

Masala

Sunshine to heal jaundiced neonates

Conventional phototherapy for neonatal hyperbilirubinaemia is often not available in low-income countries. Researchers from the University of Minnesota used customized film canopies to filter sunlight and used this instead of a phototherapy unit. In Lagos, Nigeria, they randomized 447 infants to receive either conventional phototherapy ($n=223$) or filtered sunlight ($n=224$). The primary end-point was efficacy in reducing bilirubin levels; the need for an exchange transfusion was a secondary end-point. Filtered sunlight was efficacious on 93% of treatment days that could be evaluated, as compared with 90% for conventional phototherapy. Temperatures higher than 38 °C occurred in 5% of the infants receiving filtered sunlight and in 1% of those receiving conventional phototherapy but this did not lead to any withdrawals from the study. No infant required an exchange transfusion. This low-cost technology holds promise in resource-constrained settings (*N Engl J Med* 2015;**373**:1115–24).

Bioprosthetic total artificial heart

Researchers from France report the results of the first clinical use of a total artificial heart in two patients. The device, known as the CARMAT total artificial heart (C-TAH), is an implantable electro-hydraulically actuated pulsatile biventricular pump. All components except for the batteries are kept in a single device positioned in the pericardial sac after removing the native ventricles. The C-TAH was implanted in two patients, 76 and 68 years old, with intractable heart failure. The first patient died after 74 days following device failure. The second patient left the hospital on postoperative day 150 and died of low cardiac output with multi-organ failure after 4 months (*Lancet* 2015;**386**:1556–63).

Aromatase inhibitors and breast cancer

A meta-analysis of individual data included 31 920 post-menopausal women with oestrogen-receptor-positive early breast cancer who were included in randomized trials of 5 years of aromatase inhibitor versus 5 years of tamoxifen; of 5 years of aromatase inhibitor versus 2–3 years of tamoxifen then aromatase inhibitor to year 5; and of 2–3 years of tamoxifen then aromatase inhibitor to year 5 versus 5 years of tamoxifen. Primary outcomes were recurrence, breast cancer mortality, death without recurrence and all-cause mortality. Aggregating all three types of comparison, recurrence relative risks (RRs) favoured aromatase inhibitors during periods when treatments differed (RR 0.70). Breast cancer mortality and all-cause mortality were reduced for all periods combined (RR 0.86). RRs varied little by age, body mass index, stage, grade, progesterone receptor status or HER2 status. There were fewer endometrial cancers with aromatase inhibitors than with tamoxifen but more bone fractures (*Lancet* 2015;**386**:1341–52).

Islet transplantation in type 1 diabetes: Long-term results

The Swiss–French GRAGIL multicentre transplantation network did two trials of islet transplantation in patients with type 1 diabetes—GRAGIL-1C (islet after kidney transplantation, IAK) and GRAGIL-2 (islet transplantation alone, ITA). A retrospective analysis of the 5-year results of these two trials was reported recently. ITA was done in 24 patients and IAK in 20 between September 2003 and April 2010. At 1, 4, and 5 years after islet transplantation, respectively,

83%, 67%, and 58% of ITA recipients and 80%, 70%, and 60% of IAK recipients reached HbA1c under 7% and were free of severe hypoglycaemia. Thirty-three of 44 patients remained free of insulin therapy during the follow-up period of 5 years with a median duration of insulin independence of 19.25 months (*Diabetes Care* 2015;**38**:1714–22).

Oral vaccine for Helicobacter pylori

In a randomized, double-blind, placebo-controlled, phase 3 trial at a single centre in China, healthy children aged 6–15 years ($n=4464$) without past or present *H. pylori* infection were randomly assigned to receive a recombinant *H. pylori* oral vaccine ($n=2232$) or placebo ($n=2232$). Ninety-nine per cent of participants completed the three-dose vaccination. There were 14 events in 2074.3 person-years at-risk in the vaccine group versus 50 events in 2089.6 person-years at-risk in the placebo group, resulting in a vaccine efficacy of 71.8% with serious adverse events in <1% of participants in each group. An effective vaccine against *H. pylori* could soon become a reality (*Lancet* 2015;**386**:1457–64).

Dengue vaccine: Follow-up results

A tetravalent dengue vaccine is being evaluated in three large trials involving more than 35 000 children between the ages of 2 and 16 years. The incidence of hospitalization for virologically confirmed dengue has recently been reported during follow-up in years 3 to 6 of two phase 3 trials, CYD14 (Asia-Pacific region) and CYD15 (Latin America), and one phase 2b trial, CYD23/57 (Thailand). Vaccine efficacy was assessed using pooled data from the first 25 months of CYD14 and CYD15. CYD14 included 10 275 participants, CYD15 20 869 and CYD23/57 had 4002. During year 3 in the three trials combined, the relative risks of hospitalization for dengue were significantly reduced only in those above 9 years of age (RR 0.50). Pooled rates of efficacy for symptomatic dengue during the first 25 months were 60.3% for all participants, 65.6% for those 9 years of age or older, and 44.6% for those younger than 9 years of age. Except for the surprisingly low efficacy in children below the age of 9 years, the results seem reassuring (*N Engl J Med* 2015;**373**:1195–206).

Clinical experience and the interpretation of chest pain

A prospective observational study in a UK General Hospital emergency department recruited consecutive adults with chest pain and a non-diagnostic electrocardiogram, who subsequently underwent delayed troponin testing. Based on clinical judgement, physicians recorded whether the chest pain was typical or atypical for acute coronary syndrome. Physicians were categorized as ‘experienced’ or ‘novice’ based on their postgraduate experience. Myocardial infarction was adjudicated using a high-sensitivity troponin (hs-cTn) assay and coronary artery disease was diagnosed at angiography. Of 912 patients, 114 (12.5%) had an acute myocardial infarction and 157 (17.2%) underwent angiography. When assessed by experienced physicians, specificity for the diagnosis of acute myocardial infarction was 65.8% compared to 55.4% for novices. Clinical assessment alone, even by experienced physicians, may not detect or exclude acute coronary syndromes with confidence (*Am J Med* 2015;**128**:1109–16)!

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