EXAMEN DE METODOLOGIA CERCETARII STIINTIFICE MEDICALE

A. Dentali F, Riva N, Crowther M, Turpie AG, Lip GY, Ageno W. Efficacy and safety of the novel oral anticoagulants in atrial fibrillation: a systematic review and meta-analysis of the literature. Circulation. 2012 Nov 13;126(20):2381-91.

BACKGROUND: Novel oral anticoagulants (NOACs) have been proposed as alternatives to vitamin K antagonists for the prevention of stroke and systemic embolism in patients with atrial fibrillation. Individually, NOACs were at least noninferior to vitamin K antagonists, but a clear superiority in overall and vascular mortality was not consistently proven.
METHODS AND RESULTS: We performed a meta-analysis of phase II and phase III randomized, controlled trials comparing NOACs with vitamin K antagonists in patients with atrial fibrillation. The MEDLINE and EMBASE databases, supplemented with conference abstract books and www.clinicaltrials.gov, were searched up to the first week of July 2012 with no language restriction. Two reviewers performed independent article review and study quality assessment. Data on overall and cardiovascular mortality, stroke or systemic embolism, ischemic stroke, major and intracranial bleeding, and myocardial infarction were collected. NOACs were pooled to perform a comparison with vitamin K antagonists, calculating pooled relative risks (RRs) and associated 95% confidence intervals (CIs). We retrieved 12 studies (3 administering dabigatran, 4 administering rivaroxaban, 2 administering apixaban, and 3 administering edoxaban) enrolling a total of 54,875 patients. NOACs significantly reduced total mortality (5.61% versus 6.02%; RR, 0.89; 95% CI, 0.83-0.96), cardiovascular mortality (3.45% versus 3.65%; RR, 0.89; 95% CI, 0.82-0.98), and stroke/systemic embolism (2.40% versus 3.13%; RR, 0.77; 95% CI, 0.70-0.86). There was a trend toward reduced major bleeding (RR, 0.86; 95% CI, 0.72-1.02) with a significant reduction of intracranial hemorrhage (RR, 0.46; 95% CI, 0.39-0.56). No difference in myocardial infarction was observed.

1. Ce tip de studiu este? De ce este nevoie de un astfel de studiu?
2. Cum ati descrie acest studiu (in ce consta)?
3. Care tip de tratament este mai bun, antagonistii de vitamina K sau anticoagulantele noi, sau nu este nici o diferenta? Argumentati!
4. Care sunt riscul relativ, reducerea relativa a riscului, reducerea absoluta a riscului si numarul de pacienti care trebuie tratat cu anticoagulante noi in loc de antivitamine K, pentru a salva 1 pacient in plus de la moarte (asadar, toate calculate pentru efectul „mortalitate totala”)?
5. In privinta sangerarilor majore, rezultatul este „RR, 0.86; 95% CI, 0.72-1.02”. Ce inseamna asta?
6. Daca ar fi sa gasim acest studiu pe PubMed/MEDLINE, cum ar trebui sa efectuam cautarea (unde, cu ce termeni)?

B. Liou JM, Chen CC, Chen MJ et al. for the Taiwan Helicobacter Consortium. Sequential versus triple therapy for the first-line treatment of Helicobacter pylori: a multicentre, open-label, randomised trial. Lancet. 2012 Nov 15. pii: S0140-6736(12)61579-7.

BACKGROUND: Whether sequential treatment can replace triple therapy as the standard treatment for Helicobacter pylori infection is unknown. We compared the efficacy of sequential treatment for 10 days and 14 days with triple therapy for 14 days in first-line treatment. METHODS: For this multicentre, open-label, randomised trial, we recruited patients (≥20 years of age) with H pylori infection from six centres in Taiwan. Using a computer-generated randomisation sequence, we randomly allocated patients (1:1:1; block sizes of six) to either sequential treatment (lansoprazole 30 mg and amoxicillin 1 g for the first 7 days, followed by lansoprazole 30 mg, clarithromycin 500 mg, and metronidazole 500 mg for another 7 days; with all drugs given twice daily) for either 10 days (S-10) or 14 days (S-14), of 14 days of triple therapy (T-14; lansoprazole 30 mg, amoxicillin 1 g, and clarithromycin 500 mg for 14 days; with all drugs given twice daily). Investigators were masked to treatment allocation. Our primary outcome was the eradication rate in first-line treatment by intention-to-treat (ITT) and per-protocol (PP) analyses. This trial is registered with
ClinicalTrials.gov, number NCT01042184.
FINDINGS: Between Dec 28, 2009, and Sept 24, 2011, we enrolled 900 patients: 300 to each group. The eradication rate was 90·7% (95% CI 87·4-94·0; 272 of 300 patients) in the S-14 group, 87·0% (83·2-90·8; 261 of 300 patients) in the S-10 group, and 82·3% (78·0-86·6; 247 of 300 patients) in the T-14 group. Treatment efficacy was better in the S-14 group than it was in the T-14 group in both the ITT analysis (number needed to treat of 12·0 [95% CI 7·2-34·5]; p=0·003) and PP analyses (13·7 [8·3-40], p=0·003). We recorded no significant difference in the occurrence of adverse effects or in compliance between the three groups.
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1. Ce tip de studiu este acesta?
2. Ceinseamna „randomizare” si care este scopul ei?
3. Credeti ca studiul a fost „dublu orb”? La ce foloseste orbirea in acest studiu?
4. Care reiese ca ar fi cel mai bun tratament de eradicare a *H Pylori* din acest studiu? Argumentati!
5. Credeti ca exista o legatura de cauzalitate intre tratamentul secvential si eradicarea mai buna? Argumentati!
6. Cum a fost obtinut acel *number needed to treat* de 12 pentru comparatia intre tratamentul secvential de 14 zile si tripla terapie de 14 zile (S-14 si T-14)? Ce inseamna NNT= 12 [95% CI 7.2-34.5]?
7. Daca ar fi sa gasim acest studiu pe PubMed/MEDLINE, cum ar trebui sa efectuam cautarea (unde, cu ce termeni)?