



· 指南与共识 ·

# 《中国急性缺血性卒中诊治指南2023》解读

■ 李光硕<sup>1</sup>, 赵性泉<sup>1,2</sup>

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## 作者单位

<sup>1</sup>北京 100070  
首都医科大学附属北京  
天坛医院神经病学中心  
<sup>2</sup>国家神经系统疾病临床

医学研究中心

## 通信作者

赵性泉  
zxq@vip.163.com

**【摘要】** 2024年6月,《中华神经科杂志》发布了更新版的《中国急性缺血性卒中诊治指南2023》。该指南基于最新的循证医学证据,提供了急性缺血性卒中 (acute ischemic stroke, AIS) 诊治的最新推荐意见,涵盖急性期静脉溶栓、机械取栓、二级预防抗血小板治疗等多个方面。本文深入剖析这些关键推荐,结合AIS领域的最新研究成果,对相关文献进行深入解读。本文旨在清晰呈现AIS的最新诊治规范,为临床医师提供实用的指导,以更好地服务AIS患者,改善其治疗效果。

**【关键词】** 缺血性卒中; 诊断; 治疗; 指南

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## Interpretation of the Chinese Guidelines for Diagnosis and Treatment of Acute Ischemic Stroke 2023

LI Guangshuo<sup>1</sup>, ZHAO Xingquan<sup>1,2</sup>. <sup>1</sup>Department of Neurology, Beijing Tiantan Hospital, Capital Medical University, Beijing 100070, China; <sup>2</sup>China National Clinical Research Center for Neurological Diseases, Beijing 100070, China

Corresponding Author: ZHAO Xingquan, E-mail: zxq@vip.163.com

**【Abstract】** In June 2024, the *Chinese Journal of Neurology* published an updated version of the *Chinese Guidelines for the Diagnosis and Treatment of Acute Ischemic Stroke 2023*. This guideline, grounded in the latest evidence-based medicine, provides the most recent recommendations for the diagnosis and treatment of acute ischemic stroke (AIS), covering multiple aspects, such as intravenous thrombolysis in the acute phase of AIS, mechanical thrombectomy and antiplatelet therapy in secondary prevention. This article intended to delve into these key recommendations, integrating the latest research findings in the field of AIS, and to provide a thorough interpretation of related literature. The purpose of this article is to present the most up-to-date standards of the diagnosis and treatment of AIS, offering practical guidance for clinicians, thereby enhancing the quality of service for AIS patients and improving treatment outcomes.

**【Key Words】** Ischemic stroke; Diagnosis; Treatment; Guideline

自《中国急性缺血性脑卒中诊治指南2018》发布以来,急性缺血性卒中 (acute ischemic stroke, AIS) 的诊断与治疗取得了显著进展。随着一系列大型随机对照临床试验和meta分析成果的发布,静脉溶栓新药物替奈普酶 (tenecteplase, TNK) 获得了非劣效性证据;血管内治疗适应证得到了有效扩展;基于替格瑞洛的双重抗血小板治疗获得了在携带细胞色素P450C19功能缺失等位基因的AIS患者

中的证据。这些研究成果为临床实践提供了新的循证医学证据,特别是在静脉溶栓药物的应用和血管内治疗适应证的扩展方面取得了重大进步。

基于此背景,我国发布了《中国急性缺血性卒中诊治指南2023》(以下简称《指南2023》),对AIS的急性期治疗和二级预防推荐意见进行了修订和补充。本文将系统回顾这些关键的临床研究证据,并对《指南2023》中的重

要推荐意见及相关文献进行深入解读,旨在为临床提供最新的治疗指导,从而优化患者的治疗策略。

### 1 血压及血糖管理应谨慎

缺血性卒中后70%的患者可见血压升高,多数患者的血压水平在发病后数天内可自行恢复。血压过高可能增加出血转化风险,血压过低则可能加重缺血损伤。但是,目前对于AIS的降压目标和时间窗仍没有明确结论。CATIS显示,发病48 h内的患者在入院24 h后进行降压治疗虽无明显益处,但基本安全<sup>[1]</sup>。CATIS-2指出,与延迟至第8日进行降压治疗相比,在轻中度缺血性卒中患者发病24~48 h内立即行降压治疗并未降低其90 d的依赖或死亡风险<sup>[2]</sup>。针对接受血管内治疗的患者,BP-TARGET研究发现,与标准降压(130~185 mmHg)(1 mmHg=0.133 kPa)相比,强化降压(100~129 mmHg)并未有效降低患者术后24~36 h颅内出血的发生率<sup>[3]</sup>。ENCHANTED2/MT表明,与非强化降压组(140~180 mmHg)患者相比,术后1~72 h强化降压组(<120 mmHg)患者的90 d功能预后更差,7 d内早期神经功能恶化发生率更高,且未减少症状性颅内出血的风险<sup>[4]</sup>。OPTIMAL-BP试验和BEST-II试验同样显示,血管内治疗后积极降压会减少患者的获益<sup>[5-6]</sup>。因此,《指南2023》建议,对于机械取栓术后血管完全再通的缺血性卒中患者,维持术后收缩压在140~180 mmHg可能是合理的,应避免将收缩压控制在120 mmHg以下(Ⅱ类推荐,B级证据)。

30%~40%的缺血性卒中患者可见血糖升高,但急性期血糖控制方案尚不明确。2019年的SHINE试验显示,与标准降糖治疗(<10.0 mmol/L)相比,强化降糖治疗(4.4~7.2 mmol/L)不仅未能改善AIS患者的功能结局,甚至增加了严重低血糖的风险<sup>[7]</sup>。相比于高血糖,低血糖引起的损伤尤为严重,可

导致脑损伤。因此,加强AIS患者的血糖监测是合理的,但不推荐过于积极的进行降糖干预,并应警惕低血糖的发生。

AIS患者急性期的血糖和血压变化情况较为复杂。设计临床试验探索治疗方案并深入探讨病理生理机制面临着较大困难。相比于临床试验,回顾性研究或注册登记研究结果证据等级低,不能直接用于验证临床假设。除此以外,对血糖和血压的管理也应该考虑患者基础血压/血糖水平的影响。

### 2 静脉溶栓时间窗有效拓宽

随着“缺血半暗带”理论的完善和推广,基于时间窗的溶栓适应证得到了“组织窗”的有效补充<sup>[8]</sup>。WAKE-UP试验提出了一种“扩散加权成像与液体衰减反转恢复不匹配”模式,可用于筛选能够从静脉溶栓获益的发病时间不明或醒后卒中患者<sup>[9]</sup>。EXTEND试验则借助灌注影像提出了“梗死核心-低灌注不匹配”,旨在筛选出有足够缺血半暗带的患者,成功地将静脉溶栓时间窗拓宽到9 h<sup>[10]</sup>。阿替普酶静脉溶栓未来将会惠及更多患者。另外,由“缺血半暗带”衍生出的“组织窗”理论极大地扩展了静脉溶栓的适应人群,并强调了AIS个体化精准诊疗的重要性。

### 3 替奈普酶获得非劣效证据

TNK是一种改良的溶栓药物,与阿替普酶相比,具有更强的血管再通能力和更低的出血风险,单次短时推注后患者即可进行转诊。早期多个关于TNK的Ⅲ期临床试验结果均不理想,造成其在缺血性卒中领域的应用趋于谨慎。近年来,AcT和TRACE II试验先后证实了TNK在AIS患者发病4.5 h行溶栓治疗相比于阿替普酶的非劣效性<sup>[11-12]</sup>。一项基于移动卒中单元的临床试验发现TNK在对AIS患者早期再灌注方面疗效优于传统的阿替普酶<sup>[13]</sup>。EXTEND-IA TNK试验则发现TNK在桥接取栓环境下改善再灌注的表现优于阿替普酶<sup>[14]</sup>。

这些新的研究成果表明, TNK在缺血性卒中溶栓治疗方面的疗效可能不劣于阿替普酶, 拥有广阔的应用前景。

早期TNK试验的阴性结果可能是统计效力不足。阿替普酶可以有效降低致残率。若将阿替普酶的致残风险作为对照设计临床试验证实TNK的优效性, 则要求该临床试验具有大样本且经严格设计。考虑到TNK给药的便捷性, 从非劣效角度开展临床试验是科学合理的。

#### 4 机械取栓已成为大血管闭塞的首选治疗方案, 但静脉溶栓的价值也未被否定

5项大型随机对照试验结果的发表标志着缺血性卒中机械取栓时代的到来<sup>[15]</sup>。前循环大血管闭塞患者通过溶栓桥接进行机械取栓可以极大地提高血管再通率, 改善患者结局。DAWN和DEFUSE 3试验将前循环大血管闭塞的AIS患者取栓时间窗拓宽到16~24 h<sup>[16-17]</sup>。ATTENTION和BAOCHE补充了后循环取栓的证据<sup>[18-19]</sup>。RESCUE-Japan LIMIT和ANGEL-ASPECT则提供了大梗死核心的取栓证据<sup>[20-21]</sup>。由此, 机械取栓成为了大血管闭塞所致AIS治疗的关键手段。

直接取栓是否不劣于桥接取栓是近年讨论的问题。已发表的临床试验得出了不同的研究结论, 其中DEVT和DIRECT-MT证实了直接取栓的非劣效性, 但SKIP和MR CLEAN-NO IV试验未获得上述非劣效性结论<sup>[22-25]</sup>。今后的研究可能侧重于探究直接取栓和桥接取栓各自的适宜人群。不同转诊模式也可能为直接取栓带来新的价值。基于此, 《指南2023》建议, 应遵循静脉溶栓优先原则, 如果患者符合静脉溶栓和机械取栓指征, 应该先接受静脉溶栓治疗 (I类推荐, A级证据); 对于发病4.5 h内进行桥接治疗的急性前循环大血管闭塞患者, 阿替普酶 (I类推荐, A级证据) 证据级别仍高于TNK (II类推荐, B级证据); 对存在静脉溶栓禁忌的部分患者使用机械取栓是合理的 (II类推荐, B级证据)。

#### 5 抗血小板治疗方案得到极大丰富

抗血小板治疗作为缺血性卒中二级预防的核心和基础, 可有效降低卒中复发风险。近年来, 个性化抗血小板治疗方案的涌现, 为临床医师实现精准医疗提供了助力。继CHANCE研究后, CHANCE-2研究基于CYP2C19功能基因, 提出了阿司匹林联合替格瑞洛或氯吡格雷的轻型卒中/TIA早期联合抗血小板治疗方案, 开启了脑血管病领域基因指导下的精准医疗新时代<sup>[26-27]</sup>。RESCUE BT2提出, 静脉替罗非班可作为中重度缺血性卒中 (非大-中型血管闭塞所致) 患者的早期治疗药物<sup>[28]</sup>。此外, ARAMIS试验证实, 在NIHSS评分 $\leq 5$ 分的AIS患者中, 阿司匹林联合氯吡格雷在降低患者致残风险方面的疗效不劣于静脉溶栓<sup>[29]</sup>。这些研究极大地扩展了抗血小板治疗的适应证, 并填补了早期再灌注治疗的空白。《指南2023》建议, 对于携带CYP2C19功能缺失等位基因的AIS患者, 可使用替格瑞洛和阿司匹林双重抗血小板治疗并维持21 d (II类推荐, B级证据)。

#### 6 抗凝治疗启动时间或可提前

抗凝治疗在缺血性卒中二级预防方面一直发挥独特的作用, 尤其是在心房颤动等疾病导致的栓塞性卒中患者中。然而, 在抗凝治疗时, 必须仔细权衡其带来的获益与潜在的出血风险。卒中严重程度越高, 梗死体积越大, 抗凝治疗启动时间往往相对延迟。不过, 近期的TIMING和ELAN试验表明, 抗凝治疗的启动时间可以比既往指南推荐的时间点提前, 相比于延迟启动抗凝治疗, 早期启用抗凝治疗的不良事件发生率较低, 整体较为安全, 但仍需谨慎考虑神经功能缺损的严重程度及出血风险<sup>[30-31]</sup>。《指南2023》建议, 对于伴心房颤动的AIS患者, 早期使用新型抗凝药物进行抗凝治疗是安全的, 可在充分沟通并评估卒中复发和出血风险后, 在卒中后14 d内启动新型抗凝剂进行抗凝治疗 (II类推荐, B级证据)。

### 7 神经保护剂有望获得更多临床试验支持

神经保护药物受到神经科医师关注已有数十年的时间。尽管体外实验和动物实验证实了神经保护药物可以改善缺血性卒中后的神经功能,但是临床试验一直未能获得缺血性卒中患者功能改善的证据<sup>[32-34]</sup>。近期一项多中心随机对照Ⅲ期试验,获得了依达拉奉右莰醇可改善发病48 h内AIS患者的第90日神经功能结局的证据<sup>[35]</sup>。该药物综合了清除自由基和抗炎的两种药物成分,是一种值得期待的多靶点神经保护药物。此外,多中心随机对照研究显示银杏内酯<sup>[36-37]</sup>、银杏二萜内酯葡胺<sup>[38]</sup>均可以降低AIS患者致残风险,且具有较好的安全性,是非常有潜力的神经保护药物。在溶栓和取栓等血管再通治疗进一步推广的未来,神经保护药物可能

结合血管再通治疗获得更多临床试验的支持。

### 8 总结展望

缺血性卒中诊疗正迅速发展,静脉溶栓时间窗的拓宽巩固了其在AIS治疗中的关键地位,未来将惠及更多患者。随着TNK非劣性证据的涌现,静脉溶栓治疗的选择更加多样化。机械取栓适应证的扩宽以及基于个体基因型的抗血小板治疗方案的丰富,极大地扩大了AIS患者的受益范围。高质量临床试验证实了基于基因的精准医疗在缺血性卒中治疗领域有极大的有效性和极高的可行性。未来,更多的循证医学证据将进一步提高AIS诊疗质量,减轻患者负担,改善患者预后,提升其生活质量。

**利益冲突** 所有作者均声明不存在利益冲突。

附表 临床试验名称缩写及中英文对照  
Supplementary table Abbreviations of clinical trials and Chinese-English comparison

研究缩写	英文全称	中文全称
AcT	alteplase compared to tenecteplase in patients with acute ischemic stroke	阿替普酶与替奈普酶治疗急性缺血性卒中的比较
ANGEL-ASPECT	study of endovascular therapy in acute anterior circulation large vessel occlusive patients with a large infarct core	大梗死核心急性前循环大血管闭塞患者的血管内治疗研究
ARAMIS	antiplatelet versus rt-PA for acute mild ischemic stroke	抗血小板和溶栓治疗在轻型急性缺血性卒中的比较
ATTENTION	trial of endovascular treatment of acute basilar-artery occlusion	急性基底动脉闭塞血管内治疗试验
BAOCHE	basilar artery occlusion Chinese endovascular trial	中国基底动脉闭塞血管内治疗试验
BEST-II	blood pressure after endovascular stroke treatment-II	血管内治疗卒中后的血压管理-II
BP-TARGET	blood pressure target in acute stroke to reduce hemorrhage after endovascular therapy	降低急性卒中血管内治疗后出血的血压目标
CATIS	China antihypertensive trial in acute ischemic stroke	中国急性缺血性卒中降压试验
CHANCE	clopidogrel in high-risk patients with acute non-disabling cerebrovascular events	氯吡格雷用于高危急性非致残性脑血管事件人群
DAWN	DWI or CTP assessment with clinical mismatch in the triage of wake-up and late presenting strokes undergoing neurointervention	醒后和超时间窗卒中在DWI或CTP评估联合临床错配后行神经介入
DEFUSE 3	endovascular therapy following imaging evaluation for ischemic stroke 3	影像评估筛选缺血卒中患者血管内治疗3
DEVT	direct endovascular treatment versus bridging therapy for patients with acute ischemic stroke	急性缺血性卒中直接血管内治疗与桥接治疗的比较
DIRECT-MT	direct intra-arterial thrombectomy in order to revascularize AIS patients with large vessel occlusion efficiently in Chinese tertiary hospitals	中国三级医院直接动脉取栓恢复大血管闭塞性缺血性卒中患者血流
ELAN	early versus later anticoagulation for stroke with atrial fibrillation	卒中伴心房颤动的早期与晚期抗凝治疗
ENCHANTED2/MT	intensive blood pressure control after endovascular thrombectomy for acute ischaemic stroke	急性缺血性卒中机械取栓后强化降压治疗
EXTEND	extending the time for thrombolysis in emergency neurological deficits	急性神经功能缺损患者扩展时间窗溶栓治疗
EXTEND-IA TNK	extending the time for thrombolysis in emergency neurological deficits-intra-arterial using intravenous tenecteplase	急性神经功能缺损患者扩展时间窗溶栓联合动脉治疗-替奈普酶
MR CLEAN-NO IV	intravenous treatment followed by intra-arterial treatment versus direct intra-arterial treatment for acute ischaemic stroke caused by a proximal intracranial occlusion	颅内动脉近端闭塞所致卒中静脉溶栓后桥接血管内治疗与直接血管内治疗
OPTIMAL-BP	outcome in patients treated with intraarterial thrombectomy-optimal blood pressure control	动脉取栓治疗后的患者预后-最佳血压控制



续表

研究缩写	英文全称	中文全称
RESCUE BT2	tirofiban for stroke without large or medium-sized vessel occlusion	急性非大、中血管闭塞性卒中早期替罗非班治疗
RESCUE-Japan LIMIT	recovery by endovascular salvage for cerebral ultra-acute embolism Japan large ischemic core trial	日本超急性大梗死核心脑梗死血管内治疗试验
SHINE	stroke hyperglycemia insulin network effort	卒中高血糖胰岛素治疗
SKIP	endovascular therapy with versus without intravenous tissue plasminogen activator in acute stroke with intracranial artery and M1 occlusion	颈内动脉或大脑中动脉M1段闭塞所致急性缺血性卒中伴或不伴静脉溶栓的血管内治疗
TIMING	timing of oral anticoagulant therapy in acute ischemic stroke with atrial fibrillation	急性缺血性卒中合并心房颤动患者口服抗凝治疗的时机选择
TRACE II	tenecteplase reperfusion therapy in acute ischemic cerebrovascular event-II	急性缺血性脑血管事件中的替奈普酶再灌注治疗
WAKE-UP	efficacy and safety of MRI-based thrombolysis in wake-up stroke	MRI指导醒后卒中溶栓的有效性和安全性

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