Pre-exposure prophylaxis for HIV

The US Food and Drug Administration (FDA), on 16 July 2012, approved the combination of emtricitabine and tenofovir disoproxil fumarate (marketed as Truvada) for preventing sexual transmission of HIV infection to high-risk individuals who are HIV-negative. Truvada is to be used once daily by individuals who engage in safe sex practices with HIV-infected partners. The approval was based on the results of two large trials. One of these, the Partners PrEP Study, enrolled 4758 HIV-sero-discordant couples. HIV-negative partners were randomized to receive Truvada or placebo and followed for 3 years. There was a 75% reduction in the risk of HIV transmission in those given Truvada (N Engl J Med 2012;367:399–410). An earlier trial conducted in 2010, the iPrEx trial, had found that there was a 44% reduction in the incidence of HIV after a median follow-up of 1.2 years (N Engl J Med 2010;363:2587–99). The adverse effects were found to be comparable to those occurring with placebo (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm312210.htm. accessed on 15 Aug 2012).

Re-operation after breast conserving surgery

A retrospective study from the UK obtained data from 156 National Health Service (NHS) trusts over a 3-year period on re-operation rates within 3 months of a breast conserving procedure. Of 55 297 women who underwent breast conserving surgery for carcinoma breast, 20% had at least one re-operation. Re-operation was twice as likely among women whose tumours, obtained at the initial surgery, had a component of carcinoma in situ. Given the additional morbidity associated with re-operation and the possible delay in adjuvant therapy, it is important to help women make an informed choice about the initial surgical procedure (BMJ 2012;345:e4505 doi: 10.1136/bmj.e4505).

The Berlin Heart

Extracorporeal membrane oxygenation (ECMO) has been used as a bridge to cardiac transplantation among children. However, serious adverse effects limit its use to 10–20 days. A prospective trial in the USA evaluated the EXCOR Pediatric Ventricular Assist Device (Berlin Heart), a paracorporeal circulatory support device. Children below 16 years of age awaiting a heart transplant were divided into two groups of 24 each on the basis of body surface area: >0.7 m² and 0.7 to <1.5 m². In the case of the first group, the median survival time had not been reached at 174 days. The median survival time in the historically matched ECMO control group was only 13 days. Those in the second group had a median survival of 144 days compared to 10 days in the historically matched controls. More than 90% of the children survived until transplantation or until they were weaned off the device. The serious adverse events included major bleeding, infection and stroke. On the basis of the results of this trial, the FDA has granted approval to this device (N Engl J Med 2012;367:532–41).

Radical prostatectomy for localized prostate cancer?

The USA-based Prostate Cancer Intervention versus Observation Trial (PIVOT) Study Group addressed this issue in a randomized trial, which recruited 731 men with localized prostate cancer over a 7-year period. The participants were assigned to radical prostatectomy or observation, and the median follow-up period was 10 years. Over this period, 47% of men in the radical prostatectomy group and 49.9% of those under observation died (p=0.22). Death rates due to prostate cancer were also comparable. The findings did not vary by age or histological features of the tumour. Only patients with a prostate-specific antigen (PSA) level >10 ng/ml had a better overall survival rate following surgery. Adverse events developed within a month among one-fifth of those who underwent surgery. Observation appears to be an option for patients who have localized prostate cancer and PSA levels <10 ng/ml (N Engl J Med 2012;367:203–13).

More on the risk of diabetes with statins

Investigators for the Justification for the Use of Statins in Primary Prevention: An Intervention Trial Evaluating Rosuvastatin (JUPITER) trial randomized 17 603 men and women without diabetes or cardiovascular disease at baseline to rosuvastatin 20 mg or placebo. The participants were analysed as two groups— those with and those without risk factors for developing diabetes. At the end of 5 years, there was a 39% reduction in vascular events and a 28% increase in diabetes among patients who had one or more risk factors for diabetes and who were given rosvastatin. The corresponding figures for patients who had no risk factors were 52% and 0%, respectively. These data are reassuring, but underline the need for caution when prescribing statins to those at risk for diabetes (Lancet 2012;380:565–71).

Osteoporosis in men: New guidelines

The Endocrine Society has formulated guidelines on osteoporosis among men. The recommendations include testing men above 70 years of age, or those aged 50 to 69 years with risk factors such as smoking and low body weight, using central dual-energy X-ray absorptiometry (DEXA) and laboratory testing to detect contributory causes. In addition to exercise and an adequate intake of calcium and vitamin D, pharmacological therapy is recommended for men with a T score of <−2.5 or below, as well as for men who are above 50 years of age and have had spine or hip fractures (J Clin Endocrinol Metab 2012;97:1802–22).

Spray-on skin!

Venous leg ulcers often heal poorly. In a multicentric, phase 2, double-blind trial, researchers randomized 45 adult patients, whose venous leg ulcers had persisted for 6–104 weeks, to either four-layer compression bandaging alone or bandaging plus cell therapy through the application of a novel spray of different strengths. The spray contained growth-arrested allogeneic neonatal keratinocytes and fibroblasts. At the end of 12 weeks, there was a greater mean reduction in the wound area among the patients receiving the spray, compared to those receiving placebo (p=0.0446). If the results are confirmed in larger phase 3 trials, this spray could revolutionize skin transplantation (Lancet 3 August 2012. doi:10.1016/S0140-6736(12)60644-8).