

A Meta-Analysis of Near-Long-Term Efficacy of Coronary Artery Bypass Grafting and Drug-Eluting Stent in Elderly Patients

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Abstract

Objective: To evaluate the near-long-term efficacy of coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) in the elderly (age \geq 75 years). **Methods:** We searched relevant literatures in MEDLINE (via pubmed), EMBASE, Cochrane Library from the time of building to 2017. Meanwhile, we collected conference records or gray literature from cardiovascular congresses to compare CABG and PCI for elderly patients. Meta analysis was performed using Review Manager 5.3 software. **Results:** A total of 12 articles were included in the meta-analysis, all of which were observational studies and randomized controlled studies (RCTs) were not retrieved. A total of 6877 patients were enrolled in this meta-analysis, of which 3460 (50.31%) were CABG. Meta-analysis showed that the long-term mortality rate (OR = 1.29, 95% CI (1.07, 1.57), $P = 0.009$) and the incidence rate of revascularization (OR = 5.88, 95% CI (4.68, 7.38), $P < 0.00001$) have significant difference between CABG group and PCI group. However, in-hospital mortality rate (OR = 0.78, 95% CI (0.56, 1.08), $P = 0.14$), the incidence rate of MACCE (OR = 1.01, 95% CI (0.88, 1.17), $P = 0.87$) and the incidence rate of MI (OR = 1.25, 95% CI (0.68, 2.30), $P = 0.46$) have not significant difference between CABG group and PCI group. **Conclusions:** Compared with PCI, CABG can reduce the long-term mortality rate and the incidence rate of TLR in elderly patients, but more and more randomized controlled trials are still needed for further verification.

Keywords

Coronary Artery bypass Grafting, Percutaneous Coronary Intervention, Elderly, Efficacy, Meta-Analysis

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高龄患者冠状动脉旁路移植术与置入药物洗脱支架术后近远期疗效比较的Meta分析

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摘 要

目的:系统评价高龄(年龄 ≥ 75 岁)患者冠状动脉旁路移植术(coronary artery bypass grafting, CABG)与行经皮冠状动脉介入(percutaneous coronary intervention, PCI)下置入药物洗脱支架(drug eluting stent, DES)术后近远期疗效。方法:利用计算机检索MEDLINE(via pubmed, 建库至2017年2月)、EMBASE (建库至2017年2月)、Cochrane Library (建库至2017年2月), 并辅助以手动检索会议记录或灰色文献, 收集研究高龄患者CABG与PCI下置入DES术后死亡率、主要不良心脑血管事件(main adverse cardiovascular and cerebrovascular events, MACCE)、心肌梗死(myocardial infarction, MI)以及靶病变再次血运重建(target lesion revascularization, TLR)发生率对比的英文文献资料。采用Review Manager 5.3软件进行meta分析。结果:共纳入12篇文献进入meta分析, 均为观察性研究, 未检索到随机对照研究(randomized controlled study, RCT)。本meta分析共纳入6877例患者, 其中CABG组3460例(50.31%)。Meta分析结果表明:两组患者术后远期死亡率(OR = 1.29, 95%CI (1.07, 1.57), $P = 0.009$)以及TLR发生率(OR = 5.88, 95%CI (4.68, 7.38), $P < 0.00001$)的差异具有统计学意义, 院内死亡率(OR = 0.78, 95%CI (0.56, 1.08), $P = 0.14$)、MACCE发生率(OR = 1.01, 95%CI (0.88, 1.17), $P = 0.87$)以及MI发生率(OR = 1.25, 95%CI (0.68, 2.30), $P = 0.46$)差异不具有统计学意义。结论:与PCI相比, CABG能明显减低高龄患者术后远期死亡率以及血运重建发生率, 但仍有待于更多更大的随机对照试验以进一步验证。

关键词

冠状动脉旁路移植术, 经皮冠状动脉介入, 高龄, 疗效, meta分析

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1. 引言

随着老年化进程的加速, 冠状动脉粥样硬化性心脏病(coronary artery disease, CAD)已成为全球最突出的健康问题之一[1]。有资料表明, 由CAD导致的死亡数在过去的20年里增加了40% [2]。人口激增、高危险因素如吸烟, 高胆固醇水平是导致死亡人数增长的部分原因[3] [4], 这些问题在亚洲人口中尤为突

出[5] [6] [7] [8]。

上世纪五十年代, 体外循环(cardiopulmonary bypass, CPB)技术开始应用于人类, 其后随着 CPB 技术的发展, CPB 被广泛用于冠状动脉旁路移植术(coronary artery bypass grafting, CABG) [9]。此后开始出现非体外循环冠状动脉旁路移植技术(off-pump coronary artery bypass surgery, OPCAB), 极为有效地减少了心肌缺血再灌注损伤, 使得 CABG 更为安全有效[10]。在过去的几十年里, CABG 已逐渐成为一种安全有效的标准术式。由于 CABG 手术创伤较大, 老年患者特别是高龄患者难以耐受。PCI 技术因其创伤小、院内死亡率低得以产生并迅速发展。该项技术开始时仅限于球囊成形术, 随着社会的发展, 现在 PCI 还拥有了包括斑块销蚀技术、支架植入术等在内的多项新技术[11]。药物洗脱支架的发明使得药物可自聚合物涂层中通过洗脱的方式有控制的释放, 是介入心脏病学又一重大突破。PCI 也逐渐与 CABG、内科药物治疗一起成为目前治疗 CAD 的三大主要治疗手段。

本研究纳入了 2017 年 2 月 1 日之前样本量大于 10 且临床资料齐全的相关英文研究文献进行 meta 分析, 试图比较高龄患者行 CABG 与 PCI 下置入 DES 术后近远期临床疗效的关系, 以期能为治疗高龄 CAD 患者的临床工作做出指导。

2. 材料与方法

2.1. 材料

纳入标准: ①在英文期刊杂志上发表的提供完整数据的临床研究; ②研究 CABG 与 PCI 下置入 DES 治疗高龄(年龄 ≥ 75 岁) CAD 患者临床疗效的比较; ③提供术后死亡率、MI、TLR 以及 MACCE 发生率数据; 排除标准: ①研究样本量低于 10; ②发表的病例报道、综述、动物研究; ③重复发表。若有一个研究组对同一队列患者的不同随访时期的研究, 则选择最近发表的一篇。

临床结局: ①院内死亡率: 院内或术后 30 天内全因死亡; ②心梗; ③靶病变再次血运重建; ④主要不良心脑血管事件: 死亡、非致死性心肌梗死、再次血运重建以及脑卒中、脑出血等; ⑤远期死亡率: 随访结束时的死亡率。

本研究严格遵守 PRISMA 声明进行 meta 分析。

2.2. 方法

2.2.1. 检索策略

利用计算机检索 MEDLINE(via pubmed, 建库至 2017 年 2 月)、EMBASE(建库至 2017 年 2 月)、Cochrane Library(建库至 2017 年 2 月), 并辅助以手动检索会议记录或灰色文献, 纳入符合标准的英文研究文献资料。以检索词“coronary artery bypass grafting”、“percutaneous coronary intervention”和“drug eluting stent”在三大数据库中进行检索, 其中 MEDLINE (via pubmed)具体检索策略见表 1。

2.2.2. 数据提取与研究质量评价

由两名调查者(单龄童, 肖雨洁)依据检索策略独立进行文献检索并提取文献中数据资料录入 EXCEL 表格, 如两名调查者发生分歧则与第三名调查者讨论决定。(文献检索与纳入流程图见图 1)提取资料包括三个部分: ①研究文献的基本资料(研究者、发表年份、国籍、样本量) ②研究对象基线资料(年龄、性别) ③临床结局。利用 Newcastle-Ottawa 量表对纳入的观察性临床研究进行质量评价: 病例组和对照组的选择(0~4 星), 可比性(0~2 星), 结局(0~3 星)(表 2)。

2.2.3. 统计学方法

按照 Cochrane 手册的指南, 进行数据提取与计算。通过卡方检验和 I² 检验进行异质性检验, 按

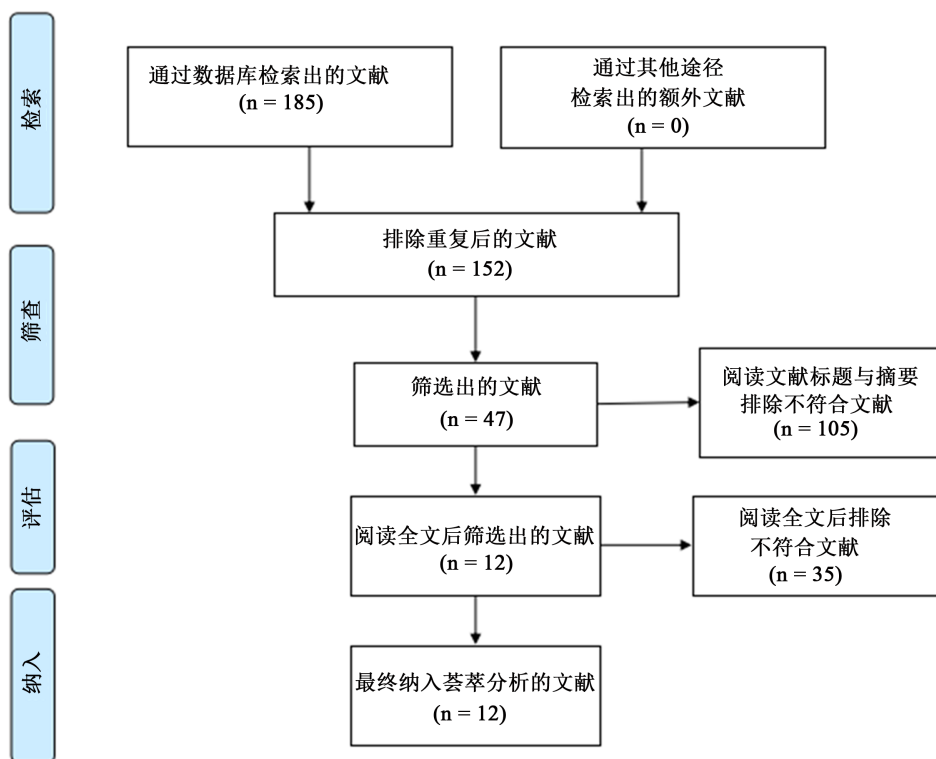


Figure 1. Flow chart
图 1. 流程图

Table 1. Retrieve policy of MEDLINE (via pubmed)
表 1. MEDLINE(via pubmed)检索策略

检索序号	检索词
#1	Search “Coronary Artery Bypass” [Mesh]
#2	Search (((((((Artery Bypass, Coronary) OR Artery Bypasses, Coronary) OR Bypasses, Coronary Artery) OR Coronary Artery Bypasses) OR Coronary Artery Bypass Surgery) OR Bypass, Coronary Artery) OR Aortocoronary Bypass) OR Aortocoronary Bypasses) OR Bypass, Aortocoronary) OR Bypasses, Aortocoronary) OR Bypass Surgery, Coronary Artery) OR Coronary Artery Bypass Grafting
#3	Search “Percutaneous Coronary Intervention”[Mesh]
#4	Search (((((((Coronary Intervention, Percutaneous) OR Coronary Interventions, Percutaneous) OR Intervention, Percutaneous Coronary) OR Interventions, Percutaneous Coronary) OR Percutaneous Coronary Interventions) OR Percutaneous Coronary Revascularization) OR Coronary Revascularization, Percutaneous) OR Coronary Revascularizations, Percutaneous) OR Percutaneous Coronary Revascularizations) OR Revascularization, Percutaneous Coronary) OR Revascularizations, Percutaneous Coronary
#5	Search “Drug-Eluting Stents”[Mesh]
#6	Search (((((((Drug Eluting Stents) OR Drug-Eluting Stent) OR Stent, Drug-Eluting) OR Stents, Drug-Eluting) OR Stents, Drug Eluting) OR Drug-Coated Stents) OR Drug Coated Stents) OR Drug-Coated Stent) OR Stent, Drug-Coated) OR Stents, Drug-Coated) OR Stents, Drug Coated
#7	#1 OR #2
#8	#3 OR #4
#9	#5 OR #6
#10	#7 AND #8 AND #9

Table 2. The Newcastle-Ottawa scale of the study included
表 2. 纳入研究的 Newcastle-Ottawa 量表评价

研究者	年份	选择	可比性	结局
D Capodanno	2012	****	**	***
EL Hannan	2014	***	**	***
F Conrotto	2014	**	**	***
F Nicolini	2015	***	**	***
H Rittger	2010	***	**	***
J Gunn	2012	***	**	***
J Rodescabau	2008	**	**	**
N Wongcharoenkiat	2012	****	**	***
R Ghenim	2009	***	**	***
T Palmerini	2007	****	**	***
Y Ben-Gal	2012	***	**	**
YY Liu	2009	****	**	***

Cochrane 手册认为, $P > 0.1$ 和 $I^2 < 50\%$ 时, 异质性可以接受, 并采用固定效应模型计算比值比(OR)和 95% 可信区间(CI), 显著性水平设定为 0.05, 绘制森林图展示合并数据后对比的结果。反之, 异质性较大时, 采用随机效应模型。纳入研究数量大于 10 时, 利用漏斗图直观检测发表偏倚。本研究所有统计分析均由 Review Manager 5.3 软件完成。

3. 结果

3.1. 纳入文献一般资料

本研究总计纳入了 12 项研究[12]-[23], 共纳入 6877 例患者。其中 3460 例(50.31%)接受了 CABG 治疗, 3427 例(49.69%)接受了 PCI 下置入 DES 治疗。纳入的 12 项研究均为观察性研究, 其中 9 项研究报道了患者术后院内死亡率, 8 项研究报道了患者随访期间 MACCE 发生率, 9 项研究报道了患者心肌梗死情况, 10 项研究报道了患者靶病变再次血运重建情况, 9 项研究报道了患者随访结束时的死亡情况(表 3)。

3.2. meta 分析结果

对报道了患者术后院内死亡率的 9 项研究进行院内死亡率荟萃分析显示 PCI 相比于 CABG 能降低高龄 CAD 患者院内死亡率(OR = 0.78, 95%CI (0.56,1.08), $P = 0.14$), 但两者间差异没有统计学意义。各研究间无明显异质性($P = 0.15$, $I^2 = 33\%$) (图 2)。

对报道了患者随访期间 MACCE 发生率的 8 项研究进行荟萃分析显示 PCI 相比于 CABG 对高龄 CAD 患者随访期间 MACCE 发生率的降低并没有显示出优势(OR = 1.01, 95%CI (0.88,1.17), $P = 0.87$), 且差异无统计学意义。各研究间无明显异质性($P = 0.54$, $I^2 = 0\%$) (图 3)。

对报道了患者心肌梗死情况的 9 项研究进行荟萃分析显示 PCI 相比于 CABG 增加了高龄 CAD 患者心肌梗死发生率(OR = 1.25, 95%CI (0.68,2.30), $P = 0.46$), 但差异有统计学意义。各研究间存在异质性($P = 0.0001$, $I^2 = 74\%$) (图 4)。

对报道了患者靶病变再次血运重建情况的 10 项研究进行荟萃分析显示 CABG 相比于 PCI 能显著的降低 CAD 患者术后靶病变再次血运重建发生率(OR = 5.88, 95% CI (4.68,7.38), $P < 0.00001$), 且差异有统计学意义。各研究间无明显异质性($P = 0.12$, $I^2 = 36\%$) (图 5)。

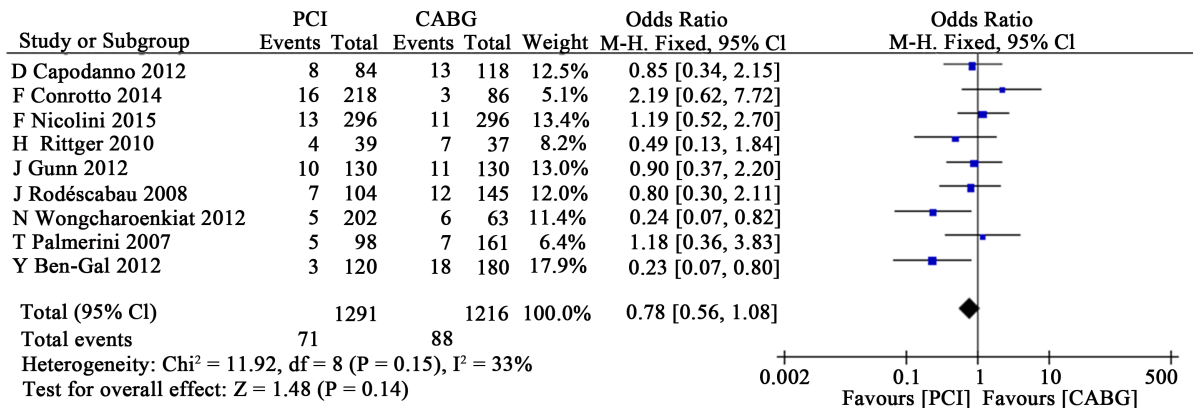


Figure 2. A meta-analysis of in-hospital mortality rate in both groups

图 2. 两组患者院内死亡率荟萃分析

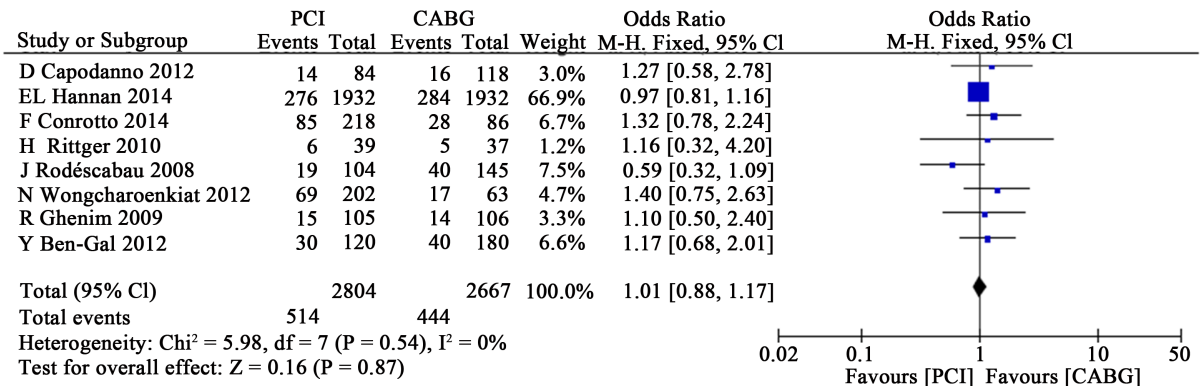


Figure 3. A meta-analysis of the incidence rate of MACCE in both groups

图 3. 两组患者术后 MACCE 发生率荟萃分析

Table 3. The baseline data of the study included

表 3. 纳入文献的基线资料

研究者	年份	研究设计	国家	样本量(例)		年龄(y)		女性(%)	
				PCI	CABG	PCI	CABG	PCI	CABG
D Capodanno	2012	前瞻性	意大利	84	118	78.8 ± 2.9	78.1 ± 2.9	32.1	33.1
EL Hannan	2014	前瞻性	美国	1932	1932	-	-	40.5	41.3
F Conrotto	2014	回顾性	意大利	218	86	83.6 ± 3.2	83.0 ± 2.9	35.3	45.3
F Nicolini	2015	回顾性	意大利	296	296	-	-	39.5	37.5
H Rittger	2010	前瞻性	德国	39	37	81.0 ± 4.0	80.0 ± 3.0	51.0	30.0
J Gunn	2012	回顾性	芬兰	130	130	82.6 ± 2.1	82.5 ± 2.0	45.0	37.0
J Rodescabau	2008	回顾性	加拿大	104	145	85.0 ± 3.0	82.0 ± 2.0	46.2	46.6
N Wongcharoenkiat	2012	回顾性	泰国	202	63	83.3 ± 3.0	82.7 ± 4.7	53.0	38.1
R Ghenim	2009	回顾性	法国	105	106	80.7 ± 3.5	79.6 ± 3.5	36.2	28.3
T Palmerini	2007	回顾性	意大利	98	161	81 (75~95)	78 (75~88)	46.0	34.0
Y Ben-Gal	2012	回顾性	以色列	120	180	84.0 ± 3.1	82.9 ± 2.5	47.5	34.8
YY Liu	2009	回顾性	中国	89	206	-	-	-	-

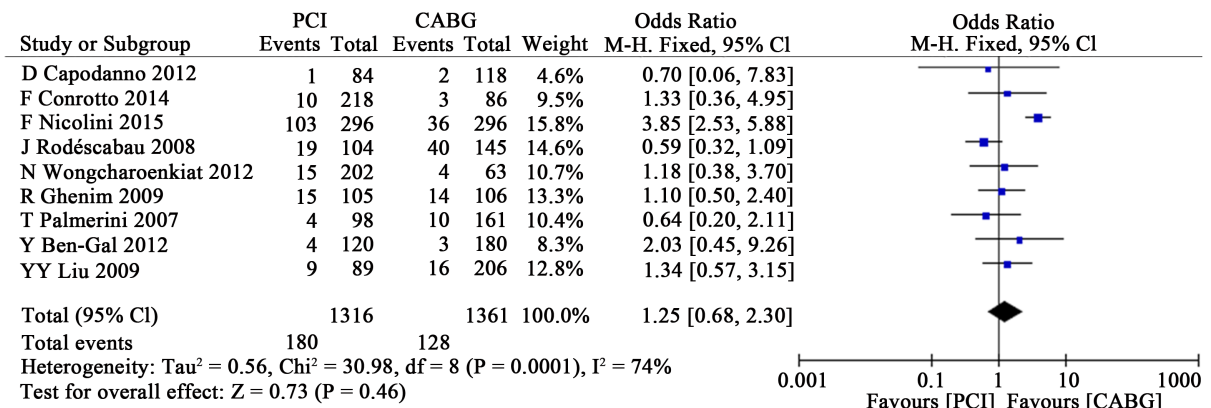


Figure 4. A meta-analysis of the incidence rate of MI in both groups

图 4. 两组患者术后 MI 发生率荟萃分析

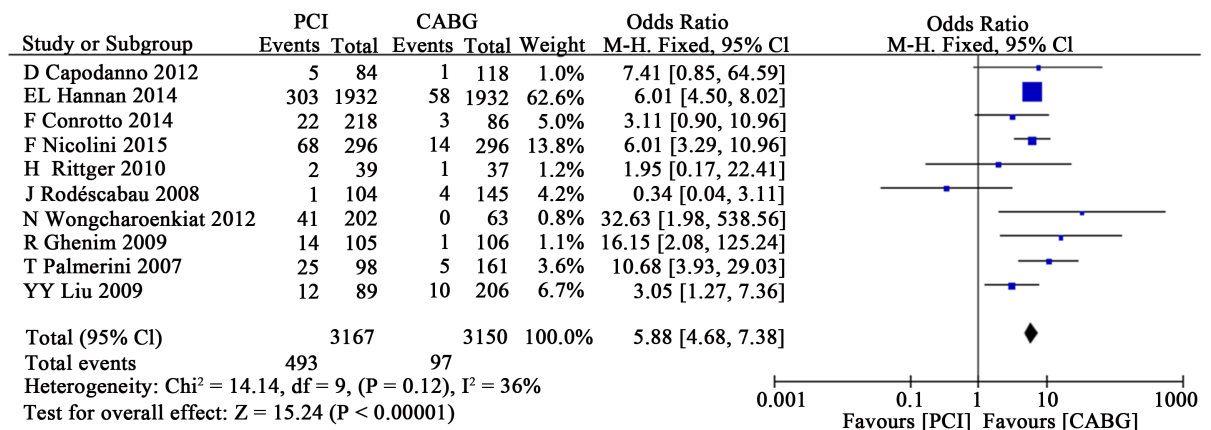


Figure 5. A meta-analysis of the incidence rate of TLR in both groups

图 5. 两组患者术后靶病变再次血运重建发生率荟萃分析

对报道了患者远期死亡率的 9 项研究进行荟萃分析显示 CABG 相比于 PCI 能显著的降低 CAD 患者远期死亡率($\text{OR} = 1.29$, 95%CI (1.07,1.57), $P = 0.009$), 且差异有统计学意义。各研究间无明显异质性($P = 0.40$, $I^2 = 4\%$) (图 6)。

3.3. 敏感性分析与发表偏倚

剔除其中一项研究重新分析以进行敏感性分析, 本研究剔除任一研究均未对结果产生较大影响, 不能改变总体统计学结果。通过软件制作漏斗图以检测是否存在发表偏倚, 本研究中以靶病变再次血运重建发生率作为临床结局制作的漏斗图显示有一项研究落在 95%可信区间外(1/10, 10%), 提示可能存在异质性与发表偏倚(图 7)。

4. 讨论

CAD 是冠状动脉粥样硬化引起官腔狭窄、阻塞, 导致心肌缺血、缺氧的心脏病, 严重危害着人类健康[24]。据既往研究报道, 冠心病导致的死亡居全球全因病死亡率前列, 特别是在人口老年化严重的西方发达国家, 有近 80%的老年患者死亡 CAD [25]。在我国, 目前约有 2.9 亿心血管疾病患者, 死亡率高居各类疾病之首, 形势十分严峻[26]。

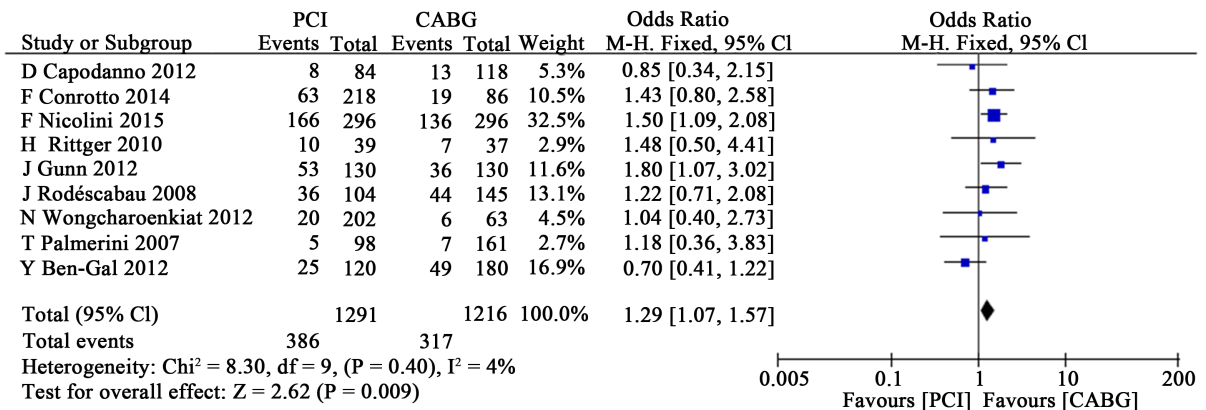


Figure 6. A meta-analysis of long-term mortality rate in both groups

图 6. 两组患者术后远期死亡率荟萃分析

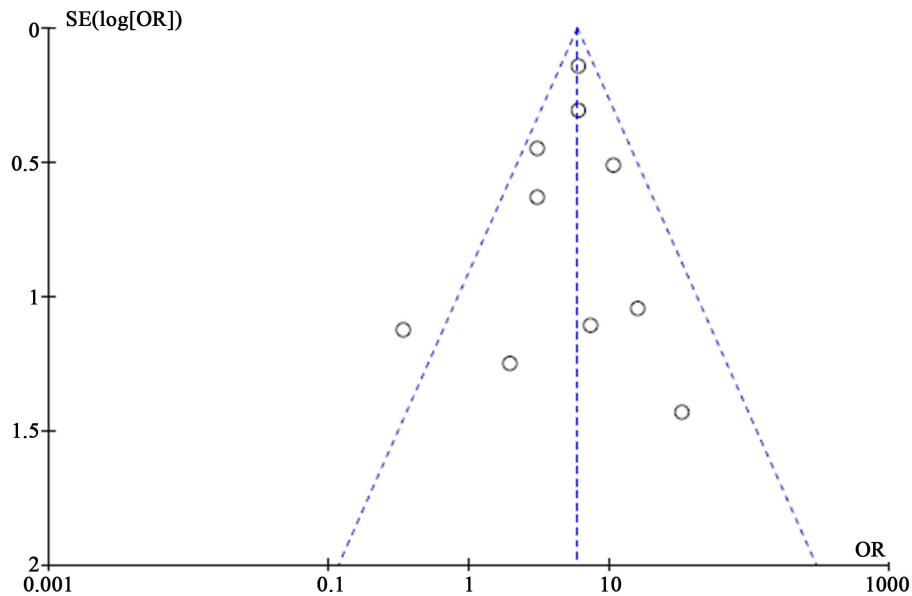


Figure 7. Funnel map

图 7. 漏斗图

内科药物治疗、CABG 与 PCI 是三种主要的治疗 CAD 的手段。药物治疗原则是缓解症状、纠正缺血、预防心脑血管不良事件进而改善患者生活质量，近来药物治疗多作为 CABG 与 PCI 的辅助治疗[27]。

CABG 与 PCI 已被广泛应用于临床，其临床疗效已得到肯定。既往已有 meta 分析[28] [29]聚焦于 CAD 患者 CABG 与 DES 的近远期临床疗效对比，认为 PCI 能有效降低 CAD 患者术后院内死亡率，但在术后靶病变再次血运重建方面与 CABG 的比较仍有待讨论。

既往的系统综述与荟萃分析很少关注于高龄患者群体[28] [29]，本文纳入了 2017 年 2 月 1 日之前样本量大于 10 且临床资料齐全的相关英文研究文献进行 meta 分析，试图比较高龄患者行 CABG 与 PCI 下置入 DES 术后近远期临床疗效的关系，以期能为治疗高龄 CAD 患者的临床工作做出指导。本研究分析表明：CABG 能明显减低高龄患者术后远期死亡率以及血运重建发生率，PCI 下置入 DES 在减低院内死亡率、MI 发生率、MACCE 发生率、TLR 发生率方面对比 CABG 具有的优势不具有统计学意义。因此我们认为 PCI 对于高龄虽然在近期安全性方面具有优势，但其远期疗效不如 CABG。

本研究中纳入的研究资料均为观察性研究，未检索到随机对照试验研究。各研究间的研究设计、患者基线资料、研究终点、随访时长等方面存在着差异，这也是 meta 分析方法的局限性。异质性分析也发现在本研究中可能存在着发表偏倚。这些因素可能会对本研究的结论产生一定影响。

CABG 尽管在高龄患者术后院内死亡率等方面表现劣于 PCI 下置入 DES，但其能够有效降低远期死亡率、靶病变再次血运重建发生率。该结论仍然需要更大规模的临床随机对照试验来进一步证明。

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