第十三屆實證醫學競賽 文獻查證進階組 潛力獎

機構:高雄醫學大學附設中和紀念醫院

組員:內科王俊偉醫師



麻醉科陳柏年醫師



李佳倫護理師



臨床場景(clinical scenario)分析1

- 李先生65歲是個長期菸瘾者有30年以上的抽菸史,他因有高血壓及糖尿病且在家附近的診所拿藥已有十來年,血壓一直控制的不錯,最近因為常常感到胸口煩悶,尤其是早晨或工作及動後,因懷疑是心絞痛被診所醫師轉介至醫院做進一步檢查。
- 到醫院後醫師表示要判斷是否有冠狀動脈阻塞,最準確的診斷方法為心導管檢查,不過風險較高,建議可先做非侵入性檢查,而檢查項目有運動心電圖,心肌灌注掃描或費用較昂貴的心臟64切電腦斷層掃描。若是確定為冠狀動脈引起的徵兆,就有做心導管檢查與治療的必要,且藥物可能要做調整。

臨床場景(clinical scenario)分析2

- 另外,醫師又建議戒菸及好好控制血糖會對身體較好且可降低心血管風險。經過醫師一系列的解釋,李先生有好幾個疑惑,就檢查方面,到底哪一種檢查對李先生是最好判斷冠狀動脈疾病工具?若真的有問題是否非得做心導管手術才可?如果現在開始戒菸,是不是來得及?並且,控制血糖到底要控制到什麼程度才是最好?
- 就在李先生正在為這些問題苦惱的幾天中,他的好朋友75歲王先生因為患急性心肌梗塞到急診就醫,急診醫師告訴他需要做心導管手術或血栓溶解劑注射擇一,雖各有優缺點,由於沒有多少時間考慮,王先生選擇了心導管手術,李先生此時又有一個疑惑,若是他也發生了類似的狀況,到底哪一種最適合他?

STEP 1: Question forming

- 臨床重要的問題
 - 判斷是否有冠狀動脈阻塞,運動心電圖,心肌灌注掃 描或費用較昂貴的心臟64切電腦斷層掃描何者較佳?
- 病人關心的問題
 - 哪一種檢查對李先生是最好判斷冠狀動脈疾病工具?
 - 冠狀動脈疾病是否非得做心導管手術才可?
 - 現在開始戒菸,是不是來得及?
 - 控制血糖到底要控制到什麼程度才是最好?
 - 急性心肌梗塞心導管手術或血栓溶解劑注射哪一種最適合?

以PICO建構臨床問題

Patient/Problem	Man suffer from AMI
I Intervention	急性心肌梗塞心導管手術(PCI)
Comparison	血栓溶解劑注射(Thrombolysis)
Outcome	Mortality rate, re-infarction rate, complications

- 問題類型:治療
- 最適合回答此問題的研究設計: Systematic Review

STEP 2: Finding evidence

選擇Key words及 Meshterms	Key words : AMI > PCI > Thrombolysis > Mortality rate > re-infarction rate
	Meshterms: Ischemic heart disease
運用的資料庫	Secondary first · Primary second 5S: UpToDate · DynaMed · ACP journal club · Cochrane Library · PubMed · CEPS
Filter & limit運用	Combine terms with Boollean operators: and \ or \ not
	Filter & limit: Human > English > elderly > systematic review

選擇Key words及Meshterms

原始關鍵字	布林	同義字		布林
	邏輯			邏輯
P(AMI	OR	ACS)	AND
I (PCI	OR	PTCA)	AND
C (Thrombolysis	OR	Fibrinolysis)	AND
O(Mortality rate	OR	re-infarction rate)	

資料庫搜尋結果

The "5S" levels of organisation of evidence from healthcare research Brian Haynes, R Evid Based Med 2006;11:162-164 System**'ş** Dynamed: 4篇,與主 題相關1篇 UpToDate. Uptodate:與主題相關3篇 **Summaries** 篇數:1篇 Synopses Systemic review: 1篇 Trails : 178篇 The Cochrane Library **Syntheses** pubmed:775篇 CEPS:1篇 **Studies**



搜尋到的文章標題及文獻等級

Title:

- Primary percutaneous coronary intervention versus fibrinolysis in acute ST elevation myocardial infarction: Clinical trials
- Overview of the acute management of ST elevation myocardial infarction
- Overview of the acute management of unstable angina and non-ST elevation myocardial infarction
- Level of evidence: la



Primary PCI with balloon angioplasty versus fibrinolysis — The early trials comparing primary PCI with balloon angioplasty to fibrinolysis showed a significant reduction in mortality with the former [25,26]. However, these trials are of limited utility to current practice for the following reasons: stenting is performed in almost all patients who undergo PCI; current generation fibrinolytic agents were not used in many of the trials; and anticoagulation and

antiplatelet protocols differed significantly from contemporary practice.

Most of the important studies were included in a 1997 meta-analysis of 10 randomized trials which included 2606 patients randomly assigned to primary PCI with balloon angioplasty or fibrinolysis [27]. The former was associated with the following benefits:

- A significantly lower mortality at 30 days or less (4.4 versus 6.5 percent, odds ratio 0.66, 95% CI 0.46-0.94): the effect was similar among the different fibrinolytic regimens used.
- A significantly lower rate of death or nonfatal reinfarction (7.2 versus 11.9 percent, odds ratio 0.58, 95% CI 0.44-0.76).
- A lower rate of total stroke (0.7 versus 2.0 percent) and hemorrhagic stroke (0.1 versus 1.1 percent).

The Primary Angioplasty in Myocardial Infarction trial (PAMI), published after the meta-analysis, randomly assigned 395 patients presenting with an acute MI within 12 hours of symptom onset to primary PCI with balloon angioplasty or 100 mg of intravenous recombinant tissue-type plasminogen activator (<u>alteplase</u>) [25]. Benefits, similar to those in the meta-analysis, were found with primary PCI with balloon angioplasty [25,28,29]. An important observation in PAMI was that high-risk groups (age >70, anterior MI, heart rate >100 on admission) derived the greatest benefit.

PCI較Thrombolysis30天內死亡率、再梗塞率、中風較低

New Search Patient Info What's New Calculators New Search Patient Info What's New Calculators		UpToDate.	AMI, PCI, Fibrino	olysis	All Topics ▼	Search			About Us
Back to Search Results for "AMI, PCI, Fibrinolysis"		<u> </u>					Thrombolysis容易出血、且易復發		
		New Search Patier	it Info What's New	Calculators					
Overview of the acute management of ST elevation myocardial infarction						6	Back to Search Results for "AMI, PCI, Fibrinolysis"		
	(Overview of the acu	e management of S	T elevation myo	cardial infarction			Find	Print (

Percutaneous coronary intervention — If high-quality PCI is available, multiple randomized trials have shown enhanced survival compared to fibrinolysis with a lower rate of intracranial hemorrhage and recurrent MI [21]. As a result, the 2007 focused update of the ACC/AHA 2004 Guidelines for the Management of Patients With STEMI recommended the use of primary PCI for any patient with an acute STEMI who can undergo the procedure within 90 minutes of first medical contact by persons skilled in the procedure (table 2) [2]. This was not changed in the 2009 update [3].

Patients with typical and persistent symptoms in the presence of a new or presumably new left bundle branch block are also considered eligible. (See "Primary percutaneous coronary intervention in acute ST elevation myocardial infarction: Determinants of outcome".)

For patients presenting 12 to 24 hours after symptom onset, the performance of primary PCI is reasonable if the patient has severe HF, hemodynamic or electrical instability, or persistent ischemic symptoms [1]. Randomized trials of routine late PCI have shown an improvement in left ventricular function but not in hard clinical end points. This approach is not recommended (table 2). (See "Coronary artery patency and outcome after myocardial infarction", section on 'Late PCI to open an occluded artery'.)

If primary PCI is not available on site, rapid transfer to a PCI center can produce better outcomes than fibrinolysis, as long as the door-to-balloon time, including interhospital transport time, is less than 90 minutes. This door-to-balloon time is difficult to obtain unless rapid transport protocols and relatively short transport distances are in place. (See "Primary percutaneous coronary intervention in acute ST elevation myocardial infarction: Determinants of outcome".)

UpToDate.	AMI, PCI, Fibrinolysis	All Topics ▼ Search	News from UpToDate Contact Us About				
	fo What's New Calculators						
S Back to Search Results for "AMI, PCI, Fibrinolysis"							
Overview of the acute management of unstable angina and non-ST elevation myocardial infarction							

EARLY REPERFUSION AND REVASCULARIZATION

Avoidance of fibrinolysis — Prospective trials have demonstrated that fibrinolytic therapy is not beneficial in patients with a non-ST elevation ACS [1,32,39]. The ACC/AHA and ACCP recommend against the routine use of fibrinolytic agents in patients with a non-ST elevation ACS [40,41]. (See "Fibrinolytic (thrombolytic) agents in unstable angina and acute non-ST elevation myocardial infarction".)

Immediate angiography and revascularization — Patients who have a non-ST elevation ACS and one or more of the following characteristics are at extremely high risk of an adverse cardiovascular event in the short term:

- · Hemodynamic instability or cardiogenic shock
- · Severe left ventricular dysfunction or heart failure
- · Recurrent or persistent rest angina despite intensive medical therapy
- New or worsening mitral regurgitation or new ventricular septal defect
- Sustained ventricular arrhythmias

建議病人接受PCI

We recommend that patients with any of these five characteristics be referred for immediate coronary arteriography and revascularization.



搜尋到的文章標題及文獻等級

• Title:

- Percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI)
- Level of evidence: la

Percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI)

Primary PCI versus thrombolytics:

- primary PCI may reduce mortality, reinfarction, and stroke rates compared to thrombolytics in patients with ST-segment elevation myocardial infarction (STEMI) (level 2 [mid-level] evidence)
 - based on 2 systematic reviews with assessment of trial quality not reported
 - systematic review of 23 randomized trials and 32 observational studies evaluating primary PCI vs. fibrinolytic therapy in patients with STEMI
 - primary PCI (at ≤ 6 week follow-up) in meta-analysis of randomized trials associated with reduced
 - mortality in 23 trials with 8,140 patients
 - reinfarction in 22 trials with 7,937 patients
 - stroke in 21 trials with 7,932 patients
 - ∘ primary PCI (at ≥ 1 year follow-up) in meta-analysis of randomized trials associated with reduced
 - mortality in 10 trials with 4,320 patients
 - reinfarction in 9 trials with 4,121 patients
 - meta-analysis of observational studies (180,900 patients) supported short-term benefits of PCI but found no difference between PCI and fibrinolytics in long-term mortality and reinfarction
 - Reference Circulation 2009 Jun 23;119(24):3101, editorial can be found in Circulation 2009 Jun 23;119(24):3047
 - meta-analysis of 23 randomized trials comparing primary transluminal coronary angioplasty (PTCA) vs. thrombolytic (streptokinase in 8 trials, fibrin-specific agent in 15 trials) in 7,739 patients with STEMI
 - o comparing PTCA vs. thrombolytic
 - combined endpoint of death, reinfarction and stroke in 8% vs. 14% (p < 0.0001, NNT 17)
 - short-term mortality in 7% vs. 9% (p = 0.0002, NNT 50)
 - nonfatal reinfarction in 3% vs. 7% (p < 0.0001, NNT 25)
 - stroke in 1% vs. 2% (p = 0.0004, NNT 100)
 - Reference Lancet 2003 Jan 4;361(9351):13, commentary can be found in Lancet 2003 Mar 15;361(9361):965, Lancet 2003 Apr 12;361(9365):1303, ACP J
 Club 2003 Jul-Aug:139(1):1. CMAJ 2003 Oct 28:169(9):925 full-text

PCI降低死亡率、再梗塞率、中風率



Percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI)

- primary PCI (if not delayed > 60-90 minutes) associated with lower mortality than thrombolytics (level 2 [mid-level] evidence)
 - based on 2 systematic reviews without assessment of trial quality
 - systematic review of 22 randomized trials comparing PCI vs. fibrinolytic therapy for acute myocardial infarction in 6,763 patients, with pooled individual patient data meta-analysis
 - o mortality not clearly related to time from symptom onset to treatment
 - o median time from symptom onset to presentation 142 minutes
 - o median PCI treatment delay 55 minutes
 - median time from presentation to fibrinolytic therapy 19 minutes
 - median time from presentation to PCI 76 minutes
 - all patients received PCI within 95 minutes of presentation
 - o primary PCI associated with reduced 30-day mortality
 - adjusted odds ratio 0.63 (95% CI 0.42-0.84)
 - NNT 23-85 with 7.9% mortality in fibrinolytics group
 - o 30-day mortality in subgroup with PCI related delay ≤ 35 minutes 2.8% with PCI vs. 8.2% with fibrinolytics
 - Reference Eur Heart J 2006 Apr;27(7):779 full-text, editorial can be found in Eur Heart J 2006 Apr;27(7):761 full-text

PCI(不延遲>60-90分)較Thrombolysis死亡率低

Percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI)

- primary PCI appears superior to thrombolytics in varied patient populations with STEMI
 - primary PCI may reduce recurrent ischemia compared to tenecteplase, but no significant differences in mortality or reinfarction in patients ≥ 75 years old (level 2 [mid-level] evidence)
 - based on randomized trial with early termination
 - 266 patients ≥ 75 years old were randomized within 6 hours of STEMI to primary PCI vs. tenecteplase 30-50 mg IV
 - o trial terminated early before enrollment of planned 570 patients due to slow recruitment resulting in inadequate statistical power for primary outcome
 - o comparing primary PCI vs. tenecteplase
 - recurrent ischemia requiring catheterization in 0.8% vs. 9.7% (p < 0.001, NNT 12)
 - mortality 13.6% vs. 17.2% (not significant)
 - reinfarction in 5.3% vs. 8.2% (not significant)
 - disabling stroke in 0.8% vs. 3% (not significant)
 - Reference Eur Heart J 2011 Jan;32(1):51 full-text
 - primary angioplasty appears more effective than streptokinase in patients > 75 years old (level 2 [mid-level] evidence)
 - based on randomized trial with allocation concealment not stated
 - 87 patients > 75 with acute myocardial infarction randomized to primary angioplasty (mean time from presentation < 60 minutes) vs. thrombolytics (streptokinase IV)
 - o comparing angioplasty to streptokinase
 - composite endpoint of death, reinfarction, or stroke at 30 days in 9% vs. 29% (p = 0.01, NNT 5)
 - composite endpoint of death, reinfarction, or stroke at 1 year in 13% vs. 44% (p = 0.001, NNT 4)
 - mortality during mean follow-up of 20 months in 15% vs. 32% (p = 0.04, NNT 6)
 - Reference J Am Coll Cardiol 2002 Jun 5;39(11):1723, commentary can be found in J Am Coll Cardiol 2002 Jun 5;39(11):1729
 - primary coronary angioplasty may be associated with reduced mortality and reinfarction rates than thrombolysis for STEMI in patients regardless of diabetes status (level 2 [mid-level] evidence)

PCI較Thrombolysis能降低死亡率及再梗塞率



搜尋到的文章標題及文獻等級

• Title:

- Review: Transfer for PCI reduces 30-day mortality more than on-site thrombolysis in STEMI
- Level of evidence: la

Transfer for primary PCI vs on-site thrombolysis in STEMI*

Study type†	Outcomes	Number of trials (n)	Weighted event rates	At 30-day follow-up	
				RRR (95% CI)	NNT (CI)
All	Mortality	11 (5741)	5.3% vs 6.8%	22% (4 to 36)	68 (41 to 394)
All	Reinfarction	11 (5741)	2.0% vs 4.7%	57% (42 to 68)	38 (32 to 51)
All	Stroke	11 (5742)	0.7% vs 1.7%	60% (33 to 76)	99 (78 to 181)
High- quality	Mortality	4 (2703)	5.4% vs 6.4%	16% (-12 to 38)	Not significant
High- quality	Reinfarction	4 (2703)	1.7% vs 4.2%	60% (36 to 75)	40 (32 to 67)
High- quality	Stroke	4 (2704)	0.6% vs 1.6%	60% (19 to 80)	105 (79 to 334)

Conclusion:

In patients with ST-segment elevation myocardial infarction, transfer for percutaneous coronary intervention reduces 30-day mortality more than on-site thrombolysis



European Heart Journal (2011) **32**, 51–60 doi:10.1093/eurheartj/ehq375

CLINICAL RESEARCH

Coronary heart disease

Primary angioplasty vs. fibrinolysis in very old patients with acute myocardial infarction: TRIANA (TRatamiento del Infarto Agudo de miocardio eN Ancianos) randomized trial and pooled analysis with previous studies

Héctor Bueno 1*, Amadeo Betriu 2, Magda Heras 2, Joaquín J. Alonso 3, Angel Cequier 4, Eulogio J. García 5, José L. López-Sendón 6, Carlos Macaya 5, and Rosana Hernández-Antolín 5, on behalf of the TRIANA Investigators †

¹Departments of Cardiology, Hospital General Universitario Gregorio Marañón, Dr Esquerdo, 46, 28007 Madrid, Spain; ²Departments of Cardiology, Hospital Clínic, Barcelona, Spain; ³Departments of Cardiology, Hospital de Fuenlabrada, Fuenlabrada, Spain; ⁴Departments of Cardiology, Hospital Bellvitge, Hospitalet de Llobregat, Barcelona, Spain; ⁵Departments of Cardiology, Hospital Universitario La Paz, Madrid, Spain

Received 24 May 2010; revised 7 July 2010; accepted 23 July 2010; online publish-ahead-of-print 22 October 2010



Aims

To compare primary percutaneous coronary intervention (pPCI) and fibrinolysis in very old patients with ST-segment elevation myocardial infarction (STEMI), in whom head-to-head comparisons between both strategies are scarce.

Methods and results

Patients \geq 75 years old with STEMI < 6 h were randomized to pPCI or fibrinolysis. The primary endpoint was a composite of all-cause mortality, re-infarction, or disabling stroke at 30 days. The trial was prematurely stopped due to slow recruitment after enroling 266 patients (134 allocated to pPCI and 132 to fibrinolysis). Both groups were well balanced in baseline characteristics. Mean age was 81 years. The primary endpoint was reached in 25 patients in the pPCI group (18.9%) and 34 (25.4%) in the fibrinolysis arm [odds ratio (OR), 0.69; 95% confidence interval (CI) 0.38–1.23; P=0.21]. Similarly, non-significant reductions were found in death (13.6 vs. 17.2%, P=0.43), re-infarction (5.3 vs. 8.2%, P=0.35), or disabling stroke (0.8 vs. 3.0%, P=0.18). Recurrent ischaemia was less common in pPCI-treated patients (0.8 vs. 9.7%, P<0.001). No differences were found in major bleeds. A pooled analysis with the two previous reperfusion trials performed in older patients showed an advantage of pPCI over fibrinolysis in reducing death, re-infarction, or stroke at 30 days (OR, 0.64; 95% CI 0.45–0.91).

Conclusion

Primary PCI seems to be the best reperfusion therapy for STEMI even for the oldest patients. Early contemporary fibrinolytic therapy may be a safe alternative to pPCI in the elderly when this is not available.

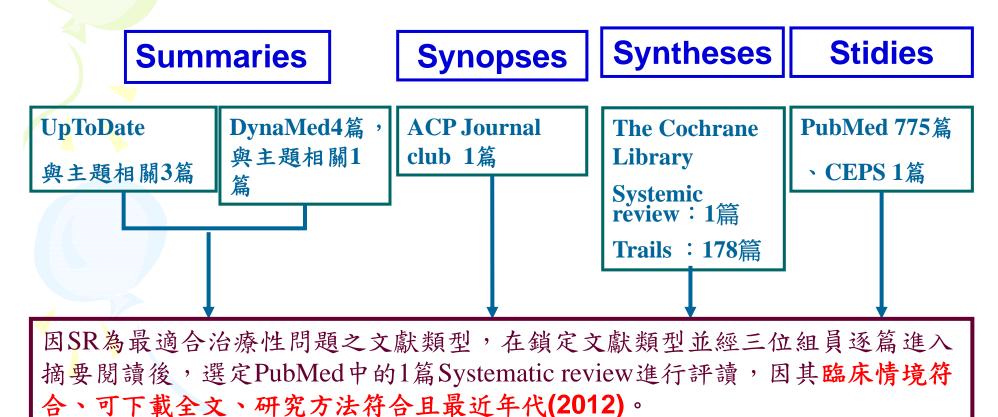
Clinicaltrials.gov # NCT00257309.

Keywords

Acute myocardial infarction • Elderly • Primary angioplasty • Fibrinolysis • Randomized controlled trial

PCI較Thrombolysis30天內死亡率、再梗塞率、中風較低

搜尋過程與結果



Percutaneous Coronary Intervention Versus Optimal Medical Therapy in Stable Coronary Artery Disease

A Systematic Review and Meta-Analysis of Randomized Clinical Trials

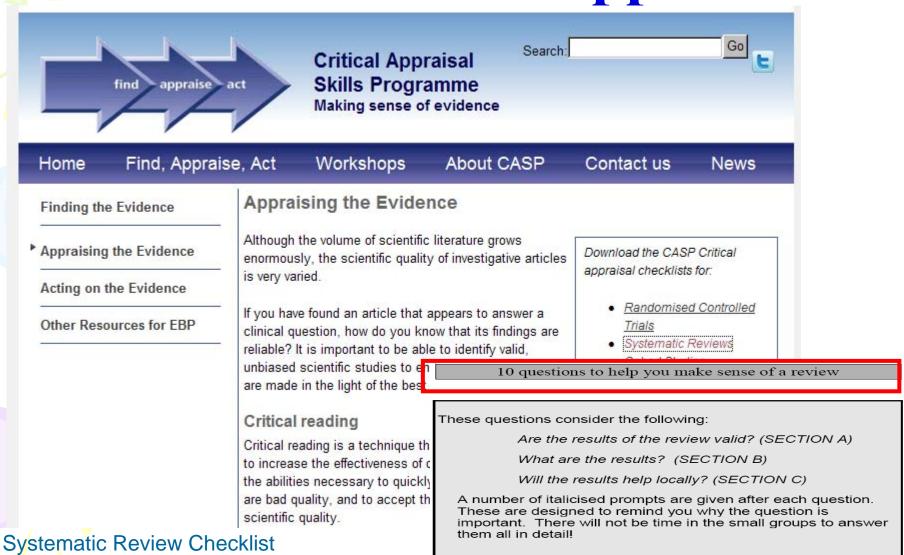
Seema Pursnani, MD, MPH; Frederick Korley, MD; Ravindra Gopaul, MBA, MPH; Pushkar Kanade, MBBS, MPH; Newry Chandra, MBBS, MPH; Richard E. Shaw, PhD, MA; Sripal Bangalore, MD, MHA

比對PICO

· 此項研究與我們的PICO是否符合?

	此項研究	我們的PICO	YES	NO
Р	patients with stable CAD	Man suffer from AMI	V	
I	PCI	急性心肌梗塞心導管手術(PCI)	V	
С	Optimal medicine treatment (OMT)	血栓溶解劑注射 (Thrombolysis)	V	
0	Mortality rate, re- infarction rate, revascularization, freedom from angina	Mortality rate, re-infarction rate, complications	V	

STEP 3: Critical appraisal



1. Did the review address a clearly focused question? 此篇綜論問題明確?



Cannot tell



Background—The role of percutaneous coronary intervention (PCI) in the management of stable coronary artery disease remains controversial. Given advancements in medical therapies and stent technology over the last decade, we sought to evaluate whether PCI, when added to medical therapy, improves outcomes when compared with medical therapy alone. Methods and Results—We performed a systematic review and meta-analysis, searching PubMed, EMBASE, and CENTRAL databases, until January 2012, for randomized clinical trials comparing revascularization with PCI to optimal medical therapy (OMT) in patients with stable coronary artery disease. The primary outcome was all-cause mortality, and secondary outcomes included cardiovascular death, nonfatal myocardial infarction, subsequent revascularization, and freedom from angina. Primary analyses were based on longest available follow-up with secondary analyses stratified by trial duration, with short-term (≤1 year), intermediate (1-5 years), and long-term (≥5 years) time points. We identified 12 randomized clinical trials enrolling 7182 participants who fulfilled our inclusion criteria. For the primary analyses, when compared with OMT, PCI was associated with no significant improvement in mortality (risk ratio [RR], 0.85; 95% CI, 0.71–1.01), cardiac death (RR, 0.71; 95% CI, 0.47-1.06), nonfatal myocardial infarction (RR, 0.93; 95% CI, 0.70-1.24), or repeat revascularization (RR, 0.93; 95% CI, 0.76-1.14), with consistent results over all follow-up time points. Sensitivity analysis restricted to studies in which there was >50% stent use showed attenuation in the effect size for all-cause mortality (RR, 0.93; 95% CI, 0.78-1.11) with PCI. However, for freedom from angina, there was a significant improved outcome with PCI, as compared with OMT (RR, 1.20; 95% CI, 1.06-1.37), evident at all of the follow-up time points.

Conclusions—In this most rigorous and comprehensive analysis in patients with stable coronary artery disease, PCI, as compared with OMT, did not reduce the risk of mortality, cardiovascular death, nonfatal myocardial infarction, or revascularization. PCI, however, provided a greater angina relief compared with OMT alone, larger studies with sufficient power are required to prove this conclusively. (Circ Cardiovasc Interv. 2012;5:1-15.)

Key Words: angina ■ coronary artery disease ■ optimal medical therapy

percutaneous coronary intervention

Systematic Review Checklist

2. Did the authors look for the appropriate sort of papers?

作者有找尋適當類別之文獻?

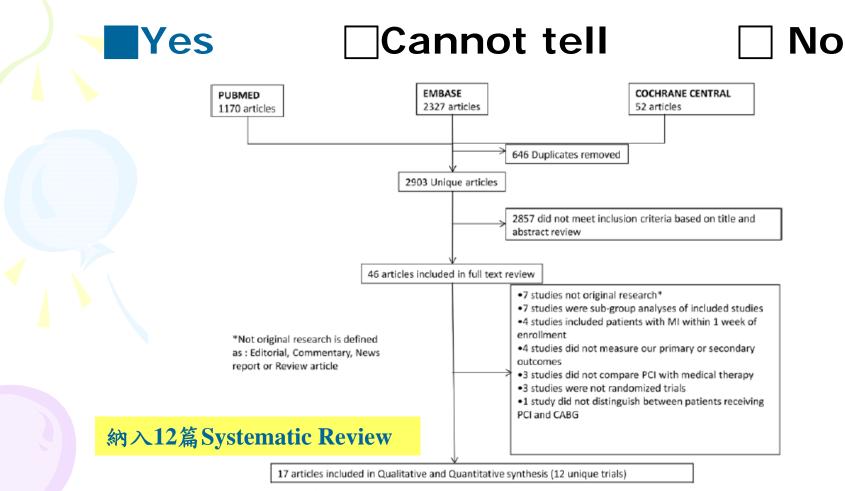
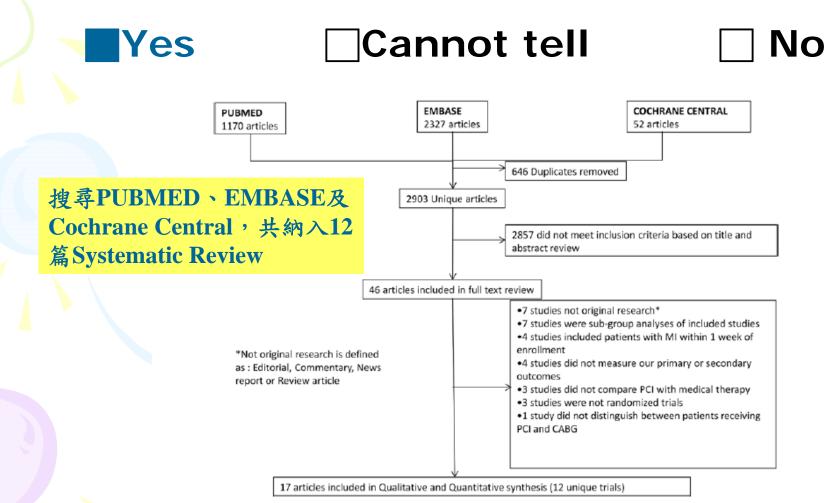


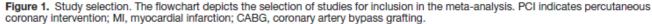
Figure 1. Study selection. The flowchart depicts the selection of studies for inclusion in the meta-analysis. PCI indicates percutaneous coronary intervention; MI, myocardial infarction; CABG, coronary artery bypass grafting.

Systematic Review Checkhai

3. Do you think the important, relevant studies were included?

重要、相關的研究都有被納入?







4. Did the review's authors do enough to assess the quality of the included studies?

綜論作者是否對納入之研究有做足夠之評估?

Yes Cannot tell No

Two independent reviewers (S.P., F.K.) abstracted data from included studies using a uniform data abstraction form for each study, with the second reviewer reentering data using double-data entry. Data abstracted included study characteristics, patient characteristics, details regarding the intervention and comparison group, and outcome measures. For the primary (all-cause mortality) and each of the secondary (cardiovascular death, nonfatal MI, repeat revascularization, and freedom from angina) outcomes, crude data was collected for the PCI and OMT groups. Where available, outcome data were abstracted at multiple follow-up time points. For trials using survival analysis design, 1-year event rates were extrapolated from the Kaplan-Meier survival curves using the Kaplan-Meier rates, in addition to the final time point data.

5. If the results of the review have been combined, was it reasonable to do so?

若此綜論之結果有被綜合,合理嗎?



All-cause mortality: PCI vs OMT RR: 0.85 (95%CI: 0.71, 1.01)

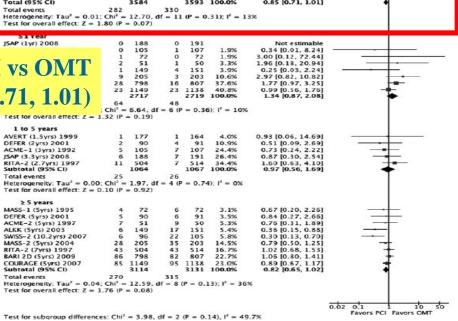


Figure 2. Percutaneous coronary intervention (PCI) vs optimal medical therapy (OMT) for the risk of all-cause mortality. The forrest plot depicts the individual trial and subtotal risk ratios and 95% CIs comparing the outcome of all-cause mortality for PCI vs OMT. The first plot shows the overall analysis, using available data for the longest duration of follow up, and subsequent plots are stratified by trial follow-up duration. ACME indicates Angioplasty Compared to Medicine; ALKK, Arbeitsgemeinschaft Leitended Kardiologische Krankenhausarzte; AVERT, Atorvastatin versus Revascularization Treatment; BARI, Bypass Angioplasty Revascularization investigation; COURAGE, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation; JSAP, Japanese Stable Angina Pectoris; MASS, Medicine, Angioplasty, or Surgery Study; RITA, Randomized Intervention Trial of unstable Angins; SWISS, Swiss Interventional Study on Silent Ischemia.

Systematic Review Cho

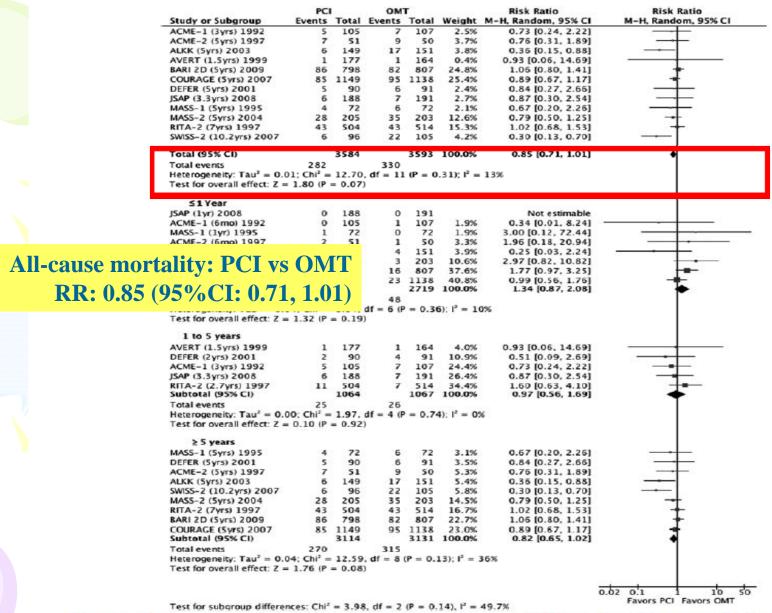


Figure 2. Percutaneous coronary intervention (PCI) vs optimal medical therapy (OMT) for the risk of all-cause mortality. The forrest plot depicts the individual trial and subtotal risk ratios and 95% CIs comparing the outcome of all-cause mortality for PCI vs OMT. The first plot shows the overall analysis, using available data for the longest duration of follow up, and subsequent plots are stratified by trial follow-up duration. ACME indicates Angioplasty Compared to Medicine; ALKK, Arbeitsgemeinschaft Leitended Kardiologische Krankenhausarzte; AVERT, Atorvastatin versus Revascularization Treatment; BARI, Bypass Angioplasty Revascularization investigation; COURAGE, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation; JSAP, Japanese Stable Angina Pectoris; MASS, Medicine, Angioplasty, or Surgery Study; RITA, Randomized Intervention Trial of unstable Angina; SWISS, Swiss Interventional Study on Silent Ischemia.

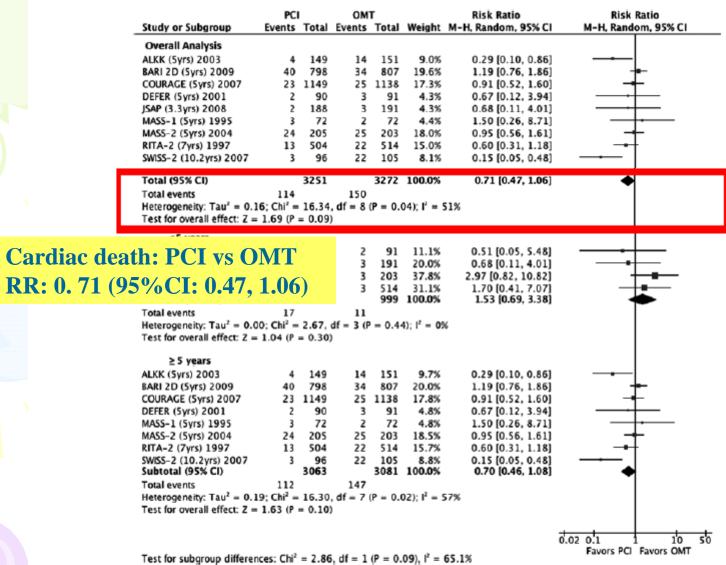


Figure 3. Percutaneous coronary intervention (PCI) vs optimal medical therapy (OMT) for the risk of cardiac death. The forrest plot depicts the individual trial and subtotal risk ratios and 95% CIs comparing the outcome of cardiac death for PCI vs OMT. The first plot shows the overall analysis, using available data for the longest duration of follow up, and subsequent plots are stratified by trial follow-up duration. ALKK indicates Arbeitsgemeinschaft Leitended Kardiologische Krankenhausarzte; BARI, Bypass Angioplasty Revascularization Investigation; COURAGE, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation; JSAP, Japanese Stable Angina Pectoris; MASS, Medicine, Angioplasty, or Surgery Study; RITA, Randomized Intervention Trial of unstable Angina; SWISS, Swiss Interventional Study on Silent Ischemia.

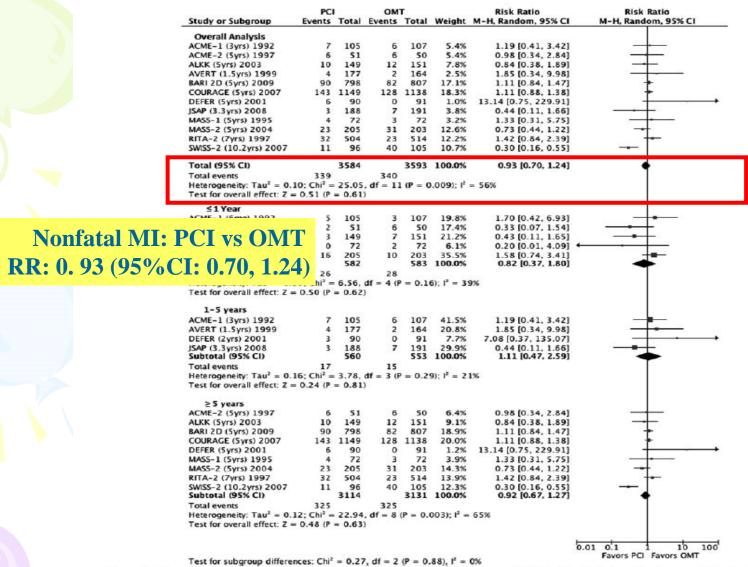


Figure 4. Percutaneous coronary intervention (PCI) vs optimal medical therapy (OMT) for the risk of nonfatal myocardial infarction (MI). The forrest plot depicts the individual trial and subtotal risk ratios and 95% CIs comparing the outcome of nonfatal MI for PCI vs OMT. The first plot shows the overall analysis, using available data for the longest duration of follow up, and subsequent plots are stratified by trial follow-up duration. ACME indicates Angioplasty Compared to Medicine; ALKK, Arbeitsgemeinschaft Leitended Kardiologische Krankenhausarzte; AVERT, Atorvastatin versus Revascularization Treatment; BARI, Bypass Angioplasty Revascularization Investigation; COURAGE, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation; JSAP, Japanese Stable Angina Pectoris; MASS, Medicine, Angioplasty, or Surgery Study; RITA, Randomized Intervention Trial of unstable Angina; SWISS, Swiss Interventional Study on Silent Ischemia.

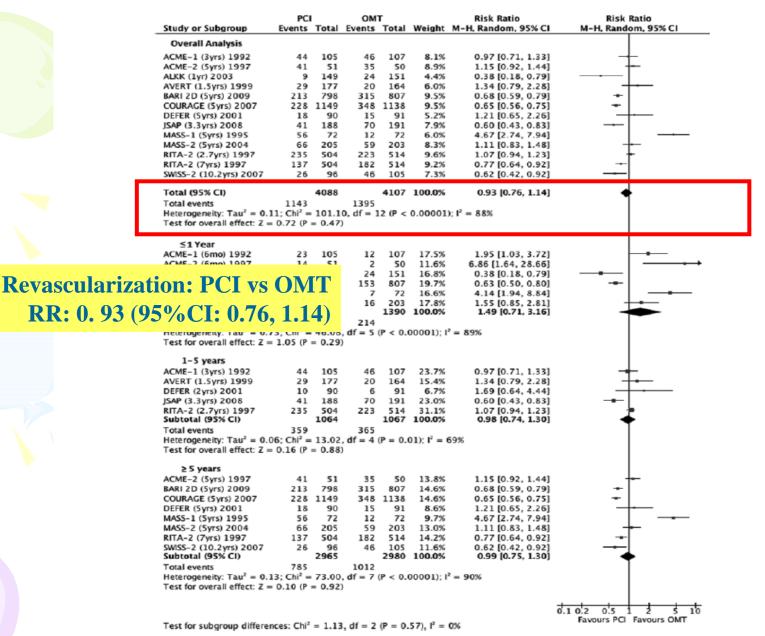


Figure 5. Percutaneous coronary intervention (PCI) vs optimal medical therapy (OMT) for the risk of revascularization. The forrest plot depicts the individual trial and subtotal risk ratios and 95% Cls comparing the outcome of revascularization for PCI vs OMT. The first plot shows the overall analysis, using available data for the longest duration of follow up, and subsequent plots are stratified by trial follow-up duration. ACME indicates Angioplasty Compared to Medicine, ALKK, Arbeitsgemeinschaft Leitended Kardiologische Krankenhausarzte; AVERT, Atorvastatin versus Revascularization Treatment; BARI, Bypass Angioplasty Revascularization Investigation; COURAGE, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation; JSAP, Japanese Stable Angina Pectoris; MASS, Medicine, Angioplasty, or Surgery Study; RITA, Randomized Intervention Trial of unstable Angina; SWISS, Swiss Interventional Study on Silent Ischemia.

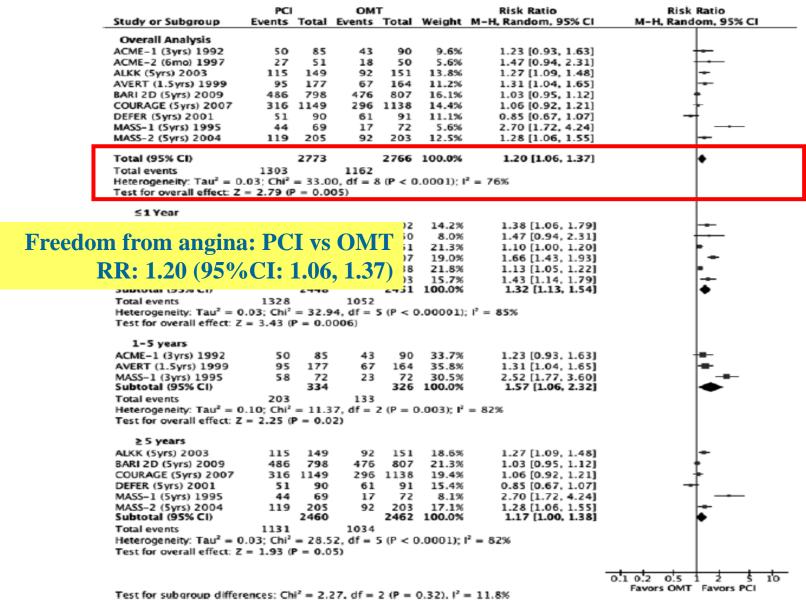


Figure 6. Percutaneous coronary intervention (PCI) vs optimal medical therapy (OMT) for the risk of freedom from angina. The forrest plot depicts the individual trial and subtotal risk ratios and 95% CIs comparing freedom from angina for PCI vs OMT. The first plot shows the overall analysis, using available data for the longest duration of follow up, and subsequent plots are stratified by trial follow-up duration. ACME indicates Angioplasty Compared to Medicine; ALKK, Arbeitsgemeinschaft Leitended Kardiologische Krankenhausarzte; AVERT, Atorvastatin versus Revascularization Treatment; BARI, Bypass Angioplasty Revascularization Investigation; COURAGE, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation; JSAP, Japanese Stable Angina Pectoris; MASS, Medicine, Angioplasty, or Surgery Study; RITA, Randomized Intervention Trial of unstable Angina; SWISS, Swiss Interventional Study on Silent Ischemia.

6. What are the overall results of the reviews? 主要結果如何呈現?

 Conclusions—In this most rigorous and comprehensive analysis in patients with stable coronary artery disease, PCI, as compared with OMT, did not reduce the risk of mortality, cardiovascular death, nonfatal myocardial infarction, or revascularization. PCI, however, provided a greater angina relief compared with OMT alone, larger studies with sufficient power are required to prove this conclusively.

7. How precise are the results?

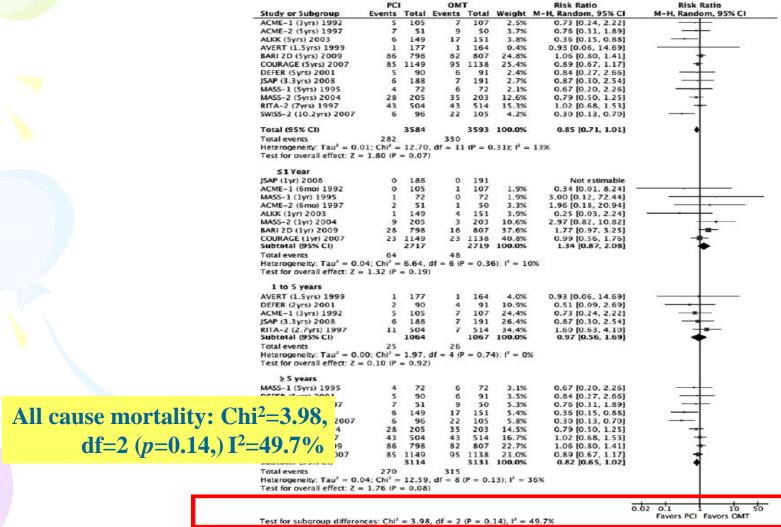


Figure 2. Percutaneous coronary intervention (PCI) vs optimal medical therapy (OMT) for the risk of all-cause mortality. The forrest plot depicts the individual trial and subtotal risk ratios and 95% CIs comparing the outcome of all-cause mortality for PCI vs OMT. The first plot shows the overall analysis, using available data for the longest duration of follow up, and subsequent plots are stratified by trial follow-up duration. ACME indicates Angioplasty Compared to Medicine; ALKK, Arbeitsgemeinschaft Leitended Kardiologische Krankenhausarzte; AVERT, Atorvastatin versus Revascularization Treatment; BARI, Bypass Angioplasty Revascularization Investigation; COURAGE, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation; JSAP, Japanese Stable Angina Pectoris; MASS, Medicine, Angioplasty, or Surgery Study; RITA, Randomized Intervention Trial of unstable Angina; SWISS, Swiss Interventional Study on Silent Isohemia.

Systematic Review

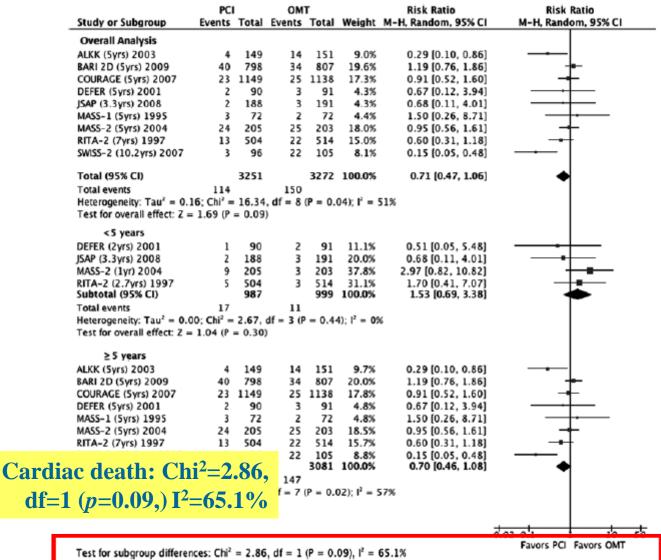


Figure 3. Percutaneous coronary intervention (PCI) vs optimal medical therapy (OM1) for the risk of cardiac death. The forrest plot depicts the individual trial and subtotal risk ratios and 95% CIs comparing the outcome of cardiac death for PCI vs OMT. The first plot shows the overall analysis, using available data for the longest duration of follow up, and subsequent plots are stratified by trial follow-up duration. ALKK indicates Arbeitsgemeinschaft Leitended Kardiologische Krankenhausarzte; BARI, Bypass Angioplasty Revascularization Investigation; COURAGE, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation; JSAP, Japanese Stable Angina Pectoris; MASS, Medicine, Angioplasty, or Surgery Study; RITA, Randomized Intervention Trial of unstable Angina; SWISS, Swiss Interventional Study on Silent Ischemia.

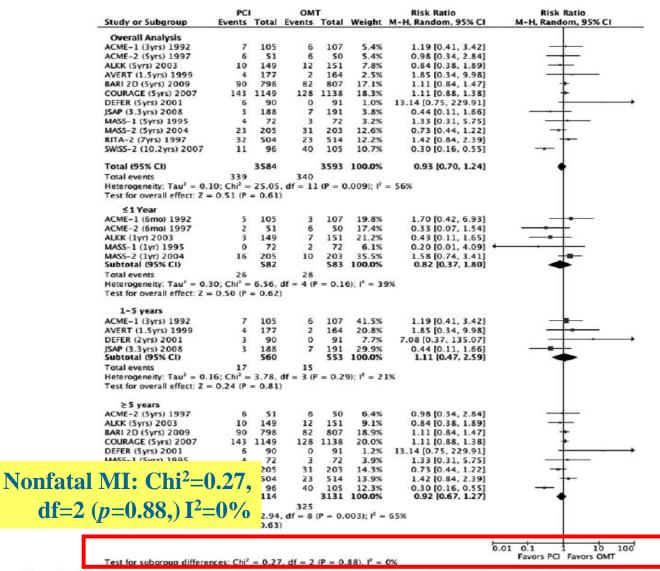


Figure 4. Percutaneous coronary intervention (PCI) vs optimal medical therapy (OMT) for the risk of nonfatal myocardial infarction (MI). The forrest plot depicts the individual trial and subtotal risk ratios and 95% Cls comparing the outcome of nonfatal MI for PCI vs OMT. The first plot shows the overall analysis, using available data for the longest duration of follow up, and subsequent plots are stratified by trial follow-up duration. ACME indicates Angioplasty Compared to Medicine; ALKK, Arbeitsgemeinschaft Leitended Kardiologische Krankenhausarzte; AVERT, Atorvastatin versus Revascularization Treatment; BARI, Bypass Angioplasty Revascularization Investigation; COURAGE, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation; JSAP, Japanese Stable Angina Pectoris; MASS, Medicine, Angioplasty, or Surgery Study; RITA, Randomized Intervention Trial of unstable Angina; SWISS, Swiss Interventional Study on Silent Ischemia.

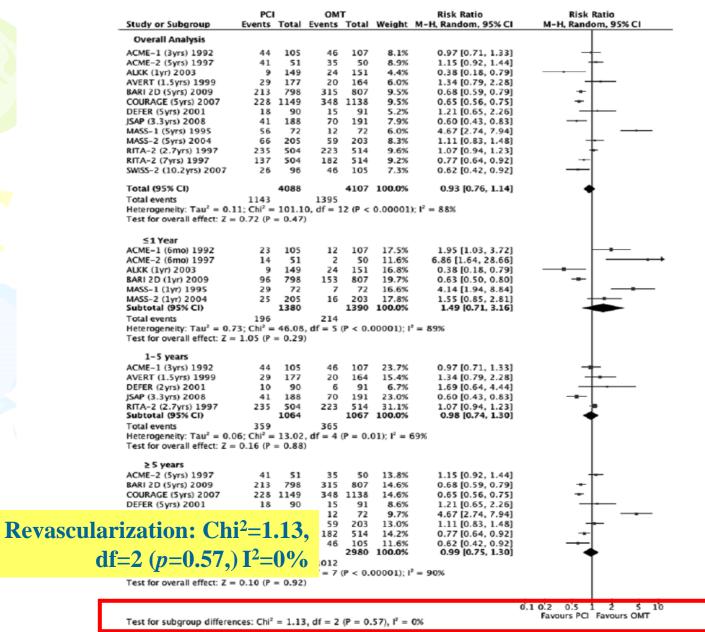


Figure 5. Percutaneous coronary intervention (PCI) vs optimal medical therapy (OMT) for the risk of revascularization. The forrest plot depicts the individual trial and subtotal risk ratios and 95% CIs comparing the outcome of revascularization for PCI vs OMT. The first plot shows the overall analysis, using available data for the longest duration of follow up, and subsequent plots are stratified by trial follow-up duration. ACME indicates Angioplasty Compared to Medicine; ALKK, Arbeitsgemeinschaft Leitended Kardiologische Krankenhausarzte; AVERT, Atorvastatin versus Revascularization Treatment; BARI, Bypass Angioplasty Revascularization Investigation; COURAGE, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation; JSAP, Japanese Stable Angina Pectoris; MASS, Medicine, Angioplasty, or Surgery Study; RITA, Randomized Intervention Trial of unstable Angina; SWISS, Swiss Interventional Study on Silent Ischemia.

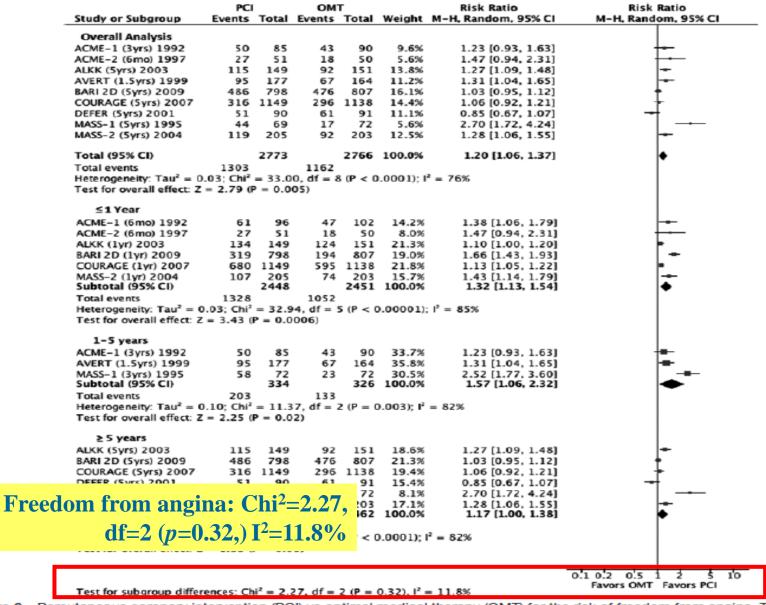


Figure 6. Percutaneous coronary intervention (PCI) vs optimal medical therapy (OMT) for the risk of freedom from angina. The forrest plot depicts the individual trial and subtotal risk ratios and 95% CIs comparing freedom from angina for PCI vs OMT. The first plot shows the overall analysis, using available data for the longest duration of follow up, and subsequent plots are stratified by trial follow-up duration. ACME indicates Angioplasty Compared to Medicine; ALKK, Arbeitsgemeinschaft Leitended Kardiologische Krankenhausarzte; AVERT, Atorvastatin versus Revascularization Treatment; BARI, Bypass Angioplasty Revascularization Investigation; COURAGE, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation; JSAP, Japanese Stable Angina Pectoris; MASS, Medicine, Angioplasty, or Surgery Study; RITA, Randomized Intervention Trial of unstable Angina; SWISS, Swiss Interventional Study on Silent Ischemia.

8. Can the results be applied to the local population?

結果可應用在本土的族群對象嗎?



□ Cannot tell



Study Years of Enrolment, Country or Region	Inclusion Criteria	Exclusion Criteria	Description of Intervention	Description of Medical Therapy	Primary Outcome	Secondary Outcomes	Follow Up,
COURAGE 1999–2004 North America	≥70% sternosis in at least 1 proximal artery, inducible ischemia on stress testing or ST depression or TWI on resting EKG	CCS class IV angina, substantial ST depression or hypotension during Bruce protocol stage 1 stress testing, refractory heart failure or cardiogenic shock, LVEF <30%, revascularization in prior 6 mo, coronary anatomy not suitable for PCI	PTCA, BMS, DES	81–325mg aspirin and 75mg copidogret; long- acting metoprolol and amlo- dipine and nitrates; lisinopril or losartan; simvasta tin alone or with ezetimibe; extended-rele ase niacin and fibrates if needed	Composite of all-cause mortality and nonfatal MI	Composite of all-cause mortality, MI, stroke, and hospitalization for unstable angina; angina functional class (CCS scale); Quality of life; resource use; cost ef- fectiveness	Median 4.6
DEFER 1997–1998 Europe, Asia	Angiography with >50% stenosis in native coronary artery and FFR ≥0.75, no evidence of reversible ischemia by noninvasive testing within the previous 2 mo	Total occlusion of the target artery, Q-wave infarction, un- stable angina, or small target arteries	PTCA, BMS	Statins, β-blockers, nitrates	Composite of all-cause mortality, M, CABG, PCI, and any proce- dure-related complica- tion requiring major in- tervention or prolonged hospital stay	Freedom from angina (CCS I) and the use of anti- anginal drugs	2
JSAP 2002–2004 Japan	≥75% (or ≥60% on quantitative coronary angiography) 1 or 2 vessel CAD, inducible ischemia on stress testing or ST depression or T-wave inversion on resting EKG	Three vessel CAD, left main or ostial LAD disease, total occlusion, ACS, LVEF <50%, tendency to bleed, disseminated intravascular coagulation, severe pneumonia, creatinine >1.5mg/dL, graft stenosis, low-risk CAD where PCI or medical therapy had already been crescribed.	PTCA, BMS	Entirely physician-depen- dent (majority received aspirin or other antiplate- let, β-blockers, nitrates, Statins, ACE/ARB)	Composite of all-cause mortality, ACS, stroke, emergent hospitalization requiring intensive care	Angina functional class (CCS scale), elective repeat revascularization	3.3
冷歐洲及 开究對象	亞洲 為日本人	occlusion, Esion length mm, involvement of the im, heavy calcification, are tortuosity, left main a, unstable angina, prior nificant valvular disease, omyopathy, LV dysfunc-	PTCA	Aspirin, nitrates, β -blockers	Composite of cardiac death, MI, or refractory angina requiring revasculariza- tion; surgical revascu- larization in PCI group	Angina functional class (CCS scale), employment status, positive stress test 2 y after enrolment, degree of CAD at 2 y angiographic follow-up	5

Systematic Review Checklist

9. Were all important outcomes considered? 重要結果是否都納入考量?



• All cause mortality、 Cardiac death、
Nonfatal MI、 Revascularization、 Freedom
from angina 皆納入考量

10. Are the benefits worth the harms and costs? 是否提出傷害與成本的利益價值?

• 文獻內並未強調傷害與成本的利益價值

		Yes	Can't tell	No
A. A	are the results of the review valid?			
1	Did the review address a clearly focused question			
2	Did the authors look for the appropriate sort of papers	V		
Is it	worth continuing?			
3	Do you think the important, relevant studies were included			
4	Did the review's authors do enough to assess the quality of the included studies	V		
5	If the results of the review have been combined, was it reasonable to do so	V		
B. V	Vhat are the results?			
6	What are the overall results of the reviews	PCI優於適當藥物治療, 病人較無angina的問題		
7	How precise are the results	部分文章異質性高		
C. V	Vill the results help locally?	·		
8	Can the results be applied to the local population	V		
9	Were all important outcomes considered	V		
10	Are the benefit worth the harms and costs	No description		-

Oxford Centre for EBM 2011 LOE (證據等級): Level I

Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	or Systematic review of cross sectional studies with consistently applied reference standard and blinding Individual cross sectional studies with consistently applied reference standard and blinding Non-consecutive studies, or studies without consistently applied reference standards**		Case-control studies, or "poor or non-independent reference standard**	Mechanism-based reasoning	
What will happen if we do not add a therapy? (Progress)			Case-series or case- control studies, or poor quality prognostic cohort study**	n/a	
Does this intervention help? (Treatment Benefits)	Systematic review of randomized trials or <i>n</i> -of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, nof-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or <i>n</i> -of-1 trial	Randomized trial or (exceptionally) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial	Non -randomized controlled cohort/follow-up study**		Mechanism-based reasoning

STEP 4 : Evidence application

臨床問題:急性心肌梗塞心導管手術是否較血栓溶解劑注射 能降低心肌梗塞病人的死亡率、復發率?

找到的證據:

Percutaneous Coronary Intervention Versus Optimal Medical Therapy in Stable Coronary Artery Disease

A Systematic Review and Meta-Analysis of Randomized Clinical Trials

Seema Pursnani, MD, MPH; Frederick Korley, MD; Ravindra Gopaul, MBA, MPH; Pushkar Kanade, MBBS, MPH; Newry Chandra, MBBS, MPH; Richard E. Shaw, PhD, MA; Sripal Bangalore, MD, MHA

證據來源:

Circ Cardiovasc Interv. 2012;5:1-15.

證據等級:Level I

STEP 4 : Evidence application

- □Evidence(研究的證據)
 - □研究證據的結果顯示PCI較藥物治療能減緩病人心絞痛
 - □研究的病患屬性部分與個案的屬性相符合
 - □PCI併支架治療健保給付約莫1萬多元,如使用自費之 塗藥支架費用可能高達7萬元,藥物治療費用約2000元 左右,然出血可能性較高,但多數研究證據仍認為病 人接受PCI治療之再梗塞率、中風率及死亡率較低,就 長期而言仍具有成本效益

STEP 4: Evidence application

- □Expectation(病人的選擇及期待)
 - □建議此檢查時宜考量病人的經濟狀況
 - □病人可能贊成的理由為可藉由藥物即可治療心肌梗塞, 但也可能因為導致出血的危險性而反對
 - □與病人討論兩種治療的優缺點及對治療結果的期待, 並建議病人考量自身經濟負擔進行選擇

STEP 4 : Evidence application

- □Experience(臨床的經驗)
 - □研究的證據並未與臨床的經驗相衝突
 - □此實證結果可提供醫療人員向病人及家屬解釋其選擇 方案時的考量
- □Environment(環境因素)
 - □推行上須考量醫院專科醫師是否有熟練的技術執行PCI 治療,以使治療過程中的合併症發生率降到最低
 - □建議各醫療院所應致力於相關專科醫師之PCI培訓,以 增進病人治療的成功率
 - □比較不同之血栓溶解劑對病人的效益,並建議醫院採購效果較佳之藥物,以增加病人的選擇性

結合實證醫學的結果與臨床專業經驗 給予病人建議

我們的臨床建議是:可利用心導管手術治療急性心肌梗塞,其死亡率、再梗塞率及中風率較血栓溶解術低,且病人較無心絞痛問題,生活品質能有所改善

-此項建議之證據等級:Level I



謝謝聆聽請多指教