

• 论著 •

颅内血肿微创穿刺清除术治疗 高血压脑出血的 Meta 分析

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【摘要】目的 评价颅内血肿微创穿刺清除术(MPST)治疗高血压脑出血(HICH)的疗效及安全性。**方法** 计算机检索2006年1月至2017年1月Cochrane临床试验数据库、中国生物医学文献数据库(CBM)、中国期刊网全文专题数据库、中国科技期刊数据库和万方电子期刊数据库等公开发表的所有MPST和内科保守治疗HICH的临床随机对照试验(RCT)。研究组给予MPST加基础治疗,对照组给予内科保守治疗。对符合纳入标准的研究用RevMan 5.0软件进行整理和分析,比较观察研究组和对照组有效率和病死率的差异,采用漏斗图分析潜在的发表偏倚。**结果** 共检索出已发表符合要求的13篇RCTs研究,1556例患者。Meta分析显示,研究组有效率明显高于对照组[优势比(OR)=4.29,95%可信区间(95%CI)3.33~5.53,P<0.01];病死率明显低于对照组(OR=0.25,95%CI 0.19~0.35,P<0.01)。漏斗图显示各研究结果变量的散点图不对称,说明有发表偏倚,这可能与研究人员在发表结果时存在主观性有关。**结论** 采用MPST治疗HICH可明显提高有效率,降低病死率。但由于纳入的临床研究质量偏低,尚需开展严格的、多中心RCT进一步验证。

【关键词】 颅内血肿微创穿刺清除术; 高血压脑出血; Meta分析

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Intracranial hematoma micro-invasive craniopuncture scavenging technique in patients with hypertensive cerebral hemorrhage: a Meta-analysis Liu Xiangzhe, Guo Pengfei, Wang Xinshi

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【Abstract】Objective To evaluate the therapeutic efficacy and safety of micro-invasive craniopuncture scavenging technique (MPST) for treatment of intracranial hematoma in patients with hypertensive cerebral hemorrhage (HICH). **Methods** All the clinical randomized controlled trial (RCT) studies published on MPST and internal medicine conservative treatment of HICH were searched via computer screening of databases including Cochrane clinical trials database, the Chinese biomedical literature database (CBM), Chinese periodical network full-text special topic database, Chinese science and technology periodical database and electronic periodicals database of Wanfang from January 2006 to January 2017. The study group was given the MPST plus basic treatment, and the control group was given conservative treatment. The studies collected meeting the eligible criteria were sorted and analyzed by the software RevMan 5.0, the differences in therapeutic effect and mortality were compared between the two groups, and a funnel chart was plotted to analyze the potential publication bias. **Results** A total of 13 RCTs published studies consistent with the eligible criteria were found, including 1556 patients. The Meta-analysis showed that the effective rate in the study group was significantly higher than that in the control group [odds ratio (OR) = 4.29, 95% confidence interval (95%CI) 3.33 – 5.53, P < 0.01]; the fatality rate was markedly lower than that of the control group (OR = 0.25, 95%CI 0.19 – 0.35, P < 0.01). The funnel graph showed that each study had asymmetrical scatter plot of the variable quantity of research results, indicating a publication bias being present, which might be related to the subjectivity of the researchers in publishing their results. **Conclusions** Using MPST to treat HICH can significantly improve the therapeutic efficiency and reduce deterioration rate. However, due to the low quality of clinical research, it is necessary to carry out rigorous and multi-center randomized controlled studies to further confirm the results.

【Key words】 Intracranial hematoma micro-invasive cranial puncture scavenging technique; Hypertensive cerebral hemorrhage; Meta-analysis

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临幊上导致颅内血肿的常见原因有外伤、自发性脑出血等,其中高血压脑出血(HICH)是最常见的类型,占原发性脑出血的80%以上^[1]。HICH发病急,病情进展迅速,患者病死率较高。高血压伴

脑小动脉瘤是原发性脑出血的常见病因,是由血压突然升高,动脉瘤破裂所致。脑出血后由于局部血肿导致脑组织水肿,引起颅内压升高,脑组织受压、移位、变形、坏死等,随后血肿压迫周围正常组织结

构导致脑疝形成^[2-3],最终影响患者呼吸及心血管中枢,严重威胁患者生命安全。并且,脑出血后血液、血红蛋白等分解物会进入脑组织,产生炎症反应等一系列继发性损害^[4]。因此在脑疝形成之前,如何积极控制颅内压,阻止病情进一步发展成为治疗HICH急性期的首要任务。而有效清除颅内血肿,减轻血肿对周围脑组织结构的压迫,无疑是最直接、最有效的方法之一。

颅内血肿微创穿刺清除术(MPST)在全国范围内广泛应用于近20年,已成功救治超过百万例颅内血肿患者,大大改善了脑出血的治疗现状^[5]。但其临床疗效报道不一,且文献样本量普遍较小,多为单中心研究。因此,本研究旨在通过全面搜集近8年来关于MPST与内科保守治疗的临床随机对照试验(RCT),评价其治疗HICH的临床应用价值。

1 资料与方法

1.1 资料来源和检索策略:检索2006年1月至2017年1月Cochrane临床试验数据库、中国生物医学文献光盘数据库、中国期刊网全文专题数据库、中国科技期刊数据库和万方电子期刊数据库等公开发表的所有MPST和内科保守治疗HICH的RCT。

1.2 文献纳入和排除标准:纳入研究对象均符合《中国脑出血诊治指南(2014)》^[1]诊断标准,均为入院后经头颅CT确诊的HICH患者。排除有潜在解剖异常(如动脉瘤或动静脉畸形)者;外伤性脑出血者;近期有开颅病史或手术史者;有血液系统疾病者;有严重的心、肺、肝、肾疾病者。

1.3 干预措施:所有患者均给予内科基础治疗,包括卧床休息、避免情绪激动、应用甘露醇(呋塞米等)脱水降颅压,维持水和电解质平衡,应用神经保护剂,控制血压、血糖,防治感染及消化道出血等。所有纳入研究的基础治疗基本相似。研究组给予MPST加基础治疗,对照组给予内科保守治疗。

1.4 结局评定指标:结局评定主要为有效(包括基本痊愈、显著进步、进步)和恶化(死亡)。根据中华神经科学会全国第四届脑血管病会议制定的脑卒中患者临床神经功能缺损程度评分标准^[6],分为基本痊愈、显著进步、进步、无变化、恶化(死亡)。

1.5 资料提取和质量评价:阅读全文后提取样本的入选标准和样本量、研究对象的基本资料、干预措施和频率、随机方法及结局等资料。采用Jadad质量分析法^[7]评价文献质量,并采用漏斗图分析潜在的发表偏倚。

1.6 统计学处理:采用RevMan 5.0软件进行统计

分析。有效率等计数资料采用优势比(OR)表示,计量资料采用均数差(MD)表示,各效应量均以95%可信区间(95%CI)表示。采用Mante-Hazenszel^[8]或DerSimonian-Laird^[9]统计方法对各纳入研究结果间的异质性进行检验,并分析导致异质性存在的原因。 $P<0.05$ 为差异有统计学意义。

2 结 果

2.1 文献筛选:对初步检出的152篇相关文献严格按照纳入和排除标准再次筛选,最后纳入13篇^[10-22]RCT文献(表1)。Jadad质量分析法得分在1~3分。漏斗图显示,各研究结果变量的散点图不对称,说明有发表偏倚,这可能与研究人员在统计发表结果时存在主观性有关(图1)。

表1 纳入研究的原始文献临床疗效分布情况

作者	有效率(%)		病死率(%)	
	研究组	对照组	研究组	对照组
傅国洲 ^[10]	83.30	63.30	3.33	13.33
吴渝宪等 ^[11]	91.10	67.75	5.93	20.09
李剑侠 ^[12]	91.30	47.50	4.35	32.50
汪兵 ^[13]	77.08	60.42	22.92	39.58
熊国文 ^[14]	95.00	72.50	5.00	27.50
王运飞 ^[15]	94.55	60.00	3.64	21.82
罗勇勇 ^[16]	67.86	35.71	21.43	46.43
苏彦果等 ^[17]	91.30	47.50	4.35	32.50
袁士博等 ^[18]	85.00	53.23	5.00	25.81
谢雄根 ^[19]	79.07	51.16	4.65	23.26
陈长春等 ^[20]	64.58	39.62	22.92	45.28
高卫丰等 ^[21]	92.00	68.00	8.00	32.00
黄中文等 ^[22]	85.29	58.82	10.29	22.06

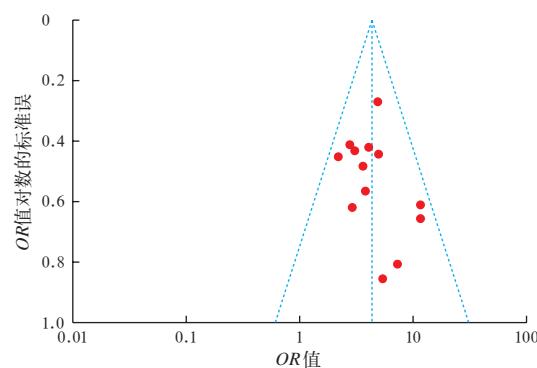


图1 研究组和对照组有效率比较的漏斗图

2.2 MPST对患者有效率的影响(图2):13篇^[10-22]文献共纳入1556例患者,其中研究组787例,有效675例(85.76%);对照组769例,有效456例(59.39%)。各研究间无统计学异质性($P=0.60, I^2=0\%$),故采用固定效应模型进行Meta分析,结果显示,研究组有效率明显高于对照组,差异有统计学意义($OR=4.29, 95\%CI=3.33 \sim 5.53, P<0.00001$)。

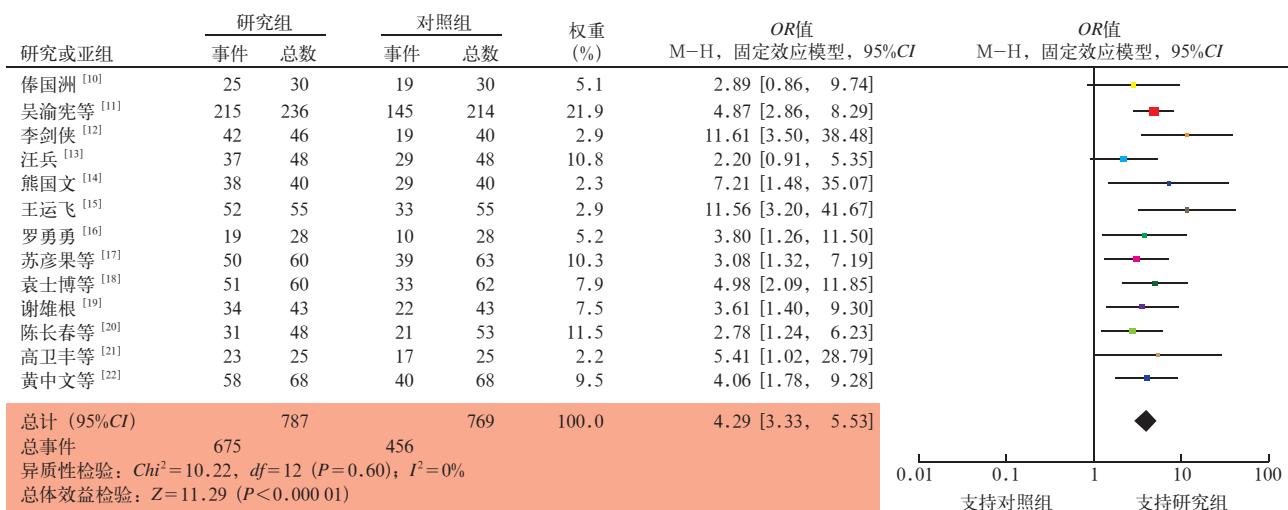


图2 研究组和对照组有效率比较的Meta分析森林图

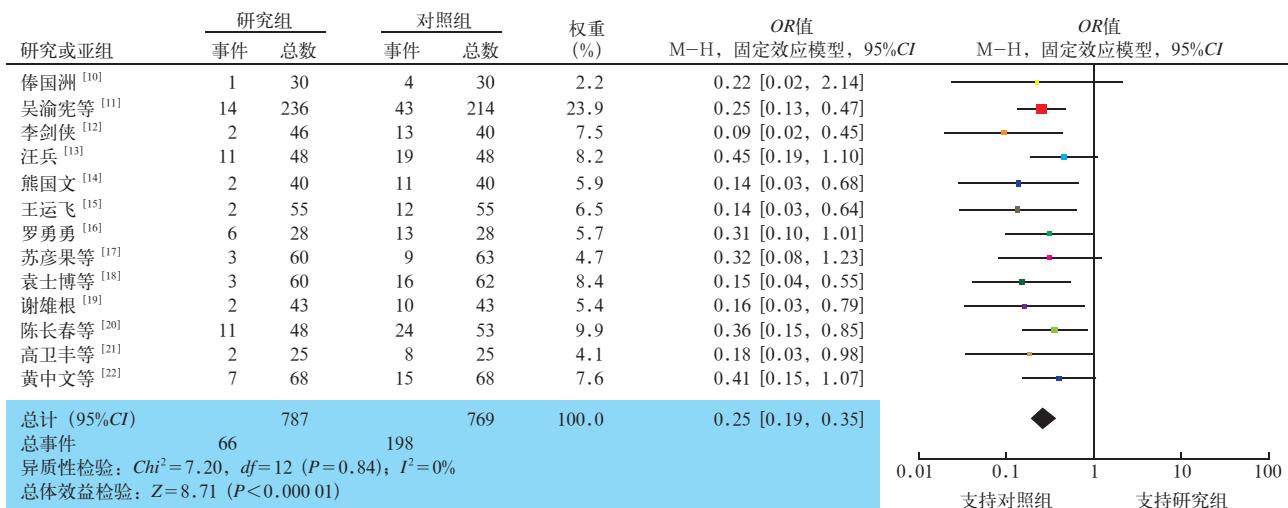


图3 研究组和对照组病死率比较的Meta分析森林图

2.3 MPST 对患者预后的影响(图3): 13篇^[10-22]文献共纳入1556例患者,研究组787例,恶化(死亡)66例(8.38%);对照组769例,恶化(死亡)198例(25.6%)。各研究间无统计学异质性($P=0.84, I^2=0\%$),故采用固定效应模型进行Meta分析,结果显示,研究组病死率明显低于对照组,差异有统计学意义($OR=0.25, 95\%CI=0.19 \sim 0.35, P<0.000 01$)。

3 讨论

HICH 起病急剧,病情凶险,病死率和致残率均较高,是急性脑血管病中最严重的一种。其危害主要原因为血肿本身的占位效应和继发性脑水肿、脑组织损伤。急性期开颅血肿清除术是神经外科治疗HICH的传统方法,也是治疗高颅压的重要方法。手术可以在直视下彻底清除血肿,达到减压目的。对于危重患者还可以同时去骨瓣减压。但开颅手术创伤大,操作过程中可能损伤血肿周围正常脑组织

和血肿内尚存的有功能脑组织,由于脑组织受压牵拉时间过长、过重,术后脑水肿严重。另外,去骨瓣减压术后颅骨缺损,手术及麻醉时间长,对患者打击较大。特别是对合并症较多的老年人,严重影响术后康复。急性期内科保守治疗方式多采用甘露醇脱水等减轻占位效应,间接缓解血肿对脑组织的压迫,但治疗效果并不理想,且对患者的肾功能损伤较大。

MPST 是在局部麻醉下进行的、通过影像学及手术辅助定位器准确定位,能有效避开大脑内的主要功能区及周边大血管区域,直接深入脑内出血部位,清除位置较深的血肿,并可精确控制血肿的排出量,较开颅血肿清除可以控制颅内压下降缓慢。由于手术时间短、出血少、脑组织暴露少,故损伤小,使术后患者意识障碍较快恢复,并发症发生率及死亡和植物生存状态的发生率下降^[23]。而且,手术适用范围较广,即使是年龄较大或身体耐受性较差的

患者,也可以通过 MPST 进行治疗。

本研究所纳入的 13 篇 RCT 文献,各研究间无统计学异质性($P=0.60, I^2=0\%$),采用固定效应模式进行 Meta 分析,结果显示,MPST 与内科保守治疗在有效率方面差异有统计学意义($OR=4.29, 95\%CI 3.33 \sim 5.53, P<0.01$)。同时,在恶化(死亡)率方面差异也有统计学意义($OR=0.25, 95\%CI 0.19 \sim 0.35, P<0.01$)。

综上所述,通过 Meta 分析结果可以看出,研究组有效率明显高于对照组,初步证明了 MPST 治疗 HICH 疗效满意,安全可靠。血肿周围水肿可能是导致继发性脑损伤的主要因素^[24],因此,微创手术能改善患者的远期预后,其机制除直接减轻血肿对脑组织的机械压迫外,更可能是降低了脑水肿等继发性脑损伤^[25]。影响 HICH 的因素很多,超早期实行 MPST 患者术后神经功能恢复很好,是 HICH 手术治疗的方向^[26]。但由于本研究未检索到国外符合条件的相关论文,纳入的研究均为国内发表文献,不能完全代表 MPST 的国际进展,且研究纳入的均为小样本 RCT,有可能产生偏倚及误差。建议有条件的单位严格遵照循证医学研究设计方案,制定统一规范的标准(操作及定位方法、时间窗等),采用立体定位设备,开展多中心、大样本 RCT,以客观全面探索 MPST 治疗 HICH 的益处和风险,并观察其远期疗效,为临床提供更为确凿的循证医学证据。

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本刊常用的不需要标注中文的缩略语

肠内营养 (enteral nutrition, EN)
 肠外营养 (parenteral nutrition, PN)
 二十碳五烯酸 (eicosapentaenoic acid, EPA)
 二十二碳六烯酸 (docosahexaenoic acid, DHA)
 γ -亚麻酸 (gamma-Linolenic Acid, GLA)
 白细胞三烯 B4 (leukotriene B4, LTB4)
 原发性肺泡蛋白沉着症 (primary alveolar proteinosis, PAP)
 粒-巨噬细胞集落因子
 (granulocyte/macrophage-colony stimulating factor, GM-CSF)
 过碘酸希夫染色 (periodic acid-Schiff staining, PAS)
 经支气管镜肺活检 (transbronchial lung biopsy, TBLB)
 阿辛蓝染色 (alcian blue staining, AB)
 结核菌 (tubercle bacillus, TB)
 癫痫持续状态 (status epilepticus, SE)
 左室射血分数 (left ventricular ejection fraction, LVEF)
 磁共振血管造影 (magnetic resonance angiography, MRA)
 数字评定量尺 (numerical rating scale, NRS)
 语言评分法 (visual rating scale, VRS)
 疼痛行为评分 (behavioral pain scale, BPS)
 重症监护疼痛观察工具
 (critical-care pain observation tool, CPOT)

格拉斯哥昏迷评分 (Glasgow coma scale, GCS)
 格拉斯哥预后评分 (Glasgow outcome scale, GOS)
 临床肺部感染评分 (clinical pulmonary infection score, CPIS)
 麻醉恢复室 (postanesthesia care unit, PACU)
 呼吸频率 (respiratory rate, RR)
 体质量指数 (body mass index, BMI)
 乳酸脱氢酶 (Lactate dehydrogenase, LDH)
 深静脉血栓 (deep venous thrombosis, DVT)
 肝肾联合移植
 (simultaneous liver-kidney transplantation, SLK)
 微粒子酶免疫法 (microparticle enzyme immunoassay, MEIA)
 机械通气 (mechanical ventilation, MV)
 内皮素 (endothelin-1, ET-1)
 左心耳 (left atrial appendage, LAA)
 经食管超声心动图 (transesophageal echocardiography, TEE)
 短暂性脑缺血发作 (temporary ischemic attack, TIA)
 世界卫生组织 (World Health Organization, WHO)
 国际抗癫痫联盟
 (International League Against Epilepsy, ILAE)
 美国麻醉医师协会
 (American Society of Anesthesiologists, ASA)