

三种结直肠癌筛查评分模型在徐州市人群中诊断效果的验证与比较

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摘要:[目的]验证和比较亚太结直肠癌筛查(Asia-Pacific colorectal screening,APCS)评分、APCS评分修订版、结直肠肿瘤(colorectal neoplasm,CN)预测评分作为初筛手段在徐州市50~74岁无症状社区人群中结直肠癌筛查中的效果。[方法]选择2017—2020年在徐州市参与结直肠癌筛查的50~74岁无症状社区居民作为研究对象,使用资格审核表评价研究对象的入选资格,所有符合条件的受试对象均签署知情同意书。使用APCS评分、APCS评分修订版、CN预测评分对符合条件的受试对象进行风险评分,分别记录评分结果和病变检出情况。比较各模型对进展期肿瘤(advanced neoplasm,AN)的诊断表现。[结果]共纳入符合条件受试对象1328人,其中男性570人(42.92%),平均年龄(59.63±6.18)岁。人群中中共检出AN46例,检出率为3.46%。APCS评分、APCS评分修订版、CN预测评分评估高风险率分别为46.54%(618/1328)、57.68%(766/1328)、43.83%(582/1328),APCS评分修订版高风险率高于APCS评分($\chi^2=33.05$, $P<0.001$)和CN预测评分($\chi^2=51.00$, $P<0.001$)。各模型评估高风险组中AN的检出率分别为4.21%(26/618)、4.70%(36/766)、4.81%(28/582),检出率间差异无统计学意义($\chi^2=0.29$, $P=0.864$)。除APCS评分外,APCS评分修订版和CN预测评分高风险组的AN检出率均高于非高风险组(APCS评分修订版: $\chi^2=8.27$, $P=0.004$;CN预测评分: $\chi^2=5.62$, $P=0.018$),但与人群AN总检出率(3.46%)间差异均无统计学意义(APCS评分: $\chi^2=0.65$, $P=0.419$;APCS评分修订版: $\chi^2=1.97$, $P=0.160$;CN预测评分: $\chi^2=1.97$, $P=0.160$)。各模型对AN诊断的灵敏度分别为56.52%(95%CI:41.10%~71.07%)、78.26%(95%CI:63.64%~89.05%)、60.87%(95%CI:45.37%~74.91%),各模型间差异无统计学意义($\chi^2=5.37$, $P=0.068$);特异度分别为53.82%(95%CI:51.05%~56.58%)、43.06%(95%CI:40.33%~45.82%)、56.79%(95%CI:54.02%~59.52%),APCS评分高于APCS评分修订版($\chi^2=29.74$, $P<0.001$),但与CN预测评分差异无统计学意义($\chi^2=2.28$, $P=0.131$),CN预测评分高于APCS评分修订版($\chi^2=48.32$, $P<0.001$);AUC分别为0.55(95%CI:0.48~0.63)、0.61(95%CI:0.54~0.67)、0.59(95%CI:0.52~0.66),各模型间差异无统计学意义($\chi^2=3.07$, $P=0.215$)。各评分模型评估高风险人群中每检出1例AN需要筛查和进行结肠镜检查的数量分别为24、21、21,均少于不进行初筛的结肠镜资源负载(29)。[结论]在徐州市50~74岁社区人群中使用APCS评分、APCS评分修订版、CN预测评分作为初筛手段的预测效果有待提升,但相比不进行初筛可以减少每检出1例AN所需的资源负载。若要使用风险评分模型作为初筛在徐州市进行大规模人群筛查,还需根据本地人群特征建立合适的风险评估模型。

关键词:结直肠肿瘤;筛查;评分模型;结肠镜;江苏

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Comparison of Three Risk Assessment Models for Colorectal Cancer Screening in Xuzhou

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Abstract: [Purpose] To compare the efficacy of the Asia-Pacific Colorectal Screening(APCS) score, the modified APCS score, and the Colorectal neoplasm(CN) prediction score in colorectal cancer screening. [Methods] Asymptomatic community residents aged 50~74 who participated in colorectal cancer screening in Xuzhou from 2017 to 2020 were enrolled in the study. The APCS score, the modified APCS score and CN prediction score were used to assess the risk of colorectal cancer in eligible subjects. The detection rate of advanced neoplasm(AN) was compared among

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high risk subjects identified by three different assessment models. [Results] A total of 1 328 eligible subjects were included in the study, including 570 males (42.92%) with an average age of 59.63 (SD=6.18) years. There were 46 cases of AN were detected with the detection rate of 3.46%. The high risk rates of the APCS score, the modified APCS score, and the CN predictive score were 46.54%(618/1 328), 57.68%(766/1 328), and 43.83%(582/1 328), respectively. The high-risk rate of the modified APCS score was higher than that of APCS score ($\chi^2=33.05$, $P<0.001$) and CN prediction score ($\chi^2=51.00$, $P<0.001$). The detection rates of AN in high-risk population were 4.21%(26/618), 4.70%(36/766) and 4.81%(28/582), respectively($\chi^2=0.29$, $P=0.864$). Except for the APCS score, the detection rate of AN in the high-risk group was higher than that in the non-high-risk group (the modified APCS score: $\chi^2=8.27$, $P=0.004$; the CN prediction score: $\chi^2=5.62$, $P=0.018$), but there was no significant difference with the total detection rate of AN in the population (3.46%)(the APCS score: $\chi^2=0.65$, $P=0.419$; the modified APCS score: $\chi^2=1.97$, $P=0.160$; the CN prediction score: $\chi^2=1.97$, $P=0.160$). The sensitivity of each model in the detection of AN was 56.52% (95% CI: 41.10%~71.07%), 78.26% (95% CI: 63.64%~89.05%) and 60.87% (95% CI: 45.37%~74.91%), respectively ($\chi^2=5.37$, $P=0.068$). The specificity was 53.82% (95%CI: 51.05%~56.58%), 43.06% (95%CI: 40.33%~45.82%) and 56.79% (95%CI: 54.02%~59.52%), respectively. The specificity of APCS score was higher than that of the modified APCS score ($\chi^2=29.74$, $P<0.001$); however, it had no significant difference from the CN prediction score($\chi^2=2.28$, $P=0.131$), and the specificity of CN prediction score was higher than that of the modified APCS score ($\chi^2=48.32$, $P<0.001$). The areas under the ROC curve(AUC) of three models were 0.55(95%CI: 0.48~0.63), 0.61(95%CI: 0.54~0.67) and 0.59(95%CI: 0.52~0.66), respectively($\chi^2=3.07$, $P=0.215$). For detecting every one case of AN, the number of high risk subjects requiring further screening and colonoscopy identified by three models was 24, 21 and 21, respectively, while the number of colonoscopy resource load without primary screening was 29. [Conclusion] Using the APCS score, the modified APCS score and the CN predictive score as preliminary screening means can reduce the colonoscopy resource load required for detection of every one AN case; however, it is necessary to establish a suitable risk assessment model according to the characteristics of the local population to further improve the prediction effect in colorectal cancer screening.

Key words: colorectal cancer; screening; scoring model; colonoscopy; Jiangsu

结直肠癌(colorectal cancer,CRC)是位列我国肿瘤发病率和死亡率第5位的恶性肿瘤^[1],近年来其发病率和死亡率不断升高,严重危害人民健康。大多数CRC被认为是通过“腺瘤-癌”途径发生于进展期腺瘤,这一过程通常持续5~10年的时间^[2-3]。因此通过筛查发现早期病变并实施干预可以有效改善CRC的发病和生存状况^[4-6]。结肠镜检查是CRC筛查的金标准,也是欧洲及北美地区最为经济有效的CRC筛查方法^[7-8]。但我国的结肠镜资源相对有限,且因其前期准备程序较繁琐、检查时伴有不适感等原因,人群依从性普遍较差^[9-10]。

人群中的CRC发病风险是不均衡的,且因性别、年龄、BMI、吸烟、饮食等因素的不同而有所差异,基于相关危险因素构建风险评估模型对人群进行风险评估,并依据风险等级给予对应的筛查策略已经成为中国CRC筛查专家共识之一^[11]。但从人群转化应用角度来看,目前国际上仍缺乏对CRC风险

评估模型的大样本前瞻性研究证据,因此最新版中国人群CRC筛查与早诊早治指南暂未对风险评估模型进行推荐^[12]。本研究拟使用2017—2020年徐州市50~74岁社区人群结直肠癌筛查结果对中国CRC筛查专家共识(2019)^[11]中推荐的亚太结直肠癌筛查(Asia-Pacific colorectal screening,APCS)评分^[13]及其修订版^[14]、结直肠肿瘤(colorectal neoplasm,CN)预测评分^[15]在徐州市50~74岁社区人群中的有效性进行验证,并对各模型的诊断效果进行比较,为徐州地区大规模人群CRC筛查方案的制定提供依据。

1 资料与方法

1.1 研究对象

本研究的研究对象为2017—2020年在徐州市参与国家重大公共卫生服务项目(城市癌症早诊早治)结直肠癌筛查的50~74岁无症状社区居民。在

结直肠癌筛查的具体实施上，该项目采用整群抽样的方法在徐州市鼓楼区、云龙区、泉山区对40~74岁常住户籍居民开展流行病学问卷调查，并使用基于“哈佛癌症风险指数”为理论基础，依据我国常见癌症流行病学资料，通过多学科专家小组讨论的个体癌症风险综合评价体系对人群进行患癌风险评估^[16]。对于评估有结直肠癌高风险的人群，项目推荐其在指定医院(徐州市肿瘤医院)进行免费结肠镜检查。所有结肠镜检查均由高年资内镜医师按照项目标准进行，所有检查图像都进行了保存。结肠镜检查中的所有异常发现都进行了病理检查。

本研究使用资格审核表按照以下标准在国家重大公共卫生服务项目(城市癌症早诊早治)结直肠筛查参与者中选择符合条件的受试对象：①签署知情同意书；②完成流行病学问卷调查；③实足年龄50~74周岁；④在项目指定医院(徐州市肿瘤医院)完成免费结肠镜检查。此外，有以下情况的受试对象将被排除：①在参与项目筛查前的5年内进行过结肠镜检查；②有结直肠癌、结直肠腺瘤或结直肠息肉病史；③在参与项目筛查前进行过结直肠癌相关治疗或进行过结直肠切除术。所有符合条件的受试对象均签署知情同意书。本研究经徐州市肿瘤医院伦理委员会审批(编号：2018-02-23-H01)。

Table 1 Screening score for colorectal cancer in asymptomatic populations

Factor	APCS score		Modified APCS score		CN prediction score	
	Criterion	Score	Criterion	Score	Criterion	Score
Sex	Male	1	Male	1	Male	1
	Female	0	Female	0	Female	0
Age(years old)	<50	0	50~54	0	50~55	0
	50~69	2	55~64	1	56~70	1
	≥70	3	65~70	2		
Smoking	Current or past	1	Current or past	1	Current or past	1
	Never	0	Never	0	Never	0
BMI(kg/m ²)	-		<23	0	<25	0
	-		≥23	1	≥25	1
Family history of CRC in a first-degree relative	Yes	2	Yes	1	Yes	1
	No	0	No	0	No	0
Diabetes	-		-		Yes	1
	-		-		No	0
Risk forecasting	0~1	AR 0		AR 0~2	AR	
	2~3	MR 1~2		MR 3~6	HR	
	4~7	HR 3~6		HR		

Notes: AR:average risk; MR:moderate risk; HR:high risk

1.2 风险评分

收集符合条件受试对象的流行病学问卷调查信息及结肠镜检查、指示性病理检查结果，使用中国结直肠癌筛查专家共识^[11]推荐的APCS评分^[13]、APCS评分修订版^[14]、CN预测评分^[15]对符合条件的受试对象进行风险评分(Table 1)，分别记录评分结果。

1.3 统计学分析

各模型对进展期肿瘤(advanced neoplasm, AN)的预测情况是本研究最重要的指标。AN包括CRC和进展期腺瘤(advanced adenoma)。进展期腺瘤的定义为：①腺瘤直径≥10 mm；②绒毛状(含有绒毛状成分)腺瘤绒毛状成分≥25%；③高级别上皮内肿瘤。使用相对危险度(relative risk, RR)、灵敏度、特异度、阳性预测值、阴性预测值、受试者工作特征曲线下面积(area under the receiver operating characteristics curve, AUC)等指标对不同模型的预测效果进行评价，使用结肠镜资源负载对每检出1例结直肠病变需要筛查和进行结肠镜的数量进行评价。数据分析采用Stata 16软件，组间比较采用 χ^2 检验，所有的检验都是双侧的，检验水准 $\alpha=0.05$ 。组间多重比较(multiple comparison)使用Bonferroni校正调整检验水准。

2 结 果

2.1 人群基本特征

本研究共纳入符合条件受试对象1328人，其中男性570人(42.92%)，平均年龄(59.63±6.18)岁。吸烟者和规律饮酒者分别占38.86%和38.70%，有74.55%的人BMI≥23 kg/m²。另有256人(19.28%)被报告有一级亲属结直肠癌家族史，170人(12.80%)被报告有糖尿病史(Table 2)。人群中中共检出CN 244例，检出率为18.37%；检出AN 46例，检出率为3.46%；检出CRC 2例，检出率为0.15%(Figure 1)。

2.2 模型评估结果及各组病变检出情况

APCS 评分、APCS 评分修订版、CN 预测评分在人群中评估高风险率分别为 46.54%(618/1 328)、57.68%(766/1 328)、43.83%(582/1 328)，各模型间高风险率有差异($\chi^2=57.29, P<0.001$)。APCS 评分修订版高风险率高于 APCS 评分 ($\chi^2=33.05, P<0.001$) 和 CN 预测评分 ($\chi^2=51.00, P<0.001$)，APCS 评分和 CN 预测评分高风险率之间差异无统计学意义 ($\chi^2=1.97, P=0.160$)。

各模型评估高风险组中 CN 的检出率分别为 20.71% (128/618)、21.67% (166/766)、20.96% (122/582)，检出率间差异无统计学意义 ($\chi^2=0.21, P=0.901$)，且均高于非高风险组 (Table 3)。但与人群 CN 总检出率(18.37%)间差异均无统计学意义(APCS 评分 : $\chi^2=1.49, P=0.222$;APCS 评分修订版 : $\chi^2=3.35, P=0.067$;CN 预测评分 : $\chi^2=1.75, P=0.186$)。

各模型评估高风险组中 AN 的检出率分别为 4.21% (26/618)、4.70% (36/766)、4.81% (28/582)，检出率间差异无统计学意义 ($\chi^2=0.29, P=0.864$)。除 APCS 评分外，APCS 评分修订版和 CN 预测评分高风险组的 AN 检出率均高于非高风险组(Table 3)，但与人群 AN 总检出率 (3.46%) 间差异均无统计学意义 (APCS 评分 : $\chi^2=0.65, P=0.419$;APCS 评分修订版 : $\chi^2=1.97, P=0.160$;CN 预测评分 : $\chi^2=1.97, P=0.160$)。

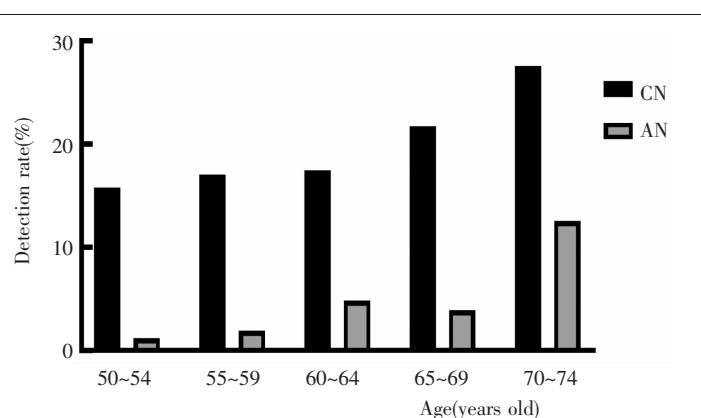
2.3 各评分模型对进展期肿瘤的诊断表现

APCS 评分、APCS 评分修订版、CN 预测评分在本研究中纳入的无症状社区人群中对 AN 诊断的灵敏度分别为 56.52%(95%CI:

41.10%~71.07%)、78.26%(95%CI:63.64%~89.05%)、60.87%(95%CI:45.37%~74.91%)，各模型间差异无统计学意义 ($\chi^2=5.37, P=0.068$)；特异度分别为 53.82% (95%CI:51.05%~56.58%)、43.06% (95%CI:40.33%~

Table 2 Characteristics of colonoscopy screening population in Xuzhou from 2017 to 2020(N=1328)

Factor	N(%)	Factor	N(%)
Gender		Drinking	
Male	570(42.92)	Current or past	514(38.70)
Female	758(57.08)	Never	814(61.30)
Age(years old)		BMI(kg/m ²)	
50~54	342(25.75)	<23	338(25.45)
55~59	316(23.80)	≥23	990(74.55)
60~64	332(25.00)	Family history of CRC in a first-degree relative	
65~69	258(19.43)	Yes	256(19.28)
70~74	80(6.02)	No	1072(80.72)
Smoking		Diabetes	
Current or past	516(38.86)	Yes	170(12.80)
Never	812(61.14)	No	1158(87.20)



CN:colorectal neoplasm;AN:advanced neoplasm

Figure 1 Detection of lesions in different age groups participating in colonoscopy screening in Xuzhou from 2017 to 2020

Table 3 Model prediction results and detection of lesions in each group

Score	Colorectal neoplasm				Advanced colorectal neoplasm			
	N(%)	χ^2	P	RR(95%CI)	N(%)	χ^2	P	RR(95%CI)
APCS Score								
Non-high risk(n=710)	116(16.34)				1	20(2.82)		1
High risk(n=618)	128(20.71)	4.21	0.040	1.27(1.01~1.59)	26(4.21)	1.91	0.167	1.49(0.84~2.65)
Modified APCS score								
Non-high risk(n=562)	78(13.88)				1	10(1.78)		1
High risk(n=766)	166(21.67)	13.12	<0.001	1.56(1.22~2.00)	36(4.70)	8.27	0.004	2.64(1.32~5.28)
CN prediction score								
Non-high risk(n=746)	122(16.35)				1	18(2.41)		1
High risk(n=582)	122(20.96)	4.63	0.031	1.28(1.02~1.61)	28(4.81)	5.62	0.018	1.99(1.11~3.57)

Notes : RR: relative risk; 95%CI: 95% confidence interval

45.82%)、56.79%(95%CI:54.02%~59.52%),APCS 评分高于 APGS 评分修订版($\chi^2=29.74, P<0.001$),但与 CN 预测评分差异无统计学意义 ($\chi^2=2.28, P=0.131$),CN 预测评分高于 APGS 评分修订版 ($\chi^2=48.32, P<0.001$);AUC 分别为 0.55 (95% CI:0.48~0.63)、0.61 (95% CI:0.54~0.67)、0.59(95% CI:0.52~0.66),各模型间差异无统计学意义($\chi^2=3.07, P=0.215$)(Table 4)。

2.4 各评分模型结肠镜资源负载

使用 APGS 评分、APGS 评分修订版、CN 预测评分作为初筛,在评估出的高风险人群中每检出 1 例 CN 需要筛查和进行结肠镜检查的数量均为 5,与不进行初筛的结肠镜资源负载(5)相同。各评分模型评估出的高风险人群中每检出 1 例 AN 需要筛查和进行结肠镜检查的数量分别为 24、21、21,均少于不进行初筛的结肠镜资源负载(29)(Table 5)。

3 讨 论

本研究是 APGS 评分、APGS 评分修订版、CN 预测评分在徐州市无症状社区人群中诊断效果的首次验证。研究结果显示除 APGS 评分外,APGS 评分修订版和 CN 预测评分评估高风险人群的 AN 检出率高于非高风险人群,但与 AN 总检出率之间差异均无统计学意义。在诊断表现方面,各模型 AUC、灵敏度之间差异无统计学意义,预测效果均有待提升。在资源负载方面,使用各风险评分模型作为初筛每检出 1 例 AN 需要筛查和进行结肠镜检查的数量均少

于不进行初筛。

APGS 评分^[13]是亚太工作组基于亚洲地区 11 个城市共 17 个中心招募的无症状受试者结肠镜诊断结果开发的针对 AN 的评分模型。亚太结直肠癌筛查共识建议^[17]中对 APGS 模型进行了推荐,认为其在亚洲或其他结肠镜资源相对有限地区的结直肠筛查工作中可以帮助识别高危个体并优先完成筛查。越南^[18]、北京^[19]、宁夏^[20]的相关研究也验证了此结论。但由于 APGS 评分只包含性别、年龄、家族史和吸烟,未纳入肥胖、糖尿病及其他可能相关的危险因素,在推广时可能需要进一步改进^[17]。APGS 评分修订版^[14]即是在 APGS 评分的基础上使用 50~70 岁中国人群数据对模型进行修订,增加 BMI 作为危险因素;CN 预测评分^[15]则是参照 APGS 评分的建立方法使用 50~70 岁中国人群数据独立开发,相比 APGS 评分增加了 BMI 和糖尿病作为危险因素。

除上述危险因素外,中国结直肠癌筛查与早诊早治指南还将大量饮酒、红肉和加工肉类的摄入等列为结直肠癌的相关危险因素^[12]。Cai 等^[21]综合年龄、性别、吸烟、糖尿病史、绿色蔬菜摄入、腌渍食品摄入、油炸食物摄入、白肉摄入建立的风险评分模型也成功实现了对高危个体的识别。为进一步提升预测效果,一些研究还尝试将流行病学信息与实验室检查结果相结合。如韩国的 SCS(Samsung Colorectal Screening)评分^[22],除纳入流行病学因素外还纳入低密度脂蛋白、癌胚抗原等实验室检查结果。Park 等^[23]则使用粪便血红蛋白浓度的平方根作为评分系统的重要风险指标。Chen 等^[24-25]

通过随机对照实验发现使用风险评估模型与 FIT 相结合的筛查策略相比单独使用 FIT 可以获得更高的 AN 诊断率。

本研究还发现使用风险评估模型作为初筛相比不进行初筛每检出 1 例 AN 所需要的结肠镜资源负载更少,这一结果与 Chen 等^[24-25]通过开展人群随机对照实验得出的结论相似。此外,问卷调查和 FIT 是我国在进

Table 4 Diagnostic performance of each score for advanced neoplasia

Index	APGS score (95%CI)	Modified APGS score (95%CI)	CN prediction score (95%CI)	χ^2	P
Sensitivity(%)	56.52(41.10~71.07)	78.26(63.64~89.05)	60.87(45.37~74.91)	5.37	0.068
Specificity(%)	53.82(51.05~56.58)	43.06(40.33~45.82)	56.79(54.02~59.52)	53.56	<0.001
PPV(%)	4.21(2.77~6.10)	4.70(3.31~6.45)	4.81(3.22~6.88)	0.29	0.864
NPV(%)	97.18(95.68~98.27)	98.22(96.75~99.14)	97.59(96.21~98.56)	1.46	0.482
AUC	0.55(0.48~0.63)	0.61(0.54~0.67)	0.59(0.52~0.66)	3.07	0.215

Notes:PPV:positive predictive value;NPV:negative predictive value;AUC:area under the receiver operating characteristics curve

Table 5 Number of individuals needed to screen and to scope to detected one colorectal lesion by different screening strategies

Colorectal lesion	Use a scoring model as a preliminary screening		No preliminary screening	
	APGS score (95%CI)	Modified APGS score (95%CI)	CN prediction score (95%CI)	screening (95%CI)
CN	5(4~5)	5(4~5)	5(4~5)	5(5~6)
AN	24(22~26)	21(20~23)	21(19~23)	29(27~30)

行结直肠癌筛查时最常用的基本方法^[11-12,26],基于调查和 FIT 结果使用风险评估模型对人群进行风险分层几乎不增加筛查成本,显示了风险评估模型作为初筛手段的潜在成本效益。

综上所述,在徐州市 50~74 岁社区人群中使用 APCS 评分、APCS 评分修订版、CN 预测评分作为初筛手段的预测效果有待提升,但相比不进行初筛可以减少每检出 1 例 AN 所需的资源负载。若要使用风险评分模型作为初筛在徐州市进行大规模人群筛查,还需根据本地人群特征建立合适的风险评估模型。

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《中国肿瘤》入选《高质量科技期刊分级目录》

2019年7月,中国科协、中宣部、教育部、科技部联合印发《关于深化改革 培育世界一流科技期刊的意见》,明确提出要遴选发布高质量科技期刊分级目录,形成全面客观反映期刊水平的评价标准。遵照同行评议、价值导向、等效应用原则,国内各大学会、协会、组织机构通过科技工作者推荐、专家评议、结果公示等规定程序,形成了本领域科技期刊分级目录的初步成果。

遵照同行评议、价值导向、等效应用原则,中华医学学会通过科技工作者推荐、专家评议、结果公示等规定程序,于2019年9月公布了第一批我国高质量科技期刊分级目录(临床医学领域科技期刊分级目录涵盖心血管病学、内分泌病学、儿科学、医学影像学四个方向);第二批9个学科(耳鼻咽喉科学、眼科学、呼吸病学、消化病学、神经病学、妇产科学、肿瘤学、烧伤外科学、整形外科学)的分级目录遴选工作业已完成。《中国肿瘤》入选临床医学领域高质量科技期刊分级目录(547种)。