

感染相关危重症评分对感染或可疑感染患者死亡风险预测价值比较的网状 Meta 分析

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【摘要】 目的 使用网状 Meta 分析方法评估序贯器官衰竭评分(SOFA)、快速序贯器官衰竭评分(qSOFA)及全身炎症反应综合征(SIRS)评分对感染或可疑感染患者死亡风险的预测价值。**方法** 应用计算机检索万方、中国知网(CNKI)、维普、美国国立医学图书馆 PubMed、科学网(Web of Science)等中英文数据库,检索时间从2016年2月23日至2020年9月5日,同时追踪已检出文献的参考文献,收集关于比较 SOFA、qSOFA 与 SIRS 评分中 2 种或以上评分对感染或可疑感染患者死亡风险预测价值的队列研究。由 2 名研究者独立筛选文献、提取资料和评价纳入研究的偏倚风险。使用 Stata 14.0 软件检验 3 种评分中两两比较的研究间的异质性,采用环不一致性检验法判断直接比较与间接比较的一致性,然后进行网状 Meta 分析并对结果进行排序,通过累积概率曲线下面积(SUCRA)评估 3 种评分的预测能力。绘制“比较-校正”漏斗图,评估纳入研究是否存在发表偏倚。**结果** 最终纳入 38 项研究,整体质量较高。网状 Meta 分析结果显示,在 3 种评分的两两比较中,SOFA 评分对感染或可疑感染患者死亡风险的预测能力优于 qSOFA 评分[均数差(MD)=0.07,95%可信区间(95%CI)为 0.05~0.09]和 SIRS 评分(MD=0.16,95%CI 为 0.14~0.18),且 qSOFA 评分优于 SIRS 评分(MD=0.09,95%CI 为 0.07~0.11)。在对感染或可疑感染患者死亡风险预测效能排序中,SOFA 评分的预测价值更高,其次是 qSOFA 评分, SIRS 评分最低, SUCRA 值分别为 1.0、0.5、0。漏斗图显示,所有研究分布于中线两侧,但分布不太对称,提示存在发表偏倚及小样本效应的可能性大。**结论** SOFA 评分对感染或可疑感染患者死亡风险的预测效能较 qSOFA 评分和 SIRS 评分更佳,但由于漏斗图提示存在小样本效应和发表偏倚,故仍需开展多中心大样本前瞻性研究进行验证。

【关键词】 序贯器官衰竭评分; 快速序贯器官衰竭评分; 全身炎症反应综合征评分; 感染; 死亡风险预测; 网状 Meta 分析

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A comparison of the infection related critical illness scores for predicting mortality in patients with infection or suspected infection: a network Meta-analysis

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【Abstract】 Objective To evaluate the prognostic accuracy of the sequential organ failure assessment (SOFA), quick sequential organ failure assessment (qSOFA) and systemic inflammatory response syndrome (SIRS) criteria in predicting the mortality in patients with infection or suspected infection by using network Meta-analysis. **Methods** Five databases including Wanfang Data, China National Knowledge Infrastructure (CNKI), China Science and Technology Journal Database (VIP), PubMed, Web of Science were searched from February 23, 2016 to September 5, 2020 to identify the relevant literatures comparing the prognostic accuracy of two or more scores for mortality in patients with infection or suspected infection. The literatures screening, data extraction and the quality assessment of the included studies were all conducted independently by two reviewers. Stata 14.0 software was used to test the heterogeneity between the original studies of pairwise comparison of each of the three scoring systems. Ring inconsistency test was used to judge the consistency between direct comparison and indirect comparison. Then network Meta-analysis was performed and the results were ranked. The predictive ability of the three scoring systems was evaluated by surface under cumulative ranking curve (SUCRA). A "comparison-correction" funnel plot was drawn to assess whether there was publication bias in the included studies. **Results** A total of 38 studies were enrolled, the overall quality was high. Network meta-analysis showed that SOFA had a great prognostic performance in predicting mortality for patients with infection or suspected infection, which was followed by qSOFA [mean difference (MD) = 0.07, 95% confidence interval (95%CI) was 0.05-0.09] and SIRS scores (MD = 0.16, 95%CI was 0.14-0.18), and the qSOFA score was better than SIRS score (MD = 0.09, 95%CI was 0.07-0.11). In the order of predicting the death risk of patients with infection or suspected infection, SOFA score had higher predictive

value, followed by qSOFA score, and SIRS score was the lowest, with SUCRA values of 1.0, 0.5 and 0, respectively. Funnel plot showed that all the studies were distributed on both sides of the midline, but the distribution was not symmetrical, suggesting that there was a high possibility of publication bias and small sample effect. **Conclusions** SOFA score had the best prognostic performance in predicting mortality of patients with infection or suspected infection as compared with qSOFA score and SIRS score. However, the funnel plot showed that included literatures may exist small sample effects or publication bias. So the final results should be validated by more prospective studies with multicenters and large samples.

【Key words】 Sequential organ failure assessment; Quick sequential organ failure assessment; Systemic inflammatory response syndrome criteria; Infection; Prediction of mortality; Network Meta-analysis

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脓毒症是重症医学科常见病症及主要死亡原因之一^[1-2]。2016 年,脓毒症的定义中确立了序贯器官衰竭评分(sequential organ failure assessment, SOFA)的诊断地位,并创新性提出快速序贯器官衰竭评分(quick sequential organ failure assessment, qSOFA)^[3],但诊断评分对预后的影响仍存在争议^[4-5]。研究表明,在重症监护病房(intensive care unit, ICU)或非 ICU, SOFA、qSOFA 和全身炎症反应综合征(systemic inflammatory response syndrome, SIRS)评分对可疑感染患者的死亡预测效能不同^[4,6]。快速诊断试验在临床中的应用价值及对病死率的预测仍为脓毒症研究重点^[7]。目前直接比较上述 3 种评分的研究较少,单项研究涉及的样本量偏小,统计学效能较低,因此本研究利用网状 Meta 分析比较了 3 种评分对感染或可疑感染患者死亡风险的预测效能,报告如下。

1 资料与方法

1.1 研究方法: 本研究严格按照系统评价和网状 Meta 分析优先报告条目进行报告,并已在系统评价国际化前瞻性注册数据库(International Prospective Register of Systematic Reviews, PROSPERO)进行注册(注册号: CRD 42020201014)。

1.2 文献纳入标准: ① 回顾性或前瞻性队列研究; ② 年龄 ≥ 16 岁,疑似或明确感染者; ③ 比较 SOFA、qSOFA、SIRS 中任意 2 种或以上评分对死亡的预测价值; ④ 结局指标包含院内、28 d 或 30 d 病死率。

1.3 文献排除标准: ① 针对特殊人群的研究(如肿瘤、孕产妇、使用免疫抑制剂等患者); ② 研究数据不完整,无法提取有效数据; ③ 重复发表。

1.4 文献检索: 检索万方、中国知网(China National Knowledge Infrastructure, CNKI)、维普、美国国立医学图书馆 PubMed、科学网(Web of Science)等数据库,检索时间为 2016 年 2 月 23 日至 2020 年 9 月 5 日。手动检索相关综述,追踪检出文献的参考文献。采用主题词与自由词相结合的方式。中文检索词:“序贯

器官衰竭评分”OR“快速序贯器官衰竭评分”OR“全身炎症反应综合征”等;英文检索词:“SOFA”OR“sequential organ failure assessment”OR“qSOFA”OR“SIRS”OR“systemic inflammatory response syndrome”OR“infection”等。

1.5 文献筛选与资料提取: 由 2 名研究者独立筛选文献,并进行交叉核对,如有分歧则通过讨论或咨询第 3 名研究者解决。提取数据包括:文献基本信息、方法学特征、患者一般情况、结局指标等。

1.6 文献偏倚风险评价: 使用纽卡斯尔-渥太华文献质量评价量表(Newcastle-Ottawa scale, NOS)对纳入文献进行质量评价。总分超过 5 分为高质量研究。

1.7 统计学分析: 使用 Stata 14.0 软件进行网状 Meta 分析。连续性变量采用均数差(mean difference, MD)及 95% 可信区间(95% confidence interval, 95% CI)表示效应量。制作网状 Meta 分析证据关系图;用 I^2 统计量检验两两比较研究间的异质性,当 $I^2 \leq 50\%$ 时,认为研究间异质性较小或不存在,采用固定效应模型;反之,则采用随机效应模型。不一致性检验若提示差异无统计学意义($P > 0.05$),则说明一致性较好。当存在闭合环时,采用环不一致性检验,通过不一致性因子(inconsistency factor, IF)判断直接比较与间接比较的一致性,IF 的 95% CI 起点为 0,说明直接证据与间接证据一致。通过累积概率曲线下面积(surface under cumulative ranking curve, SUCRA)对 3 种评分的预测能力进行排序。 $P < 0.05$ 为差异有统计学意义。通过“比较-校正”漏斗图评估文献发表偏倚。

2 结果

2.1 文献筛选结果及特征: 检索到相关内容题录 5 853 篇(万方 2 517 篇, CNKI 759 篇, 维普 559 篇, PubMed 546 篇, Web of Science 1 472 篇),排除重复文献 1 376 篇,不符合纳入标准 4 400 篇,内容不相关 18 篇,数据不完整 15 篇,信件 6 篇,最终纳入 38 篇文献^[4,8-44]。纳入研究基本特征见表 1。

表 1 感染相关危重症评分对感染或可疑感染患者死亡风险预测价值比较的网状 Meta 分析
纳入研究基本信息及偏倚风险评价

纳入文献	国家	样本量 (例)	年龄(岁,均数 或中位数)	研究对象	评分系统	结局指标	NOS 评分 (分)
Seymour 等 ^{[4]a}	美国	7 932	62.0	可疑感染患者	①②③	院内病死率	8
Seymour 等 ^{[4]b}	美国	66 522	60.0	可疑感染患者	①②③	院内病死率	8
Williams 等 ^[8]	澳大利亚	8 871	49.0	可疑感染患者	②③	30 d 病死率	9
Wang 等 ^[9]	中国	477	73.0	临床诊断感染患者	①②	28 d 病死率	7
Ranzani 等 ^[10]	西班牙	6 874	66.0	临床诊断 CAP 患者	①②③	院内病死率	7
Raith 等 ^[11]	澳大利亚、新西兰	184 875	62.9	可疑感染患者	①②③	院内病死率	7
Park 等 ^[12]	韩国	1 009	67.4	可疑感染患者	①②③	院内病死率	7
Moskowitz 等 ^[13]	美国	24 164	63.8	可疑感染患者	②③	院内病死率	8
Goulden 等 ^[14]	英国	1 818	68.0	可疑感染患者	②③	院内病死率	7
Freund 等 ^[15]	欧洲	879	67.0	可疑感染患者	①②③	院内病死率	9
Finkelshtein 等 ^[16]	美国	152	64.0	可疑感染患者	②③	院内病死率	8
Churpek 等 ^[17]	美国	30 677	58.0	可疑感染患者	②③	院内病死率	7
April 等 ^[18]	美国	214	68.1	可疑或明确感染患者	①②③	院内病死率	8
Zhou 等 ^[19]	中国	336	76.0	CAP 患者	①②	28 d 病死率	7
Kovach 等 ^[20]	美国	10 942	52.0	可疑感染患者	①②③	28 d 病死率	8
Innocenti 等 ^[21]	意大利	742	75.0	脓毒症或脓毒性休克患者 (Sepsis-2)	①②	28 d 病死率	8
Haydar 等 ^[22]	美国	199	71.0	可疑感染患者	②③	院内病死率	7
Khwannimit 等 ^[23]	泰国	1 589	63.0	临床诊断感染患者	①②	院内病死率	6
Khwannimit 等 ^[24]	泰国	2 350	62.0	临床诊断感染患者	①②③	院内病死率	6
Sinto 等 ^[25]	印度尼西亚	1 213	51.0	可疑感染患者	①②③	28 d 病死率	8
Songsangjinda 等 ^[26]	泰国	2 152	61.0	脓毒症患者(Sepsis-2)	①②③	院内病死率	7
Li 等 ^[27]	中国	10 512	未报道	脓毒症患者(Sepsis-3)	①②	28 d 病死率	8
Yu 等 ^[28]	中国	1 318	64.0	可疑感染患者	②③	院内病死率	7
Liu 等 ^[29]	中国	1 865	57.0	脓毒症患者(Sepsis-2)	①②	院内病死率	8
Gaini 等 ^[30]	丹麦	323	66.0	可疑感染患者	①②③	28 d 病死率	6
Abdullah 等 ^[31]	丹麦	2 112	73.1	明确感染患者	②③	28 d 病死率	8
Chen 等 ^[32]	中国	69 115	63.1	可疑感染患者	②③	28 d 病死率	8
Brink 等 ^[33]	荷兰	8 204	57.0	可疑脓毒症患者	②③	30 d 病死率	8
胡晓彤等 ^[34]	中国	692	67.8	脓毒症患者(Sepsis-2/Sepsis-3)	①②③	28 d 病死率	7
王盛标等 ^[35]	中国	311	63.0	脓毒症患者(Sepsis-2)	①②③	28 d 病死率	7
罗竞超 ^[36]	中国	203	54.0	感染患者	①②③	28 d 病死率	9
韩玉 ^[37]	中国	498	64.8	感染或可疑感染患者	①②③	院内病死率	6
秦秀菊等 ^[38]	中国	1 059	72.3	感染患者	①②	院内病死率	5
王子琪等 ^[39]	中国	412	50.6	感染患者	②③	28 d 病死率	5
叶志澄等 ^[40]	中国	163	76.4	可疑感染患者	①②③	28 d 病死率	7
丁国钰等 ^[41]	中国	80	58.6	明确感染患者	①②	28 d 病死率	5
蒋丽蕾等 ^[42]	中国	413	70.0	感染或可疑感染患者及脓毒症 患者(Sepsis-1 和 Sepsis-3)	①③	院内病死率	7
邵俊等 ^[43]	中国	527	68.0	感染或可疑感染患者	①②③	28 d 病死率	6
凤尔稳 ^[44]	中国	125	73.0	脓毒症患者(Sepsis-3)	①②	院内病死率	6

注:CAP 为社区获得性肺炎,NOS 为纽卡斯尔-渥太华文献质量评价量表;a 代表重症监护病房(ICU)患者,b 代表非 ICU 患者;评分系统包括:①为序贯器官衰竭评分(SOFA),②为快速序贯器官衰竭评分(qSOFA),③为全身炎症反应综合征(SIRS)评分

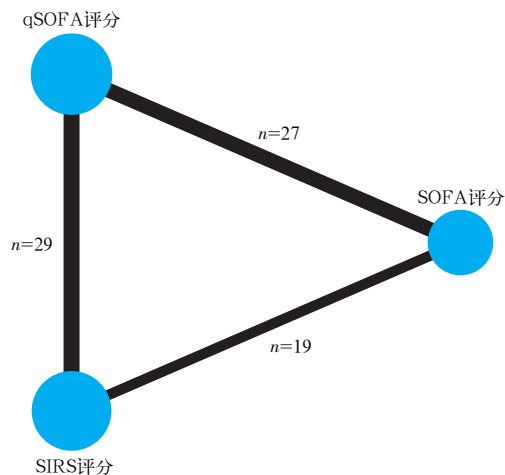
2.2 文献质量评价(表 1):12 项研究未对暴露的确定(严格的记录)进行详细描述,20 项研究未对结果进行混杂因素校正,7 项研究在研究开始无研究对象发生结局事件,1 项研究纳入人群主要来自养老院。35 项研究(92.1%)NOS 评分在 5 分以上,为高质量研究;仅 3 项研究(7.9%)评分相对较低,为 5 分。

2.3 网状 Meta 分析结果

2.3.1 网状关系图(图 1):38 项研究中,3 种评分形成 3 对直接比较,并构成了 1 个三角形闭合环。

2.3.2 异质性检验与不一致性检验:异质性检验显示, $I^2 > 50\%$,故采用随机效应模型;不一致性检验显示, $P = 0.917$,提示研究一致性较好;环不一致性检验显示,IF 为 0.00,95%CI 为 0.00 ~ 0.06,95%CI 下限包含 0,表示无显著环不一致性。表明纳入研究一致性较好,可在一致性模型下进行网状 Meta 分析。

2.3.3 死亡风险预测效能分析:共产生 3 对两两比较,在预测感染或可疑感染患者死亡风险能力方面,SOFA 评分优于 qSOFA 评分和 SIRS 评分,qSOFA 评



注: SOFA 为序贯器官衰竭评分, qSOFA 为快速序贯器官衰竭评分, SIRS 为全身炎症反应综合征; 蓝点代表每种评分涉及研究数; 2 种评分间有实线连接说明二者存在直接比较的证据 (实线越粗代表相关研究越多), n 为每对两两比较的研究数

图 1 感染相关危重症评分对感染或可疑感染患者死亡风险预测价值比较的网状关系图

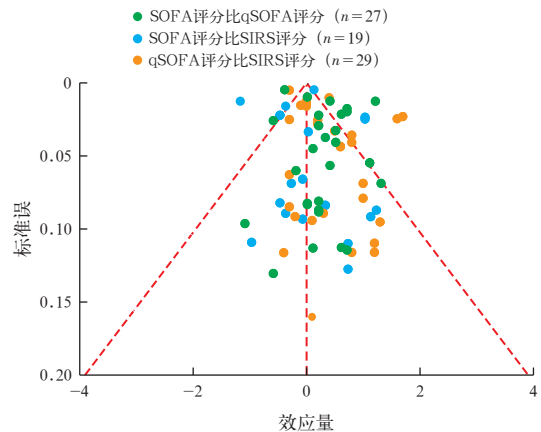
分优于 SIRS 评分(图 2; 表 2)。3 种评分预测感染或可疑感染患者死亡风险的 SUCRA 排序为 SOFA 评分 > qSOFA 评分 > SIRS 评分, 分别为 1.0、0.5、0。

2.3.4 发表偏倚(图 3): 漏斗图显示, 所有研究分布于中线两侧, 但分布不太对称, 提示可能存在发表偏倚及小样本效应。

表 2 感染相关危重症评分对感染或可疑感染患者死亡风险预测价值比较的网状 Meta 分析结果

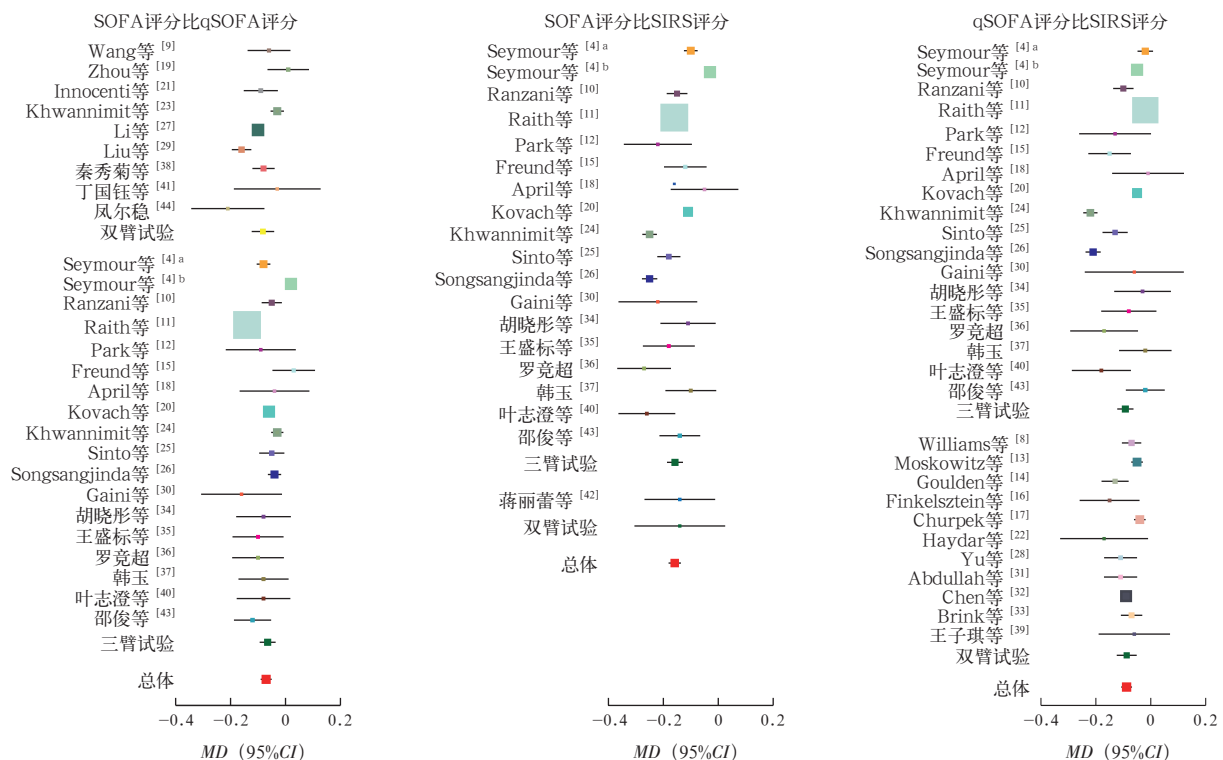
评分	合并效应量 [MD (95%CI)]	
	SOFA 评分	qSOFA 评分
qSOFA 评分	0.07 (0.05 ~ 0.09)	
SIRS 评分	0.16 (0.14 ~ 0.18)	0.09 (0.07 ~ 0.11)

注: SOFA 为序贯器官衰竭评分, qSOFA 为快速序贯器官衰竭评分, SIRS 为全身炎症反应综合征; 均数差 (MD) > 0 表示数据所在列评分的预测价值优于其所在行评分的预测价值, 95% 可信区间 (95%CI) 不包括 0 表示差异有统计学意义; 空白代表无此项



注: SOFA 为序贯器官衰竭评分, qSOFA 为快速序贯器官衰竭评分, SIRS 为全身炎症反应综合征评分

图 3 感染相关危重症评分对感染或可疑感染患者死亡风险预测价值比较网状 Meta 分析的比较-校正漏斗图



注: SOFA 为序贯器官衰竭评分, qSOFA 为快速序贯器官衰竭评分, SIRS 为全身炎症反应综合征, MD 为均数差, 95%CI 为 95% 可信区间; 双臂试验代表研究设计为 2 种评分比较, 三臂试验代表研究设计为 3 种评分比较; 3 种评分比较研究的整体异质性检验: $\chi^2=0.51, P=0.917$

图 2 感染相关危重症评分对感染或可疑感染患者死亡风险预测价值比较的网状 Meta 分析

3 讨论

SOFA 评分主要用于对各种原因导致的多器官功能障碍综合征的评估,并被用来判断预后。一项来自 16 个国家 40 家 ICU 的前瞻性研究中将 SOFA 评分用于评估脓毒症患者器官功能障碍并得到了验证^[45]。此后多项研究围绕 SOFA 评分对脓毒症死亡风险的预测效能进行评估,并提出与本研究一致的结论^[11, 20]。脓毒症时机体对感染的反应是免疫、凝血、内分泌代谢等多个系统失衡的综合结果,SOFA 评分能更全面地评估各器官功能,这可能也解释了为何以 SIRS 为核心的 Sepsis-1 和 Sepsis-2 并不能很好地预测预后。然而,SOFA 评分的获取过于依赖实验室检查,增加了对非 ICU 患者的评估难度^[46]。

SIRS 评分对实验室检查依赖较少,且在 ICU 外有较长的应用历史,是经典的全身感染诊断指标。但 SIRS 评分依据的发热、呼吸与心率增快、白细胞异常实际上只是常见炎症反应的表现,并不能用来鉴别非感染性疾病引起的炎症反应^[47]。Kaukonen 等^[48]发现,感染导致的器官功能障碍患者中有近 1/8 不满足 SIRS, SIRS 阴性与 SIRS 阳性患者校正死亡风险差异无统计学意义,提示 SIRS 评分判断预后的效果一般,与本研究结果一致。虽然 SIRS 评分判断预后的特异度低,但敏感度较 qSOFA 评分高^[13]。因此, SIRS 评分更适用于对全身感染的筛查。

qSOFA 评分中数据的获得完全不依赖实验室检查,相对快捷简单。从本研究结果来看, qSOFA 评分比 SIRS 评分对感染或可疑感染患者院内死亡风险的预测效能更好。但 qSOFA 评分作为全身感染的筛查指标,其特异度较高而敏感度仅 48.7%,假阳性患者约占 10%,假阴性患者却高达 1/3^[49]。以上结论在对急诊感染患者发生器官功能障碍的分析中也得到证实^[8]。因此, qSOFA 评分可能存在漏诊风险,但与 SIRS 评分相比更容易识别出危重症患者。

本研究样本量大, 92.1% 的文献为高质量文献,统计效能较高,对临床医师有一定参考价值。但本研究纳入文献均为观察性研究,可能造成结果偏倚;研究来自多个国家,种族差异可能增加临床异质性;漏斗图提示可能存在小样本效应和发表偏倚。

综上所述,SOFA 评分对感染或可疑感染患者死亡风险的预测效能较 qSOFA 评分和 SIRS 评分更佳,然而受研究的限制,仍需开展多中心大样本前瞻性研究进行验证。

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