abstract of

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Bivalirudin in patients with acute coronary syndromes undergoing percutaneous coronary intervention: a subgroup analysis from the Acute Catheterization and Urgent Intervention Triage strategy (ACUITY) trial-Stone, G.W., Harvey D White, E Magnus Ohman, Michel E Bertrand, A Michael Lincoff, Brent T McLaurin, David A Cox, James H Ware, Frederick Feit, Antonio Colombo, Steven V Manoukian, Alexandra J Lansky, Roxana Mehran, and Jeffrey W Moses


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WORLD REPORT
(Since these articles has no abstract, we just provided an extract of the first 100 words of the full text and any section headings)


The number of mainland Chinese women choosing to give birth in Hong Kong has risen rapidly over the past 10 years, putting health services in the region under pressure. Now new laws have been introduced in a bid to quell the influx. Margaret Harris Cheng reports from Hong Kong. Mr Ng was furious. The proud prospective father had brought his wife to one of Hong Kong’s major public hospitals for her first antenatal visit only to be told that because his wife was mainland Chinese he had to come up with HK$39 before she could set foot in the clinic. Mr Ng, an itinerant worker, asked if he could pay in instalments. But the clerk behind the glass panel was adamant: no money, no baby.


When universities grant exclusive licences to commercial companies for the discoveries of their scientists, they may unwittingly hamper university research. Now new licensing guidelines aim to address the problem and protect the public interest. Michael McCarthy reports. When universities license their researchers’ inventions, they should negotiate agreements that allow for the widest dissemination of the new technology, according to a set of guidelines released on March 6 by 11 top US universities in conjunction with the Association of American Medical Colleges (AAMC). Universities should “be mindful of their primary mission to use patents to promote technology development for the benefit of society”, the guidelines say.


Over 20 US states are considering laws to make vaccination against the human papilloma virus mandatory for pre-teen girls. But the push is meeting resistance from a broad spectrum of groups, including some in public health. Laurie Udesky reports from California. Deepi Brar, an Oakland, California, mother was not opposed to vaccinating her young daughter Zoya against mumps and measles, but when she read that California lawmakers were hoping to make the human papilloma virus (HPV) vaccine mandatory, she thought the state was overstepping its authority. “Since it’s not a communicable disease you can catch in a classroom setting, it’s not really the school’s place to tell parents that they must go out and have their children vaccinated”, said Brar.

ARTICLES


Carbamazepine is widely accepted as a drug of first choice for patients with partial onset seizures. Several newer drugs possess efficacy against these seizure types but previous randomised controlled trials have failed to inform a choice between these drugs. We aimed to assess efficacy with regards to longer-term outcomes, quality of life, and health economic outcomes. SANAD was an unblinded randomised controlled trial in hospital-based outpatient clinics in the UK. Arm A recruited 1721 patients for whom carbamazepine was deemed to be standard treatment, and they were randomly assigned to receive carbamazepine, gabapentin, lamotrigine, oxcarbazepine, or topiramate. Primary outcomes were time to treatment failure, and time to 12-months remission, and assessment was by both intention to treat and per protocol. For time to treatment failure, lamotrigine was significantly better than carbamazepine (hazard ratio [HR] 0.78 [95% CI 0.63-0.97]), gabapentin (0.65 [0.52-0.80]), and topiramate (0.64 [0.52-0.79]), and had a non-significant advantage compared with oxcarbazepine (1.15 [0.86-1.54]). For time to 12-month remission carbamazepine was significantly better than gabapentin (0.75 [0.63-0.90]), and estimates suggest a non-significant advantage for carbamazepine against lamotrigine (0.91 [0.77-1.09]), topiramate (0.86 [0.72-1.03]), and oxcarbazepine (0.92 [0.73-1.18]). In a per-protocol analysis, at 2 and 4 years the difference (95% CI) in the proportion achieving a 12-month remission (lamotrigine-carbamazepine) is 0 (-8 to 7) and 5 (-3 to 12), suggesting non-inferiority of lamotrigine compared with carbamazepine. Lamotrigine is clinically better than carbamazepine, the standard drug treatment, for time to treatment failure outcomes and is therefore a cost-effective alternative for patients diagnosed with partial onset seizures.


Spinal fusion can be complicated by accelerated degeneration of the adjacent segments. Artificial disc replacements have been developed, but results are variable. Successful transplantations of intervertebral disc autografts, fresh allografts, and fresh-frozen allografts—ie, a non-fusion strategy—in which the mobility and stability of the spinal segment were preserved have been done in a primate model. Our aim was to determine the feasibility, safety, and long-term clinical results of disc transplantation in human beings. Five patients, average age 47 years, with cervical disc herniation underwent transplantation of fresh-frozen composite disc allografts after disc excision. Serial MRI and static and dynamic radiographs were used to monitor the status of the grafts and the sagittal stability and
mobility of the segment. Good union of the graft endplates was seen by the end of 3 months after surgery in all patients. At a minimum follow-up of 5 years, the neurological symptoms of all patients had improved from before surgery levels. No immunoreaction was encountered. There was no olisthesis and only mild degenerative changes of the transplanted discs. All except one of the discs showed preservation of 70–113% of sagittal motion at the final follow-up. MRI at 5 years showed preservation of hydration in at least two discs. Despite signs of mild disc degeneration, the motion and stability of the spinal unit was preserved after transplantation of fresh-frozen allogenic intervertebral discs in our patients. With further refinements, such transplantations could be an effective treatment for degenerative disc disease.


The aim of this study was to assess anticoagulation with the direct thrombin inhibitor bivalirudin during percutaneous coronary intervention in individuals with moderate and high-risk acute coronary syndromes. 137819 individuals in the Acute Catheterization and Urgent Intervention Triage strategy (ACUITY) trial were prospectively randomly assigned to receive heparin (unfractionated or enoxaparin) plus glycoprotein IIb/IIIa inhibitors, bivalirudin plus glycoprotein IIb/IIIa inhibitors, or bivalirudin alone. Of these individuals, 7789 underwent percutaneous coronary intervention after angiography. The effect of the three regimens on the primary 30-day endpoints of composite ischaemia (death, myocardial infarction, or unplanned revascularisation for ischaemia), major bleeding, and net clinical outcomes (composite ischaemia or major bleeding) was assessed in this subgroup. Analyses were done by intention to treat. Of the individuals who underwent percutaneous coronary intervention, 2561 received heparin plus glycoprotein IIb/IIIa inhibitors, 2609 received bivalirudin plus glycoprotein IIb/IIIa inhibitors, or bivalirudin alone. 26 (0.3%) individuals dropped out or were lost to follow-up. There was no significant difference in the proportion of individuals with composite ischaemia, major bleeding, or net clinical outcomes at 30 days between those who received bivalirudin plus glycoprotein IIb/IIIa inhibitors and those who received heparin plus glycoprotein IIb/IIIa inhibitors (composite ischaemia: 243 [9%] patients vs 210 [8%] patients, p=0.16; major bleeding: 196 [8%] patients vs 174 [7%] patients, p=0.32; net clinical outcomes: 389 [15%] patients vs 341 [13%] patients, p=0.1). Rates of composite ischaemia were much the same in those who received bivalirudin alone and those who received heparin plus glycoprotein IIb/IIIa inhibitors (230 [9%] patients vs 210 [8%] patients, p=0.45); however, there were significantly fewer individuals who experienced major bleeding among those who received bivalirudin alone than among those who received heparin plus glycoprotein IIb/IIIa inhibitors (92 [4%] patients vs 174 [7%] patients, p<0.0001, relative risk 0.52, 95% CI 0.40–0.66), resulting in a trend towards better 30-day net clinical outcomes (303 [12%] patients vs 341 [13%] patients, p=0.057; 0.87, 0.75–1.00). Substitution of unfractionated heparin or enoxaparin with bivalirudin results in comparable clinical outcomes in patients with moderate and high-risk acute coronary syndromes treated with glycoprotein IIb/IIIa inhibitors in whom percutaneous coronary intervention is done. Anticoagulation with bivalirudin alone suppresses adverse ischaemic events to a similar extent as does heparin plus glycoprotein IIb/IIIa inhibitors, while significantly lowering the risk of major haemorrhagic complications.


Studies from Asia have suggested that zinc supplementation can reduce morbidity and mortality in children, but evidence from malnourished populations in Africa has been inconsistent. Our aim was to assess the effects of zinc supplementation on overall mortality in children in Pemba, Zanzibar. We enrolled 427546 children aged 1–36 months, contributing a total of 567507 child-years in a randomised, double-blind, placebo-controlled trial in Pemba, Zanzibar. Randomisation was by household. 21274 children received daily supplementation with zinc 10 mg (5 mg in children younger than 12 months) for mean 484.7 days (SD 306.6). 21272 received placebo. The primary endpoint was overall mortality, and analysis was by intention to treat. Overall, there was a non-significant 7% (95% CI -6% to 19%; p=0.29) reduction in the relative risk of all-cause mortality associated with zinc supplementation. We believe that a meta-analysis of all studies of mortality and morbidity, will help to make evidence-based recommendations for the role of zinc supplementation in public health policy to improve mortality, morbidity, growth, and development in young children.

SEMINAR


Bipolar II disorder (recurrent depressive and hypomanic episodes) and related disorders (united in the bipolar spectrum) are understood, despite a prevalence of about 5% in the community and about 50% in depressed outpatients. The apparent increase in prevalence of the bipolar spectrum is related to several changes in diagnostic criteria, including improved probing for history of hypomania (focused more on overactivity than on mood change), lower minimum duration of hypomania, and inclusion of unipolar depressions with bipolar signs (eg, family history of bipolar disorder, mixed depression). Prevalence of mixed depression,
a combination of depression and manic or hypomanic symptoms, is high in patients with bipolar disorders.


Pelvic organ prolapse is downward descent of female pelvic organs, including the bladder, uterus or post-hysterectomy vaginal cuff, and the small or large bowel, resulting in protrusion of the vagina, uterus, or both. Prolapse development is multifactorial, with vaginal child birth, advancing age, and increasing body-mass index as the most consistent risk factors. Vaginal delivery, hysterectomy, chronic straining, normal ageing, and abnormalities of connective tissue or connective-tissue repair predispose some women to disruption, stretching, or dysfunction of the levator ani complex, connective-tissue attachments of the vagina, or both, resulting in prolapse. Patients generally present with several complaints, including bladder, bowel, and pelvic symptoms; however, with the exception of vaginal bulging, none is specific to prolapse. Women with symptoms suggestive of prolapse should undergo a pelvic examination and medical history check. Radiographic assessment is usually unnecessary. Many women with pelvic organ prolapse are asymptomatic and do not need treatment. When prolapse is symptomatic, options include observation, pessary use, and surgery.

REVIEW


Although functional somatic syndromes (FSS) show substantial overlap, treatment research is mostly confined to single syndromes, with a lack of valid and generally accepted diagnostic criteria across medical specialties. Here, we review management for the full variety of FSS, drawn from systematic reviews and meta-analyses since 2001, and give recommendations for a stepped care approach that differentiates between uncomplicated and complicated FSS. Non-pharmacological treatments involving active participation of patients, such as exercise and psychotherapy, seem to be more effective than those that involve passive physical measures, including injections and operations. Pharmacological agents with CNS action seem to be more consistently effective than drugs aiming at restoration of peripheral physiological dysfunction. A balance between biomedical, organ-oriented, and cognitive interpersonal approaches is most appropriate at this truly psychosomatic interface. In view of the iatrogenic component in the maintenance of FSS, doctor-centred interventions and close observation of the doctor–patient relationship are of particular importance.


Politicians, policymakers, and public-health professionals make complex decisions on the basis of estimates of disease burden from different sources, many of which are “marketed” by skilled advocates. To help people who rely on such statistics make more informed decisions, we explain how health estimates are developed, and offer basic guidance on how to assess and interpret them. We describe the different levels of estimates used to quantify disease burden and its correlates; understanding how closely linked a type of statistic is to disease and death rates is crucial in designing health policies and programmes. We also suggest questions that people using such statistics should ask and offer tips to help separate advocacy from evidence-based positions. Global health agencies have a key role in communicating robust estimates of disease, as do policymakers at national and subnational levels where key public-health decisions are made.

SERIES


Sound statistics are a key component of evidence. However, many institutional, political, and practical barriers impede effective use of data to inform policy. In the fourth paper in this Series on health statistics, we look at the relation between health statistics and policymaking at country and global levels. We propose a fourfold framework to help the transition from data to policy. Good practices include: (1) reconciling statistics from different sources; (2) fostering communication and transparency, including reaching out to the media for dissemination; (3) promoting country ownership of data and statistical analyses; and (4) addressing conflicts of interest, including those arising when workers responsible for attainment of health goals are also charged with measurement and monitoring of progress.

HEALTHPOLICY


Drug misuse and abuse are major health problems. Harmful drugs are regulated according to classification systems that purport to relate to the harms and risks of each drug. However, the methodology and processes underlying classification systems are generally neither specified nor transparent, which reduces confidence in their accuracy and undermines health education messages. We developed and explored the feasibility of the use of a nine-category matrix of harm, with an expert delphic procedure, to assess the harms of a range of illicit drugs in an evidence-based fashion. We also included five legal drugs of misuse (alcohol, khat, solvents, alkyl nitrites, and tobacco) and one that has since been classified (ketamine) for reference. The process proved practicable, and yielded roughly similar scores and rankings of drug harm when used by two separate groups of experts.