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养心汤结合针灸对气虚血瘀型胸痹患者血脂代谢的影响——系统回顾的方案

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摘　要

背景：近年来，养心汤结合针刺(Yangxin Decoction and Acupuncture) (YXDA)治疗气虚血瘀型胸痹的临床研究有所增加，但效果不一。本研究的目的是探讨YXDA对胸痹气虚血瘀型血脂代谢的影响。方法：我们将收集任何随机对照试验，评估YXDA对CBS-QDBS中BLMB的影响，这些试验来自PUBMED、EMBASE、Cochrane图书馆、PsycINFO、CINAHL、联合和补充医学数据库和中国国家知识基础设施。所有这些数据库都将从最初的时间到现在进行搜索。所有语言限制将被强加。文献选择、信息收集和偏倚风险评估将分别由两位作者独立完成。所有数据分析将使用RevMan 5.3软件进行。结果：本研究将总结文献检索的系统性及其评估研究质量和分析所有相关结果数据的方法。考虑到不一致的结果，本研究将改进现有的关于YXDA对CBS-QDBS中BLMB的影响的证据。结论：本研究将介绍YXDA对CBS-QDBS患者BLMB的最新证据。

关键词

针灸，胸痹，气虚血瘀型，养心汤

Yangxin Decoction Combined Acupuncture on Blood Lipid Metabolism in Qi Deficiency and Blood Stasis Type of Chest Bi-Syndrome—A Protocol of Systematic Review

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Abstract

Background: In recent years, clinical studies about Yangxin Decoction combined acupuncture (YXDA) for the treatment of Qi deficiency and blood stasis type of chest bi-syndrome (CBS-QDBS) has been increased, but the results are different. The aim of this study is to investigate the effect of YXDA on blood lipid metabolism (BLMB) in patients with CBS-QDBS. Methods: We will collect any randomized controlled trials that assess the effect of YXDA on BLMB in CBS-QDBS from PUBMED, EMBASE, Cochrane Library, PsycINFO, CINAHL, Allied and Complementary Medicine Database, and China National Knowledge Infrastructure. All of these databases will be searched from their initial time to the present. All language limitations will be imposed. Literature selection, information collection, and risk of bias assessment will be performed independently by two authors, respectively. All data analysis will be undertaken using RevMan 5.3 Software. Results: This study will summarize the systematic nature of the literature search and its methods for assessing study quality and analyzing all relevant outcome data. Considering the inconsistent results, this study will improve the existing evidence on the effect of YXDA on BLMB in CBS-QDBS. Conclusion: The findings of this study will present the latest evidence of YXDA on BLMB in patients with CBS-QDBS.

Keywords

Acupuncture, Chest Bi-Syndrome, Qi Deficiency and Blood Stasis Type, Yangxin Decoction

1. 引言

胸痹(中医称为胸痛)是颅内科和急诊科常见的心肌梗死主诉和症状[1] [2] [3] [4]，是全球死亡率和发病率的主要原因[5] [6]。美国有 800 多万次胸痛急诊，其中约 30%至 80%是由急性冠状动脉综合征(ACS)引起的[7] [8]。它包括 ST 段抬高心肌梗塞和非 ST 段抬高心肌梗塞[9]。研究报告称，它可能与体液和组织代谢异常有关，如血脂代谢(BLMB) [10] [11]。前人研究报道养心汤结合针灸(YXDA)可用于治疗气虚血瘀型 CBS (CBS-QDBS) [12]-[23]。然而，没有系统地研究调查这个问题。因此，本系统研究旨在探讨 YXDA 对慢性脑供血不足-QDBS 患者脑血流量的影响。

2. 方法和分析

2.1. 研究注册

本研究注册于美国国家科学院院刊 202070047，其设计基于系统综述和荟萃分析方案声明指南的首选报告项目。

2.2. 研究选择的纳入标准

2.2.1. 研究类型

将包括 YXDA 对患有 CBS-QDBS 的 BLMB 患者的随机对照试验(RCTs)，而不考虑盲法、出版时间和语言。然而，实验室研究、观察研究和非随机对照试验将被排除在外[24] [25]。

2.2.2. 参与者类型

无论种族、性别和国家，确诊为 CBS-QDBS 的参与者(18 岁或以上)都将包括在内。

2.2.3. 干预类型

在实验组，所有参与者都接受了任何形式的 YXDA。但是，针灸或养心汤的任何单次给药都将被排除。在对照组中，患者接受任何类型的治疗，但不接受任何形式的针灸或养心汤或 YXDA。

2.2.4. 结果测量的类型

主要结果是胸痛，通过心电图或任何相关检查进行测量。次要结果包括胆固醇、甘油三酯、磷脂、尿常规检查、丙氨酸氨基转移酶、天冬氨酸氨基转移酶、肌酐血液检查、血尿素氮检查和任何不良事件。

2.3. 文献检索

以下电子数据库将从最初的时间到现在进行检索：PUBMED、EMBASE、Cochrane 图书馆、PsycINFO、CINAHL、联合和补充医学数据库、中国国家知识基础设施。我们不会对语言和出版状态施加任何限制。为了进行全面和系统的搜索，将邀请一名经验丰富的图书管理员为所有电子数据库制定搜索策略。PUBMED 的详细搜索策略如表 1 所示。相同的搜索策略将被修改并用于其他电子数据库。此外，我们将确定会议摘要、从临床注册网站进行的试验以及相关综述的参考列表。

2.4. 文献选择和数据收集

2.4.1. 文献选择

在搜索了所有的记录后，他们的标题和摘要将由两位独立作者审查，以根据先前定义的资格标准检查潜在的试验。然后，我们将阅读所有潜在试验的全文，以确定它们是否合格。我们将记录每个排除的研究，并给出具体的原因。两位作者之间的任何冲突都将由第三位作者通过讨论来解决。我们将在流程图中描述学习过程的选择。

2.4.2. 数据收集和管理

两位独立作者将根据 Cochrane 干预系统综述手册推荐的标准表格收集数据。两个作者之间的任何冲突都会在第三个作者的帮助下通过讨论解决。数据收集表包括第一作者、标题、出版年份、国家、研究设置、研究持续时间、年龄、性别、诊断标准、样本量、所有实验和对照干预措施的细节、结果、资金和任何其他相关数据。必要时，如果我们发现任何缺失或不清楚的数据，我们将联系主要作者请求他们。

Table 1. Search strategy for MEDLINE
表 1. MEDLINE 的搜索策略

Number	Search terms
1	双综合征(Bi-Syndrome)
2	胸痛(Chest pain)
3	气虚(Qi Deficiency)
4	血瘀(Blood Stasis)

Continued

5	血脂(Blood lipid)
6	新陈代谢(Metabolism)
7	或者(or) 1~6
8	中医(Chinese medicine)
9	草药(Herbal medicine)
10	草药配方(Herbal formulas)
11	草药煎剂(Herbal decoction)
12	针刺(疗法)(Acupuncture)
13	电针(Electroacupuncture)
14	针灸手册(Manual acupuncture)
15	或者(or) 8~14
16	随机对照试验(Randomized controlled trials)
17	RCTs
18	随机(Random)
19	随机(Randoms)
20	控制(Control)
21	对照组(Comparator)
22	隐藏(Concealment)
23	空白组(Blind)
24	分配(Allocation)
25	安慰剂(Placebo)
26	研究(Study)
27	测试组(Trial)
28	或者(or) 16~27
29	7、15、28

2.5. 纳入研究中偏倚风险的评估

两名独立作者将根据 Cochrane 干预系统评价手册的指南，使用 Cochrane 协作的“偏倚风险”工具评估每个合格研究的偏倚风险。每项研究的所有偏差风险都将通过 7 个方面进行检查，每个方面都被分为低、不清楚或高偏差风险。两位作者之间的任何冲突都将由第三位作者通过讨论来解决。

2.6. 统计分析

2.6.1 数据分析

统计分析将使用 RevMan 5.3 软件进行。二分数据将表示为风险比和 95%置信区间，而连续数据将表示为平均差异或标准化平均差异和 95%置信区间。将使用 I2statistic 检查研究之间的异质性水平。合理的异质性会被认为是 $I2 \leq 50\%$，如果可能的话，我们将采用混合效应模型以及荟萃分析性能。如果 $I2 > 50\%$，将考虑显著的异质性，我们将使用随机效应模型。与此同时，我们将进行亚组分析或荟萃回归，以探索实质性异质性的可能原因。此外，将根据数据收集流程部分概述的因素，通过对收集的数据提供详细的书面评论来解释汇总结果。这将有助于提高我们对气虚血瘀疾病患者(BLMB)中 YXDA 的认识。

2.6.2. 亚组分析

如果有足够的研究，我们将根据干预、控制和结果的差异进行亚组分析。

2.6.3. 敏感性分析

我们将进行敏感性分析，通过排除具有高偏差风险的研究来检查结果的稳健性。

2.6.4. 报告偏差评估

如果包含超过 10 项合格的研究，我们将运行漏斗图和埃格斯回归测试[26] [27]来检查报告偏差。

2.7. 伦理与传播

本研究是对已发表数据的二次分析；因此，不需要伦理批准。我们计划在同行评议的期刊或会议进程中发表这项研究。

3. 讨论

中医如 YXDA、针灸等已广泛用于治疗 CBS-QDBS。然而，其结果仍然不一致，没有系统地进行研究来检查 YXDA 对 CBSQDBS 患者 BLMB 的影响。因此，本研究将特别关注于研究 YXDA 气虚血瘀 BLMB 的影响。它可能会提供一个详细的总结，本研究的结果可为临床医生和未来研究人员治疗 CBS-QDBS 提供有益的证据。

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简称

ACS = 急性冠脉综合征，BLMB = 血脂代谢，CBS = 胸痹综合征，CBS-QDBS = 气虚血瘀型 CBS，CIs = 置信区间，MI = 心肌梗死，RCTs = 随机对照试验，YXDA (Yangxin Decoction and Acupuncture) = 养心汤合针刺

Abbreviations

ACS = acute coronary syndrome, BLMB = blood lipid metabolism, CBS = Chest Bi-Syndrome, CBS-QDBS = Qi Deficiency and Blood Stasis type of CBS, CIs = confidence intervals, MI = myocardial infarction, RCTs = randomized controlled trials, YXDA = Yangxin Decoction combined acupuncture, YXDA = Yangxin Decoction combined acupuncture