对患者生活质量产生多方面复杂影响。许多用于治疗恶性肿瘤的化疗药物都要经过肾脏清除,同时化疗引起的恶心呕吐及伴随的液体和电解质流失会导致肾功能受损或体重减轻^[19-20]。肾功能异常患者常伴电解质紊乱,而钙、镁等电解质紊乱

会进一步干扰神经的正常生理功能,使患者感觉异常和运动障碍加剧,降低生活自理能力,影响生活质量。肿瘤TNM分期是化疗引起周围神经病变患者生活质量的独立影响因素。癌症晚期可能导致患者对自己身体状态不自信和对未来不确定,这类患者的生理和心理状态容易受到负面影响,难以适应疾病相关因素带来的身心压力,导致其无法积极应对疾病恢复,对治疗缺乏信心^[21]。化疗药物通过多种机制导致神经毒性,可通过抑制细胞代谢、细胞分裂和血管生成造成毛细血管损伤、神经炎症、肿胀和纤维化等,导致周围神经受压^[22];同时大多数化疗药物以活跃分裂的细胞为目标,以破坏快速增殖的癌细胞,因此在发挥抗癌作用时缺乏靶向性,会在快速分裂癌细胞的同时对正常细胞造成无差别损伤,如消化道上皮细胞、骨髓细胞和毛囊,进而引发一系列难以避免的副作用,如恶心、呕吐、骨髓抑制、脱发以及肝肾功能损害等^[23-24]。如铂类药物损伤的主要解剖结构是背根神经节,表现为感觉神经病变,伴由于周围神经过度兴奋或神经肌强直引起的异常性疼痛和肌肉痉挛^[25]。疼痛、呕吐、失眠、嗜睡均属于化疗并发症,伴随上述症状会显著影响CIPN患者生活质量水平。其中疼痛是导致CIPN患者生

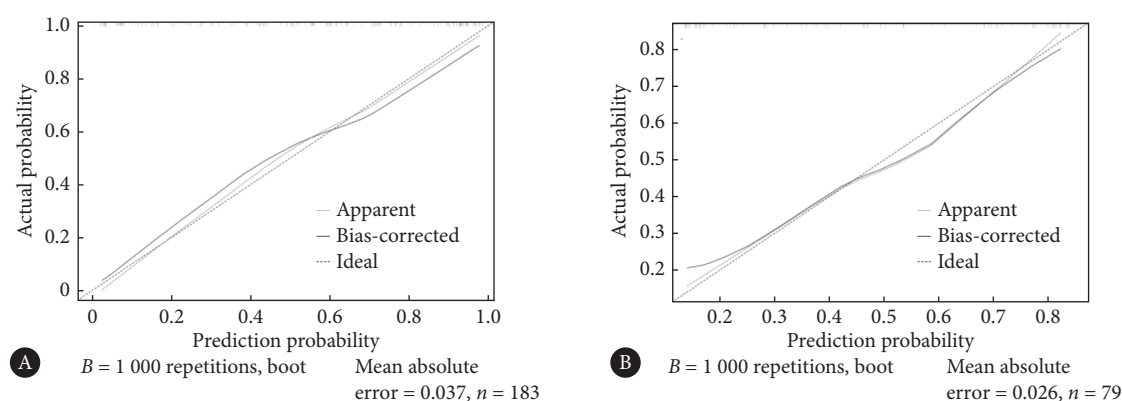


图3 CIPN患者生活质量预测模型的校准曲线

Fig 3 Calibration curves of the quality-of-life prediction model for patients with CIPN

A, Training cohort; B, validation cohort.

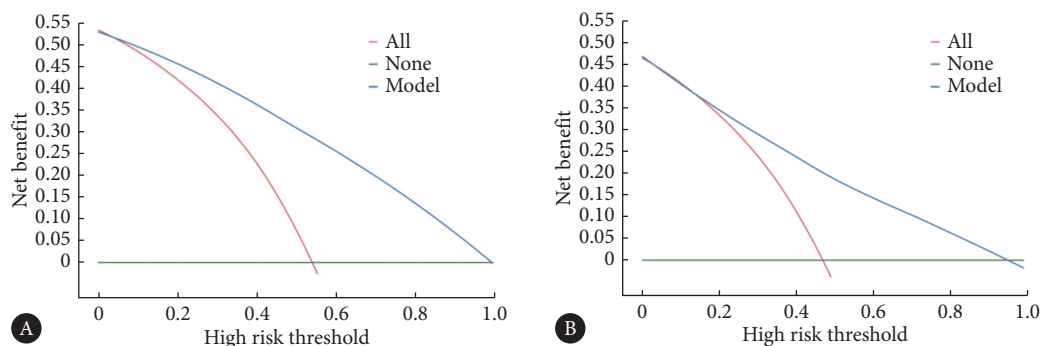


图4 CIPN患者生活质量预测模型的DCA曲线

Fig 4 Decision curve analysis (DCA) curves of the quality-of-life prediction model for patients with CIPN

A, Training cohort; B, validation cohort

生活质量恶化的主要原因,主要由炎症、神经性和癌症特异性机制驱动需行药物治疗^[26]。情绪能力在癌症幸存者的生活质量和健康管理中起着重要作用。但由于化疗后毒副反应较多且持续时间较长难以缓解,这种身体上的症状又会引起不同程度的精神压力,患者很可能出现焦虑、抑郁、恐慌、悲伤等情绪问题,进一步对患者的身体机能、生活质量和治疗依从性产生负面影响^[27-28]。上述结果提示癌症患者化疗后存在较多与生活质量相关的症状,这会降低患者治疗依从性,影响患者的康复情况和生活质量,基于早期肿瘤疼痛管理和良好的心理干预可减轻痛苦并改善患者生活质量,医护人员可紧密结合患者出院后的症状群特征为癌症患者制定延续护理方案。

综上所述,婚姻状况、肾功能异常、肿瘤TNM分期、焦虑情绪和疼痛、呕吐、失眠、嗜睡是CIPN患者生活质量的独立影响因素。基于此构建的CIPN患者生活质量风险预测列线图模型具有良好的区分度、校准度及临床应用价值。这一结果提示,通过有效评估肿瘤分期、减轻患者焦虑抑郁情绪,缓解CIPN症状,有望提升癌症患者的生活质量水平。但本研究为单中心、小样本研究,存在

一定局限性,今后将进一步纳入更多样本,深入探究生活质量的影响因子,并根据患者的具体情况制定个体化的治疗方案,以最大程度减轻CIPN症状对患者生活质量的负面影响。

* * *

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Author Contribution HONG Hui is responsible for conceptualization, data curation, formal analysis, investigation, methodology, project administration, resources, and writing--original draft. MO Lijun is responsible for conceptualization, data curation, formal analysis, investigation, and methodology. SUN Yongmei is responsible for conceptualization, data curation, formal analysis, investigation, methodology, project administration, supervision, and writing--review and editing. WU Fenglei is responsible for data curation, writing--original draft, and writing--review and editing. All authors consented to the submission of

the article to the Journal. All authors approved the final version to be published and agreed to take responsibility for all aspects of the work.

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Declaration of Conflicting Interests All authors declare no competing interests.

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(2025-05-07收稿, 2025-08-18修回)

编辑 刘 华



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