Role of Routine Follow-up Coronary Angiography After Percutaneous Coronary Intervention

— Systematic Review and Meta-Analysis —

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Background: Prior studies have shown that routine follow-up coronary angiography (CAG) following percutaneous coronary intervention (PCI) increases the incidence of revascularization without a clear reduction in major adverse clinical events. However, none of these prior studies were adequately powered to evaluate hard clinical endpoints such as myocardial infarction (MI) or death and thus the clinical utility of such practice remains to be determined.

Methods and Results: We conducted a systematic review and meta-analysis of randomized trials that compared clinical outcomes after PCI between patients who underwent routine follow-up CAG and those who only had clinical follow-up. Five randomized trials, totaling 4,584 patients met our inclusion criteria, including studies that used sub-randomization and ones that assigned consecutive patients per study protocol. Our results showed that routine follow-up CAG was associated with a lower rate of MI (odds ratio [OR] 0.65; 95% confidence interval [CI] 0.46–0.91; $P=0.01$) without reduction in all-cause mortality (OR 0.87; 95% CI 0.59–1.28; $P=0.48$), and a higher rate of target lesion revascularization (OR 1.73; 95% CI 1.42–2.11; $P<0.001$).

Conclusions: Our meta-analysis demonstrated that routine follow-up CAG after PCI was associated with a higher rate of revascularization, but also with a reduction in the rate of subsequent MI. Further studies investigating the potential role of routine follow-up angiography may be warranted.

Key Words: Angiographic follow-up; Myocardial infarction; Percutaneous coronary intervention; Restenosis; Routine angiography

Routine follow-up coronary angiography (CAG) after percutaneous coronary intervention (PCI) is commonly implemented to assess the efficacy and safety of new revascularization devices. Although routine angiographic surveillance has undoubtedly furnished valuable scientific data, contributing to the advancement of coronary intervention, the direct clinical benefits remain poorly defined. In fact, prior studies have shown that routine follow-up CAG following PCI increases repeat revascularization without a clear reduction in myocardial infarction (MI) or death.^{1–3}

Accordingly, the 2012 ACCF/SCAI appropriate use criteria for diagnostic catheterization rated follow-up CAG as inappropriate in stable or asymptomatic post-PCI patients, discouraging its universal application.⁴ However, none of the prior studies evaluating the potential benefits of routine angiographic follow-up were adequately powered to evaluate hard clinical endpoints such as MI or death. In this context, we conducted a systematic review and meta-analysis to assess the potential clinical benefits associated with routine follow-up angiography post-PCI.

Methods

We performed a meta-analysis of randomized trials in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis guideline.⁵ The protocol for this systematic review was registered in the PROSPERO database (<https://www.crd.york.ac.uk/PROSPERO;CRD42017056193>). We searched MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials through January 2017 using the following search terms: “angiographic follow-up” or “routine coronary angiography” or “follow-up coronary angiography” or “scheduled coronary angiography” or “routine angiography” or “follow-up angiography” or “angiographic surveillance” or “surveillance angiography” or “surveillance coronary angiography”. The search was restricted to randomized controlled trials and there were no language restrictions. Studies were also identified by searching references cited in the screened articles and relevant review articles.

Eligible studies were refined to randomized trials that compared clinical outcomes based on follow-up strategies

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between routine follow-up CAG and clinical follow-up only in patients who underwent PCI. We also included a study investigating revascularization devices or medications that sub-randomized patients to routine angiography or clinical follow-up only strategies and a study that non-arbitrarily assigned consecutive patients to either strategy per study protocol (such as the one that assigned the first half of the patients to protocol-mandated angiographic follow-up). We did not establish any inclusion or exclusion criteria regarding the timing for follow-up CAG.

Two investigators (N.M. and A.K.) independently assessed trial eligibility using the predefined inclusion criteria. After initial screening of all titles and abstracts of identified articles, potential studies were reviewed in full-text to determine their eligibility. Disagreements were resolved through discussion between the reviewers.

The primary outcome of interest was MI, as defined by each study, and the secondary outcome of interest were all-cause death (or cardiac death, if all-cause death was not reported) and target lesion revascularization (TLR) (or target vessel revascularization, if TLR was not reported).

Relevant data were independently extracted by 2 investigators (N.M. and A.K.). Disagreements were resolved through discussion between the reviewers. Data were abstracted to include the following information: first author's name, year of publication, study period, country, study design, sample size, clinical characteristics of the study population, definitions of the outcomes used in each study, timing of follow-up CAG, follow-up duration, and incidence of primary and secondary outcomes of interest. Quality assessment for each study was performed using the Cochrane Collaboration's risk of bias tool.⁶

Statistical Analysis

Summary estimates were calculated as odds ratios [OR] with 95% confidence intervals [CI] using a prespecified random effects model based on DerSimonian and Laird's meta-analytic statistical method.⁷ In addition, we performed a subgroup analysis according to stent use: (1) studies in which stents (either bare-metal [BMS] or drug-eluting [DES]) were used in more than 80% of the patients and (2)

studies in which DES were used in more than 80% of the patients. We performed additional sensitivity analyses using the “one study removed” method by removing individual studies to assess the effect of each study on overall outcome. We also performed a cumulative meta-analysis to examine the stability of our results over time and different standards of therapy. Using the OR log-transformed as an independent variable, meta-regression analysis was performed with prespecified study year as a moderator to test the effect of publication year on the pooled effect measure. The I^2 index was used to summarize the proportion of total variability in the estimate. The I^2 statistic is derived from the Q statistic and describes the percentage of total variation across studies that is due to heterogeneity; values of 25%, 50%, and 75% correspond to low, moderate, and high heterogeneity, respectively.^{8,9} Assessment of publication bias using Funnel plot and the Begg's test was not performed, because of the limited number of included studies. The statistical level of significance was 2-tailed $P < 0.05$. All statistical analyses were performed using Comprehensive Meta-analysis version 3.0 software (Biostat, Inc., NJ, USA).

Results

The result of our search strategy is illustrated in **Figure 1**. Of 843 screened articles, 20 potential studies were reviewed in full-text to determine eligibility. A total of 5 randomized controlled trials met our inclusion criteria, including 2 studies that used sub-randomization^{1,2} and 2 studies that non-arbitrarily assigned consecutive patients to either strategy per study protocol.^{3,10} The total number of patients included in our final analysis was 4,584.

The characteristics of included studies and patients are shown in **Table 1** and **Table 2**. Two studies were deemed to have a high risk of bias because of the use of cluster assignment instead of formal randomization (**Table 3**). The 2 most recent studies mainly used DES, and the 2 studies conducted in the 1990s used either balloon angioplasty or BMS.^{1-3,11} The majority of the patients who were assigned to angiographic surveillance underwent follow-up angiography. Follow-up duration ranged from 1 to 4.6 years.

Table 1. Characteristics of the Studies Included in a Meta-Analysis of Routine Follow-up Coronary Angiography After PCI

Author	Year of publication	Study country	Study description	Follow-up duration	
Ruygrok et al ¹	1999	The Netherlands	Sub-randomization in the RCT (Benestent II trial) comparing balloon angioplasty vs. bare-metal stent	1 year	
ten Berg et al ²	2001	The Netherlands	Sub-randomization in the RCT (BAAS trial) comparing aspirin vs. aspirin plus coumadin	1 year	
Pinto et al ¹⁰	2006	USA	Cluster assignment (protocol-mandated angiography in the first 536 patients) in the RCT (TAXUS-IV trial) comparing paclitaxel-eluting stents vs. bare-metal stent	1 year	
Lansky et al ³	2012	USA	Cluster assignment (protocol-mandated angiography in the first 564 patients) in the RCT (SPIRIT III trial) comparing everolimus-eluting stent vs. paclitaxel-eluting stent	3 years	
Shiomi et al ¹¹	2017	Japan	RCT primarily comparing angiographic follow-up and clinical follow-up	4.6 years (median)	
Study inclusion criteria			Major exclusion criteria		
Ruygrok et al ¹	Stable or unstable angina		Left main lesion and bifurcation lesion with a large side-branch		
ten Berg et al ²	Symptomatic CAD		Acute MI within 24 h		
Pinto et al ¹⁰	Stable or unstable angina with 1 de novo lesion		Acute MI within 72 h, LVEF <25%		
Lansky et al ³	Stable or unstable angina with 1 or 2 de novo lesion		Acute and recent MI, and left main lesion and bifurcation lesion		
Shiomi et al ¹¹	All patients who underwent successful PCI without planned staged PCI		No exclusion criteria		
	Total sample size	Angiographic follow-up	Clinical follow-up	Timing of follow-up angiography	Rate of follow-up angiography in angiographic follow-up group
Ruygrok et al ¹	706*	357	349	6 months	92%
ten Berg et al ²	1,058	531	527	6 months	90%
Pinto et al ¹⁰	1,118	536	582	9 months	83%
Lansky et al ³	1,002	564	438	8 months	77%
Shiomi et al ¹¹	700	349	351	8–12 months	85%
Definition of MI					
Ruygrok et al ¹	New pathological Q waves, or an increase in serum creatine kinase to more than twice upper limit of normal, together with a pathological increase of myocardial isoenzymes				
ten Berg et al ²	Prolonged chest pain with new Q waves or a new left bundle-branch block, or a rise in creatine kinase to more than twice upper limit of normal				
Pinto et al ¹⁰	Pathologic Q waves with an elevated creatine kinase MB fraction level or in the absence of pathologic Q waves, an elevation in creatine kinase levels to more than twice the upper limit of normal with an elevated creatine kinase MB level				
Lansky et al ³	New pathologic Q waves, or as an elevation of creatine kinase levels to twice the upper limit of normal with an elevated creatine kinase MB level				
Shiomi et al ¹¹	Defined according to the Academic Research Consortium definitions				

*After excluding 121 patients who died or underwent angiography within 6 months. CAD, coronary artery disease; LVEF, left ventricular ejection fraction; MI, myocardial infarction; PCI, percutaneous coronary intervention; RCT, randomized controlled trial.

The major adverse clinical outcomes from each study are shown in **Table 4**. **Figure 2** illustrates the Forest plot reporting OR with 95% CI for MI, all-cause death and TLR. Routine follow-up CAG was associated with a lower rate of MI (OR 0.65; 95% CI 0.46–0.91; $P=0.01$) without reduction in all-cause death (OR 0.87; 95% CI 0.59–1.28; $P=0.48$), and a higher rate of TLR (OR 1.73; 95% CI 1.42–2.11; $P<0.001$). No significant change was noted when the data were analyzed using the fixed effects model (data not shown).

The results from the subgroup analysis according to the type or method of revascularization are shown in **Figure 3** and **Figure 4**. The lower rate of MI with angiographic follow-up was also seen in subgroup analysis where stents (either BMS or DES) were used in more than 80% of patients (OR 0.60; 95% CI 0.40–0.92; $P=0.02$).^{3,10,11} In the

subgroup analysis where DES were used in more than 80% of patients, there was a similar but statistically non-significant trend for lower rates of MI in the angiographic follow-up group (OR 0.70; 95% CI 0.41–1.18; $P=0.18$).^{3,11} A higher incidence of TLR was seen with angiographic follow-up in all tested subgroups. No significant interactions were noted in the rate of MI and TLR between studies stratified by (1) stent use (either BMS or DES) in >80% of the patients or (2) DES use in >80% of the patients. The higher incidence of TLR with routine angiographic follow-up was less apparent in studies that mainly used DES (OR 1.48; 95% CI 1.04–2.10) compared with those that used balloon angioplasty or BMS (OR 1.87; 95% CI 1.47–2.37).

Sensitivity analyses using the “one study removed” method did not show significant changes in the summary OR estimates for any outcome assessed (**Figure S1**).

Table 2. Characteristics of the Patients in Each Study Included in a Meta-Analysis of Routine Follow-up Coronary Angiography After PCI

Author	Age (years)	Male	Hypertension	Diabetes	Dyslipidemia	Smoking
Ruygrok et al ¹	59	79%	40%	12%	NA	26%
ten Berg et al ²	60	78%	21%	9%	29%	31%
Pinto et al ¹⁰	62	72%	70%	24%	67%	44%
Lansky et al ³	63	69%	75%	29%	72%	23%
Shiomi et al ¹¹	69	79%	76%	45%	78%	18%
	Prior MI	Prior PCI	ACS	BMS use	DES use	
Ruygrok et al ¹	26%	8%	42%	NA	0%	
ten Berg et al ²	39%	15%	35%	36%	0%	
Pinto et al ¹⁰	30%	NA	34%	50%*	50%*	
Lansky et al ³	NA	NA	20%	0%	100%	
Shiomi et al ¹¹	18%	32%	37%	15%	85%	

*Per study protocol. ACS, acute coronary syndrome; BMS, bare-metal stent; DES, drug-eluting stent; NA, not available. Other abbreviations as in Table 1.

Table 3. Bias Risk Assessment of the Studies Included in a Meta-Analysis of Routine Follow-up Coronary Angiography After PCI

Author	Random sequence generation	Allocation concealment	Blind participants and personnel	Blind outcome assessment	Incomplete outcome data	Selective reporting
Ruygrok et al ¹	Low risk	Low risk	Low risk	Low risk	Unclear risk	Low risk
ten Berg et al ²	Unclear risk	Low risk	Low risk	Low risk	Unclear risk	Low risk
Pinto et al ¹⁰	High risk	High risk	Low risk	Low risk	Unclear risk	Low risk
Lansky et al ³	High risk	High risk	Low risk	Low risk	Low risk	Low risk
Shiomi et al ¹¹	Unclear risk	Unclear risk	Low risk	Low risk	Low risk	Low risk

PCI, percutaneous coronary intervention.

Table 4. Clinical Outcomes in Each Study Included in a Meta-Analysis of Routine Follow-up Coronary Angiography After PCI

Author	MI		All-cause death		TLR	
	Angiographic follow-up	Clinical follow-up	Angiographic follow-up	Clinical follow-up	Angiographic follow-up	Clinical follow-up
Ruygrok et al ¹	2/357 (0.6%)	4/349 (1.1%)	3/357 (0.8%)	2/349 (0.6%)	40/357 (11.2%)	21/349 (6.0%)
ten Berg et al ²	17/531 (3.2%)	21/527 (4.0%)	6/531 (1.1%)	6/527 (1.1%)	102/531 (19.2%)	61/527 (11.6%)
Pinto et al ¹⁰ *	12/536 (2.3%)	27/582 (4.7%)	6/536 (1.1%)	6/582 (1.0%)	64/536 (11.9%)**	39/582 (6.7%)**
Lansky et al ³	21/522 (4.0%)	23/412 (5.6%)	9/522 (1.7%)***	7/412 (1.7%)***	55/532 (10.3%)	31/416 (7.5%)
Shiomi et al ¹¹	6/349 (1.7%)	9/351 (2.6%)	30/349 (8.6%)	37/351 (10.5%)	34/349 (9.7%)	23/351 (6.6%)

*Event numbers calculated by reported incidences, **target vessel revascularization, ***cardiac death. TLR, target lesion revascularization. Other abbreviations as in Table 1.

Cumulative meta-analysis showed a relatively stable accumulation of evidence for reduction of MI and increase in TLR associated with angiographic follow-up (**Figure S2**). Meta-regression analysis showed that treatment effect does not change significantly depending on publication year (**Figure S3**).

Discussion

Our meta-analysis of 5 randomized trials including 4,584 patients confirmed that routine follow-up CAG following PCI was associated with a higher rate of repeat revascularization. Importantly, our analysis also demonstrated a lower rate of MI associated with routine follow-up CAG post-PCI. Subgroup analysis according to stent use and type of stent showed a similar reduction in MI and increase

in TLR associated with routine angiographic follow-up. To our knowledge, this is the first meta-analysis that addresses the potential clinical benefits associated with routine follow-up angiography post-PCI.

Prior studies have repeatedly demonstrated that routine angiographic surveillance increases the rate of TLR without a clear reduction in major adverse cardiac events.¹⁻³ However, none of those studies were adequately powered to evaluate hard clinical endpoints such as death or MI. It is important to emphasize that a negative result from an underpowered study does not prove “absence of benefit”. For example, among 17 randomized trials investigating the mortality benefit of β -blocker in heart failure patients between the years 1985 to 1997, only 1 study showed a significant reduction in mortality with β -blocker use while 13 studies demonstrated a similar but statistically non-

A) Myocardial infarction **B) All cause mortality** **C) Target lesion revascularization**

Figure 2. Forest plot of myocardial infarction, all-cause mortality, and TLR. Routine follow-up angiography was associated with significant reduction in (A) myocardial infarction (OR 0.65; 95% CI 0.46–0.91, $P=0.01$), but no significant change in (B) all-cause death. Routine follow up angiography was associated with significant increase in (C) TLR (OR 1.73; 95% CI 1.42–2.11, $P<0.001$). CI, confidence interval; df, degrees of freedom; MH, Mantel-Haenszel; OR, odds ratio; TLR, target lesion revascularization.

significant trend towards mortality reduction.¹² However, when a meta-analysis combining the 17 trials was performed, β -blockade treatment was associated with a significant reduction in death with an OR of 0.69 (95% CI 0.54–0.88).¹²

All 5 studies included in our analysis showed a similar trend for reduction in MI with routine angiographic follow-up. No heterogeneity was noted among studies, supporting the robustness of the association between angiographic follow-up and reduction in MI. This interesting and somewhat surprising finding may illustrate an opportunity to further improve clinical outcomes after PCI. Nevertheless, these results should be interpreted with caution given the several reasons described next.

The devices and medications used in the 2 trials from the 1990s were very different from contemporary practice. Stent use was infrequent and P2Y12 inhibitors (except for ticlopidine) were unavailable during that time. In addition, balloon angioplasty, the mainstay of coronary revascularization during this time, is known to be associated with a significantly higher rate of restenosis and ischemia-driven revascularization compared with stenting.¹³ Thus, the results

from these earlier trials may not apply to current practice. Nevertheless, the subgroup analysis of studies that used stents in $>80\%$ of the patients showed a similar reduction in MI, supporting the presence of this association applicable to current practice. The reduction in MI was not statistically significant when the inclusion was restricted to the studies that primarily used DES in our analysis. This appears to simply stem from small sample size and small numbers of the clinical events. For example, the most recent trial showed a very low incidence of MI over a median follow-up period of 4.6 years (1.7% vs. 2.6%).¹¹ The absence of significant difference in the reduction of MI in the DES era may also be related to the reduced incidence of restenosis and late stent thrombosis with recent advancement in stent and polymer designs,¹⁴ although our cumulative meta-analysis based on the publication year, as well as the meta-regression analysis, did not show significant effect of the year of publication on the OR of the clinical outcomes. Further studies in the current DES era are awaited.

Despite the observed association between angiographic follow-up and reduction in MI, the presence of an association does not necessarily indicate a causal relationship,

Figure 3. Forest plot of myocardial infarction (MI) according to subgroups. The reduction in MI was significant among studies where stents (either bare-metal or drug-eluting [DES]) were used in more than 80% of patients (OR 0.60; 95% CI 0.40–0.92; $P=0.02$). In subgroup analysis where DES were used in more than 80% of patients, there was a similar but statistically non-significant trend for lower rates of MI in the angiographic follow-up group (OR 0.70; 95% CI 0.41–1.18; $P=0.18$). Importantly, no significant interactions were noted in the rate of MI between studies stratified by (1) DES use in >80% of the patients or (2) stent use (either bare-metal or DES) in >80% of the patients. Abbreviations as in Figure 2.

because of possible confounders. For example, significant differences in medication regimens may have existed between the 2 groups that underwent angiographic follow-up or clinical follow-up only. Patients who underwent repeat PCI for restenosis during angiographic surveillance may have been treated with a prolonged dual antiplatelet therapy (DAPT), which has been shown to reduce MI based on recent large-scale randomized trials.^{15,16} In addition, a recent study showed that patients who were treated with 24 months DAPT after PCI for restenosis had a lower rate of death and MI compared with those treated with 6 months of DAPT.¹⁷ Unfortunately, the details of the medications used in each study, especially DAPT, were not reported in the studies included in our analysis.

Presumably, the primary purpose of follow-up CAG in post-PCI patients is to assess the presence of restenosis in stable patients, because acute coronary syndrome (ACS) or refractory angina would warrant repeat CAG regardless of planned follow-up strategy. Early intervention for restenosis following routine angiography can potentially prevent future cardiovascular events, as restenosis may manifest as ACS.¹⁸ Several studies suggested that PCI reduces the incidence of ACS in patients with stable angina.^{19,20} However, in terms of hard clinical endpoints such as MI or death, the current evidence does not support a benefit of PCI in stable patients except for anatomically high-risk subgroup such as those with left main disease.^{21–23} Further investigation is warranted to evaluate a potential

causality between reduction of MI and angiographic follow-up.

Hypothetically, if a direct causal benefit from angiographic follow-up was present, the extent of benefit may vary according to lesion characteristics, yielding a larger benefit to a subgroup of patients. For example, in patients with a large area of myocardium at risk, such as those with left main disease, either percutaneous or surgical revascularization is recommended to improve survival.^{22,24} Thus, angiographic follow-up in these high-risk patients with subsequent revascularization for hemodynamically significant restenosis may be beneficial. Our meta-analysis did not show a difference in mortality; however, this could be related to a low overall event rates and short-term follow-up. In addition, patients who underwent left main stenting and who may have benefited from such practice were excluded from most of the studies. In the past, according to 2005 ACC/AHA PCI guidelines follow-up angiography was recommended (Class IIa) between 2 and 6 months after PCI in patients who underwent unprotected left main revascularization.²⁵ This recommendation was removed in the 2009 focused update.²⁶ To date, no prior study has prospectively evaluated the clinical effect of follow-up CAG in such high-risk patients. In a recent observational study, the lack of angiographic follow-up was associated with increased mortality in patients who underwent PCI for left main lesion after adjusting for propensity score.²⁷ Although the observed survival benefit was likely inflated

Figure 4. Forest plot of TLR according to subgroups. The increase in TLR incidence was significant in all tested subgroups. No significant interactions were noted in the rate of TLR between studies stratified by (1) drug-eluting stent use in >80% of the patients or (2) stent use (either bare-metal or drug-eluting stents) in >80% of the patients. Abbreviations as in Figure 2.

by selection bias in that study, the result signifies the need for a prospective study to evaluate the role of follow-up CAG in this specific high-risk subgroup.

Multidetector computed tomography (MDCT) CAG appears to be an alternative modality once the clinical decision is made to evaluate in-stent restenosis. Although its lesser invasiveness makes MDCT CAG attractive, the assessment of the in-stent segment is more challenging due to artifacts from stents, compared with assessment of native coronary lesions. The rates of “non-evaluable” segments in stented lesions with use of 64-slice MDCT CAG has been reported to be approximately 12%.^{28,29} To date, the clinical effect of routine follow-up MDCT CAG after PCI has not been prospectively evaluated.

Study Limitations

Our meta-analysis has several limitations. First, 2 studies were deemed to have a high risk of bias because of the use of cluster assignment instead of formal randomization. The open-label nature of the trials may also be a potential source for bias. Second, the follow-up duration was not uniform across the studies, which were relatively short, limiting the evaluation of any long-term effect associated with follow-up angiography. Third, although the clinical benefits of invasive intervention should be carefully evaluated by balancing its benefits and risks, the rates of complications related to angiographic follow-up were only available in a limited number of studies. Fourth, as discussed, the results from the trials conducted in 1990s may not apply to current practice. Lastly, we could not evaluate or exclude

the possibility of publication bias related to the limited number of included studies.

In summary, our meta-analysis showed that routine follow-up CAG after PCI was associated with a lower risk of MI and a higher rate of TLR. Considering the potential value of routine angiographic follow-up in reducing MI vs. evidence of increased repeat procedures, and given the hypothesis generating nature of our data, it is prudent to individualize the application of follow-up angiography practice according to various risk factors predicting future ischemic events and possible restenosis. Further studies examining the potential role of routine follow-up angiography, especially in high-risk patients, may be warranted.

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Disclosure of Any Relationship With Industry

None.

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Supplementary Files

Supplementary File 1

Figure S1. 'One study removed' analysis of (A) myocardial infarction, (B) all-cause mortality and (C) target lesion revascularization showing no significant effect on the removal of any study on the overall cumulative odds ratio estimates.

Figure S2. Cumulative meta-analysis of (A) myocardial infarction, (B) all-cause mortality and (C) target lesion revascularization stratified by the year of publication.

Figure S3. Meta-regression analysis using the log-transformed odds ratio as dependent variable and the year of publication as moderator.

Please find supplementary file(s);
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