

doi: 10.13241/j.cnki.pmb.2014.08.040

脑心通胶囊辅助治疗不稳定型心绞痛的临床疗效和安全性的 Meta 分析

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摘要 目的:系统评价脑心通胶囊辅助治疗不稳定型心绞痛的临床疗效及其安全性。**方法:**计算机检索 PubMed(1966~2012.3)、EMbase(1974~2012.3)、Cochrane Library(2012 年第 3 期)、CBM(1978~2012.3)、CNKI(1994~2012.3)、VIP(1989~2012.3)。纳入脑心通胶囊联合常规药物治疗不稳定型心绞痛的随机对照试验(RCT),并补充检索纳入研究的参考文献;按 Cochrane 系统评价方法对纳入研究进行资料提取及质量评估后,采用 RevMan 5.1 软件进行统计学分析。**结果:**共纳入 11 个 RCT,包括共 1384 例患者,Meta 分析结果显示:与常规药物治疗相比,脑心通胶囊联合常规药物明显缓解不稳定型心绞痛患者的临床症状,差异有统计学意义[RR=1.24,95%CI(1.18-1.31),P<0.01],提高了心电图的改善率[RR=1.35,95%CI(1.24-1.47),P<0.01]。**结论:**目前研究表明脑心通胶囊辅助治疗不稳定型心绞痛的短期疗效明显优于常规治疗,但其不良反应和远期疗效尚不确定,需要更多高质量随机对照试验进一步证实。

关键词:脑心通胶囊;不稳定型心绞痛;临床疗效;安全性;Meta 分析

中图分类号:R541.4 文献标识码:A 文章编号:1673-6273(2014)08-1545-05

The Clinical Curative Effect and Safety of Naoxintong Capsules in the Treatment of Unstable Angina: A Meta-analysis

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ABSTRACT Objective: To review the clinical curative effect and safety of Naoxintong Capsules in the treatment of patients with Unstable Angina. **Methods:** PubMed(1966-2012.3), EMbase (1974-2012.3), Cochrane Library(Issue3,2012), CBM(1978-2012.3), CNKI (1994-2012.3), VIP (1989-2012.3) were electronically searched. Randomized controlled trials (RCTs) about Naoxintong Capsules plus conventional drugs in the treatment of Unstable Angina were included, and the relevant references of the included papers were also manually searched. Study selection and analysis were undertaken according to the Cochrane Handbook, and RevMan 5.1 was applied for statistical analyses. **Results:** Eleven RCTs involving 1384 patients with Unstable Angina were included. The results of meta-analysis showed that the improvement of symptoms [RR=1.24, 95%CI (1.18-1.31),P<0.01], the improve of ECG [RR=1.35, 95%CI(1.24-1.47), P<0.01] were superior in the combination arm to the conventional drugs alone arm. **Conclusion:** The current evidence available showed that the combination of Naoxintong Capsules and conventional drugs may significantly improve the short-term efficacy comparing with conventional drugs alone. However, long-term efficacy and adverse events were not clear yet; more high-quality RCTs should be conducted.

Key words: Naoxintong Capsules; Unstable angina; Clinical efficacy; Safety; Meta-analysis

Chinese Library Classification(CLC): R541.4 **Document code:** A

Article ID: 1673-6273(2014)08-1545-05

前言

不稳定型心绞痛(unstable angina, UA)是一种临床常见疾病,属于心血管急症之一^[1]。目前治疗以硝酸酯类、钙通道阻滞剂及β受体阻滞剂等和介入治疗为主^[2]。近年来,许多中成药的出现,给 UA 的治疗带来了新的希望。脑心通胶囊是一种中药复方制剂,现代药理研究认为其具有保护血管内皮细胞和心肌细胞、改善微循环的作用^[3]。本文对其应用于 UA 的随机对照试

验进行了 Meta 分析,旨在评价脑心通胶囊联合常规药物治疗 UA 的临床疗效及其安全性,为 UA 的治疗提供更多的参考依据。

1 资料与方法

1.1 纳入与排除标准

1.1.1 **研究类型** 随机对照试验,语种不限,无论是否采用盲法或隐蔽分组。

1.1.2 **研究对象** 诊断明确的 UA 患者,符合 1979 年 WHO 制定的缺血性心脏病命名及诊断标准,经心电图及临床表现确诊。排除:非随机对照试验、无法提取资料或资料不全及重复发表的文献。

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(收稿日期:2013-07-08 接受日期:2013-07-29)

1.1.3 干预措施 试验组脑心通胶囊联合常规药物, 对照组为常规药物。

1.1.4 结局指标 ①心绞痛症状改善情况,有效(包括显效和有效)、无效(包括无效和加重);②心电图(ECG)改善情况。

1.2 检索策略

计算机检索 PubMed(1996-2012.3)、EMbase(1984-2012.3)、Cochrane Library (2012 年第 3 期)、CBM(1978-2012.3)、CNKI(1994-2012.3)、VIP(1989-2012.3)。英文检索词:Unstable Angina, UA,Naoxintong Capsules, Nao xin tong Capsules; 限定条件为:“Humans”,“Randomized controlled trial”。中文检索词:脑心通、不稳定型心绞痛、治疗;限定条件为:“人类”和“随机对照试验”。使用 Google、百度等搜索引擎及手工检索作为补充,追查纳入文献的参考文献。

1.3 质量评价

按照 Cochrane Reviewers Handbook 5.1.0 评价标准对纳入研究的①随机分配方法;②分配方案隐藏;③盲法;④是否描述退出失访情况,是否采用意向处理;⑤有无选择性报告研究结果;⑥有无其他偏倚来源六方面进行评价。

1.4 资料提取

由两名评价员按照纳入与排除标准独立完成,填写预先设计好的资料提取数据库,包括文献方法学质量、患者一般人口

学特征、干预措施及结局指标,并逐一交叉核对,遇分歧时通过查阅原始资料讨论解决。若遇资料不全则通过联系通讯作者或第一作者获取,最终未获得相关资料的剔除该项研究。

1.5 统计学分析

采用 Cochrane 协作网提供的 RevMan5.1 统计软件进行 Meta 分析。计数资料采用计数资料采用相对危险度(RR)为疗效分析效应量并计算其 95% 可信区间(CI)。采用卡方检验对各项纳入研究结果间的异质性进行检验,若 $P>0.1$ 和 $I^2<50\%$ 则异质性检验结果无统计学意义采用固定效应模型进行 Meta 分析;若 $P<0.1$ 和 $I^2\geq 50\%$ 则异质性检验结果有统计学意义,先分析异质性来源,确定是否能采用随机效应模型,如果研究间存在明显的临床异质性,只对其进行描述性分析,必要时采用敏感性分析。

2 结果

2.1 检索结果

共检出相关文献 224 篇,其中中文文献 224 篇,英文文献 0 篇。通过阅读题目和摘要排除动物实验、非 RCT、重复文献和综述等共 45 篇。对可能符合要求的 179 篇文献阅读全文后排除不符合纳入标准和结局指标缺失的文献 167 篇,最终纳入 11 个 RCT[4-14],共 1384 例患者。纳入文献的基本情况见表 1。

表 1 纳入研究的基本情况
Table 1 Baseline characteristics of included studies

Study	Age(T/C) (year)	Number (T/C)	Treatment programs		Time (day)	Outcome measures
			T	C		
KAI Y 2008 ^[4]	40-78/42-79	45/45	C+Naoxintong Capsules,po, 2 capsules each time ,tid	C	42	①②
LV GQ 2008 ^[5]	40-70/41-69	32/30	C+Naoxintong Capsules,po, 3 capsules each time ,tid	C	30	①②
HU ChL 2009 ^[6]	35-65/37-65	342/150	C+Naoxintong Capsules,po, 4 capsules each time ,tid	C	28	①②
YANG HY 2009 ^[7]	56-87/45-81	64/64	C+Naoxintong Capsules,po, 3 capsules each time ,tid	C	28	①②
CUI CX 2010 ^[8]	48-81/48-81	40/42	C+Naoxintong Capsules,po, 3 capsules each time ,tid	C	56	①②
JING DQ 2010 ^[9]	40-81/41-80	60/60	C+Naoxintong Capsules,po, 3 capsules each time ,tid	C	21	①②
LI YB 2010 ^[10]	40-60/40-60	35/35	C+Naoxintong Capsules,po, 2-4 capsules each time ,tid	C	28	①②
JIN R Sh2011 ^[11]	50-82/55-79	40/40	C+Naoxintong Capsules,po, 2 capsules each time ,tid	C	42	①②
YIN Sh Y2010 ^[12]	52-77/50-78	60/60	C+Naoxintong Capsules,po, 4 capsules each time ,tid	C	28	①②
SONG JX2011 ^[13]	48-74/48-74	40/38	C+Naoxintong Capsules,po, 2 capsules each time ,tid	C	28	①②
WANG XL2012 ^[14]	40-70/41-69	32/30	C+Naoxintong Capsules,po, 3 capsules each time ,tid	C	30	①②

注:T 试验组(常规药物+脑心通胶囊);C:对照组(常规药物);①症状改善情况,②心电图改善情况

Note: T: trial group (Naoxintong Capsules+ Conventional drugs), C: Control group(Conventional drugs);

① Improvement of symptoms, ② The ECG to improve situation.

2.2 方法学质量评价

纳入的 11 个 RCT 总计 1384 例 UA 患者,均为随机分组,未具体描述随机方法,没有研究提到对随机分配方案的隐藏;

仅有 1 个研究^[6]说明采用单盲,未描述盲法的具体实施办法。纳入研究均未提及患者因不良反应失访或退出。纳入研究的方法学质量评价结果见表 2。

表 2 纳入研究的方法学质量评价
Table 2 Methodological quality of included studies

Study	Randomization	Allocation concealment	Blinding	Loss/ Quit	ITT Analysis	Selective reporting	Other bias
KAI Y2008 ^[4]	admission order	Not stated	No	No	Not stated	Not stated	Not stated
LV GQ2008 ^[5]	Not stated	Not stated	No	No	Not stated	Not stated	Not stated
HU ChL2009 ^[6]	Not stated	Not stated	Single blind	No	Not stated	Not stated	Not stated
YANG HY2009 ^[7]	Not stated	Not stated	No	No	Not stated	Not stated	Not stated
CUI CX2010 ^[8]	Not stated	Not stated	No	No	Not stated	Not stated	Not stated
JING DQ2010 ^[9]	Not stated	Not stated	No	No	Not stated	Not stated	Not stated
LI YB2010 ^[10]	Not stated	Not stated	No	No	Not stated	Not stated	Not stated
JIN R Sh2011 ^[11]	Not stated	Not stated	No	No	Not stated	Not stated	Not stated
YIN Sh Y2010 ^[12]	Not stated	Not stated	No	No	Not stated	Not stated	Not stated
SONG X2011 ^[13]	Not stated	Not stated	No	No	Not stated	Not stated	Not stated
WANG L2012 ^[14]	Not stated	Not stated	No	No	Not stated	Not stated	Not stated

2.3 Meta 分析结果

2.3.1 症状改善情况 纳入的 11 项研究均报告了该指标,各研究结果间无统计学异质性($\chi^2=5.67$, $P=0.84$, $I^2=0\%$),故采用固定效应模型进行 Meta 分析。结果显示,脑心通胶囊联合常规药

物组对不稳定型心绞痛临床症状的有效率是单纯使用常规药物组的 1.24 倍,两组症状改善差异有统计学意义[RR=1.24, 95% CI(1.18~1.31), $P<0.01$](图 1)。

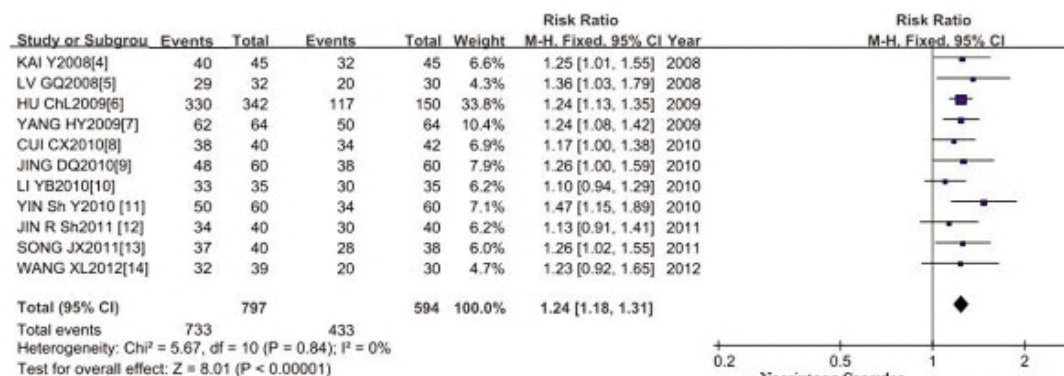


图 1 脑心通胶囊联合常规药物与常规药物单用治疗不稳定型心绞痛的症状改善情况

Fig.1 The symptoms of Naoxintong Capsules +conventional drugs and conventional drugs alone for UA

2.3.2 心电图的改善情况 纳入的 11 项研究均心电图改善情况以计数资料表示,其效应量同质性好($\chi^2=5.87$, $P=0.83$, $I^2=0\%$),故采用固定效应模型进行 Meta 分析。结果显示,脑心

通胶囊联合常规药物组对不稳定型心绞痛心电图的改善率是单纯使用常规药物组的 1.35 倍,两组心电图改善差异有统计学意义[RR=1.35, 95% CI(1.24~1.47), $P<0.01$](图 2)。

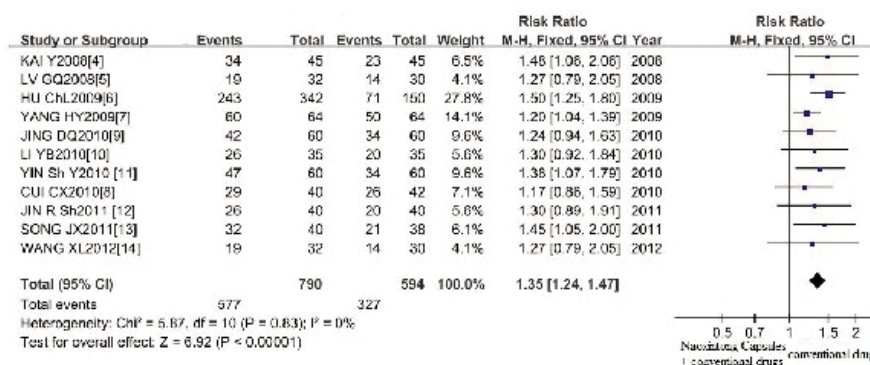


图 2 脑心通胶囊联合常规药物与单用常规药物治疗不稳定型心绞痛的心电图改善情况

Fig.2 The ECG of Naoxintong Capsules + conventional drugs and conventional drugs alone for UA

2.3.3 安全性 纳入的 7^[7-13]项研究显示治疗过程中未发现明显不良反应,4 项研究^[4,6,14]简要描述了服用药物后的不良反应。4 例患者在服用脑心通胶囊的第 1 周有轻度上腹不适,未经特殊处理,继续用药后可耐受,无其他不良反应^[4],3 例患者用药后自诉上腹部不适,服用雷尼替丁胶囊后症状缓解,治疗后血、尿、粪常规及肝肾功能检查未见异常^[5]。7 例患者用药后出现胃部不适或胃痛,改为饭后服用后上述不适消失^[6]。3 例患者诉上腹部不适,服用雷尼替丁胶囊后症状缓解^[14],4 项研究的不良反应资料均为描述性分析,无法进行 Meta 分析。

3 讨论

UA 是急救工作中常遇到的急危病症^[15],在中医《内经》中属“真心痛”的范畴,心气虚弱、运血无力导致心脉瘀阻是形成本病的重要原因,“虚”是本,“瘀”是标,治疗关键在于益气补虚、活血化瘀、通络止痛、标本同治^[9]。西医认为其生理、病理基础是易损动脉粥样硬化斑块形成及斑块破裂血栓形成^[16],以往的治疗以抗血小板聚集、抗凝和抗心肌缺血等综合治疗,其中抗心肌缺血的药物以硝酸酯类为主。虽取得了肯定疗效,也有许多令人不满意之处,近年研究表明部分心绞痛患者对硝酸酯类药物并不敏感^[17,18],而中药用于 UA 的治疗则逐渐受到人们的重视。

本 Meta 分析结果显示,脑心通胶囊联合常规药物治疗 UA 患者临床症状的有效率和心电图的改善率均优于单纯使用常规药物,其原因可能为脑心通是一复方中药制剂,可通过减少蛋白质水解酶、受损的血管内皮释放,抑制凝血途径的激活^[7],降低血液黏度,改善血液微循环,有利于侧支循环的建立。也有学者认为,脑心通具有抑制血小板聚集,降低血液黏稠度的作用,同时使血管内皮生长因子(VEGF)表达明显增高,促进了血管的增生,改善了血液循环,促进缺血区的修复^[19]。但由于缺乏统计资料无法对药物的不良反应进行 Meta 分析。

本研究的局限在于:纳入研究的总体样本量偏小,研究质量总体不高,仅有一项研究^[4]按入院顺序分为联合用药组和单药组,余纳入研究随机方法均不清楚,所有纳入分配隐匿不明确。仅有 1 个研究^[6]说明采用单盲,但未详细描述盲法的具体实施办法,余 10 项研究可能由于客观的原因均无盲法设计;而且本研究入选的文献都是中文文献,缺少外文文献,可能产生发表偏倚。

综上所述,对于 UA 患者,脑心通胶囊联合常规药物在临床症状的缓解和心电图的改善两方面均有一定的优势。但由于本次 Meta 分析纳入文献大部分为低质量研究,同时缺乏不良反应及长期随访资料,因此上述结果尚需更多高质量证据进一步证实。

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