

经皮椎体成形术与非手术疗法 治疗骨质疏松性椎体压缩骨折疗效比较的 Meta 分析

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摘要 目的:系统评价经皮椎体成形术(percutaneous vertebroplasty, PVP)和非手术疗法治疗骨质疏松性椎体压缩骨折(osteoporotic vertebral compression fracture, OVCF)的临床疗效。**方法:**应用计算机检索中国知网、万方数据库、维普网、PubMed、Embase、Cochrane Library、Medline 中比较 PVP 和非手术疗法治疗 OVCF 临床疗效的随机对照试验,检索时限均为建库至 2022 年 1 月。同时通过人工检索纳入文献的参考文献进行补充。手术组干预措施为 PVP,非手术组干预措施为固定制动、物理治疗、口服镇痛药等非手术疗法。由 2 名研究人员独立筛选文献、提取数据并评价纳入研究的偏倚风险后,采用 RevMan5.3 软件进行 Meta 分析。**结果:**共纳入 8 项随机对照试验,涉及 748 例患者,手术组 380 例、非手术组 368 例。Meta 分析结果显示,手术组治疗后的腰背部疼痛视觉模拟量表(visual analogue scale, VAS)评分低于非手术组[MD = -1.62, 95% CI(-1.91, -1.32), P = 0.000],其中治疗后 1 个月内、治疗后 1~3 个月和治疗后 3 个月以上,手术组的腰背部疼痛 VAS 评分均低于非手术组[MD = -1.78, 95% CI(-2.63, -0.93), P = 0.000; MD = -1.71, 95% CI(-2.11, -1.31), P = 0.000; MD = -1.29, 95% CI(-1.69, -0.88), P = 0.000]。手术组治疗后的欧洲骨质疏松基金会生活质量问卷(quality of life questionnaire of the European Foundation for Osteoporosis, QUALEFFO)评分低于非手术组[MD = -5.62, 95% CI(-8.94, -2.30), P = 0.001],其中治疗后 1 个月内手术组的 QUALEFFO 评分低于非手术组[MD = -6.25, 95% CI(-11.69, -0.81), P = 0.000];治疗后 1~3 个月和治疗后 3 个月以上,2 组 QUALEFFO 评分的差异均无统计学意义[MD = -6.49, 95% CI(-15.32, 2.33), P = 0.150; MD = -3.48, 95% CI(-9.64, 2.68), P = 0.270]。基于治疗后疼痛 VAS 评分进行发表偏倚分析,Egger's 检验显示纳入的研究不存在发表偏倚(治疗后 1 个月内:P = 0.452;治疗后 1~3 个月:P = 0.633;治疗后 3 个月以上:P = 0.532)。**结论:**PVP 治疗 OVCF 的临床疗效优于非手术疗法。

关键词 骨质疏松性骨折;脊柱骨折;椎体成形术;非手术疗法;专题 Meta 分析

Clinical outcomes of percutaneous vertebroplasty versus non-operative therapies for treatment of osteoporotic vertebral compression fracture: a meta-analysis

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ABSTRACT Objective: To systematically review the clinical outcomes of percutaneous vertebroplasty (PVP) versus non-operative therapies in treatment of osteoporotic vertebral compression fracture (OVCF). **Methods:** All the randomized controlled trial (RCT) articles about the clinical outcomes of PVP (operation group) versus non-operative therapies (non-operation group) in treatment of OVCF included from database establishing to January 2022 were retrieved from the China National Knowledge Internet, Wanfang Database, Vip Database, PubMed, Embase, Cochrane Library and Medline through computer, meanwhile, the references of the included articles were manually retrieved for supplementing. The patients in operation group were treated with PVP, while the ones in non-operation group with non-operative therapies such as fixing and bracing, physiotherapeutics and oral application of analgesics. The articles were screened and the information was extracted independently by two researchers according to the inclusion and exclusion criteria. The methodological quality of research in the articles was evaluated respectively independently by the same two researchers, and if any disagreement was found between them, discussion was conducted or another researcher was invited for making a final decision, and then a Meta-analysis was conducted by using RevMan5.3 software.

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Results: Eight RCT articles (748 patients) were included in the final analysis, 380 patients in operation group and 368 ones in non-operation group. The results of Meta-analysis revealed that the posttreatment low back pain visual analogue scale (VAS) score and the posttreatment quality of life questionnaire of the European Foundation for Osteoporosis (QUALEFFO) score were lower in operation group compared to non-operation group ($MD = -1.62, 95\% CI(-1.91, -1.32), P = 0.000; MD = -5.62, 95\% CI(-8.94, -2.30), P = 0.001$). The results of subgroup analysis showed that the low back pain VAS scores were all lower in operation group compared to non-operation group within 1 month after the treatment, at 1-3 months after the treatment and over 3 months after the treatment respectively ($MD = -1.78, 95\% CI(-2.63, -0.93), P = 0.000; MD = -1.71, 95\% CI(-2.11, -1.31), P = 0.000; MD = -1.29, 95\% CI(-1.69, -0.88), P = 0.000$). The QUALEFFO score was lower in operation group compared to non-operation group within 1 month after the treatment ($MD = -6.25, 95\% CI(-11.69, -0.81), P = 0.000$), while, at 1-3 months after the treatment and over 3 months after the treatment, there was no statistical difference between the 2 groups ($MD = -6.49, 95\% CI(-15.32, 2.33), P = 0.150; MD = -3.48, 95\% CI(-9.64, 2.68), P = 0.270$). Publication bias was analyzed based on the posttreatment pain VAS scores, and the results of Egger's test showed that there was no publication bias in the included articles (within 1 month after the treatment: $P = 0.452$; at 1-3 months after the treatment: $P = 0.633$; over 3 months after the treatment: $P = 0.532$). **Conclusion:** PVP is better than non-operative therapies in clinical outcomes in treatment of OVCF.

Keywords osteoporotic fractures; spinal fractures; vertebroplasty; nonoperative therapy; meta-analysis as topic

骨质疏松性椎体压缩骨折 (osteoporotic vertebral compression fracture, OVCF) 在老年群体中较为常见^[1], 可严重影响患者的生活质量, 增加死亡风险^[2]。经卧床休息、固定制动、物理治疗和口服镇痛药等非手术方法治疗后, 大部分患者的骨折会在几个月内愈合, 但仍有部分患者会残留长期疼痛或残疾^[3]。此外, 长期卧床、口服镇痛药等非手术疗法会增加老年患者发生褥疮、坠积性肺炎、胃肠道反应等并发症的风险^[4-6]。很多研究者主张 OVCF 不必采用非手术治疗, 一旦确诊就应尽快行经皮椎体成形术 (percutaneous vertebroplasty, PVP) 或经皮椎体后凸成形术, 以迅速缓解疼痛症状, 使患者短期内恢复正常生活^[7-9]。但也有研究显示, PVP 与非手术疗法相比并无明显优势, 甚至有增加二次骨折或引起肺栓塞的风险^[10-13]。为此, 我们采用 Meta 分析方法比较了 PVP 和非手术疗法治疗 OVCF 的临床疗效, 以期临床确定 OVCF 的诊疗方案提供参考。

1 资料与方法

1.1 文献检索 应用计算机检索中国知网、万方数据库、维普网、PubMed、Embase、Cochrane Library、Medline。中文检索词包括: 骨质疏松性椎体压缩骨折、骨质疏松压缩性骨折、椎体骨折、经皮椎体成形术、随机对照试验、脊柱。英文检索词包括: osteoporotic vertebral compression fractures、OVCF、percutaneous vertebroplasty、PVP、RCT、vertebral fracture、spine。检索时限均为建库至 2022 年 1 月。同时通过人工检索纳入文献

的参考文献进行补充。

1.2 文献筛选 由 2 名研究者按照文献纳入和排除标准独立筛选文献, 意见不一致时请第 3 名研究者协助裁定。

1.2.1 文献纳入标准 ①研究类型为随机对照试验; ②研究对象为 OVCF 患者, 骨折原因不包括恶性肿瘤及创伤; ③手术组干预措施为 PVP, 非手术组干预措施为固定制动、物理治疗、口服镇痛药等非手术疗法; ④结局指标中包括腰背部疼痛视觉模拟量表 (visual analogue scale, VAS) 评分和欧洲骨质疏松基金会生活质量问卷 (quality of life questionnaire of the European Foundation for Osteoporosis, QUALEFFO) 评分中的 1 种。

1.2.2 文献排除标准 ①无法获取全文的文献; ②数据不完整的文献; ③重复发表的文献取较早发表的 1 篇, 数据重复的文献取数据最全的 1 篇。

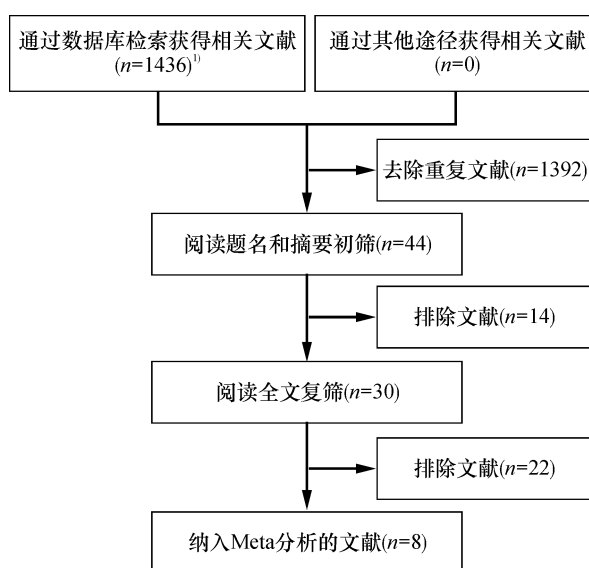
1.3 数据提取和纳入研究的偏倚风险评价 由 2 名研究者分别对纳入的研究进行数据提取和偏倚风险评价, 意见不一致时请第 3 名研究者协助裁定。提取的数据包括第 1 作者、出版时间、样本量、患者基本信息、干预措施、随访时间、结局指标等。研究中未提供原始数据时, 按照 Cochrane 手册中的方法进行计算; 数据以图像形式展示时, 采用 GetData Graph Digitizer 2.26 软件进行数据提取。偏倚风险评价采用 Cochrane 偏倚风险评估工具。

1.4 数据统计 采用 RevMan 5.3 软件进行数据统计

分析。腰背部疼痛 VAS 评分和 QUALEFFO 评分均以 MD 作为综合效应量。若纳入合并分析的各研究之间不存在明显异质性 ($P > 0.100$, 且 $I^2 \leq 40\%$), 则采用固定效应模型 Meta 分析; 若纳入合并分析的各研究之间存在明显异质性 ($P \leq 0.100$, 且 $I^2 > 40\%$), 则采用随机效应模型 Meta 分析。采用 R4.1.3 软件进行 Egger's 检验评价发表偏倚。检验水准 $\alpha = 0.05$ 。

2 结果

2.1 文献检索及筛选结果 共检索到 1436 篇文献, 经过逐层筛选最终纳入 8 篇文献^[14-21]。文献检索流程见图 1。



1) 1436 篇文献分别来源于中国知网 ($n = 332$)、万方数据库 ($n = 189$)、维普网 ($n = 330$)、PubMed ($n = 459$)、Cochrane Library ($n = 126$)。

图 1 文献筛选流程图

2.2 纳入研究的基本特征 纳入的 8 项研究共涉及 748 例患者, 手术组 380 例、非手术组 368 例。纳入研究的基本特征见表 1。

2.3 纳入研究的偏倚风险评价结果 纳入研究的偏倚风险评价结果见图 2。

2.4 Meta 分析结果

2.4.1 腰背部疼痛 VAS 评分 8 项研究^[14-21]比较了腰背部疼痛 VAS 评分, 各研究之间存在明显异质性; 随机效应模型分析结果显示, 手术组治疗后的腰背部疼痛 VAS 评分低于非手术组。按照随访时间进行亚组分析, 结果显示治疗后 1 个月内、治疗后 1~3 个月和治疗后 3 个月以上, 手术组的腰背部疼痛 VAS 评分均低于非手术组。见图 3。

2.4.2 QUALEFFO 评分 4 项研究^[14,16,18,20]比较了

QUALEFFO 评分, 各研究之间存在明显异质性; 随机效应模型分析结果显示, 手术组治疗后的 QUALEFFO 评分低于非手术组。按照随访时间进行亚组分析, 结果显示: 治疗后 1 个月内手术组的 QUALEFFO 评分低于非手术组; 治疗后 1~3 个月和治疗后 3 个月以上, 2 组 QUALEFFO 评分的差异均无统计学意义。见图 4。

2.5 发表偏倚分析结果 基于治疗后腰背部疼痛 VAS 评分进行发表偏倚分析。Egger's 检验显示, 纳入的研究不存在发表偏倚 (治疗后 1 个月内: $P = 0.452$; 治疗后 1~3 个月: $P = 0.633$; 治疗后 3 个月以上: $P = 0.532$)。

3 讨论

OVCF 是老年人常见的脊柱损伤之一, 主要症状为严重的腰背部疼痛^[22]。非手术疗法和 PVP 等微创手术是目前针对该病最常用的治疗方法。对于这两类疗法的选择, 目前临床中存在较多争议。

本研究的结果显示, PVP 治疗 OVCF 在缓解疼痛方面优于非手术疗法。这与 Buchbinder 等^[23]的研究结论一致。在生活质量改善方面, 手术组治疗后的 QUALEFFO 评分低于非手术组, 其中治疗后 1 个月内手术组的 QUALEFFO 评分低于非手术组, 而治疗后 1~3 个月和治疗后 3 个月以上, 2 组 QUALEFFO 评分的差异均无统计学意义。这提示 PVP 较非手术疗法可以更快地改善 OVCF 患者的生活质量。Kobayashi 等^[24]的研究也证实, 80% 以上的 OVCF 患者在 PVP 术后 24 h 即可活动, 可避免或减少长期卧床导致的各种并发症。这可能与 PVP 通过骨水泥强化椎体, 从而稳定骨折、恢复椎体力学强度、缓解疼痛有关^[25]。椎体高度丢失是导致 OVCF 患者持续疼痛的主要因素之一^[26]。OVCF 患者治疗后伤椎的椎体高度与治疗方式有关^[27-29]。PVP 和经皮椎体后凸成形术理论上具有椎体强化作用, 能够避免伤椎进一步塌陷, 但也有 PVP 术后 6 个月内发生伤椎再压缩的报道^[30-31]。因此, 后续还需对 PVP 术后椎体高度丢失的原因进行分析。

以往比较 PVP 和非手术疗法治疗 OVCF 的临床研究, 其结论存在较大差异。我们认为各研究病例纳入和排除标准的差异是主要原因。骨折至治疗时间、疾病严重程度和骨密度等, 都可能对 OVCF 患者治疗后疼痛症状的缓解和生活质量的改善产生影响。

因此,在设计此类研究方案时,随机化和治疗决策的选择应该以分类评分为指导,进行分层治疗及疗效评价^[32]。

现有的证据表明,PVP 治疗 OVCF 的临床疗效优

于非手术疗法。需要注意的是,此次 Meta 分析纳入的研究较少,各项研究间也存在明显异质性,而且很多研究没有进行临床试验注册及原始数据披露,这些都可能影响研究结果的准确性。

表 1 纳入研究的基本特征

研究	样本量/例		性别/(男/女,例)		平均年龄/岁		非手术组 干预措施	随访时间	结局 指标 ³⁾
	T ¹⁾	C ²⁾	T ¹⁾	C ²⁾	T ¹⁾	C ²⁾			
Voormolen 2007 ^[14]	18	16	14/4	14/2	72	74	药物	2 周	①②
Rousing 2009 ^[15]	25	24	19/6	21/3	80	80	护具	12 个月	①
Klazen 2010 ^[16]	101	101	70/31	70/31	75.2	75.4	药物	12 个月	①
Farrokhi 2011 ^[17]	40	42	30/10	30/12	72	74	药物	36 个月	①
Blasco 2012 ^[18]	64	61	47/17	50/11	71.3	75.3	药物	12 个月	①②
Chen 2014 ^[19]	46	43	32/14	30/13	64.6	66.5	药物	12 个月	①
Yang 2016 ^[20]	56	51	36/20	33/18	77.1	76.2	药物	12 个月	①②
冯智峰 2021 ^[21]	30	30	18/12	17/13	67.12	67.21	药物	3 个月	①

注:1) T 为手术组;2) C 为非手术组;3) 中①为腰背部疼痛视觉模拟量表评分,②为欧洲骨质疏松基金会生活质量问卷评分。

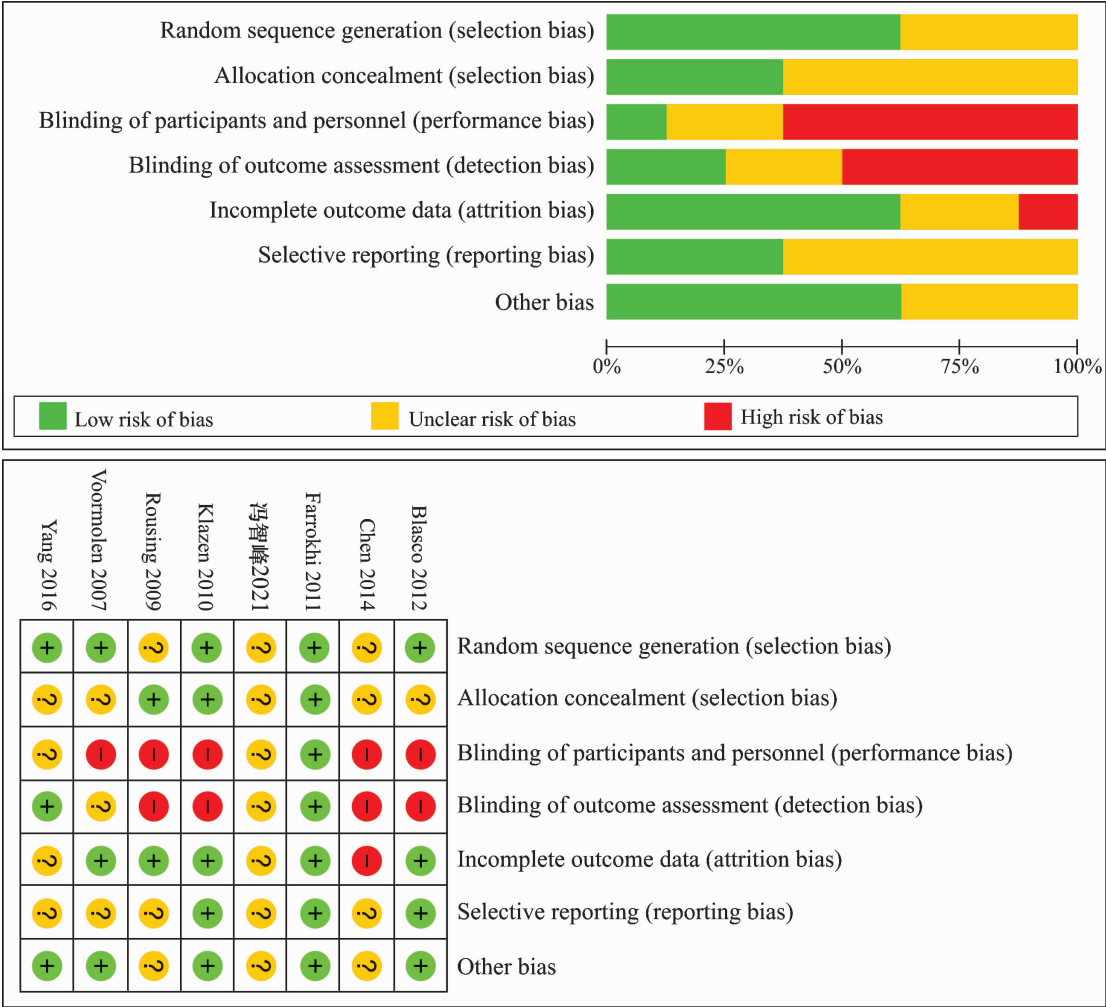


图 2 纳入研究的偏倚风险评价结果

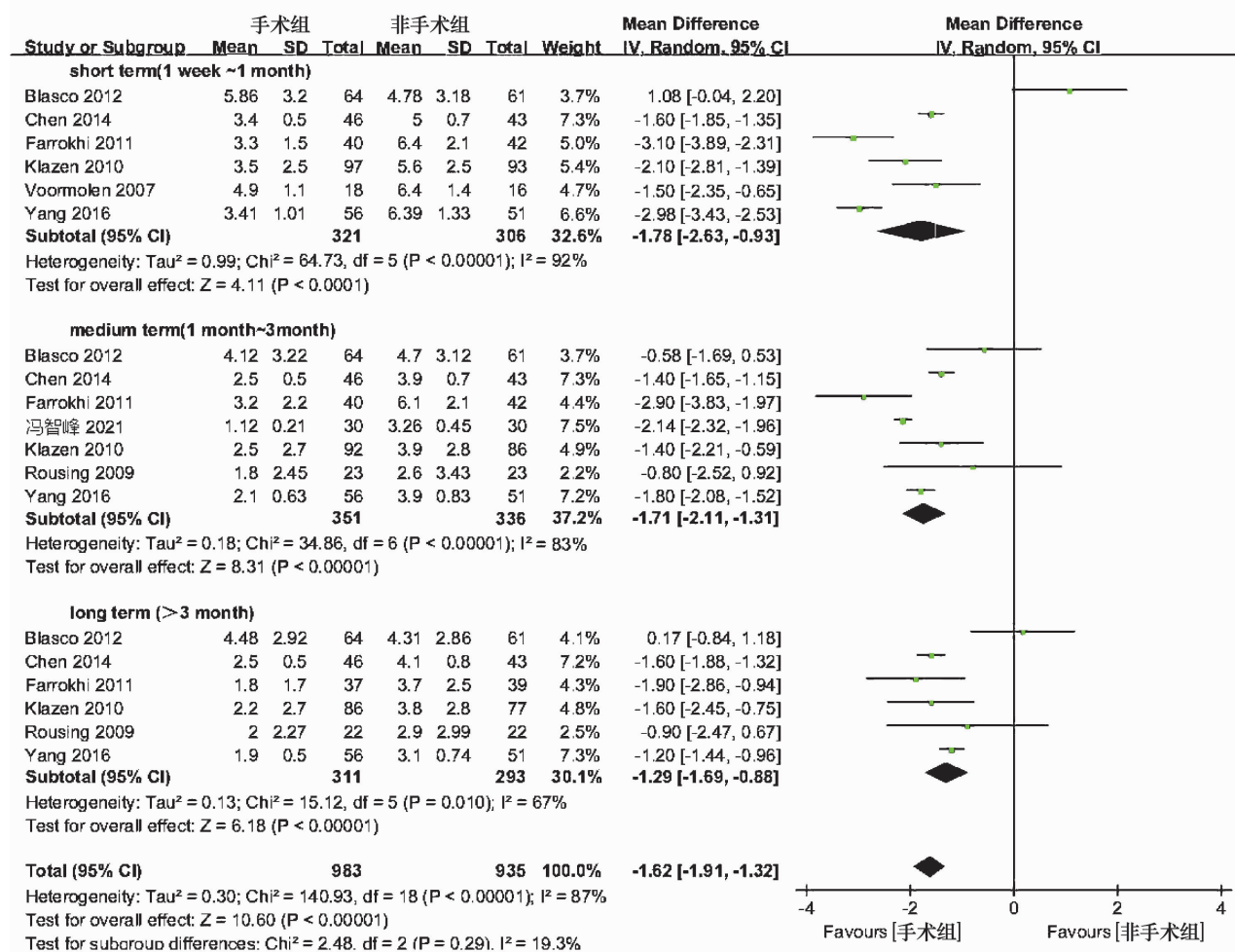


图 3 治疗后腰背部疼痛视觉模拟量表评分的 Meta 分析森林图

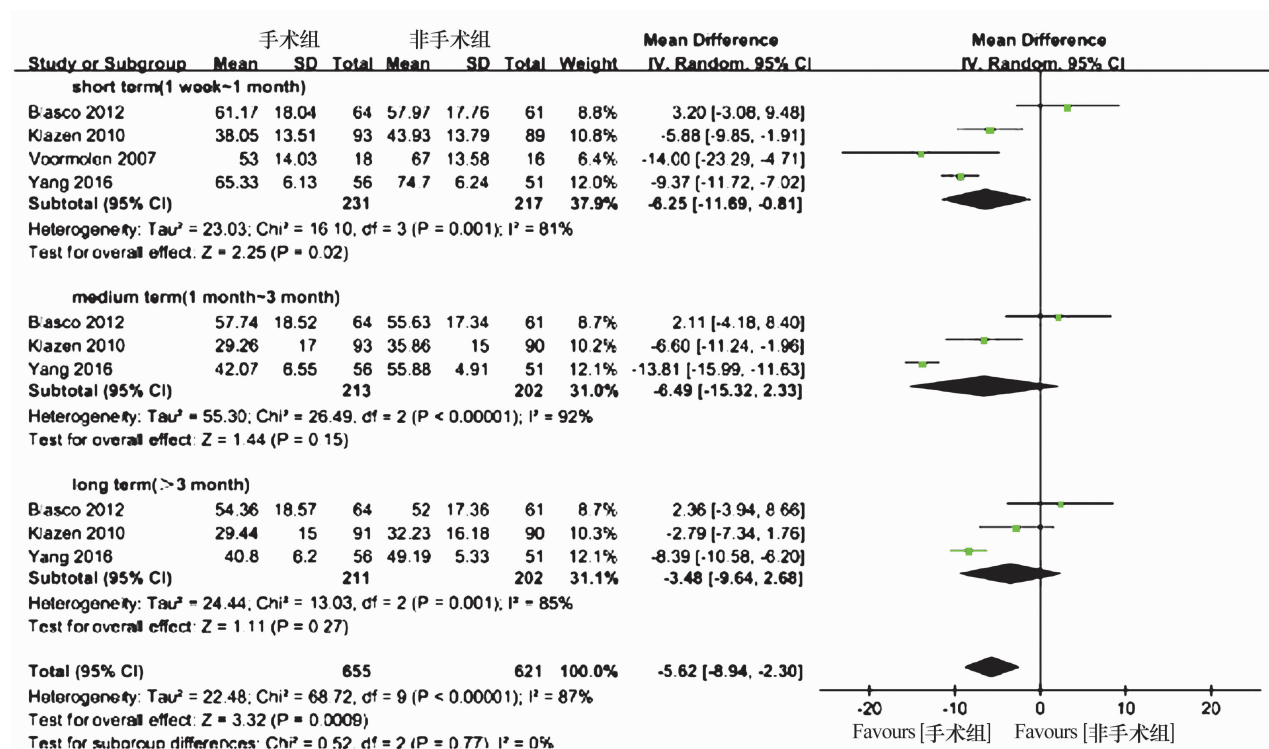


图 4 治疗后欧洲骨质疏松基金会生活质量问卷评分的 Meta 分析森林图

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