

# Boletín de Artículos Científicos

# 1. ARTÍCULO Nº: 4168

Henry JT, Christiansen E, Garberich RF, Handran CB, Larson DM, Unger BT et al. *Satisfaction with emergent transfer for percutaneous coronary interventions on patients with ST-segment-elevation myocardial infarction and their families.* Circ.Cardiovasc.Qual.Outcomes. 2014; 7(2): 244-250.

BACKGROUND: Transfer for primary percutaneous coronary intervention (PCI) is superior to fibrinolysis if performed in a timely manner but frequently requires dislocation of patients and their families from their local community. Although patient satisfaction is increasingly viewed as an important quality indicator, there are no data on how emergent transfer for PCI affects patients with ST-segment-elevation myocardial infarction and their families. METHODS AND RESULTS: The Minneapolis Heart Institute's Level 1 Regional ST-Segment-Elevation Myocardial Infarction program is designed to facilitate emergent transfer for PCI in patients with ST-segment-elevation myocardial infarction from 31 rural and community hospitals. To determine the effect of emergent transfer, questionnaires were given to 152 patients and their families who survived to hospital discharge with a 65.8% response rate (mean age, 63.9 years; 29% women). Ninety-five percent of patients felt the reasons and process of transfer were well explained, and 97% felt transfer for care was necessary. Despite this, 15% of patients would have preferred to stay in their local hospital. The majority of the families felt the transfer process (88%) and family member's condition (94%) were well explained. Although 99% felt it was necessary for their family member to be transferred for specialized care, 11% of families still would have preferred that their family members remain at the local community hospital. CONCLUSIONS: Our results suggest that ST-segment-elevation myocardial infarction patients and families can be informed, even in time-critical situations, about the transfer process for PCI and understand the need for specialized care. Still, a significant minority would prefer to stay at their local hospital, despite acknowledging transfer for PCI provided optimal care.

# 2. ARTÍCULO Nº: 4169

Austin PC, Reeves MJ. *Effect of provider volume on the accuracy of hospital report cards: a Monte Carlo study*. Circ.Cardiovasc.Qual.Outcomes. 2014; 7(2): 299-305.

BACKGROUND: Hospital report cards, in which outcomes after the provision of medical or surgical care are compared across healthcare providers, are being published with increasing frequency. However, the accuracy of such comparisons is controversial, especially when case volumes are small. The objective was to determine the relationship between hospital case volume and the accuracy of hospital report cards. METHODS AND RESULTS: Monte Carlo simulations were used to examine the influence of hospital case volume on the accuracy of hospital report cards in a setting in which true hospital performance was known with certainty, and perfect risk - adjustment was feasible. The parameters used to generate the

simulated data sets were obtained from empirical analyses of data on patients hospitalized with acute myocardial infarction in Ontario, Canada, in which the overall 30-day mortality rate was 11.1%. We found that provider volume had a strong effect on the accuracy of hospital report cards. However, provider volume had to be >300 before >/=70% of hospitals were correctly classified. Furthermore, hospital volume had to be >1000 before >/=80% of hospitals were correctly classified. CONCLUSIONS: Producers and users of hospital report cards need to be aware that, even when perfect risk adjustment is possible, the accuracy of hospital report cards is, at best, modest for small to medium-sized case loads (i.e., 100-300). Hospital report cards displayed high degrees of accuracy only when provider volumes exceeded the typical annual hospital case load for many cardiovascular conditions and procedures.

# 3. ARTÍCULO Nº: 4170

Jackevicius CA. *How do the 2013 cholesterol guidelines compare with previous cholesterol guideline reports?* Circ.Cardiovasc.Qual.Outcomes. 2014; 7(2): 306-310.

## 4. ARTÍCULO Nº: 4171

Korevaar DA, van Enst WA, Spijker R, Bossuyt PM, Hooft L. *Reporting quality of diagnostic accuracy studies: a systematic review and meta-analysis of investigations on adherence to STARD.* Evid.Based.Med. 2014; 19(2): 47-54.

BACKGROUND: Poor reporting of diagnostic accuracy studies impedes an objective appraisal of the clinical performance of diagnostic tests. The Standards for Reporting of Diagnostic Accuracy Studies (STARD) statement, first published in 2003, aims to improve the reporting quality of such studies. OBJECTIVE: To investigate to which extent published diagnostic accuracy studies adhere to the 25-item STARD checklist, whether the reporting quality has improved after STARD's launch and whether there are any factors associated with adherence. STUDY SELECTION: We performed a systematic review and searched MEDLINE, EMBASE and the Methodology Register of the Cochrane Library for studies that primarily aimed to examine the reporting quality of articles on diagnostic accuracy studies in humans by evaluating adherence to STARD. Study selection was performed in duplicate; data were extracted by one author and verified by the second author. FINDINGS: We included 16 studies, analysing 1496 articles in total. Three studies investigated adherence in a general sample of diagnostic accuracy studies; the others did so in a specific field of research. The overall mean number of items reported varied from 9.1 to 14.3 between 13 evaluations that evaluated all 25 STARD items. Six studies quantitatively compared post-STARD with pre-STARD articles. Combining these results in a random-effects meta-analysis revealed a modest but significant increase in adherence after STARD's introduction (mean difference 1.41 items (95% CI 0.65 to 2.18)). CONCLUSIONS: The reporting quality of diagnostic accuracy studies was consistently moderate, at least through halfway the 2000s. Our results suggest a small improvement in the years after the introduction of STARD. Adherence to STARD should be further promoted among researchers, editors and peer reviewers.

# 5. <u>ARTÍCULO №: 4172</u>

Rupp ME. Central venous catheters coated or impregnated with antimicrobial agents effectively prevent microbial colonisation and catheter-related bloodstream infections. Evid.Based.Med. 2014; 19(2): 56



Gorelick PB, Farooq MU. *Aspirin plus clopidogrel in acute minor ischaemic stroke or transient ischaemic attack is superior to aspirin alone for stroke risk reduction: CHANCE trial.* Evid.Based.Med. 2014; 19(2): 58

# 7. ARTÍCULO Nº: 4174

Bulliard JL. *Estimating the cost-effectiveness of modern screening mammography programmes*. Evid.Based.Med. 2014; 19(2): 80

# 8. ARTÍCULO Nº: 4175

Jain S, Ting HT, Bell M, Bjerke CM, Lennon RJ, Gersh BJ et al. *Utility of left bundle branch block as a diagnostic criterion for acute myocardial infarction*. Am.J.Cardiol. 2011; 107(8): 1111-1116.

The clinical utility of new or "presumably new" left bundle branch block (LBBB) as an electrocardiographic criterion equivalent to ST-segment elevation myocardial infarction in contemporary practice is not well established. The aim of this study was to investigate the hypothesis that new or presumably new LBBB in symptomatic patients frequently leads to an overdiagnosis of acute myocardial infarction (AMI). A retrospective analysis of data from consecutive patients in the Mayo Clinic's ST-segment elevation myocardial infarction network from July 2004 to August 2009 was conducted among 892 patients, 36 (4%) of whom had new LBBB. The frequency, clinical characteristics, serum troponin levels, coronary angiographic findings, and outcomes of patients with new LBBB suspected of having AMI were evaluated. Compared with patients without LBBB (n = 856), those with new LBBB were older (64.5 vs 72.9 years, p < 0.001), had higher Thrombolysis In Myocardial Infarction (TIMI) risk scores (22.7 vs 31.0, p < 0.005), were less likely to undergo primary percutaneous coronary intervention (86% vs 22%, p < 0.001), and had longer door-to-balloon times. Only 14 patients (39%) had final diagnoses of acute coronary syndromes, of which 12 were AMI, while 13 (36%) had cardiac diagnoses other than acute coronary syndrome and 9 (25%) had noncardiac diagnoses. Of the patients with AMI, 5 had occluded culprit arteries, of which 2 involved the left anterior descending coronary artery. A Sgarbossa score >/= 5 had low sensitivity (14%) but 100% specificity in diagnosing AMI in the presence of new LBBB. In conclusion, new or presumably new LBBB in patients suspected of having AMI identifies a high-risk subgroup, but only a small number have AMI. Two thirds of these patients are discharged from the hospital with alternative diagnoses. The Sgarbossa criteria appear to have limited utility in clinical practice because of their low sensitivity.

# 9. ARTÍCULO Nº: 4176

Kasenda B, von EE, You J, Blumle A, Tomonaga Y, Saccilotto R et al. *Prevalence, characteristics, and publication of discontinued randomized trials*. JAMA. 2014; 311(10): 1045-1051.

IMPORTANCE: The discontinuation of randomized clinical trials (RCTs) raises ethical concerns and often wastes scarce research resources. The epidemiology of discontinued RCTs, however, remains unclear. OBJECTIVES: To determine the prevalence, characteristics, and publication history of discontinued RCTs and to investigate factors associated with RCT discontinuation due to poor recruitment and with nonpublication. DESIGN AND SETTING: Retrospective cohort of RCTs based on archived protocols approved by 6 research ethics committees in Switzerland, Germany, and Canada between 2000 and 2003. We recorded trial characteristics and planned recruitment from included protocols. Last follow-up of RCTs was April 27, 2013. MAIN OUTCOMES AND MEASURES: Completion status, reported reasons for discontinuation, and publication status of RCTs as determined by correspondence with the research ethics committees, literature searches, and investigator surveys.



RESULTS: After a median follow-up of 11.6 years (range, 8.8-12.6 years), 253 of 1017 included RCTs were discontinued (24.9% [95% CI, 22.3%-27.6%]). Only 96 of 253 discontinuations (37.9% [95% CI, 32.0%-44.3%]) were reported to ethics committees. The most frequent reason for discontinuation was poor recruitment (101/1017; 9.9% [95% CI, 8.2%-12.0%]). In multivariable analysis, industry sponsorship vs investigator sponsorship (8.4% vs 26.5%; odds ratio [OR], 0.25 [95% CI, 0.15-0.43]; P < .001) and a larger planned sample size in increments of 100 (-0.7%; OR, 0.96 [95% CI, 0.92-1.00]; P = .04) were associated with lower rates of discontinuation due to poor recruitment. Discontinued trials were more likely to remain unpublished than completed trials (55.1% vs 33.6%; OR, 3.19 [95% CI, 2.29-4.43]; P < .001). CONCLUSIONS AND RELEVANCE: In this sample of trials based on RCT protocols from 6 research ethics committees, discontinuation was common, with poor recruitment being the most frequently reported reason. Greater efforts are needed to ensure the reporting of trial discontinuation to research ethics committees and the publication of results of discontinued trials.

## 10. ARTÍCULO Nº: 4177

Brown JR, Sox HC, Goodman DC. *Financial incentives to improve quality: skating to the puck or avoiding the penalty box?* JAMA. 2014; 311(10): 1009-1010.

# 11. ARTÍCULO Nº: 4178

Hayes JH, Barry MJ. *Screening for prostate cancer with the prostate-specific antigen test: a review of current evidence*. JAMA. 2014; 311(11): 1143-1149.

IMPORTANCE: Prostate cancer screening with the prostate-specific antigen (PSA) test remains controversial. OBJECTIVE: To review evidence from randomized trials and related modeling studies examining the effect of PSA screening vs no screening on prostate cancer-specific mortality and to suggest an approach balancing potential benefits and harms. EVIDENCE ACQUISITION: MEDLINE, EMBASE, and the Cochrane Register of Controlled Trials were searched from January 1, 2010, to April 3, 2013, for PSA screening trials to update a previous systematic review. Another search was performed in EMBASE and MEDLINE to identify modeling studies extending the results of the 2 large randomized trials identified. The American Heart Association Evidence-Based Scoring System was used to rate level of evidence. RESULTS: Two trials-the Prostate, Lung, Colorectal and Ovarian (PLCO) screening trial and the European Randomized Study of Screening for Prostate Cancer (ERSPC)-dominate the evidence regarding PSA screening. The former trial demonstrated an increase in cancer incidence in the screening group (relative risk [RR], 1.12; 95% Cl, 1.07-1.17) but no cancer-specific mortality benefit to PSA screening after 13-year follow-up (RR, 1.09; 95% Cl, 0.87-1.36). The ERSPC demonstrated an increase in cancer incidence with screening (RR, 1.63; 95% CI, 1.57-1.69) and an improvement in the risk of prostate cancer-specific death after 11 years (RR, 0.79; 95% CI, 0.68-0.91). The ERSPC documented that 37 additional men needed to receive a diagnosis through screening for every 1 fewer prostate cancer death after 11 years of follow-up among men aged 55 to 69 years (level B evidence for prostate cancer mortality reduction). Harms associated with screening include false-positive results and complications of biopsy and treatment. Modeling studies suggest that this high ratio of additional men receiving diagnoses to prostate cancer deaths prevented will decrease during a longer follow-up (level B evidence). CONCLUSIONS AND RELEVANCE: Available evidence favors clinician discussion of the pros and cons of PSA screening with average-risk men aged 55 to 69 years. Only men who express a definite preference for screening should have PSA testing. Other strategies to mitigate the potential harms of screening include considering biennial screening, a higher PSA threshold for biopsy, and conservative therapy for men receiving a new diagnosis of prostate cancer.



Di AE, Gao P, Khan H, Butterworth AS, Wormser D, Kaptoge S et al. *Glycated hemoglobin measurement and prediction of cardiovascular disease*. JAMA. 2014; 311(12): 1225-1233.

IMPORTANCE: The value of measuring levels of glycated hemoglobin (HbA1c) for the prediction of first cardiovascular events is uncertain. OBJECTIVE: To determine whether adding information on HbA1c values to conventional cardiovascular risk factors is associated with improvement in prediction of cardiovascular disease (CVD) risk. DESIGN, SETTING, AND PARTICIPANTS: Analysis of individual-participant data available from 73 prospective studies involving 294,998 participants without a known history of diabetes mellitus or CVD at the baseline assessment. MAIN OUTCOMES AND MEASURES: Measures of risk discrimination for CVD outcomes (eg, C-index) and reclassification (eg, net reclassification improvement) of participants across predicted 10-year risk categories of low (<5%), intermediate (5% to <7.5%), and high (>/=7.5%) risk. RESULTS: During a median follow-up of 9.9 (interquartile range, 7.6-13.2) years, 20,840 incident fatal and nonfatal CVD outcomes (13,237 coronary heart disease and 7603 stroke outcomes) were recorded. In analyses adjusted for several conventional cardiovascular risk factors, there was an approximately J-shaped association between HbA1c values and CVD risk. The association between HbA1c values and CVD risk changed only slightly after adjustment for total cholesterol and triglyceride concentrations or estimated glomerular filtration rate, but this association attenuated somewhat after adjustment for concentrations of high-density lipoprotein cholesterol and C-reactive protein. The C-index for a CVD risk prediction model containing conventional cardiovascular risk factors alone was 0.7434 (95% CI, 0.7350 to 0.7517). The addition of information on HbA1c was associated with a C-index change of 0.0018 (0.0003 to 0.0033) and a net reclassification improvement of 0.42 (-0.63 to 1.48) for the categories of predicted 10-year CVD risk. The improvement provided by HbA1c assessment in prediction of CVD risk was equal to or better than estimated improvements for measurement of fasting, random, or postload plasma glucose levels. CONCLUSIONS AND RELEVANCE: In a study of individuals without known CVD or diabetes, additional assessment of HbA1c values in the context of CVD risk assessment provided little incremental benefit for prediction of CVD risk.

# 13. ARTÍCULO Nº: 4180

Pace LE, Keating NL. *A systematic assessment of benefits and risks to guide breast cancer screening decisions*. JAMA. 2014; 311(13): 1327-1335.

IMPORTANCE: Breast cancer is the second leading cause of cancer deaths among US women. Mammography screening may be associated with reduced breast cancer mortality but can also cause harm. Guidelines recommend individualizing screening decisions, particularly for younger women. OBJECTIVES: We reviewed the evidence on the mortality benefit and chief harms of mammography screening and what is known about how to individualize mammography screening decisions, including communicating risks and benefits to patients. EVIDENCE ACQUISITION: We searched MEDLINE from 1960-2014 to describe (1) benefits of mammography, (2) harms of mammography, and (3) individualizing screening decisions and promoting informed decision making. We also manually searched reference lists of key articles retrieved, selected reviews, meta-analyses, and practice recommendations. We rated the level of evidence using the American Heart Association guidelines. RESULTS: Mammography screening is associated with a 19% overall reduction of breast cancer mortality (approximately 15% for women in their 40s and 32% for women in their 60s). For a 40- or 50-year-old woman undergoing 10 years of annual mammograms, the cumulative risk of a false-positive result is about 61%. About 19% of the cancers diagnosed during that 10-year period would not have become clinically apparent without screening (overdiagnosis), although there is



uncertainty about this estimate. The net benefit of screening depends greatly on baseline breast cancer risk, which should be incorporated into screening decisions. Decision aids have the potential to help patients integrate information about risks and benefits with their own values and priorities, although they are not yet widely available for use in clinical practice. CONCLUSIONS AND RELEVANCE: To maximize the benefit of mammography screening, decisions should be individualized based on patients' risk profiles and preferences. Risk models and decision aids are useful tools, but more research is needed to optimize these and to further quantify overdiagnosis. Research should also explore other breast cancer screening strategies.

# 14. ARTÍCULO Nº: 4181

Hadely KA, Power E, O'Halloran R. *Speech pathologists' experiences with stroke clinical practice guidelines and the barriers and facilitators influencing their use: a national descriptive study.* BMC.Health Serv.Res. 2014; 14: 110

BACKGROUND: Communication and swallowing disorders are a common consequence of stroke. Clinical practice guidelines (CPGs) have been created to assist health professionals to put research evidence into clinical practice and can improve stroke care outcomes. However, CPGs are often not successfully implemented in clinical practice and research is needed to explore the factors that influence speech pathologists' implementation of stroke CPGs. This study aimed to describe speech pathologists' experiences and current use of guidelines, and to identify what factors influence speech pathologists' implementation of stroke CPGs. METHODS: Speech pathologists working in stroke rehabilitation who had used a stroke CPG were invited to complete a 39-item online survey. Content analysis and descriptive and inferential statistics were used to analyse the data. RESULTS: 320 participants from all states and territories of Australia were surveyed. Almost all speech pathologists had used a stroke CPG and had found the guideline "somewhat useful" or "very useful". Factors that speech pathologists perceived influenced CPG implementation included the: (a) guideline itself, (b) work environment, (c) aspects related to the speech pathologist themselves, (d) patient characteristics, and (e) types of implementation strategies provided. CONCLUSIONS: There are many different factors that can influence speech pathologists' implementation of CPGs. The factors that influenced the implementation of CPGs can be understood in terms of knowledge creation and implementation frameworks. Speech pathologists should continue to adapt the stroke CPG to their local work environment and evaluate their use. To enhance guideline implementation, they may benefit from a combination of educational meetings and resources, outreach visits, support from senior colleagues, and audit and feedback strategies.

# 15. ARTÍCULO Nº: 4182

Hughes AM, Burridge JH, Demain SH, Ellis-Hill C, Meagher C, Tedesco-Triccas L et al. *Translation of evidence-based Assistive Technologies into stroke rehabilitation: users' perceptions of the barriers and opportunities*. BMC.Health Serv.Res. 2014; 14: 124

BACKGROUND: Assistive Technologies (ATs), defined as "electrical or mechanical devices designed to help people recover movement", demonstrate clinical benefits in upper limb stroke rehabilitation; however translation into clinical practice is poor. Uptake is dependent on a complex relationship between all stakeholders. Our aim was to understand patients', carers' (P&Cs) and healthcare professionals' (HCPs) experience and views of upper limb rehabilitation and ATs, to identify barriers and opportunities critical to the effective translation of ATs into clinical practice. This work was conducted in the UK, which has a state funded healthcare system, but the findings have relevance to all healthcare systems. METHODS: Two structurally comparable questionnaires, one for P&Cs and one



for HCPs, were designed, piloted and completed anonymously. Wide distribution of the questionnaires provided data from HCPs with experience of stroke rehabilitation and P&Cs who had experience of stroke. Questionnaires were designed based on themes identified from four focus groups held with HCPs and P&Cs and piloted with a sample of HCPs (N = 24) and P&Cs (N = 8). Eight of whom (four HCPs and four P&Cs) had been involved in the development. RESULTS: 292 HCPs and 123 P&Cs questionnaires were analysed. 120 (41%) of HCP and 79 (64%) of P&C respondents had never used ATs. Most views were common to both groups, citing lack of information and access to ATs as the main reasons for not using them. Both HCPs (N = 53 [34%]) and P&C (N = 21 [47%]) cited Functional Electrical Stimulation (FES) as the most frequently used AT. Research evidence was rated by HCPs as the most important factor in the design of an ideal technology, yet ATs they used or prescribed were not supported by research evidence. P&Cs rated ease of set-up and comfort more highly. CONCLUSION: Key barriers to translation of ATs into clinical practice are lack of knowledge, education, awareness and access. Perceptions about arm rehabilitation post-stroke are similar between HCPs and P&Cs. Based on our findings, improvements in AT design, pragmatic clinical evaluation, better knowledge and awareness and improvement in provision of services will contribute to better and cost-effective upper limb stroke rehabilitation.

# 16. ARTÍCULO Nº: 4183

Bondevik GT, Hofoss D, Hansen EH, Deilkas EC. *The safety attitudes questionnaire - ambulatory version: psychometric properties of the Norwegian translated version for the primary care setting.* BMC.Health Serv.Res. 2014; 14: 139

BACKGROUND: Patient safety culture is how leader and staff interaction, attitudes, routines and practices protect patients from adverse events in healthcare. The Safety Attitudes Questionnaire is the most widely used instrument to measure safety attitudes among health care providers. The instrument may identify possible weaknesses in clinical settings, and motivate and guide quality improvement interventions and reductions in medical errors. The Safety Attitudes Questionnaire -Ambulatory Version was developed for measuring safety culture in the primary care setting. The original version includes six major patient safety factors: Teamwork climate, Safety climate, Job satisfaction, Perceptions of management, Working conditions and Stress recognition. We describe the results of a validation study using the Norwegian translation of the questionnaire in the primary care setting, and present the psychometric properties of this version. METHODS: The study was done in seven Out-of-hours casualty clinics and 17 regular GP practices employing a total of 510 primary health care providers (194 nurses and 316 medical doctors). In October and November 2012, the translated Safety Attitudes Questionnaire - Ambulatory Version was distributed by e-mail. Data were collected electronically using the program QuestBack, whereby the participants responded anonymously. SPSS was used to estimate the Cronbach's alphas, item-to-own-factor correlations, intercorrelations of factors and item-descriptive statistics. The confirmatory factor analysis was done by AMOS. RESULTS: Of the 510 invited health care providers, 266 (52%) answered the questionnaire -72% of the registered nurses (n = 139) and 39% of the medical doctors (n = 124). In the confirmatory factor analysis, the following five factor model was shown to have acceptable goodness-of-fit values in the Norwegian primary care setting: Teamwork climate, Safety climate, Job satisfaction, Working conditions and Perceptions of management. CONCLUSIONS: The results of our study indicate that the Norwegian translated version of the Safety Attitudes Questionnaire - Ambulatory Version, with the five confirmed factors, might be a useful tool for measuring several aspects of patient safety culture in the primary care setting. Further research should investigate whether there is an association between patient safety culture in primary care, as measured by the Safety Attitudes Questionnaire -Ambulatory Version, and occurrence of medical errors and negative patient outcome.



Bafeta A, Trinquart L, Seror R, Ravaud P. *Reporting of results from network meta-analyses: methodological systematic review*. BMJ. 2014; 348: g1741

OBJECTIVE: To examine how the results of network meta-analyses are reported. DESIGN: Methodological systematic review of published reports of network meta-analyses. DATA SOURCES: Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Medline, and Embase, searched from inception to 12 July 2012. STUDY SELECTION: All network meta-analyses comparing the clinical efficacy of three or more interventions in randomised controlled trials were included, excluding meta-analyses with an open loop network of three interventions. DATA EXTRACTION AND SYNTHESIS: The reporting of the network and results was assessed. A composite outcome included the description of the network (number of interventions, direct comparisons, and randomised controlled trials and patients for each comparison) and the reporting of effect sizes derived from direct evidence, indirect evidence, and the network meta-analysis. RESULTS: 121 network meta-analyses (55 published in general journals; 48 funded by at least one private source) were included. The network and its geometry (network graph) were not reported in 100 (83%) articles. The effect sizes derived from direct evidence, indirect evidence, and the network meta-analysis were not reported in 48 (40%), 108 (89%), and 43 (36%) articles, respectively. In 52 reports that ranked interventions, 43 did not report the uncertainty in ranking. Overall, 119 (98%) reports of network meta-analyses did not give a description of the network or effect sizes from direct evidence, indirect evidence, and the network meta-analysis. This finding did not differ by journal type or funding source. CONCLUSIONS: The results of network meta-analyses are heterogeneously reported. Development of reporting guidelines to assist authors in writing and readers in critically appraising reports of network meta-analyses is timely.

## 18. ARTÍCULO Nº: 4185

Little P, Moore M, Kelly J, Williamson I, Leydon G, McDermott L et al. *Ibuprofen, paracetamol, and steam for patients with respiratory tract infections in primary care: pragmatic randomised factorial trial*. BMJ. 2013; 347: f6041

OBJECTIVE: To assess strategies for advice on analgesia and steam inhalation for respiratory tract infections. DESIGN: Open pragmatic parallel group factorial randomised controlled trial. SETTING: Primary care in United Kingdom. PARTICIPANTS: Patients aged >/= 3 with acute respiratory tract infections. INTERVENTION: 889 patients were randomised with computer generated random numbers in pre-prepared sealed numbered envelopes to components of advice or comparator advice: advice on analgesia (take paracetamol, ibuprofen, or both), dosing of analgesia (take as required v regularly), and steam inhalation (no inhalation v steam inhalation). OUTCOMES: Primary: mean symptom severity on days 2-4; symptoms rated 0 (no problem) to 7 (as bad as it can be). Secondary: temperature, antibiotic use, reconsultations. RESULTS: Neither advice on dosing nor on steam inhalation was significantly associated with changes in outcomes. Compared with paracetamol, symptom severity was little different with ibuprofen (adjusted difference 0.04, 95% confidence interval -0.11 to 0.19) or the combination of ibuprofen and paracetamol (0.11, -0.04 to 0.26). There was no evidence for selective benefit with ibuprofen among most subgroups defined before analysis (presence of otalgia; previous duration of symptoms; temperature >37.5 degrees C; severe symptoms), but there was evidence of reduced symptoms severity benefit in the subgroup with chest infections (ibuprofen -0.40, -0.78 to -0.01; combination -0.47; -0.84 to -0.10), equivalent to almost one in two symptoms rated as a slight rather than a moderately bad problem. Children might also benefit from treatment with ibuprofen (ibuprofen: -0.47, -0.76 to -0.18; combination: -0.04, -0.31 to 0.23). Reconsultations with



new/unresolved symptoms or complications were documented in 12% of those advised to take paracetamol, 20% of those advised to take ibuprofen (adjusted risk ratio 1.67, 1.12 to 2.38), and 17% of those advised to take the combination (1.49, 0.98 to 2.18). Mild thermal injury with steam was documented for four patients (2%) who returned full diaries, but no reconsultations with scalding were documented. CONCLUSION: Overall advice to use steam inhalation, or ibuprofen rather than paracetamol, does not help control symptoms in patients with acute respiratory tract infections and must be balanced against the possible progression of symptoms during the next month for a minority of patients. Advice to use ibuprofen might help short term control of symptoms in those with chest infections and in children. TRIAL REGISTRATION: ISRCTN 38551726.

# 19. ARTÍCULO Nº: 4186

Little P, Moore M, Kelly J, Williamson I, Leydon G, McDermott L et al. *Delayed antibiotic prescribing strategies for respiratory tract infections in primary care: pragmatic, factorial, randomised controlled trial*. BMJ. 2014; 348: g1606

OBJECTIVE: To estimate the effectiveness of different strategies involving delayed antibiotic prescription for acute respiratory tract infections. DESIGN: Open, pragmatic, parallel group, factorial, randomised controlled trial. SETTING: Primary care in the United Kingdom. PATIENTS: 889 patients aged 3 years and over with acute respiratory tract infection, recruited between 3 March 2010 and 28 March 2012 by 53 health professionals in 25 practices. INTERVENTIONS: Patients judged not to need immediate antibiotics were randomised to undergo four strategies of delayed prescription: recontact for a prescription, post-dated prescription, collection of the prescription, and be given the prescription (patient led). During the trial, a strategy of no antibiotic prescription was added as another randomised comparison. Analysis was intention to treat. MAIN OUTCOME MEASURES: Mean symptom severity (0-6 scale) at days 2-4 (primary outcome), antibiotic use, and patients' beliefs in the effectiveness of antibiotic use. Secondary analysis included comparison with immediate use of antibiotics. RESULTS: Mean symptom severity had minimal differences between the strategies involving no prescription and delayed prescription (recontact, post-date, collection, patient led; 1.62, 1.60, 1.82, 1.68, 1.75, respectively; likelihood ratio test chi(2) 2.61, P=0.625). Duration of symptoms rated moderately bad or worse also did not differ between no prescription and delayed prescription strategies combined (median 3 days v 4 days; 4.29, P=0.368). There were modest and non-significant differences in patients very satisfied with the consultation between the randomised groups (79%, 74%, 80%, 88%, 89%, respectively; likelihood ratio test chi(2) 2.38, P=0.667), belief in antibiotics (71%, 74%, 73%, 72%, 66%; 1.62, P=0.805), or antibiotic use (26%, 37%, 37%, 33%, 39%; 4.96, P=0.292). By contrast, most patients given immediate antibiotics used antibiotics (97%) and strongly believed in them (93%), but with no benefit for symptom severity (score 1.76) or duration (median 4 days). CONCLUSION: Strategies of no prescription or delayed antibiotic prescription result in fewer than 40% of patients using antibiotics, and are associated with less strong beliefs in antibiotics, and similar symptomatic outcomes to immediate prescription. If clear advice is given to patients, there is probably little to choose between the different strategies of delayed prescription. TRIAL REGISTRATION: ISRCTN38551726.

# 20. ARTÍCULO Nº: 4187

Cundy T, Ackermann E, Ryan EA. *Gestational diabetes: new criteria may triple the prevalence but effect on outcomes is unclear*. BMJ. 2014; 348: g1567



Coulter A, Locock L, Ziebland S, Calabrese J. *Collecting data on patient experience is not enough: they must be used to improve care*. BMJ. 2014; 348: g2225

# 22. ARTÍCULO Nº: 4189

Theodoratou E, Tzoulaki I, Zgaga L, Ioannidis JP. *Vitamin D and multiple health outcomes: umbrella review of systematic reviews and meta-analyses of observational studies and randomised trials.* BMJ. 2014; 348: g2035

OBJECTIVE: To evaluate the breadth, validity, and presence of biases of the associations of vitamin D with diverse outcomes. DESIGN: Umbrella review of the evidence across systematic reviews and meta-analyses of observational studies of plasma 25-hydroxyvitamin D or 1,25-dihydroxyvitamin D concentrations and randomised controlled trials of vitamin D supplementation. DATA SOURCES: Medline, Embase, and screening of citations and references. ELIGIBILITY CRITERIA: Three types of studies were eligible for the umbrella review: systematic reviews and meta-analyses that examined observational associations between circulating vitamin D concentrations and any clinical outcome; and meta-analyses of randomised controlled trials assessing supplementation with vitamin D or active compounds (both established and newer compounds of vitamin D). RESULTS: 107 systematic literature reviews and 74 meta-analyses of observational studies of plasma vitamin D concentrations and 87 meta-analyses of randomised controlled trials of vitamin D supplementation were identified. The relation between vitamin D and 137 outcomes has been explored, covering a wide range of skeletal, malignant, cardiovascular, autoimmune, infectious, metabolic, and other diseases. Ten outcomes were examined by both meta-analyses of observational studies and meta-analyses of randomised controlled trials, but the direction of the effect and level of statistical significance was concordant only for birth weight (maternal vitamin D status or supplementation). On the basis of the available evidence, an association between vitamin D concentrations and birth weight, dental caries in children, maternal vitamin D concentrations at term, and parathyroid hormone concentrations in patients with chronic kidney disease requiring dialysis is probable, but further studies and better designed trials are needed to draw firmer conclusions. In contrast to previous reports, evidence does not support the argument that vitamin D only supplementation increases bone mineral density or reduces the risk of fractures or falls in older people. CONCLUSIONS: Despite a few hundred systematic reviews and meta-analyses, highly convincing evidence of a clear role of vitamin D does not exist for any outcome, but associations with a selection of outcomes are probable.

## 23. ARTÍCULO Nº: 4190

A'Court C, McManus RJ. *Why are doctors still measuring blood pressure?* Br.J.Gen.Pract. 2014; 64(621): 168-169.

# 24. ARTÍCULO Nº: 4191

Spencer R, Bell B, Avery AJ, Gookey G, Campbell SM. *Identification of an updated set of prescribing-safety indicators for GPs*. Br.J.Gen.Pract. 2014; 64(621): e181-e190.

BACKGROUND: Medication error is an important contributor to patient morbidity and mortality and is associated with inadequate patient safety measures. However, prescribing-safety tools specifically designed for use in general practice are lacking. AIM: To identify and update a set of prescribing-safety indicators for assessing the safety of prescribing in general practice, and to estimate the risk of harm to patients associated with each indicator. DESIGN AND SETTING: RAND/UCLA consensus development of indicators in UK general practice. METHOD: Prescribing indicators were identified



from a systematic review and previous consensus exercise. The RAND Appropriateness Method was used to further identify and develop the indicators with an electronic-Delphi method used to rate the risk associated with them. Twelve GPs from all the countries of the UK participated in the RAND exercise, with 11 GPs rating risk using the electronic-Delphi approach. RESULTS: Fifty-six prescribing-safety indicators were considered appropriate for inclusion (overall panel median rating of 7-9, with agreement). These indicators cover hazardous prescribing across a range of therapeutic indications, hazardous drug-drug combinations and inadequate laboratory test monitoring. Twenty-three (41%) of these indicators were considered high risk or extreme risk by 80% or more of the participants. CONCLUSION: This study identified a set of 56 indicators that were considered, by a panel of GPs, to be appropriate for assessing the safety of GP prescribing. Twenty-three of these indicators were considered with high or extreme risk to patients and should be the focus of efforts to improve patient safety.

# 25. ARTÍCULO Nº: 4192

Black JA, Sharp SJ, Wareham NJ, Sandbaek A, Rutten GE, Lauritzen T et al. *Change in cardiovascular risk factors following early diagnosis of type 2 diabetes: a cohort analysis of a cluster-randomised trial*. Br.J.Gen.Pract. 2014; 64(621): e208-e216.

BACKGROUND: There is little evidence to inform the targeted treatment of individuals found early in the diabetes disease trajectory. AIM: To describe cardiovascular disease (CVD) risk profiles and treatment of individual CVD risk factors by modelled CVD risk at diagnosis; changes in treatment, modelled CVD risk, and CVD risk factors in the 5 years following diagnosis; and how these are patterned by socioeconomic status. DESIGN AND SETTING: Cohort analysis of a cluster-randomised trial (ADDITION-Europe) in general practices in Denmark, England, and the Netherlands. METHOD: A total of 2418 individuals with screen-detected diabetes were divided into quartiles of modelled 10-year CVD risk at diagnosis. Changes in treatment, modelled CVD risk, and CVD risk factors were assessed at 5 years. RESULTS: The largest reductions in risk factors and modelled CVD risk were seen in participants who were in the highest quartile of modelled risk at baseline, suggesting that treatment was offered appropriately. Participants in the lowest quartile of risk at baseline had very similar levels of modelled CVD risk at 5 years and showed the least variation in change in modelled risk. No association was found between socioeconomic status and changes in CVD risk factors, suggesting that treatment was equitable. CONCLUSION: Diabetes management requires setting of individualised attainable targets. This analysis provides a reference point for patients, clinicians, and policymakers when considering goals for changes in risk factors early in the course of the disease that account for the diverse cardiometabolic profile present in individuals who are newly diagnosed with type 2 diabetes.

# 26. ARTÍCULO Nº: 4193

Clark CE, Horvath IA, Taylor RS, Campbell JL. *Doctors record higher blood pressures than nurses: systematic review and meta-analysis.* Br.J.Gen.Pract. 2014; 64(621): e223-e232.

BACKGROUND: The magnitude of the 'white coat effect', the alerting rise in blood pressure, is greater for doctors than nurses. This could bias interpretation of studies on nurse-led care in hypertension, and risks overestimating or overtreating high blood pressure by doctors in clinical practice. AIM: To quantify differences between blood pressure measurements made by doctors and nurses. DESIGN AND SETTING: Systematic review and meta-analysis using searches of MEDLINE, CENTRAL, CINAHL, Embase, journal collections, and conference abstracts. METHOD: Studies in adults reporting mean blood pressures measured by doctors and nurses at the same visit were selected, and mean blood



pressures extracted, by two reviewers. Study risk of bias was assessed using modified Cochrane criteria. Outcomes were pooled across studies using random effects meta-analysis. RESULTS: In total, 15 studies (11 hypertensive; four mixed hypertensive and normotensive populations) were included from 1899 unique citations. Compared with doctors' measurements, nurse-measured blood pressures were lower (weighted mean differences: systolic -7.0 [95% confidence interval {CI} = -4.7 to -9.2] mmHg, diastolic -3.8 [95% CI = -2.2 to -5.4] mmHg). For studies at low risk of bias, differences were lower: systolic -4.6 (95% CI = -1.9 to -7.3) mmHg; diastolic -1.7 (95% CI = -0.1 to -3.2) mmHg. White coat hypertension was diagnosed more frequently based on doctors' than on nurses' readings: relative risk 1.6 (95% CI = 1.2 to 2.1). CONCLUSIONS: The white coat effect is smaller for blood pressure measurements made by nurses than by doctors. This systematic difference has implications for hypertension diagnosis and management. Caution is required in pooling data from studies using both nurse- and doctor-measured blood pressures.

# 27. ARTÍCULO Nº: 4194

Gervas J, Perez-Fernandez M. *Sobrediagnóstico, un problema clínico, ético y social*. FMC. 2014; 21(3): 137-142.

Puntos clave:

- Diagnosticar acertada y oportunamente da prestigio y reputación a los médicos, pues es una actividad central en su profesión.

- El diagnóstico es importante porque se liga al pronóstico y permite establecer pautas de tratamiento y seguimiento que modifican a mejor (en el sentido deseado por el paciente y la sociedad) el curso natural de los acontecimientos.

- El diagnóstico es, pues, una actividad importante porque conlleva más beneficios que daños. No se justifica el diagnóstico que provoca más perjuicios que beneficios.

- El sobre diagnóstico es un diagnóstico cierto que conlleva más daños que beneficios. El sobrediagnóstico no es un falso diagnóstico en el sentido de falso positivo. No hay error diagnóstico en el sobrediagnóstico.

- El sobrediagnóstico es un error pronóstico. El sobrediagnóstico atribuye el mismo pronóstico a diagnósticos similares por sus características pero de impacto muy distinto en la vida del paciente.

- Hay sobrediagnósticos por errores en la consideración de variaciones de la normalidad. Así, es posible llevar una vida sana por completo a pesar de tener cáncer y/o mutaciones genéticas patológicas.

- Hay sobrediagnóstico por avances tecnológicos que llevan a poder diagnosticar eventos desconocidos que en su expresión clínica son siempre una enfermedad. Así, es posible tener microémbolos pulmonares en una tomografía espiral multicorte y estar sano, y/o tener herniación cerebral sin ninguna consecuencia clínica.

- Hay sobrediagnóstico cuando el diagnóstico no modifica ni la calidad ni la expectativa de vida. Así, sería sobrediagnóstico diagnosticar esclerosis lateral amiotrófica inicial en un paciente con cáncer de pulmón y terminal.

- Hay sobrediagnóstico cuando el diagnóstico es casual, sin impacto en la vida del paciente. Así, los incidentalomas y/o los resultados anormales tipo hiperuricemia en los chequeos.

- Hay sobrediagnóstico cuando se diagnostican enfermedades inventadas o cuyos límites se amplían sin que añada nada el consiguiente tratamiento. Así, en el diagnóstico de andropausia, prehipertensión y otros.



Maroto-Martin S, Casado-Pardo J, Avila-Tomas JF. *Herramientas de búsqueda de información sanitaria de calidad. Más allá de los buscadores tradicionales.* FMC. 2014; 21(3): 176-180.

# 29. ARTÍCULO Nº: 4196

Enseñat-Grau MP. *Abordaje del paciente complejo a través de la gestión de casos.* FMC. 2013; 20(4): 217-221.

#### Puntos clave:

- La gestión de casos se aplica con el objetivo de mejorar la resolución de problemas en atención primaria.

- La gestión de casos es una estrategia que se incorpora a la atención de aquellas personas con problemas de salud complejos de forma complementaria, coordinando e integrando la aportación de todos los profesionales en el plan de acción.

- Implica un abordaje intensivo, integral e integrado de los pacientes que se encuentran en una situación compleja de salud y de un modo eficaz y sostenible para el sistema sanitario.

- La enfermera gestora de casos interviene especialmente en la promoción de la autonomía de los pacientes para mejorar así su autocuidado, y favorece la participación e implicación de la persona cuidadora en el plan de cuidados del paciente.

## 30. ARTÍCULO Nº: 4197

Ryan A, Sutton M, Doran T. *Does winning a pay-for-performance bonus improve subsequent quality performance? Evidence from the Hospital Quality Incentive Demonstration*. Health Serv.Res. 2014; 49(2): 568-587.

OBJECTIVE: To test whether receiving a financial bonus for quality in the Premier Hospital Quality Incentive Demonstration (HQID) stimulated subsequent quality improvement. DATA: Hospital-level data on process-of-care quality from Hospital Compare for the treatment of acute myocardial infarction (AMI), heart failure, and pneumonia for 260 hospitals participating in the HQID from 2004 to 2006; receipt of quality bonuses in the first 3 years of HQID from the Premier Inc. website; and hospital characteristics from the 2005 American Hospital Association Annual Survey. STUDY DESIGN: Under the HQID, hospitals received a 1 percent bonus on Medicare payments for scoring between the 80th and 90th percentiles on a composite quality measure, and a 2 percent bonus for scoring at the 90th percentile or above. We used a regression discontinuity design to evaluate whether hospitals with quality scores just above these payment thresholds improved more in the subsequent year than hospitals with quality scores just below the thresholds. In alternative specifications, we examined samples of hospitals scoring within 3, 5, and 10 percentage point "bandwidths" of the thresholds. We used a Generalized Linear Model to estimate whether the relationship between quality and lagged quality was discontinuous at the lagged thresholds required for quality bonuses. PRINCIPAL FINDINGS: There were no statistically significant associations between receipt of a bonus and subsequent quality performance, with the exception of the 2 percent bonus for AMI in 2006 using the 5 percentage point bandwidth (0.8 percentage point increase, p<.01), and the 1 percent bonus for pneumonia in 2005 using all bandwidths (3.7 percentage point increase using the 3 percentage point bandwidth, p<.05). CONCLUSIONS: We found little evidence that hospitals' receipt of quality bonuses was associated with subsequent improvement in performance. This raises questions about whether winning in pay-for-performance programs, such as Hospital Value-Based Purchasing, will lead to subsequent quality improvement.



Ladova K, Vlcek J, Vytrisalova M, Maly J. *Healthy adherer effect - the pitfall in the interpretation of the effect of medication adherence on health outcomes*. J.Eval.Clin.Pract. 2014; 20(2): 111-116.

RATIONALE, AIMS AND OBJECTIVES: Different designs of studies monitoring adherence may cause bias and subsequent unavailability to compare results. Healthy adherer effect (HAE) is a type of bias reflecting patient behaviour. It cannot be easily monitored in study population and can favourably affect health outcomes that may be incorrectly attributed to drug therapy. The aim of this paper was to assess the HAE impact on health outcomes of studies concerning medication adherence. METHODS: Systematic review of literature from PubMed, EMBASE and Cochrane Register of Controlled Trials identified all randomized controlled or observational studies dealing with HAE. Included studies were analysed with respect to relationships between HAE, adherence to therapy and health outcomes. RESULTS: Seven studies were identified - two randomized controlled and five cohort studies. Significant occurrence of HAE in relation to mortality was not observed while one study indicated the presence of HAE in relation to surrogate (bone mineral density). Cohort studies were mainly based on drug class effect, but HAE was not revealed. Factors associated with patient behaviour (e.g. smoking, regular preventive screening) were also not clearly associated with the occurrence of HAE, but their inclusion in design of cohort studies can help to detect health seeking behaviour. CONCLUSION: Only a few studies concerning HAE were found, but they did not obtain any consistent conclusions. HAE impact was supposed particularly on treatment outcomes that may be easier affected by patient behaviour. However, researchers and clinicians should be still aware of HAE, interpret results carefully and verified them in further studies.

# 32. ARTÍCULO Nº: 4199

Fernandez Sierra MA, Rodriguez del Aguila MM, Navarro Espigares JL, Enriquez Maroto MF. *Effect of patient safety strategies on the incidence of adverse events*. J.Eval.Clin.Pract. 2014; 20(2): 184-190.

OBJECTIVE: This study aims to estimate the incidence of adverse events (AEs) and avoidable AE in four hospital services before and after applying strategies for patient safety. DESIGN: Retrospective study of two cohorts (2006 and 2009). SETTING: General Surgery, Internal Medicine, Intensive Care Unit and Oncology services. PARTICIPANTS: A sample of 365 patients (2006) and 232 in 2009 randomly selected from the services previously cited. INTERVENTIONS: Strategies to improve patient safety (e.g. hand-hygiene campaign). MAIN OUTCOME MEASURES: Analyses were made of the change in the incidence and type of AE and avoidable AE, number of procedures and additional days of hospital stay, and the concordance between two recording systems. RESULTS: The incidence of patients with AE was 20.8% in 2006 compared with 28.9% in 2009 (P < 0.05). Oncology had twofold more AE than did General Surgery [odds ratio (OR) = 2.07, 95% confidence interval (CI): 1.12-3.86] for the same length of stay and number of extrinsic risk factors. In 2006, 84.6% were considered avoidable, compared with 57.1% of 2009 (P < 0.001). There was no difference in the average length of additional stay. In 2006, there were more additional procedures compared to 2009 (OR = 2.75, 95% CI: 1.28-6.06). A concordance of 61% was found for the detection of AE with the two recording systems. CONCLUSIONS: An increased incidence in AEs was found after the strategies, while avoidable AE decreased, as did additional treatments and procedures. The measures implemented constitute a further step in reducing avoidance and a greater awareness of recording AEs in the discharge report.

## 33. ARTÍCULO Nº: 4200

Ray-Barruel G, Polit DF, Murfield JE, Rickard CM. *Infusion phlebitis assessment measures: a systematic review*. J.Eval.Clin.Pract. 2014; 20(2): 191-202.



RATIONALE, AIMS AND OBJECTIVES: Phlebitis is a common and painful complication of peripheral intravenous cannulation. The aim of this review was to identify the measures used in infusion phlebitis assessment and evaluate evidence regarding their reliability, validity, responsiveness and feasibility. METHOD: We conducted a systematic literature review of the Cochrane library, Ovid MEDLINE and EBSCO CINAHL until September 2013. All English-language studies (randomized controlled trials, prospective cohort and cross-sectional) that used an infusion phlebitis scale were retrieved and analysed to determine which symptoms were included in each scale and how these were measured. We evaluated studies that reported testing the psychometric properties of phlebitis assessment scales using the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines. RESULTS: Infusion phlebitis was the primary outcome measure in 233 studies. Fifty-three (23%) of these provided no actual definition of phlebitis. Of the 180 studies that reported measuring phlebitis incidence and/or severity, 101 (56%) used a scale and 79 (44%) used a definition alone. We identified 71 different phlebitis assessment scales. Three scales had undergone some psychometric analyses, but no scale had been rigorously tested. CONCLUSION: Many phlebitis scales exist, but none has been thoroughly validated for use in clinical practice. A lack of consensus on phlebitis measures has likely contributed to disparities in reported phlebitis incidence, precluding meaningful comparison of phlebitis rates.

# 34. ARTÍCULO Nº: 4201

McKinlay JB, Trachtenberg F, Marceau LD, Katz JN, Fischer MA. *Effects of patient medication requests on physician prescribing behavior: results of a factorial experiment.* Med.Care. 2014; 52(4): 294-299.

BACKGROUND: Because of internet searches, advice from friends, and pharmaceutical advertising, especially direct-to-consumer advertising, patients are increasingly activated to request medications during a physician encounter. OBJECTIVES: To estimate the effect of patient requests for medications on physician-prescribing behavior, unconfounded by patient, physician, and practice-setting factors. RESEARCH DESIGN: Two experiments were conducted among 192 primary care physicians, each using different video-based scenarios: an undiagnosed "patient" with symptoms strongly suggesting sciatica, and a "patient" with already diagnosed chronic knee osteoarthritis. Half of patients with sciatica symptoms requested oxycodone, whereas the other half requested something to help with pain. Similarly, half of knee osteoarthritis patients specifically requested celebrex and half requested something to help with pain. SUBJECTS: To increase generalizability and ensure sufficient numbers were available, we recruited 192 primary care physicians from 6 US states. MEASURES: The primary outcome was whether physicians would accede to a patient's request for a medication. Alternative pain medications prescribed were secondary outcomes. RESULTS: 19.8% of sciatica patients requesting oxycodone would receive a prescription for oxycodone, compared with 1% of those making no specific request (P=0.001). Fifty-three percent of knee osteoarthritis patients requesting celebrex would receive it, compared with 24% of patients making no request (P=0.001). Patients requesting oxycodone were more likely to receive a strong narcotic (P=0.001) and less likely to receive a weak narcotic (P=0.01). Patients requesting celebrex were much less likely to receive a nonselective nonsteroidal anti-inflammatory drugs (P=0.008). No patient attributes, physician, or organizational factors influenced a physician's willingness to accede to a patient's medication request. CONCLUSIONS: In both scenarios, activated patient requests for a medication substantially affected physician-prescribing decisions, despite the drawbacks of the requested medications.



Carle AC, Jean-Pierre P, Winters P, Valverde P, Wells K, Simon M et al. *Psychometric Evaluation of the Patient Satisfaction With Logistical Aspects of Navigation (PSN-L) Scale Using Item Response Theory.* Med.Care. 2014; 52(4): 354-361.

BACKGROUND: Patient navigation-the provision of logistical, educational, and emotional support needed to help patients "navigate around" barriers to high-quality cancer treatment offers promise. No patient-reported outcome measures currently exist that assess patient navigation from the patient's perspective. We use a partial independence item response theory model to report on the psychometric properties of the Patient Satisfaction with Navigation, Logistical measure developed for this purpose. METHODS: We used data from an ethnically diverse sample (n=1873) from the National Cancer Institute Patient Navigation Research Program. We included individuals with the presence of an abnormal breast, cervical, colorectal, or prostate cancer finding. RESULTS: The partial independence item response theory model fit well. Results indicated that scores derived from responses provide extremely precise and reliable measurement between -2.5 SD below and 2 SD above the mean and acceptably precise and reliable measurement across nearly the entire range. CONCLUSIONS: Our findings provide evidence in support of the Patient Satisfaction with Navigation, Logistical. Scale users should utilize 1 of the 2 described methods to create scores.

## 36. ARTÍCULO Nº: 4203

Kipnis P, Liu V, Escobar GJ. *Accuracy of hospital standardized mortality rates: effects of model calibration*. Med.Care. 2014; 52(4): 378-384.

BACKGROUND: Risk-adjusted mortality rates are commonly used in quality report cards to compare hospital performance. The risk adjustment depends on models that are assessed for goodness-of-fit using various discrimination and calibration measures. However, the relationship between model fit and the accuracy of hospital comparisons is not well characterized. OBJECTIVES: To evaluate the impact of imperfect model calibration (miscalibration) on the accuracy of hospital comparisons. METHODS: We constructed Monte Carlo simulations where a risk-adjustment model is used in a population with a different mortality distribution than in the original model. We estimated the power of calibration metrics to detect miscalibration. We estimated the sensitivity and specificity of a hospital comparisons method under different imperfect model calibration scenarios using an empirical method. RESULTS: The U-statistics showed the highest power to detect intercept and slope deviations in the calibration curve, followed by the Hosmer-Lemeshow, and the calibration intercept and slope tests. The specificity decreased with increased intercept and slope deviations and with hospital size. The effect of an imperfect model fit on sensitivity is a function of the true standardized mortality ratio, the underlying mortality rate, sample size, and observed intercept and slope deviations. Poorly performing hospitals can appear as good performers and vice versa, depending on the deviation magnitude and direction. CONCLUSIONS: Deviations from perfect model calibration have a direct impact on the accuracy of hospital comparisons. Publishing the calibration intercept and slope of risk-adjustment models would allow the users to monitor their performance against the true standard population.

# 37. ARTÍCULO Nº: 4204

Mostaza JM, Lahoz C. *[New approaches for the treatment of dyslipidemia]*. Med.Clin.(Barc.). 2014; 142(7): 306-309.



Reduction in the risk of cardiovascular complications through modification of lipids is currently focused on lowering low density lipoproteins-cholesterol, with statins being the preferred drugs. New agents, under research, such as antibodies neutralizing PCSK9, will have a special place for the management of patients with intolerance to statins of severe dyslipemias. Drugs used to modify the concentration of high density lipoproteins-cholesterol and triglycerides have not been accompanied by the expected reductions in the rate of cardiovascular complications.

# 38. ARTÍCULO Nº: 4205

Comin-Colet J, Verdu-Rotellar JM, Vela E, Cleries M, Bustins M, Mendoza L et al. *Efficacy of an Integrated Hospital-primary Care Program for Heart Failure: A Population-based Analysis of 56 742 Patients*. Rev.Esp.Cardiol. 2014; 67(4): 283-293.

INTRODUCTION AND OBJECTIVES: The efficacy of heart failure programs has been demonstrated in clinical trials but their applicability in the real world practice setting is more controversial. This study evaluates the feasibility and efficacy of an integrated hospital-primary care program for the management of patients with heart failure in an integrated health area covering a population of 309 345. METHODS: For the analysis, we included all patients consecutively admitted with heart failure as the principal diagnosis who had been discharged alive from all of the hospitals in Catalonia, Spain, from 2005 to 2011, the period when the program was implemented, and compared mortality and readmissions among patients exposed to the program with the rates in the patients of all the remaining integrated health areas of the Servei Catala de la Salut (Catalan Health Service). RESULTS: We included 56 742 patients in the study. There were 181 204 hospital admissions and 30 712 deaths during the study period. In the adjusted analyses, when compared to the 54 659 patients from the other health areas, the 2083 patients exposed to the program had a lower risk of death (hazard ratio=0.92 [95% confidence interval, 0.86-0.97]; P=.005), a lower risk of clinically-related readmission (hazard ratio=0.71 [95% confidence interval, 0.66-0.76]; P<.001), and a lower risk of readmission for heart failure (hazard ratio=0.86 [95% confidence interval, 0.80-0.94]; P<.001). The positive impact on the morbidity and mortality rates was more marked once the program had become well established. CONCLUSIONS: The implementation of multidisciplinary heart failure management programs that integrate the hospital and the community is feasible and is associated with a significant reduction in patient morbidity and mortality. Full English text available from: www.revespcardiol.org/en.

## 39. ARTÍCULO Nº: 4206

Urbach DR, Govindarajan A, Saskin R, Wilton AS, Baxter NN. *Introduction of surgical safety checklists in Ontario, Canada*. N.Engl.J.Med. 2014; 370(11): 1029-1038.

BACKGROUND: Evidence from observational studies that the use of surgical safety checklists results in striking improvements in surgical outcomes led to the rapid adoption of such checklists worldwide. However, the effect of mandatory adoption of surgical safety checklists is unclear. A policy encouraging the universal adoption of checklists by hospitals in Ontario, Canada, provided a natural experiment to assess the effectiveness of checklists in typical practice settings. METHODS: We surveyed all acute care hospitals in Ontario to determine when surgical safety checklists were adopted. Using administrative health data, we compared operative mortality, rate of surgical complications, length of hospital stay, and rates of hospital readmission and emergency department visits within 30 days after discharge among patients undergoing a variety of surgical procedures before and after adoption of a checklist. RESULTS: During 3-month periods before and after adoption of a surgical safety checklist, a total of 101 hospitals performed 109,341 and 106,370 procedures, respectively. The adjusted risk of death during a hospital stay or within 30 days after surgery was



0.71% (95% confidence interval [CI], 0.66 to 0.76) before implementation of a surgical checklist and 0.65% (95% CI, 0.60 to 0.70) afterward (odds ratio, 0.91; 95% CI, 0.80 to 1.03; P=0.13). The adjusted risk of surgical complications was 3.86% (95% CI, 3.76 to 3.96) before implementation and 3.82% (95% CI, 3.71 to 3.92) afterward (odds ratio, 0.97; 95% CI, 0.90 to 1.03; P=0.29). CONCLUSIONS: Implementation of surgical safety checklists in Ontario, Canada, was not associated with significant reductions in operative mortality or complications. (Funded by the Canadian Institutes of Health Research.).

# 40. ARTÍCULO Nº: 4207

Leape LL. The checklist conundrum. N.Engl.J.Med. 2014; 370(11): 1063-1064.

#### 41. ARTÍCULO Nº: 4208

Magill SS, Edwards JR, Bamberg W, Beldavs ZG, Dumyati G, Kainer MA et al. *Multistate point-prevalence survey of health care-associated infections*. N.Engl.J.Med. 2014; 370(13): 1198-1208.

BACKGROUND: Currently, no single U.S. surveillance system can provide estimates of the burden of all types of health care-associated infections across acute care patient populations. We conducted a prevalence survey in 10 geographically diverse states to determine the prevalence of health care-associated infections in acute care hospitals and generate updated estimates of the national burden of such infections. METHODS: We defined health care-associated infections with the use of National Healthcare Safety Network criteria. One-day surveys of randomly selected inpatients were performed in participating hospitals. Hospital personnel collected demographic and limited clinical data. Trained data collectors reviewed medical records retrospectively to identify health care-associated infections active at the time of the survey. Survey data and 2010 Nationwide Inpatient Sample data, stratified according to patient age and length of hospital stay, were used to estimate the total numbers of health care-associated infections and of inpatients with such infections in U.S. acute care hospitals in 2011. RESULTS: Surveys were conducted in 183 hospitals. Of 11,282 patients, 452 had 1 or more health care-associated infections (4.0%; 95% confidence interval, 3.7 to 4.4). Of 504 such infections, the most common types were pneumonia (21.8%), surgical-site infections (21.8%), and gastrointestinal infections (17.1%). Clostridium difficile was the most commonly reported pathogen (causing 12.1% of health care-associated infections). Device-associated infections (i.e., central-catheter-associated bloodstream infection, catheter-associated urinary tract infection, and ventilator-associated pneumonia), which have traditionally been the focus of programs to prevent health care-associated infections, accounted for 25.6% of such infections. We estimated that there were 648,000 patients with 721,800 health care-associated infections in U.S. acute care hospitals in 2011. CONCLUSIONS: Results of this multistate prevalence survey of health care-associated infections indicate that public health surveillance and prevention activities should continue to address C. difficile infections. As device- and procedure-associated infections decrease, consideration should be given to expanding surveillance and prevention activities to include other health care-associated infections.

#### 42. ARTÍCULO Nº: 4209

Ruff CT, Giugliano RP, Braunwald E, Hoffman EB, Deenadayalu N, Ezekowitz MD et al. *Comparison of the efficacy and safety of new oral anticoagulants with warfarin in patients with atrial fibrillation: a meta-analysis of randomised trials.* Lancet. 2014; 383(9921): 955-962.

BACKGROUND: Four new oral anticoagulants compare favourably with warfarin for stroke prevention in patients with atrial fibrillation; however, the balance between efficacy and safety in subgroups



needs better definition. We aimed to assess the relative benefit of new oral anticoagulants in key subgroups, and the effects on important secondary outcomes. METHODS: We searched Medline from Jan 1, 2009, to Nov 19, 2013, limiting searches to phase 3, randomised trials of patients with atrial fibrillation who were randomised to receive new oral anticoagulants or warfarin, and trials in which both efficacy and safety outcomes were reported. We did a prespecified meta-analysis of all 71,683 participants included in the RE-LY, ROCKET AF, ARISTOTLE, and ENGAGE AF-TIMI 48 trials. The main outcomes were stroke and systemic embolic events, ischaemic stroke, haemorrhagic stroke, all-cause mortality, myocardial infarction, major bleeding, intracranial haemorrhage, and gastrointestinal bleeding. We calculated relative risks (RRs) and 95% CIs for each outcome. We did subgroup analyses to assess whether differences in patient and trial characteristics affected outcomes. We used a random-effects model to compare pooled outcomes and tested for heterogeneity. FINDINGS: 42,411 participants received a new oral anticoagulant and 29,272 participants received warfarin. New oral anticoagulants significantly reduced stroke or systemic embolic events by 19% compared with warfarin (RR 0.81, 95% CI 0.73-0.91; p<0.0001), mainly driven by a reduction in haemorrhagic stroke (0.49, 0.38-0.64; p<0.0001). New oral anticoagulants also significantly reduced all-cause mortality (0.90, 0.85-0.95; p=0.0003) and intracranial haemorrhage (0.48, 0.39-0.59; p<0.0001), but increased gastrointestinal bleeding (1.25, 1.01-1.55; p=0.04). We noted no heterogeneity for stroke or systemic embolic events in important subgroups, but there was a greater relative reduction in major bleeding with new oral anticoagulants when the centre-based time in therapeutic range was less than 66% than when it was 66% or more (0.69, 0.59-0.81 vs 0.93, 0.76-1.13; p for interaction 0.022). Low-dose new oral anticoagulant regimens showed similar overall reductions in stroke or systemic embolic events to warfarin (1.03, 0.84-1.27; p=0.74), and a more favourable bleeding profile (0.65, 0.43-1.00; p=0.05), but significantly more ischaemic strokes (1.28, 1.02-1.60; p=0.045). INTERPRETATION: This meta-analysis is the first to include data for all four new oral anticoagulants studied in the pivotal phase 3 clinical trials for stroke prevention or systemic embolic events in patients with atrial fibrillation. New oral anticoagulants had a favourable risk-benefit profile, with significant reductions in stroke, intracranial haemorrhage, and mortality, and with similar major bleeding as for warfarin, but increased gastrointestinal bleeding. The relative efficacy and safety of new oral anticoagulants was consistent across a wide range of patients. Our findings offer clinicians a more comprehensive picture of the new oral anticoagulants as a therapeutic option to reduce the risk of stroke in this patient population. FUNDING: None.

# 43. ARTÍCULO Nº: 4210

Kahn SE, Cooper ME, Del PS. *Pathophysiology and treatment of type 2 diabetes: perspectives on the past, present, and future.* Lancet. 2014; 383(9922): 1068-1083.

Glucose metabolism is normally regulated by a feedback loop including islet beta cells and insulin-sensitive tissues, in which tissue sensitivity to insulin affects magnitude of beta-cell response. If insulin resistance is present, beta cells maintain normal glucose tolerance by increasing insulin output. Only when beta cells cannot release sufficient insulin in the presence of insulin resistance do glucose concentrations rise. Although beta-cell dysfunction has a clear genetic component, environmental changes play an essential part. Modern research approaches have helped to establish the important role that hexoses, aminoacids, and fatty acids have in insulin resistance and beta-cell dysfunction, and the potential role of changes in the microbiome. Several new approaches for treatment have been developed, but more effective therapies to slow progressive loss of beta-cell function are needed. Recent findings from clinical trials provide important information about methods to prevent and treat type 2 diabetes and some of the adverse effects of these interventions. However, additional long-term



studies of drugs and bariatric surgery are needed to identify new ways to prevent and treat type 2 diabetes and thereby reduce the harmful effects of this disease.

# 44. ARTÍCULO Nº: 4211

Tuomi T, Santoro N, Caprio S, Cai M, Weng J, Groop L. *The many faces of diabetes: a disease with increasing heterogeneity*. Lancet. 2014; 383(9922): 1084-1094.

Diabetes is a much more heterogeneous disease than the present subdivision into types 1 and 2 assumes; type 1 and type 2 diabetes probably represent extremes on a range of diabetic disorders. Both type 1 and type 2 diabetes seem to result from a collision between genes and environment. Although genetic predisposition establishes susceptibility, rapid changes in the environment (ie, lifestyle factors) are the most probable explanation for the increase in incidence of both forms of diabetes. Many patients have genetic predispositions to both forms of diabetes, resulting in hybrid forms of diabetes (eg, latent autoimmune diabetes in adults). Obesity is a strong modifier of diabetes risk, and can account for not only a large proportion of the epidemic of type 2 diabetes in Asia but also the ever-increasing number of adolescents with type 2 diabetes. With improved characterisation of patients with diabetes, the range of diabetic subgroups will become even more diverse in the future.

## 45. ARTÍCULO Nº: 4212

Harmsen CG, Kristiansen IS, Larsen PV, Nexoe J, Stovring H, Gyrd-Hansen D et al. *Communicating risk using absolute risk reduction or prolongation of life formats: cluster-randomised trial in general practice*. Br.J.Gen.Pract. 2014; 64(621): e199-e207.

BACKGROUND: It is important that patients are well-informed about risks and benefits of therapies to help them decide whether to accept medical therapy. Different numerical formats can be used in risk communication but It remains unclear how the different formats affect decisions made by real-life patients. AIM: To compare the impact of using Prolongation Of Life (POL) and Absolute Risk Reduction (ARR) information formats to express effectiveness of cholesterol-lowering therapy on patients' redemptions of statin prescriptions, and on patients' confidence in their decision and satisfaction with the risk communication. DESIGN AND SETTING: Cluster-randomised clinical trial in general practices. Thirty-four Danish GPs from 23 practices participated in a primary care-based clinical trial concerning use of quantitative effectiveness formats for risk communication in health prevention consultations. METHOD: GPs were cluster-randomised (treating practices as clusters) to inform patients about cardiovascular mortality risk and the effectiveness of statin treatment using either POL or ARR formats. Patients' redemptions of statin prescriptions were obtained from a regional prescription database. The COMRADE questionnaire was used to measure patients' confidence in their decision and satisfaction with the risk communication. RESULTS: Of the 240 patients included for analyses, 112 were allocated to POL information and 128 to ARR. Patients redeeming a statin prescription totalled six (5.4%) when informed using POL, and 32 (25.0%) when using ARR. The level of confidence in decision and satisfaction with risk communication did not differ between the risk formats. CONCLUSION: Patients redeemed statin prescriptions less often when their GP communicated treatment effectiveness using POL compared with ARR.

# 46. ARTÍCULO Nº: 4213

Pluddemann A, Wallace E, Bankhead C, Keogh C, Van der WD, Lasserson D et al. *Clinical prediction rules in practice: review of clinical guidelines and survey of GPs*. Br.J.Gen.Pract. 2014; 64(621): e233-e242.



BACKGROUND: The publication of clinical prediction rules (CPRs) studies has risen significantly. It is unclear if this reflects increasing usage of these tools in clinical practice or how this may vary across clinical areas. AIM: To review clinical guidelines in selected areas and survey GPs in order to explore CPR usefulness in the opinion of experts and use at the point of care. DESIGN AND SETTING: A review of clinical guidelines and survey of UK GPs. METHOD: Clinical guidelines in eight clinical domains with published CPRs were reviewed for recommendations to use CPRs including primary prevention of cardiovascular disease, transient ischaemic attack (TIA) and stroke, diabetes mellitus, fracture risk assessment in osteoporosis, lower limb fractures, breast cancer, depression, and acute infections in childhood. An online survey of 401 UK GPs was also conducted. RESULTS: Guideline review: Of 7637 records screened by title and/or abstract, 243 clinical guidelines met inclusion criteria. CPRs were most commonly recommended in guidelines regarding primary prevention of cardiovascular disease (67%) and depression (67%). There was little consensus across various clinical guidelines as to which CPR to use preferentially. Survey: Of 401 responders to the GP survey, most were aware of and applied named CPRs in the clinical areas of cardiovascular disease and depression. The commonest reasons for using CPRs were to guide management and conform to local policy requirements. CONCLUSION: GPs use CPRs to guide management but also to comply with local policy requirements. Future research could focus on which clinical areas clinicians would most benefit from CPRs and promoting the use of robust, externally validated CPRs.

# 47. ARTÍCULO Nº: 4214

Hannan EL, Samadashvili Z, Walford G, Holmes DR, Jr., Jacobs AK, Stamato NJ et al. *Culprit vessel percutaneous coronary intervention versus multivessel and staged percutaneous coronary intervention for ST-segment elevation myocardial infarction patients with multivessel disease.* JACC.Cardiovasc.Interv. 2010; 3(1): 22-31.

OBJECTIVES: The purpose of this study was to examine the differences in in-hospital and longer-term mortality for ST-segment elevation myocardial infarction (STEMI) patients with multivessel disease as a function of whether they underwent single-vessel (culprit vessel) percutaneous coronary interventions (PCIs) or multivessel PCI. BACKGROUND: The optimal treatment of patients with STEMI and multivessel disease is of continuing interest in the era of drug-eluting stents. METHODS: STEMI patients with multivessel disease undergoing PCIs in New York between January 1, 2003, and June 30, 2006, were subdivided into those who underwent culprit vessel PCI and those who underwent multivessel PCI during the index procedure, during the index admission, or staged within 60 days of the index admission. Patients were propensity-matched and mortality rates were calculated at 12, 24, and 42 months. RESULTS: A total of 3,521 patients (87.5%) underwent culprit vessel PCI during the index procedure. A total of 259 of them underwent staged PCI during the index admission and 538 patients underwent staged PCI within 60 days of the index procedure. For patients without hemodynamic compromise, culprit vessel PCI during the index procedure was associated with lower in-hospital mortality than multivessel PCI during the index procedure (0.9% vs. 2.4%, p = 0.04). Patients undergoing staged multivessel PCI within 60 days after the index procedure had a significantly lower 12-month mortality rate than patients undergoing culprit vessel PCI only (1.3% vs. 3.3%, p =0.04). CONCLUSIONS: Our findings support the American College of Cardiology/American Heart Association (ACC/AHA) recommendation that culprit vessel PCI be used for STEMI patients with multivessel disease at the time of the index PCI when patients are not hemodynamically compromised. However, staged PCI within 60 days after the index procedure, including during the index admission, is associated with risk-adjusted mortality rates that are comparable with the rate for culprit vessel PCI alone.



Toma M, Buller CE, Westerhout CM, Fu Y, O'Neill WW, Holmes DR, Jr. et al. *Non-culprit coronary artery percutaneous coronary intervention during acute ST-segment elevation myocardial infarction: insights from the APEX-AMI trial*. Eur.Heart J. 2010; 31(14): 1701-1707.

AIMS: To examine the incidence of and propensity for non-culprit interventions performed at the time of the primary percutaneous coronary intervention (PCI) and its association with 90-day outcomes. METHODS AND RESULTS: We examined the incidence, propensity for, and associated 90-day outcomes following non-culprit interventions performed at the time of primary PCI among ST-elevation myocardial infarction patients with multi-vessel coronary artery disease (MVD). Of the 5373 patients who underwent primary PCI in the APEX-AMI trial, 2201 had MVD. Of those, 217 (9.9%) underwent non-infarct-related arteries (IRA) PCI, whereas 1984 (90.1%) underwent PCI of the IRA alone. Ninety-day death and death/CHF/shock were higher in the non-IRA group compared with the IRA-only PCI group (12.5 vs. 5.6%, P (log-rank) < 0.001 and 17.4 vs. 12.0%, P (log-rank) = 0.020, respectively). After adjusting for patient and procedural characteristics as well as propensity for performing non-IRA PCI, this procedure remained independently associated with an increased hazard of 90-day mortality [adjusted hazard ratio 2.44, 95% CI (1.55-3.83), P < 0.001]. CONCLUSION: Non-culprit coronary interventions were performed at the time of primary PCI in 10% of MVD patients and were significantly associated with increased mortality. Our data support current guideline recommendations discouraging the performance of such procedures in stable primary PCI patients. Prospective randomized study of this issue may be warranted.

# 49. ARTÍCULO Nº: 4216

Vlaar PJ, Mahmoud KD, Holmes DR, Jr., van VG, Hillege HL, van dH, I et al. *Culprit vessel only versus multivessel and staged percutaneous coronary intervention for multivessel disease in patients presenting with ST-segment elevation myocardial infarction: a pairwise and network meta-analysis.* J.Am.Coll.Cardiol. 2011; 58(7): 692-703.

OBJECTIVES: The purposes of this study were to investigate whether, in patients with ST-segment elevation myocardial infarction (STEMI) and multivessel disease (MVD), percutaneous coronary intervention (PCI) should be confined to the culprit or also nonculprit vessels and, when performing PCI for nonculprit vessels, whether it should take place during primary PCI or staged procedures. BACKGROUND: A significant percentage of STEMI patients have MVD. However, the best PCI strategy for nonculprit vessel lesions is unknown. METHODS: Pairwise and network meta-analyses were performed on 3 PCI strategies for MVD in STEMI patients: 1) culprit vessel only PCI strategy (culprit PCI), defined as PCI confined to culprit vessel lesions only; 2) multivessel PCI strategy (MV-PCI), defined as PCI of culprit vessel as well as >/=1 nonculprit vessel lesions; and 3) staged PCI strategy (staged PCI), defined as PCI confined to culprit vessel, after which >/=1 nonculprit vessel lesions are treated during staged procedures. Prospective and retrospective studies were included when research subjects were patients with STEMI and MVD undergoing PCI. The primary endpoint was short-term mortality. RESULTS: Four prospective and 14 retrospective studies involving 40,280 patients were included. Pairwise meta-analyses demonstrated that staged PCI was associated with lower short- and long-term mortality as compared with culprit PCI and MV-PCI and that MV-PCI was associated with highest mortality rates at both short- and long-term follow-up. In network analyses, staged PCI was also consistently associated with lower mortality. CONCLUSIONS: This meta-analysis supports current guidelines discouraging performance of multivessel primary PCI for STEMI. When significant nonculprit vessel lesions are suitable for PCI, they should only be treated during staged procedures.



Sinnaeve PR, Van de WF. *Primary percutaneous coronary intervention not always the best reperfusion strategy?* Circulation. 2014; 129(16): 1623-1625.

# 51. ARTÍCULO Nº: 4218

Danchin N, Puymirat E, Steg PG, Goldstein P, Schiele F, Belle L et al. *Five-year survival in patients with ST-segment-elevation myocardial infarction according to modalities of reperfusion therapy: the French Registry on Acute ST-Elevation and Non-ST-Elevation Myocardial Infarction (FAST-MI) 2005 Cohort.* Circulation. 2014; 129(16): 1629-1636.

BACKGROUND: Although primary percutaneous coronary intervention (pPCI) is the preferred reperfusion method for ST-segment-elevation myocardial infarction, it remains difficult to implement in many areas, and fibrinolytic therapy is still widely used. METHODS AND RESULTS: We assessed 5-year mortality in patients with ST-segment-elevation myocardial infarction from the French Registry of Acute ST-Elevation or Non-ST Elevation Myocardial Infarction (FAST-MI) 2005 according to use and type of reperfusion therapy. Of 1492 patients with ST-segment-elevation myocardial infarction with a first call </=12 hours from onset, 447 (30%) received fibrinolysis (66% prehospital; 97% with subsequent angiography, 84% with subsequent PCI), 583 (39%) had pPCI, and 462 (31%) received no reperfusion. Crude 5-year survival was 88% for the fibrinolytic-based strategy, 83% for pPCI, and 59% for no reperfusion. Adjusted hazard ratios for 5-year death were 0.73 (95% confidence interval, 0.50-1.06) for fibrinolysis versus pPCI, 0.57 (95% confidence interval, 0.36-0.88) for prehospital fibrinolysis versus pPCI, and 0.63 (95% confidence interval, 0.34-0.91) for fibrinolysis versus pPCI beyond 90 minutes of call in patients having called </=180 minutes from onset. In propensity score-matched populations, however, survival rates were not significantly different for fibrinolysis and pPCI, both in the whole population (88% lysis, 85% pPCI) and in the population seen early (87% fibrinolysis, 85% pPCI beyond 90 minutes from call). CONCLUSIONS: In a real-world setting, on a nationwide scale, a pharmaco-invasive strategy constitutes a valid alternative to pPCI, with 5-year survival at least equivalent to that of the reference reperfusion method. CLINICAL TRIAL REGISTRATION URL: www.clinicaltrials.gov. Unique identifier: NCT00673036.

# 52. ARTÍCULO Nº: 4219

Hochman JS, Lamas GA, Buller CE, Dzavik V, Reynolds HR, Abramsky SJ et al. *Coronary intervention for persistent occlusion after myocardial infarction*. N.Engl.J.Med. 2006; 355(23): 2395-2407.

BACKGROUND: It is unclear whether stable, high-risk patients with persistent total occlusion of the infarct-related coronary artery identified after the currently accepted period for myocardial salvage has passed should undergo percutaneous coronary intervention (PCI) in addition to receiving optimal medical therapy to reduce the risk of subsequent events. METHODS: We conducted a randomized study involving 2166 stable patients who had total occlusion of the infarct-related artery 3 to 28 days after myocardial infarction and who met a high-risk criterion (an ejection fraction of <50% or proximal occlusion). Of these patients, 1082 were assigned to routine PCI and stenting with optimal medical therapy, and 1084 were assigned to optimal medical therapy alone. The primary end point was a composite of death, myocardial reinfarction, or New York Heart Association (NYHA) class IV heart failure. RESULTS: The 4-year cumulative primary event rate was 17.2% in the PCI group and 15.6% in the medical therapy group (hazard ratio for death, reinfarction, or heart failure in the PCI group as compared with the medical therapy group, 1.16; 95% confidence interval [CI], 0.92 to 1.45; P=0.20). Rates of myocardial reinfarction (fatal and nonfatal) were 7.0% and 5.3% in the two groups, respectively (hazard ratio, 1.36; 95% CI, 0.92 to 2.00; P=0.13). Rates of nonfatal reinfarctions (0.6%) were related to assigned PCI procedures. Rates of NYHA class IV



heart failure (4.4% vs. 4.5%) and death (9.1% vs. 9.4%) were similar. There was no interaction between treatment effect and any subgroup variable (age, sex, race or ethnic group, infarct-related artery, ejection fraction, diabetes, Killip class, and the time from myocardial infarction to randomization). CONCLUSIONS: PCI did not reduce the occurrence of death, reinfarction, or heart failure, and there was a trend toward excess reinfarction during 4 years of follow-up in stable patients with occlusion of the infarct-related artery 3 to 28 days after myocardial infarction. (ClinicalTrials.gov number, NCT00004562 [ClinicalTrials.gov].).

# 53. ARTÍCULO Nº: 4220

Ioannidis JP, Katritsis DG. *Percutaneous coronary intervention for late reperfusion after myocardial infarction in stable patients*. Am.Heart J. 2007; 154(6): 1065-1071.

BACKGROUND: Results of randomized trials that have compared mechanical coronary artery recanalization versus medical therapy for total occlusion late after myocardial infarction (MI) have been conflicting. METHODS: We performed a meta-analysis of randomized trials comparing percutaneous coronary intervention (PCI) with medical therapy in stable patients with an occluded artery 1 to 45 days after MI. Six trials and one substudy were included with data on 2617 patients for the clinical outcomes and 653 patients for determination of ejection fraction (EF) during follow-up. Outcomes included death, MI, death or MI, congestive heart failure (CHF), and change in left ventricular EF. RESULTS: There were no statistically significant differences for any clinical outcome, with trends for an increase in MI (risk ratio 1.26, P = .19) and decrease in CHF (risk ratio 0.67, P = .19) in the PCI arm. The PCI arm showed a slight superiority in left ventricular EF (2%, 95% CI 0.1%-2.8%). Early smaller studies showed formally statistically significant benefits for CHF and EF, but the much larger Occluded Artery Trial and Total Occlusion Study of Canada 2 found no benefit. For CHF, the difference between early smaller studies and Occluded Artery Trial was beyond chance (P = .02). CONCLUSIONS: Percutaneous coronary intervention does not seem to confer any benefits when used for late revascularization of occluded arteries after MI in stable patients.

## 54. ARTÍCULO Nº: 4221

Menon V, Pearte CA, Buller CE, Steg PG, Forman SA, White HD et al. *Lack of benefit from percutaneous intervention of persistently occluded infarct arteries after the acute phase of myocardial infarction is time independent: insights from Occluded Artery Trial.* Eur.Heart J. 2009; 30(2): 183-191.

AIMS: The Occluded Artery Trial (OAT) (n = 2201) showed no benefit for routine percutaneous intervention (PCI) (n = 1101) over medical therapy (MED) (n = 1100) on the combined endpoint of death, myocardial infarction (MI), and class IV heart failure (congestive heart failure) in stable post-MI patients with late occluded infarct-related arteries (IRAs). We evaluated the potential for selective benefit with PCI over MED for patients enrolled early in OAT. METHODS AND RESULTS: We explored outcomes with PCI over MED in patients randomized to the </=3 calendar days and </=7 calendar days post-MI time windows. Earlier, times to randomization in OAT were associated with higher rates of the combined endpoint (adjusted HR 1.04/day: 99% CI 1.01-1.06; P < 0.001). The 48-month event rates for </=3 days, </=7 days post-MI enrolled patients were similar for PCI vs. MED for the combined and individual endpoints. There was no interaction between time to randomization defined as a continuous (P = 0.55) or categorical variable with a cut-point of 3 days (P = 0.98) or 7 days (P = 0.64) post-MI and treatment effect. CONCLUSION: Consistent with overall OAT findings, patients enrolled in the </=3 day and </=7 day post-MI time windows derived no benefit with PCI over MED with no interaction between time to randomization and treatment effect. Our findings do not support routine PCI of the occluded IRA in trial-eligible patients even in the earliest 24-72 h time window.

