



· 指南与共识 ·

注射用丹参多酚酸治疗脑梗死临床应用中国专家共识

■ 中国中西医结合学会神经科专业委员会

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【摘要】 为规范脑梗死的中西医结合合理用药,中国中西医结合学会神经科专业委员会成立专家组,在纳入现有医学科学证据的基础上,结合专家临床经验,经多次讨论后制定了《注射用丹参多酚酸治疗脑梗死临床应用中国专家共识》。本专家共识意见的制订综合考虑了注射用丹参多酚酸治疗脑梗死的证据质量、临床疗效、不良反应及其他相关因素;共识内容包括注射用丹参多酚酸的化学成分、药理机制、用药时机、联合用药方案、疗效优势、安全性及不良反应等多个方面。本共识旨在为临床应用注射用丹参多酚酸治疗脑梗死提供规范的指导,从而优化其临床疗效并保障用药安全。

【关键词】 脑梗死;注射用丹参多酚酸;中西医结合;合理用药;专家共识

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Chinese Expert Consensus on the Clinical Application of Salvianolic Acid for Injection in the Treatment of Cerebral Infarction

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【Abstract】 To standardize the integration of traditional and western medicine for rational drug use in cerebral infarction, the Neurology Specialty Committee of the Chinese Association of Integrative Medicine convened an expert panel. Based on existing medical and scientific evidence, combined with clinical expertise, the *Chinese Expert Consensus on the Clinical Application of Salvianolic Acid for Injection in the Treatment of Cerebral Infarction* was developed through multiple discussions. The formulation of this expert consensus comprehensively considered evidence quality, clinical efficacy, adverse reactions, and other related factors regarding the use of salvianolic acid for injection in the treatment of cerebral infarction. This consensus includes the chemical composition, pharmacological mechanisms, timing of administration, combination therapy strategies, therapeutic advantages, and safety of salvianolic acid for injection. This consensus aims to provide standardized guidance for the clinical practice of salvianolic acid for injection in the treatment of cerebral infarction, thereby optimizing therapeutic outcomes and ensuring medication safety.

【Key Words】 Cerebral infarction; Salvianolic acid for injection; Integration of traditional and western medicine; Rational drug use; Expert consensus

传统中药丹参是唇形科植物丹参 (*Salvia miltiorrhiza* Bge.) 的干燥根和根茎,其味苦,性微寒,归心、肝经,主要功效为活血祛瘀、通经止痛、清心除烦、凉血消痈等^[1],广泛用于心

脑血管疾病、肝炎及慢性肾功能衰竭的治疗^[2]。

注射用丹参多酚酸 (salvianolic acid for injection, SAFI) 是以丹参为原药材,采用现代工艺制备的冻干粉针剂。SAFI于2011年经

国家药品监督管理局批准上市,主要用于脑梗死的治疗,适用于中风病瘀血阻络证,症见半身不遂、口舌歪斜、舌强言謇、偏身麻木等。目前,《中国脑梗死中西医结合诊治指南(2017)》《中医康复临床实践指南·缺血性脑卒中(脑梗死)》《脑卒中中西医结合康复临床循证实践指南》等指南均推荐SAFI用于脑梗死急性期、恢复期及后遗症期的治疗^[3-5]。《丹参类中药注射剂治疗急性缺血性脑卒中有效性和安全性的网状meta分析》显示,在急性脑梗死的治疗中,SAFI联合常规治疗的总有效率优于其他丹参类中药注射剂联合常规治疗^[6]。

为规范脑梗死的中西医结合合理用药,中国中西医结合学会神经科专业委员会成立了专家组,制定了《注射用丹参多酚酸治疗脑梗死临床应用中国专家共识》(以下简称共识)。本共识包括药物基本信息、专家共识编制方法、药效学研究、临床应用建议、禁忌证、注意事项6部分,旨在为中医、西医及全科医师在内的临床医护人员合理使用SAFI治疗脑梗死提供指导和参考。

1 药物基本信息

SAFI的主要化学成分为丹酚酸B、迷迭香酸、紫草酸、原儿茶醛、丹酚酸D、丹参素钠等水溶性成分。高压液相色谱法测得SAFI中以上6种成分占总固体成分的67.4%^[7]。

2 专家共识编制方法

2.1 专家共识编制过程

本共识由中国中西医结合学会神经科专业委员会组织的47名专家共同编写。专家组成员围绕SAFI的临床疗效及安全性设置核心议题,经过3次线下会议讨论,最终制定了该专家共识。

本共识专家组通过数据库检索中英文相关文献进行meta分析,并基于分析结果生成证据条目。中文检索词:“注射用丹参多酚酸”“丹参多酚酸注射液”“丹参多酚酸注射

剂”“丹参多酚酸”“脑梗死”“脑梗塞”“脑栓塞”“卒中”“缺血性卒中”“中风”;英文检索词:“salvianolic acid for injection”“salvianolic acid injection”“salvianolic injection”“salvianolic acid”“dan shen duo fen suan”“cerebrovascular accident”“brain infarction”“stroke”“ischemic stroke”。采用主题词和自由词结合的方式,分别检索了中国知网、万方数据知识服务平台、中文科技期刊数据库(维普网)、中国生物医学文献服务系统等中文数据库,以及PubMed、Cochrane Library、Web of Science和Embase等英文数据库。检索时间范围从数据库建立之日起至2024年7月1日。

2.2 证据等级和推荐强度

共识专家组基于汇总的证据质量,对SAFI治疗脑梗死的有效性和安全性进行评估:如证据充分,则采用推荐分级评估、制订与评价(grade of recommendations assessment, development and evaluation, GRADE)系统计票规则,形成有证据支持的共识推荐意见(表1);如证据不充分,则采用多数计票规则,形成共识建议^[8]。共识专家组通过讨论和投票,形成7个共识推荐意见,并在此基础上撰写了本共识的征求意见稿。通过线下会议和函评方式广泛征求意见,完成征求意见稿的同行评议和修订,形成送审稿;经专家论证并再次修订后,最终形成定稿。

2.3 临床问题

本次共识制订所关注的7个核心临床问题如下:①SAFI能否用于脑梗死急性期的治疗,疗效如何?②SAFI联合rt-PA治疗脑梗死的效果如何,是否增加出血风险?③SAFI治疗脑梗死能否改善患者的认知功能?④SAFI治疗脑梗死恢复期的效果如何?⑤SAFI治疗进展性脑梗死的效果如何?⑥SAFI治疗TIA的效果如何?⑦SAFI的安全性如何,不良反应有哪些?



表1 GRADE证据等级和推荐强度的标准
Table 1 Criteria for GRADE evidence levels and recommendation strength

证据等级和推荐强度	描述	主要依据
高级证据 (A级)	对真实的效应值接近效应估计值有高度信心	多项高质量的RCT或高质量meta分析
中级证据 (B级)	对效应估计值有中等程度的信心: 真实值有可能接近估计值, 但二者仍存在明显差异的可能性	研究存在局限性 (如偏倚风险、样本量不足) 或结果存在异质性, 但总体方向明确
低级证据 (C级)	对效应值的信心有限, 真实值可能与估计值存在明显差异	观察性研究为主, 或RCT存在局限性, 如方法缺陷、结果不精确等
极低级证据 (D级)	对效应值的估计非常不确定, 真实值可能与估计值差异较大	证据来源于个案报告、专家意见, 或研究存在严重偏倚和异质性
推荐强度	强	明确显示干预措施利大于弊或弊大于利
	弱	干预措施的利弊不确定或无论质量高低的证据均显示利弊相当

注: GRADE——推荐分级评估、制订与评价; RCT——随机对照试验。

3 药效学研究

迅速实现闭塞血管复流再通是脑梗死急性期治疗成功的前提; 延长脑细胞耐受缺氧的时间、增强复流再通后脑细胞的生存能力, 是治疗成功的基本保证^[9]。SAFI可通过抗血栓形成、改善脑部微循环、促进血管新生、减轻炎症损伤、抗氧化应激、抗细胞凋亡、促进神经再生等机制发挥改善脑缺血区血液循环、保护脑细胞的作用^[10-11]。

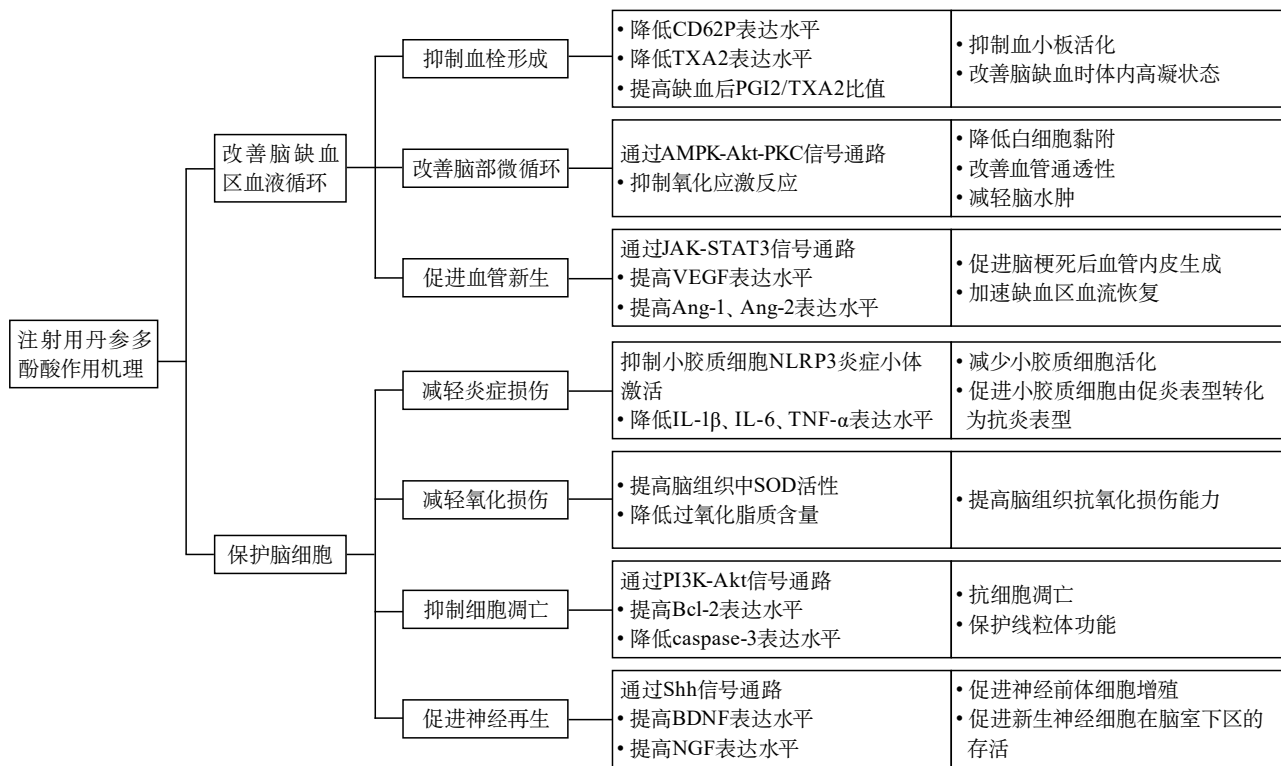
3.1 改善脑缺血区血液循环

既往研究显示, SAFI可通过多种机制改善脑缺血区的血液循环 (图1)。①抑制缺血再灌注后血栓素A2 (thromboxane A2, TXA2) 水平升高, 且不影响前列腺素 (prostaglandin I2, PGI2) 的水平, 提高脑梗死后PGI2/TXA2 比值, 从而抑制血小板活化, 改善脑缺血时体内的高凝状态, 减少血栓形成^[12-13]; ②通过腺苷一磷酸活化蛋白激酶-蛋白激酶B-蛋白激酶C (adenosine monophosphate-activated protein kinase-protein kinase B-protein kinase C, AMPK-Akt-PKC) 信号通路抑制氧化应激反应, 降低白细胞黏附性, 减轻脑水肿, 改善血管的通透性及微循环障碍^[14]; ③激活Janus激酶-信号转导和转录激活因子3 (Janus kinase-signal transducer and activator of transcription 3, JAK-STAT3) 信号通路, 以及血管内皮生长因子 (vascular

endothelial growth factor, VEGF)、血管生成素-1 (angiopoietin-1, Ang-1) 及血管生成素-2 (angiopoietin-2, Ang-2) 的表达, 促进脑梗死后血管内皮生成及神经血管微循环重构, 加速缺血区的血流恢复^[15-16]。

3.2 保护脑细胞

SAFI可通过多种机制保护脑细胞 (图1)。①抑制小胶质细胞中NOD样受体家族蛋白3 (NOD-like receptor family protein 3, NLRP3) 炎症小体的激活, 促进小胶质细胞由促炎表型 (M1) 转化为抗炎表型 (M2), 降低IL-1 β 、IL-6、TNF- α 等炎症因子的表达, 抑制细胞凋亡^[17-20]; ②提高脑组织中超氧化物歧化酶 (superoxide dismutase, SOD) 的活性, 降低过氧化脂质含量, 提高机体抗氧化损伤的能力, 发挥脑保护作用^[21]; ③通过磷脂酰肌醇3激酶-蛋白激酶B (phosphatidylinositol 3 kinase-protein kinase B, PI3K-Akt) 信号通路调节星形胶质细胞半胱天冬酶-3 (cysteine-aspartic protease-3, caspase-3) 和B细胞淋巴瘤-2 (B-cell lymphoma-2, Bcl-2) 蛋白的表达, 抑制神经细胞凋亡, 保护脑神经^[22-23]; ④通过激活音猬因子 (sonic hedgehog, Shh) 信号通路, 增加脑源性神经营养因子 (brain-derived neurotrophic factor, BDNF) 和神经生长因子 (nerve growth factor, NGF) 的分泌, 促进神经前体细胞增殖及新生神经细胞在脑室下区



TXA2——血栓素A2; PGI2——前列环素; AMPK——腺苷一磷酸活化蛋白激酶; Akt——蛋白激酶B; PKC——蛋白激酶C; JAK——Janus激酶; STAT3——信号转导和转录激活因子3; VEGF——血管内皮生长因子; Ang——血管生成素; NLRP——NOD样受体家族蛋白; SOD——超氧化物歧化酶; PI3K——磷脂酰肌醇3激酶; Bcl——B细胞淋巴瘤; caspase——半胱天冬酶; Shh——音猬因子; BDNF——脑源性神经营养因子; NGF——神经生长因子。

图1 注射用丹参多酚酸治疗脑梗死的作用机制

Figure 1 The mechanisms of action of salviaolic acid for injection in treating cerebral infarction

的存活,从而改善脑梗死后的神经再生和神经功能恢复^[24]。

4 临床应用建议

4.1 问题1: SAFI能否用于脑梗死急性期的治疗,疗效如何?

推荐意见: SAFI可用于脑梗死急性期的治疗。使用该药治疗14 d后,患者的NIHSS评分降低,神经功能改善(强推荐, C级证据); Barthel指数升高,生活质量提升(强推荐, C级证据); 90 d mRS评分0~2分比例升高,预后改善(强推荐, B级证据)。

推荐说明: 本共识撰写组进行了SAFI治疗对脑梗死急性期NIHSS评分影响的meta分析,纳入了71项随机对照试验(randomized controlled trial, RCT),共7523例脑梗死急性

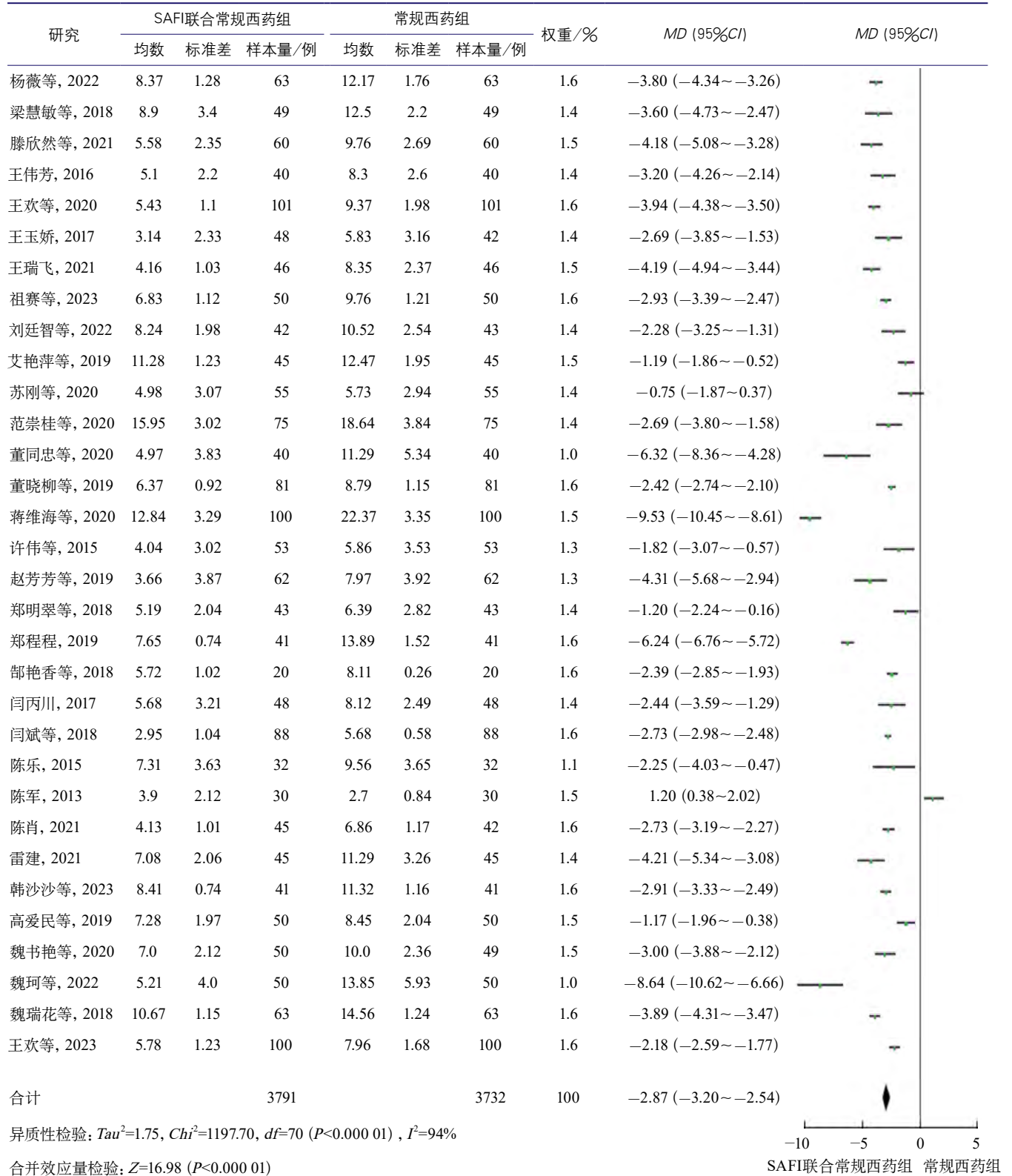
期患者,其中SAFI联合常规西药组3791例,常规西药组3732例^[25-95]。两组均接受14 d的药物治疗。分析结果显示,与常规西药组相比,SAFI联合常规西药组治疗14 d后NIHSS评分降低($MD -2.87, 95\%CI -3.20 \sim -2.54, P < 0.000 01$) (图2)。SAFI联合常规西药治疗较常规西药治疗可进一步改善脑梗死患者的神经功能。

本共识撰写组进行了SAFI治疗对脑梗死急性期Barthel指数影响的meta分析,纳入了34项RCT,共3605例脑梗死急性期患者,其中SAFI联合常规西药组1812例,常规西药组1793例^[41-64, 96-105]。两组均接受14 d的药物治疗。分析结果显示,与常规西药组相比,SAFI联合常规西药组治疗14 d后Barthel指数升高($MD 12.34, 95\%CI 10.71 \sim 13.98, P < 0.000 01$) (图3)。



研究	SAFI联合常规西药组			常规西药组			权重/%	MD (95%CI)	MD (95%CI)
	均数	标准差	样本量/例	均数	标准差	样本量/例			
于晓云, 2019	6.73	2.09	46	8.35	2.18	46	1.5	-1.62 (-2.49~-0.75)	
于超男等, 2020	6.74	3.87	53	8.75	3.71	53	1.2	-2.01 (-3.45~-0.57)	
付慧丹, 2020	13.5	3.2	68	22.3	4.6	68	1.3	-8.80 (-10.13~-7.47)	
任晓佳等, 2019	4.55	2.35	20	6.15	2.45	20	1.2	-1.60 (-3.09~-0.11)	
何国锐, 2018	3.75	2.37	39	5.19	2.16	39	1.4	-1.44 (-2.45~-0.43)	
党樊聘等, 2020	3.64	2.75	100	5.48	3.30	100	1.5	-1.84 (-2.68~-1.00)	
关翠英等, 2019	27.78	6.93	34	31.59	6.82	34	0.6	-3.81 (-7.08~-0.54)	
冯涛, 2020	4.7	1.18	50	5.61	1.51	50	1.6	-0.91 (-1.44~-0.38)	
刘丹等, 2020	11.4	2.6	58	16.2	2.2	50	1.5	-4.80 (-5.71~-3.89)	
刘华丽等, 2022	3.64	1.86	60	7.96	3.93	60	1.4	-4.32 (-5.42~-3.22)	
刘良敏等, 2020	5.3	2.21	42	8.1	2.43	43	1.4	-2.80 (-3.79~-1.81)	
刘银芳等, 2020	4.63	4.64	41	7.56	6.03	41	0.9	-2.93 (-5.26~-0.60)	
卢军栋等, 2018	6.15	1.33	40	8.15	1.79	40	1.5	-2.00 (-2.69~-1.31)	
史蕙青, 2020	5.35	1.76	20	7.5	2.87	20	1.2	-2.15 (-3.63~-0.67)	
司肖曼等, 2019	5.82	2.5	30	8.0	2.77	30	1.3	-2.18 (-3.52~-0.84)	
夏志宏等, 2020	6.65	1.06	60	10.18	1.76	60	1.6	-3.53 (-4.05~-3.01)	
孙丽霞, 2015	5.2	2.4	38	8.2	2.5	36	1.4	-3.00 (-4.12~-1.88)	
孙德阳等, 2020	7.76	0.99	34	10.00	1.26	34	1.6	-2.24 (-2.78~-1.70)	
孟欣等, 2024	5.14	1.69	50	7.46	2.25	50	1.5	-2.32 (-3.10~-1.54)	
尚雨露等, 2019	8.42	0.65	48	11.64	0.73	48	1.6	-3.22 (-3.50~-2.94)	
常琪, 2023	7.86	1.50	105	9.92	1.75	105	1.6	-2.06 (-2.50~-1.62)	
张丽芳等, 2017	7.76	0.99	34	10.00	1.26	34	1.6	-2.24 (-2.78~-1.70)	
张凤等, 2015	5.77	5.11	35	8.11	3.89	35	1.0	-2.34 (-4.47~-0.21)	
张娟等, 2021	3.15	2.52	20	7.10	3.74	20	1.0	-3.95 (-5.93~-1.97)	
张建娥, 2018	3.21	1.75	100	4.76	2.97	100	1.5	-1.55 (-2.23~-0.87)	
张晶, 2018	2.56	2.31	35	2.69	3.59	35	1.3	-0.13 (-1.54~1.28)	
张洪波等, 2021	7.91	1.79	52	11.15	2.08	51	1.5	-3.24 (-3.99~-2.49)	
张潇涵等, 2019	5.79	2.42	75	7.16	3.11	75	1.5	-1.37 (-2.26~-0.48)	
张玉霞, 2014	9.69	7.07	62	13.06	7.09	62	0.9	-3.37 (-5.86~-0.88)	
张秀清等, 2019	6.25	0.83	73	8.46	1.07	73	1.6	-2.21 (-2.52~-1.90)	
张莉莉, 2019	3.18	1.43	56	5.62	1.79	56	1.6	-2.44 (-3.04~-1.84)	
张萌等, 2016	0.86	1.2	100	1.3	1.01	60	1.6	-0.44 (-0.79~-0.09)	
徐晓玉等, 2020	3.13	2.08	56	7.81	2.43	56	1.5	-4.68 (-5.52~-3.84)	
李春颖, 2016	3.23	1.79	80	4.75	3.02	80	1.5	-1.52 (-2.29~-0.75)	
李海军, 2015	4.93	1.31	50	8.42	3.12	50	1.4	-3.49 (-4.43~-2.55)	
李芳芳, 2020	12.24	1.98	51	16.52	2.54	51	1.5	-4.28 (-5.16~-3.40)	
杜若男, 2020	5.66	1.45	50	7.31	1.78	50	1.5	-1.65 (-2.29~-1.01)	
杨明妍等, 2019	4.1	2.1	30	7.1	2.4	30	1.4	-3.00 (-4.14~-1.86)	
杨晓云, 2019	8.56	2.73	40	10.27	3.18	40	1.3	-1.71 (-3.01~-0.41)	

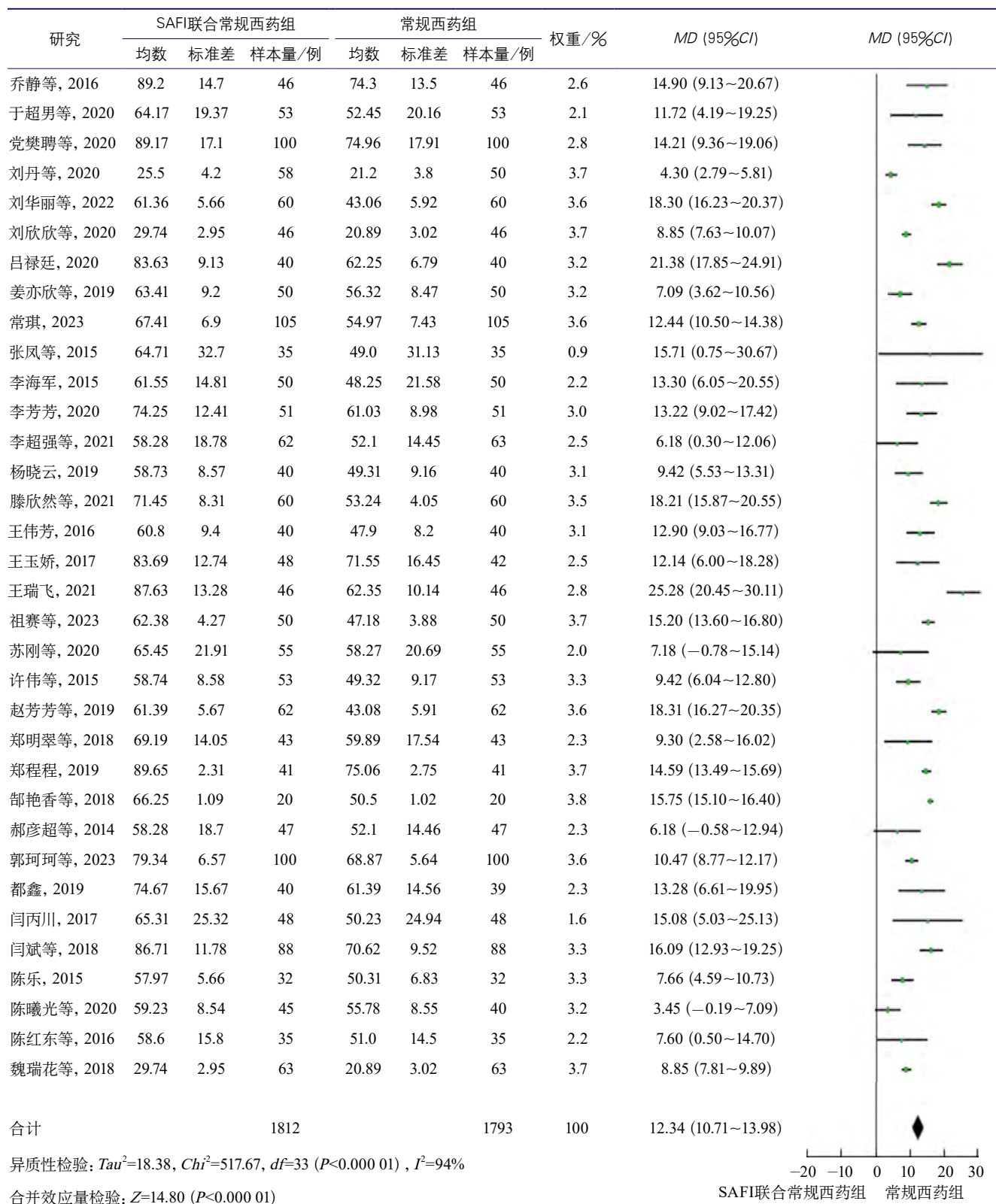
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SAFI——注射用丹参多酚酸。

图2 SAFI对脑梗死急性期NIHSS评分影响的meta分析: SAFI联合常规西药与单独常规西药治疗比较

Figure 2 Meta-analysis of the effects of SAFI on NIHSS score in the acute phase of cerebral infarction: SAFI combined with conventional western medicine versus conventional western medicine alone



SAFI——注射用丹参多酚酸。

图3 SAFI对脑梗死急性期Barthel指数影响的meta分析: SAFI联合常规西药与单独常规西药治疗比较

Figure 3 Meta-analysis of the effects of SAFI on Barthel index in the acute phase of cerebral infarction: SAFI combined with conventional western medicine versus conventional western medicine alone

SAFI联合常规西药治疗较常规西药治疗可进一步改善脑梗死患者的生活能力。

本共识撰写组进行了SAFI治疗对脑梗死急性期mRS评分影响的meta分析,纳入了4项RCT,共有1780例脑梗死急性期患者,其中SAFI联合常规西药组1149例,常规西药组631例^[71, 98, 106-107]。两组均接受14 d的药物治疗。分析结果显示,SAFI联合常规西药组中90 d mRS评分0~2分的患者比例为61.35%,常规西药组中该比例为48.96% (RR 1.28, 95% CI 1.17~1.41, $P<0.000\ 01$) (图4)。SAFI联合常规西药治疗较单纯西药治疗可进一步改善脑梗死患者的预后。

4.2 问题2: SAFI联合rt-PA治疗脑梗死的效果如何,是否增加出血风险?

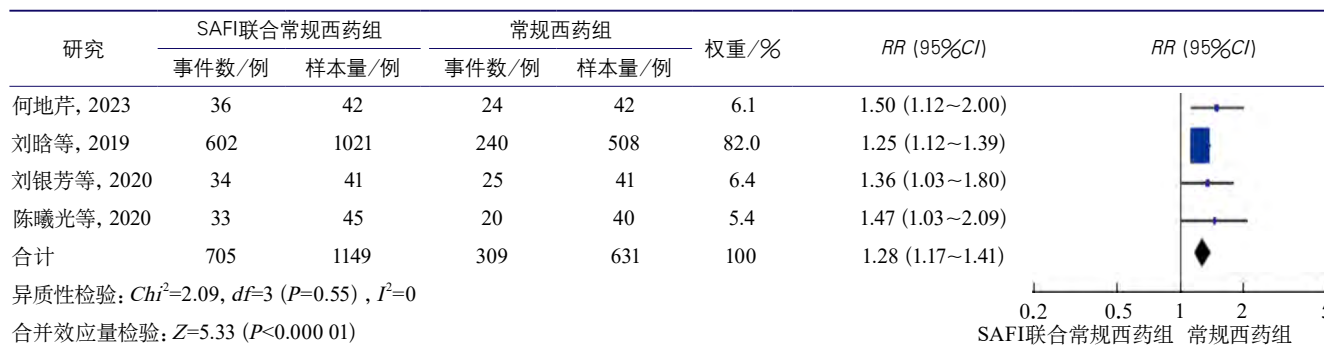
推荐意见: 对于接受rt-PA静脉溶栓的脑梗死患者,溶栓后使用SAFI治疗14 d后,NIHSS评分降低,神经功能改善(强推荐, C级证据); Barthel指数升高,生活质量提升(强推荐, C级证据); 90 d mRS评分0~2分比例升高,预后改善(强推荐, C级证据); SAFI不增加rt-PA静脉溶栓患者的出血风险(强推荐, C级证据),用药时机需结合患者的具体病情综合判断。

推荐说明: 本共识撰写组进行了SAFI联合rt-PA静脉溶栓对脑梗死急性期NIHSS评分影响的meta分析,纳入了6项RCT,共625例脑梗死急性期患者,其中,SAFI联合rt-PA组

313例,rt-PA组312例^[35, 99, 108-111]。分析结果显示,与rt-PA组相比,SAFI联合rt-PA组治疗14 d后NIHSS评分明显降低 (MD -3.23, 95% CI -5.03~-1.44, $P=0.0004$) (图5)。SAFI联合rt-PA静脉溶栓较单纯rt-PA静脉溶栓可进一步改善脑梗死患者的神经功能。

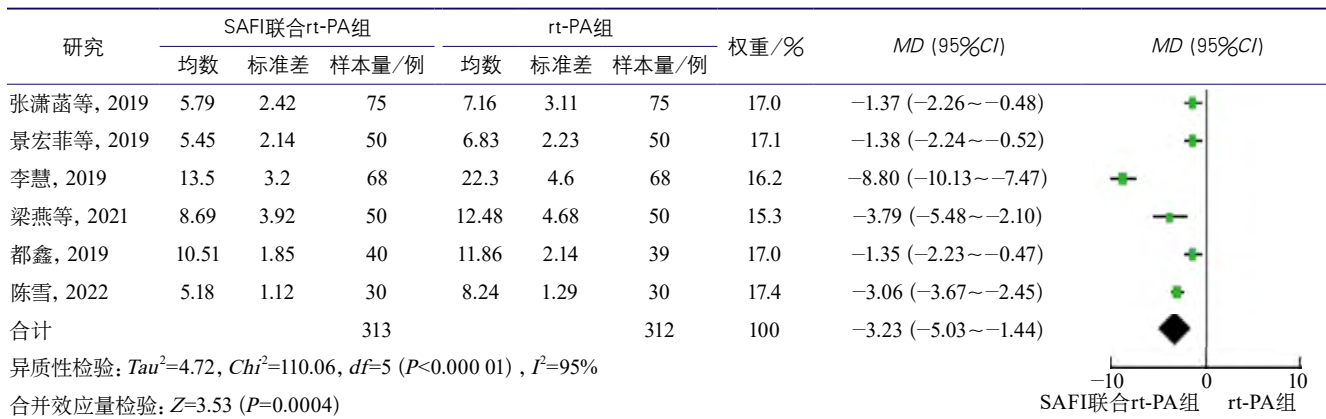
本共识撰写组进行了SAFI联合rt-PA静脉溶栓对脑梗死急性期Barthel指数影响的meta分析,纳入了2项RCT,共179例脑梗死急性期患者,其中,SAFI联合rt-PA组90例,rt-PA组89例^[99, 111]。分析结果显示,与rt-PA组相比,SAFI联合rt-PA组接受治疗14 d后Barthel指数升高 (MD 12.82, 95% CI 9.38~16.26, $P<0.000\ 01$) (图6)。SAFI联合rt-PA静脉溶栓较单纯rt-PA静脉溶栓可进一步改善脑梗死患者的生活能力。

本共识撰写组进行了SAFI联合rt-PA静脉溶栓对脑梗死急性期mRS评分影响的meta分析,纳入了2项RCT^[98, 110],共185例脑梗死急性期患者,其中,SAFI联合rt-PA组95例,rt-PA组90例。分析结果显示,与rt-PA组相比,SAFI联合rt-PA组接受治疗14 d后,90 d mRS评分0~2分的患者比例升高 (RR 2.47, 95% CI 1.35~4.50, $P=0.003$) (图7),且未增加出血风险 (RR 1.36, 95% CI 0.45~4.11, $P=0.59$) (图8)。SAFI联合rt-PA静脉溶栓较



SAFI——注射用丹参多酚酸。

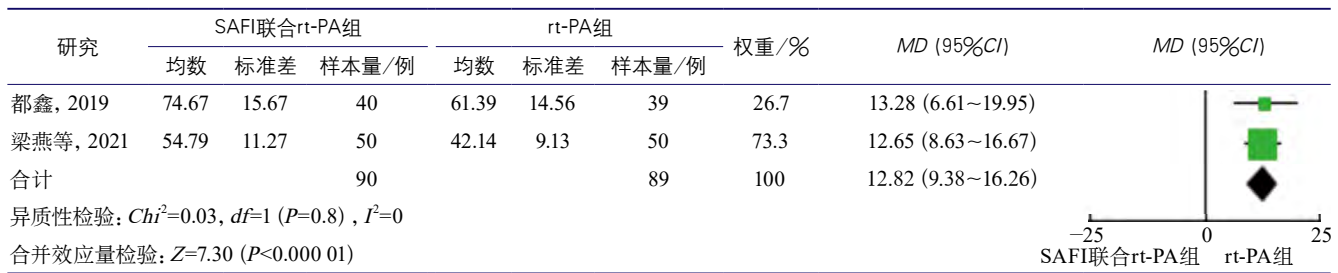
图4 SAFI对脑梗死急性期90 d mRS评分(0~2分比例)影响的meta分析: SAFI联合常规西药与单独常规西药治疗比较
Figure 4 Meta-analysis of the effects of SAFI on the proportion of patients with mRS scores 0-2 at 90 days in the acute phase of cerebral infarction: SAFI combined with conventional western medicine versus conventional western medicine alone



SAFI——注射用丹参多酚酸。

图5 SAFI联合rt-PA对脑梗死急性期NIHSS评分影响的meta分析: SAFI联合rt-PA溶栓与单独rt-PA溶栓比较

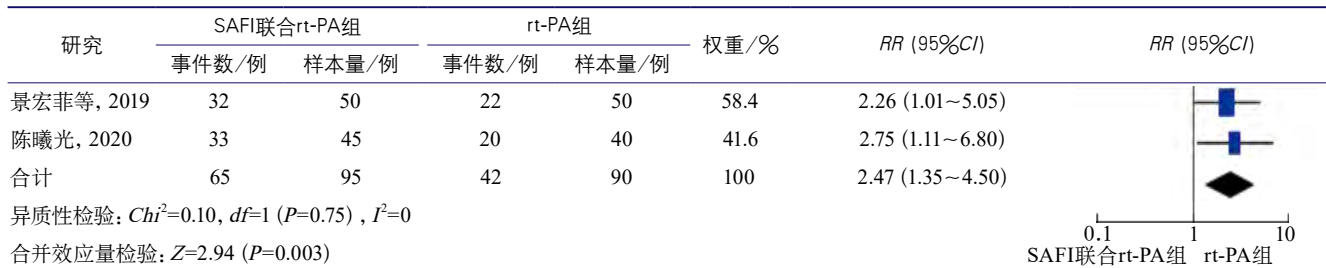
Figure 5 Meta-analysis of the effects of SAFI combined with rt-PA versus rt-PA alone on NIHSS score in the acute phase of cerebral infarction



SAFI——注射用丹参多酚酸。

图6 SAFI联合rt-PA对脑梗死急性期Barthel指数影响的meta分析: SAFI联合rt-PA溶栓与单独rt-PA溶栓比较

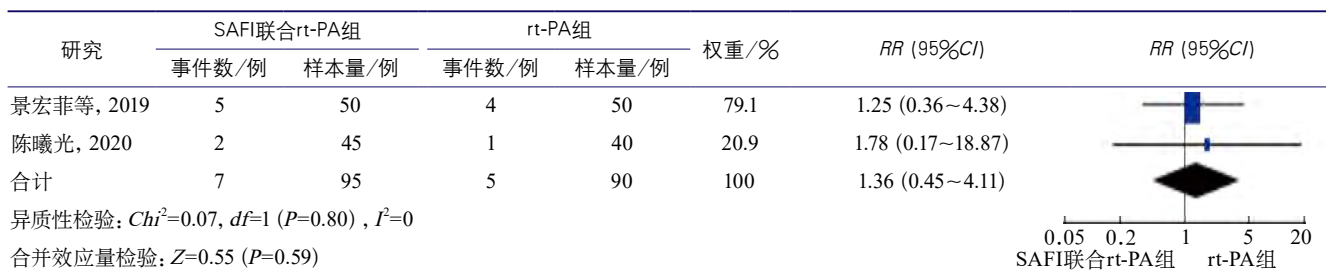
Figure 6 Meta-analysis of the effects of SAFI combined with rt-PA versus rt-PA alone on Barthel index in the acute phase of cerebral infarction



SAFI——注射用丹参多酚酸。

图7 SAFI联合rt-PA对脑梗死急性期90 d mRS评分 (0~2分比例) 影响的meta分析: SAFI联合rt-PA溶栓与单独rt-PA溶栓比较

Figure 7 Meta-analysis of the effects of SAFI combined with rt-PA versus rt-PA alone on the proportion of patients with mRS scores 0-2 at 90 days in the acute phase of cerebral infarction



SAFI——注射用丹参多酚酸。

图8 SAFI联合rt-PA对脑梗死治疗后出血风险影响的meta分析: SAFI联合rt-PA溶栓与单独rt-PA溶栓比较

Figure 8 Meta-analysis of the effects of SAFI combined with rt-PA versus rt-PA alone on bleeding risk after treatment for cerebral infarction

单纯rt-PA静脉溶栓可进一步改善脑梗死患者的预后且不增加出血风险。

4.3 问题3: SAFI治疗脑梗死能否改善患者的认知功能?

推荐意见: 脑梗死急性期在常规西药治疗基础上联合SAFI治疗14 d后, 患者的MoCA评分升高, 认知功能改善(强推荐, B级证据)。

推荐说明: 本共识撰写组进行了SAFI治疗对脑梗死MoCA评分影响的meta分析, 纳入了12项RCT, 共1079例脑梗死急性期患者, 其中SAFI联合常规西药组541例, 常规西药组538例^[31, 39, 45, 50-51, 53, 58, 61, 104, 112-114]。分析结果显示, 接受治疗14 d后, 与常规西药组相比, SAFI联合常规西药组的MoCA评分升高(MD 2.08, 95%CI 1.80~2.37, $P<0.000\ 01$) (图9)。SAFI联合常规西药治疗可改善脑梗死患者的认知功能。

4.4 问题4: SAFI治疗脑梗死恢复期的效果如何?

推荐意见: 若脑梗死恢复期患者仍存在明

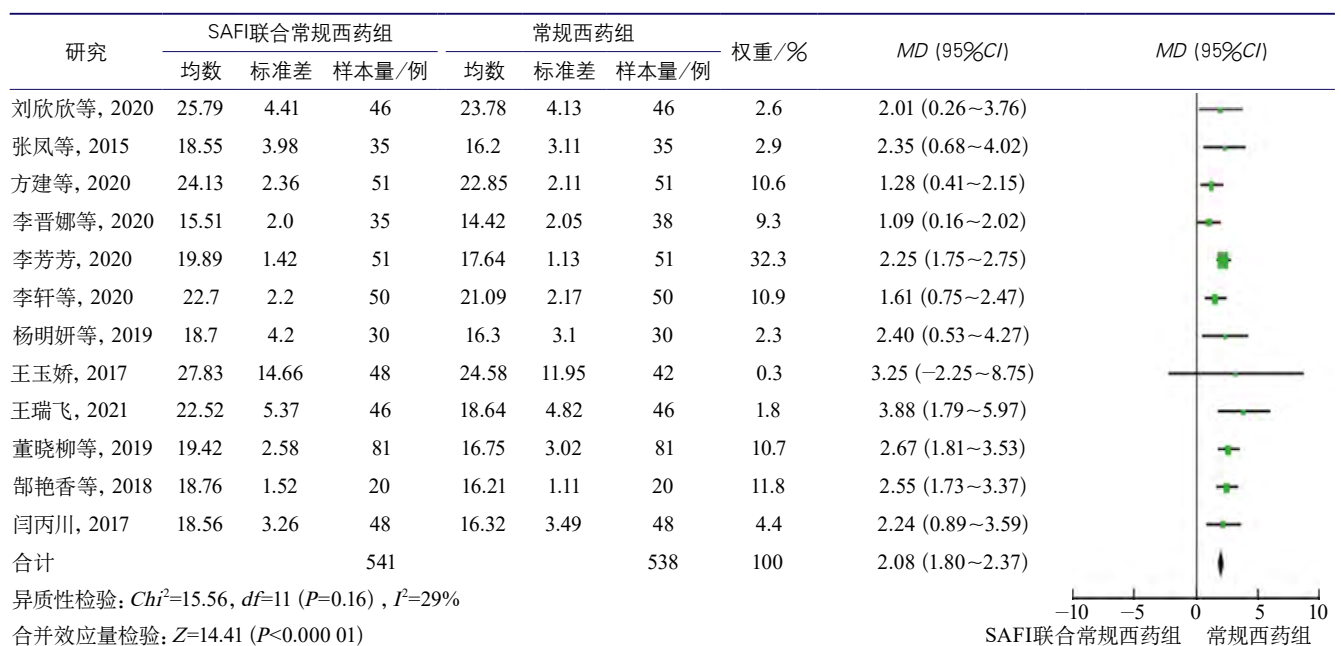
显的神经功能缺损症状, 可使用SAFI进行治疗(共识建议)。

推荐说明: 一项纳入80例脑干梗死恢复期患者的研究证实, SAFI可改善患者的神经功能缺损症状, 提高其生活质量, 且用药安全^[115]。另一项纳入120例前循环脑梗死恢复期患者的研究表明, SAFI可改善患者的神经功能缺损症状, 提高其日常生活能力, 且安全性良好^[116]。此外, 一项纳入72例脑梗死恢复期患者的研究显示, SAFI治疗可降低患者的炎性因子水平, 有效改善其神经功能缺损症状, 增强其日常活动能力^[117]。

4.5 问题5: SAFI治疗进展性脑梗死的效果如何?

推荐意见: SAFI治疗可以降低进展性脑梗死患者的NIHSS评分, 改善其神经功能(共识建议)。

推荐说明: 一项纳入82例急性进展性脑梗死患者的研究显示, SAFI联合替罗非班治疗与单独应用替罗非班比较, 可减轻患者的神经功



SAFI——注射用丹参多酚酸。

图9 SAFI对脑梗死急性期MoCA评分影响的meta分析: SAFI联合常规西药与单独常规西药治疗比较

Figure 9 Meta-analysis of the effects of SAFI on MoCA score in the acute phase of cerebral infarction: SAFI combined with conventional western medicine versus conventional western medicine alone



能缺损症状,改善其预后,且安全性良好^[71]。另一项纳入106例进展性脑梗死患者的研究表明,与单独应用肝素相比,SAFI联合肝素能通过抗炎、抗氧化、保护血管内皮功能等机制减轻患者的神经功能障碍,改善患者的预后,且安全性良好^[52]。此外,一项纳入80例进展性脑梗死患者的研究证实,与单独应用常规西药治疗相比,SAFI联合常规西药治疗能进一步改善患者的神经功能缺损症状及肢体功能^[43]。

4.6 问题6: SAFI治疗TIA的效果如何?

推荐意见:SAFI可有效控制TIA(共识建议)。

推荐说明:一项纳入76例椎基底动脉系统TIA患者的研究表明,SAFI可有效改善TIA,缓解血管痉挛症状,治疗过程中未发现明显肝肾功能异常及其他不良反应,安全性良好^[118]。另一项纳入120例TIA患者的研究发现,SAFI联合阿司匹林等西药治疗TIA疗效显著,可有效缓解患者的临床症状,改善其临床预后^[119]。此外,一项纳入80例TIA患者的研究证实,SAFI能改善患者的脑血流动力学,有效改善其脑缺血症状^[120]。

4.7 问题7: SAFI的安全性如何,不良反应有哪些?

推荐意见:SAFI的不良反应发生率低,具有较高的安全性(强推荐, B级证据)。

推荐说明:一项SAFI上市后的临床应用安全性研究纳入了3430例脑梗死患者(涉及63家临床中心)。研究共报告SAFI不良反应16例(29例次),且均为轻度反应,说明SAFI临床应用的不良反应发生率低,安全性较高(表2)^[121]。一项针对SAFI治疗脑梗死急性期的meta分析纳入了34项RCT,共3401例脑梗死急性期患者,其中,SAFI联合常规西药治疗组1705例,常规西药治疗组1696例。结果表明,SAFI联合常规西药治疗组的不良反应发生率与常规西药治疗组相比,差异无统计学意义($OR\ 1.43, 95\%CI\ 0.94\sim 2.17, P=0.09$)^[122]。

表2 SAFI不良反应发生的分类统计

Table 2 Classification statistics of adverse reactions of SAFI

不良反应	具体表现	发生数量 (发生率)/例次(%)
胃肠道系统疾病	腹胀、呕吐	2 (0.058)
耳及迷路疾病	耳鸣	1 (0.029)
神经系统疾病	困倦、头痛	5 (0.146)
血管与淋巴管系统疾病	血压升高	9 (0.262)
免疫系统疾病	输液反应、荨麻疹	4 (0.117)
皮肤及皮下组织疾病	面部水肿、皮疹瘙痒	4 (0.117)
心脏器官疾病	心悸	2 (0.058)
局部反应	输液部位出汗	2 (0.058)

注:共纳入3430例患者。SAFI——注射用丹参多酚酸。

5 禁忌证

对SAFI或丹参类药物有过敏史或严重不良反应史者禁用。孕、产妇及哺乳期女性禁用,有生育需求的女性孕前半年内慎用。中药“十八反”中指出,丹参与藜芦药性相反,合用会减效增毒。因此,丹参类注射剂在临床应用中,应避免与含藜芦的药品配伍使用^[123]。

6 注意事项

在使用SAFI前应详细询问患者有无丹参制剂过敏史。过敏体质患者应慎用本品。SAFI宜单独使用,不建议与其他药物同容器混合滴注。用药过程中,首次滴注前30 min及输注完成后30 min内,应密切关注患者的临床表现,如患者出现疑似与药物输注相关不良反应,须立即采取相应处理措施。用药过程中出现皮疹、咽干、头痛、心慌等症状,建议立即停药,密切观察病情变化,并予以积极处理。

编者注 本共识撰写组进行的meta分析中,纳入的各项研究数据与其发表数据保持一致,故本文中的部分指标数据小数点后位数不一致。

作者贡献 确定研究思路或设计, 研究计划、执行的管理和协调, 对研究工作全面负责, 确保论文的准确性和诚信, 筹措、提供研究资金(杨文明、张祥建); 获取数据, 起草、撰写、修改研究论文(乔会敏、王炳雷、张聪、王彩娟); 分析或解释数据, 参与共识推荐的讨论,

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