

Niacin trial sparks controversy



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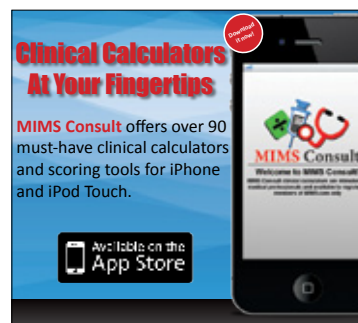


Penatalaksanaan infeksi rongga mulut

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Turning the tide on chronic diseases in Asia: The need for innovative solutions

Excerpted from a presentation by Professor Harvey Fineberg, president of the Institute of Medicine and former Dean of the Harvard School of Public Health, Cambridge, Massachusetts, US, during the National University of Singapore Initiative to Improve Health in Asia (NIHA) forum held in Singapore recently.



The two elements in the title, chronic diseases and Asia, are each heterogeneous and complicated.

The countries of Asia range from a population of 400,000 in Brunei to more than 1 billion each in India and China. The range of economic development in the region is equally disparate. The countries also vary in their stage of epidemiologic transition, with many simultaneously facing a high burden of infectious diseases and chronic diseases. Although a single solution is unlikely to suit every country in the region, certain lessons and principles can apply across all.

The terminology of non-communicable diseases is problematic. Many chronic diseases have infectious origins, including liver cancer (hepatitis B and C) gastric cancer (*H. pylori*) cervical and oral cancers (human papillomavirus). Similarly, a number of acute illnesses are not infectious.

The separation between acute and

chronic, communicable and non-communicable is thus imperfect. What unites our concern about these diseases is that they persist over time, are prevalent in all parts of the world, and are rising in their incidence and significance as part of the total disease burden.

Cancers, heart disease, lung disease, diabetes, and neurological and mental problems fall into this category. We tend to overlook this last group, but neurodegenerative diseases and mental illnesses such as depression will soon constitute the leading cause of the global disease burden.

We need to apply our creative talent in new, innovative ways to come up with novel solutions. One useful perspective is to consider diseases according to the stage of life and stage of disease evolution in individuals and populations, eg, problems of the young, the middle-aged, and the elderly.

Another useful perspective is to design interventions according to the stage of disease development, including pre-disease, disposition to disease, early disease, full blown disease, and sequelae of disease. The activities of the Global Taskforce on Expanded Access to Cancer Care and Control in Developing Countries, which focuses on low and middle income countries and organizes its thinking according

to detection, diagnosis, prevention, treatment, survivorship, and palliation of cancer, is a good example of this type of approach.

Framing strategies according to risk factors represents another useful, strategic framework, beyond the classification by population and the stage of development of disease.

Tobacco, for example, leads to a number of chronic diseases including heart disease, lung disease, and cancer. Diet and obesity similarly contribute to a number of disease problems, including diabetes. Reducing a single source of risk can often reduce the incidence of multiple diseases.

Six criteria can guide the choice of interventions against chronic diseases:

- **Impact.** Is the intervention effective, aimed at an important problem, and scalable to apply to the totality of the problem?
- **Adoptability.** Is the intervention politically and culturally acceptable? This depends on the specific design of the intervention and on the political, social, and cultural context of each jurisdiction.
- **Affordability.** Is the intervention economically justified, cost-effective, and affordable? The diversity of economic situations in different countries may dictate different answers for the same intervention.
- **Implementability.** Is the strategy practical and implementable? Can you manage all the steps necessary to go from an idea to tangible change based on this strategy?
- **Sustainability.** Some interventions may be completed in a single step, such as immunization against HPV or

hepatitis B, while others, such as diet, demand daily attention.

- **Evaluation.** Can you demonstrate whether the intervention has worked in a way that would convince a skeptic?

If we can design strategies that fit these criteria — that will have impact, are adoptable and affordable, implementable, sustainable, and amenable to evaluation — then we will have made significant progress.

At least 10 modes of action can be employed in the design of intervention strategies: (1) the legal foundation (such as tax policy or environmental laws) needed to mount the intervention; (2) regulatory policy and infrastructure for foods, tobacco, drugs and devices; (3) research (basic, translational, applied and evaluative) to devise new tools and assess what has worked; (4) monitoring, surveillance and measurement to get a more accurate picture of disease burden over time; (5) education of the spectrum of health professionals, including inter-professional training; (6) advocacy and public communication, including information technology and the use of social and entertainment media; (7) organization and preparedness of the health system to provide needed services; (8) capacity for implementation, including authority and decision control systems; (9) adequate financing mechanisms; and (10) alignment of action across ministries, universities and other institutions, public health and medicine, and public and private sectors.

These mutually inclusive modalities represent great opportunities individually and in combination. Successful strategic combinations that fulfill the six criteria hold the prospect of great progress against chronic diseases in Asia and in other parts of the world.

Penatalaksanaan infeksi rongga mulut

Hardini Arivianti

Infeksi di rongga mulut dan maksilofasial cukup sering dijumpai dalam praktik sehari-hari, baik dokter gigi maupun bidang spesialis lainnya yang masih berangung dalam kedokteran gigi. Infeksi rongga mulut tidak hanya disebabkan oleh karies. Beberapa penyebab lainnya, adalah gigi, kelenjar liur dan tulang rahang, dan nekrosis (osteomielitis, osteoradionekrosis, dan 'biphosponate-related osteonecrosis of the jaws'/BRONJS). Hal ini dikemukakan oleh Prof. DR. Drg. Benny S Latief, SpBM(K) pada seminar sehari yang bertemakan 'Pengobatan Terkini Kasus Infeksi' beberapa waktu lalu.

"Karies yang tidak ditangani dapat menyebar ke rongga mulut dan bisa menjadi fatal jika penyebaran infeksi mencapai jantung. Tidak itu saja, bakteri di lubang gigi dan gusi dapat masuk ke dalam sirkulasi darah dan menyerang katup jantung," tukas Presiden 'Asian Association Oral and Maxillofacial Surgeon' ini lebih lanjut.

Infeksi dento alveolar yang disebabkan oleh karies dapat menyebar ke bagian yang berdekatan. Bila mencapai leher dengan cepat turun melalui 'lincoln highway' dan mencapai area mediastinum sehingga timbul mediastinitis.

Infeksi rongga mulut yang disebabkan oleh gigi biasanya dimulai dengan karies yang dapat menyebar ke bagian yang berdekatan. Infeksi pada gigi lainnya adalah impaksi geraham baik geraham atas maupun bawah. "Sekitar 60-70% pasien datang akibat infeksi atau rasa sakit yang ditimbulkan oleh impaksi," lanjutnya.



Yang disebabkan oleh kelenjar liur biasanya diakibatkan adanya batu kelenjar liur (sialolitiasis) atau ada faktor lain yang mempengaruhi fungsi dari kelenjar-kelenjar seperti parotis, submandibula dan sublingualis. Selain itu, xerostomia, *sjogren syndrome*, mumps juga bisa sebabkan kondisi ini. Osteomielitis dan osteoradionekrosis dapat disebabkan oleh kelanjutan dari trauma dengan perawatan yang tidak adekuat/memadai.

Infeksi yang disebabkan oleh kelainan pada kelenjar liur yang tidak diterapi menyebabkan pasien datang dengan bengkak di rongga mulut. Dokter perlu menanyakan kapan mulai timbul bengkak tersebut, saat atau setelah melihat makanan. Bila saat melihat makanan, maka kemungkinan kuat disebabkan oleh stagnasi pada kelenjar liur

Pemberian antibiotik

Infeksi oromaksial bisa dimulai dengan

gradasi rendah hingga menimbulkan kefatalan. Penanganan awal dengan pemberian antibiotika yang sesuai dan tepat dapat mengurangi komplikasi lebih lanjut.

Bila setiap kelainan diberikan antibiotik, lanjut drg. Benny, maka dapat timbulkan superinfeksi. Bila hal ini terjadi dalam rongga mulut dapat menimbulkan jamur yang berbeda dengan jamur akibat HIV. Pasien mengalami sulit menelan, mulut berwarna keputihan, dan gambaran jamur ini sangat khas. Dokter perlu menghentikan obat antibiotika yang menyebabkannya dan berikan antikandida.

Basic treatment pada infeksi rongga

mulut meliputi tiga faktor yaitu antibiotika, drainase dan penghilangan faktor kausatif. Pemberian antibiotik pada rongga mulut tidak semuanya sama, jelas drg. Benny, tergantung infeksi tersebut menyerang jaringan lunak, mukosa, dasar mulut, jaringan keras/tulang, atau kelenjar liur. Golongan sefalosporin (oral dan parenteral) dapat menjadi pilihan bila infeksi menyerang jaringan lunak.

Bila infeksi menyerang jaringan keras/tulang, golongan klindamisin dapat diberikan. "Ada beberapa golongan antibiotik yang tidak cocok diberikan pada infeksi rongga mulut," lanjut drg. Benny. ■

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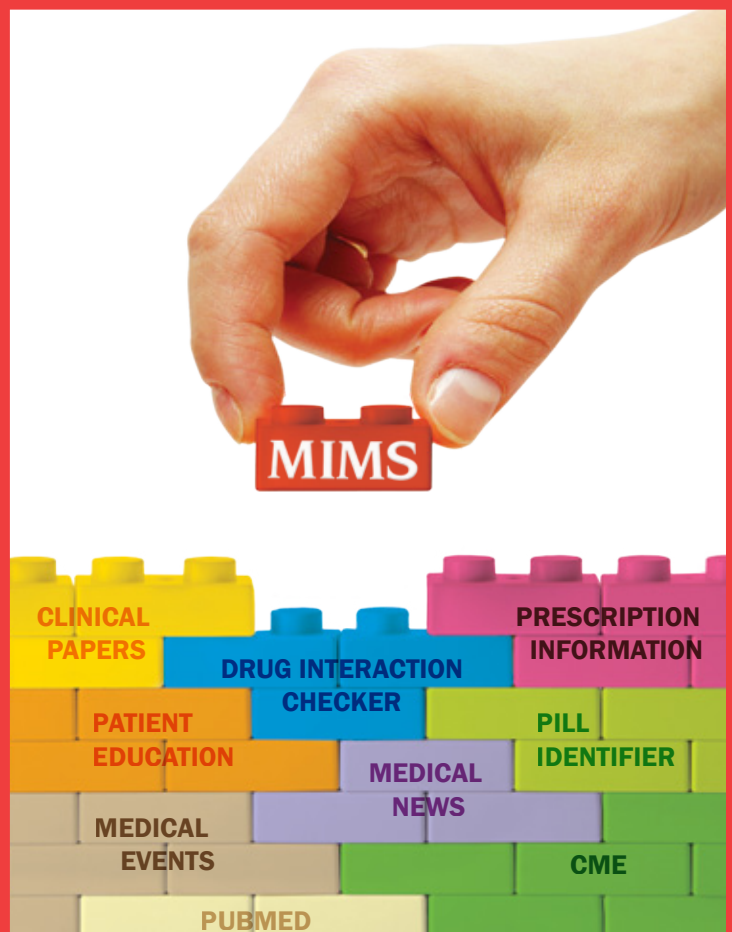
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Pemeriksaan pada inkontinensia uri

Hardini Arivianti

Proses berkemih merupakan hasil kerjasama antara kandung kemih, saluran di bawahnya dan dasar panggul. Persamaan antara pria dan wanita, hanya pada kandung kemih, sedangkan salurannya berbeda. Pria memiliki sfingter (otot polos) yang berguna untuk menahan proses berkemih, sedangkan wanita hanya memiliki otot dasar panggul yang dapat diperkuat oleh senam Kegel, salah satunya. Hal ini dikemukakan oleh Dr. dr. Nur Rasyid, SpU beberapa waktu lalu.

Proses penuaan, perubahan kadar hormon, kegemukan, riwayat persalinan, penyakit neurologis, diabetes merupakan beberapa faktor yang dapat mempengaruhi proses berkemih atau dapat menyebabkan inkontinensia. Inkontinensia terjadi bila urin keluar di saat yang tidak diinginkan dan kondisi ini dapat dialami oleh pria dan wanita.

Penyebab inkontinensia uri cukup banyak dan yang paling penting dokter harus tahu cara mendiagnosa dan tahu apa yang harus dilakukan selanjutnya, apakah dengan pemberian obat atau melakukan operasi. "Diagnosis akurat merupakan syarat keberhasilan terapi gangguan berkemih," lanjut dr. Nur Rasyid.

Dalam keadaan fisiologis, saat pengisian kandung kemih, kandung kemih harus dapat relaksasi dengan baik dan tekanan didalamnya pun tidak boleh naik. Bila tekanan tersebut meninggi, sudah dalam kondisi tidak normal. Selain itu, sfingter harus dapat menutup dengan baik. Pada individu dengan inkontinen,

begitu volume tertentu tidak bisa ditahan lagi. "Normalnya, kemih harus habis dan bila masih tersisa, dapat disebabkan oleh pompa kurang baik, adanya sumbatan, dll," tukasnya.

Ada 6 jenis inkontinensia uri, yaitu *stress incontinence*, *urge incontinence*, *over flow incontinence*, *mixed incontinence*, *nocturnal enuresis* dan *post micturition dribbling* dan *incontinencia continua*. Jenis yang bermacam-macam ini, lanjut dr. Nur Rasyid, memerlukan prosedur diagnostik yang akurat guna menentukan terapi yang tepat

Pemeriksaan klinik

Pemeriksaan yang dilakukan berupa uro-flowmetri dan urodinamik. Urodinamik, selain dapat menentukan terapi, juga dapat memprediksi hasil akhir terapi. Biasanya klinik urologi dilengkapi dengan alat uro-flowmetri, untuk memastikan diagnosis gangguan berkemih. Syaratnya jumlah urin yang keluar harus mencapai volume tertentu, biasanya sekitar 150 cc. Namun, alat ini memiliki kelemahan, hanya mencatat *maximum flow rate* dan tidak bisa memprediksi penyebabnya sehingga kadang pemeriksaan ini saja dapat menyebabkan 'over/undertreatment'.

Pada pasien dengan diabetes tidak dapat dipastikan apakah kelainannya disebabkan pompa kandung kemih yang buruk atau pancarannya yang melemah. Kondisi tersebut bisa disebabkan oleh striktur akibat penyakit hubungan seksual, radang uretra yang tidak diobati dengan tuntas. Bila hasil pemeriksaan tersebut masih meragukan, dokter perlu data obyektif

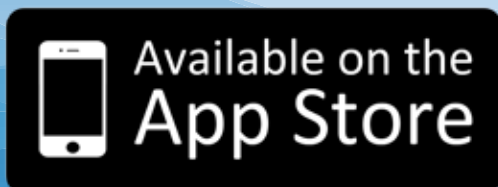
dari pemeriksaan urodinamik.

Untuk penatalaksanaannya, perlu dilakukan 3 hal yaitu terapi non-farmakologis, farmakologis dan pembedahan. Non farmakologis meliputi terapi perilaku yang mencakup diet, program latihan berkemih, latihan otot dasar panggul. Farmakoterapi bisa diberikan tergantung jenis inkontinensianya: antikolinergik untuk tipe *urge*,

golongan α adrenoreseptor agonis atau serotonin-noradrenalin reuptake inhibitor diberikan pada tipe stres, golongan parasimpatomimetik untuk tipe *overflow*, sedangkan golongan desmopresin diberikan pada *nocturnal enuresis*. Pada tipe stres dan urge, bila terapi perilaku dan farmakoterapi tidak berhasil, patut dipertimbangkan tindakan pembedahan. 

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Tantangan terapi pada HAP dan VAP

Hardini Arivianti

Diagnosis 'Hospital-Acquired Pneumonia' (HAP) – terutama 'Ventilator-Associated Pneumonia' (VAP) – tidaklah mudah, karena para klinisi seringkali menghadapi dilema untuk menentukan apakah hal tersebut merupakan infeksi atau non infeksi karena gejala tidak pasti. Dari aspek mikrobiologi juga tidak mudah, karena dalam kultur sering dihadapkan pada kolonisasi atau patogen, yang bisa menjadi masalah tersendiri.

"Kami berharap klinisi dan laboratorium – dalam hal ini mikrobiologi klinis – untuk bersama-sama menentukan pasien tersebut infeksi atau tidak dan memerlukan antibiotik. Harus diingat gejala non-infeksi juga bisa menyerupai gejala klinis pada HAP/VAP," jelas dr. Anis Karuniawati, SpMK, yang mengangkat topik 'How to Optimize Antibiotic Therapy in HAP/VAP Resistant Organisms' pada RESPINA ke -13. RESPINA kali ini bertemakan 'Bridging the Past and the Future in Respiratory Care'.

Sebagai etiologi, berbagai jurnal menyebutkan, pasien yang sudah menjalani terapi dengan antibiotik sebelumnya dan sudah lama dirawat di rumah sakit maka kemungkinan sudah terpapar mikroba-mikroba yang ada di rumah sakit, yang kemungkinan sudah resisten terhadap pengobatan.

Menurut data terbaru di Asia, kebanyakan mikroba penyebab HAP dan VAP tidak jauh berbeda. *P aeruginosa*, *S aureus*, *Acinetobacter spp* dan *K pneumonia* merupakan penyebab HAP. Sedangkan

VAP disebabkan oleh *Acinetobacter spp*, *P Aeruginosa*, *K pneumonia*, dan *S aureus*. Ada beberapa faktor yang dapat meningkatkan resistensi antimikroba pada HAP/VAP, yaitu pengobatan dengan antibiotik sebelumnya, lama rawat inap, penggunaan peralatan invasif, dan kontrol penggunaan antibiotik yang tidak adekuat. "Perlu diwaspadai bila menggunakan peralatan di rumah sakit terutama air untuk penguapan di ICU yang seringkali mengandung *P aeruginosa*," tukas dr. Anis.

Tujuan pemberian antimikroba adalah memastikan seleksi yang optimal yang meliputi dosis dan durasi yang mengarah pada hasil klinis yang terbaik. Penggunaan antimikroba yang tidak teratur tidak hanya memicu timbulnya resistensi, tetapi juga secara langsung dapat membahayakan pasien dengan meningkatkan risiko pasien terhadap efek samping. Selain itu, dokter perlu melakukan evaluasi terapi setiap hari agar tidak terjadi resistensi.

Saat memilih dan menentukan dosis atau cara pemberian, dokter juga harus perhatikan sifat antibiotik, yaitu 'concentration dependent', 'time dependent' dan efek persisten (kumulatif). 'Concentration dependent' dan 'time dependent', yang penting adalah waktu di atas MIC, dengan waktu lebih lama akan lebih bagus, contohnya adalah beta laktam.

Karbapenem memegang peran penting sebagai pengobatan pada infeksi berat. Sebagian besar obat ini efektif mengatasi

bakteri MDR gram negatif, seperti *P. Aeruginosa*, dan obat ini juga efektif pada pasien dengan *immunocompromised*.

Kebanyakan penyebab HAP dan VAP adalah mikroba yang multiresisten, itu sebabnya dokter harus memilih antibiotik. "Tidak semua HAP harus diterapi dengan karbapenem namun sebaiknya pertimbangkan penggunaan antibiotik sebelumnya dan juga pertimbangkan faktor lainnya seperti lama perawatan di rumah sakit, dan penggunaan alat invasif. Bila ada faktor tersebut, harus mengarah pada MDR."

Harus diingat, tidak semua MDR bisa menggunakan karbapenem. Yang penting antibiotik bukan satu-satunya alat eradikasi namun harus ingat sistem imun tubuh. Dokter perlu berhati-hati pemberian antibiotik pada pasien dengan *immunocompromised*. Pemberian karbapenem (termasuk dalam 'time dependent') secara *prolong infusion* (interval 8 jam atau 3 kali sehari) akan memberikan efek yang lebih bagus. Bila dibandingkan beta laktam lainnya (sefalosporin dan penisilin), karbapenem hanya memerlukan 40% dari waktunya untuk berada di atas MIC agar dapat mengeradikasi mikroba yang multiresisten.

Dokter perlu menggunakan hasil uji sensitivitas untuk menentukan terapi. Beberapa mikroba sudah menjadi resisten terhadap karbapenem akibat terlalu banyak digunakan. Mikroba penghasil karbapenemase tidak selalu menjadi patogen penyebab infeksi, namun bisa saja hanya kolonisasi yang tidak perlu diterapi. "Untuk mencegah resistensi, mohon para klinis untuk berhati-hati dan tidak sembarangan menggunakan karbapenem sehingga obat ini dapat

digunakan lebih lama," himbau dr. Anis.

Pemahaman konsep PK/PD sangat diperlukan agar pemberian terapi antibiotik menjadi tepat. Pertumbuhan patogen yang resisten dapat menimbulkan masalah tersendiri dalam pengobatan HAP/VAP sehingga peran karbapenem juga menjadi penting. Untuk jenis karbapenem yang baru – doripenem – bisa digunakan dengan infus dengan durasi 4 jam atau interval 3 kali sehari.

Pengobatan HAP

Sesuai dengan panduan, definisi HAP adalah pneumonia yang timbul ≥ 48 jam setelah masuk rawat inap di rumah sakit sedangkan VAP merupakan pneumonia yang timbul dalam waktu $> 48-72$ jam setelah dilakukannya intubasi. Sedangkan 'Healthcare Associated Pneumonia' (HCAP) meliputi HAP dan VAP. Pneumonia (HCAP) ini ditemukan pada pasien-pasien yang menjalani perawatan di fasilitas akut RS lebih dari 2 hari dan terinfeksi dalam waktu 90 hari, pasien yang mengunjungi rumah sakit atau fasilitas hemodialisa, sedang menjalani terapi imunosupresif atau perawatan luka setelah 30 hari terinfeksi. Hal ini dikemukakan oleh Prof. dr. Hadiarto Mangunnegoro, SpP(K), yang membahas 'Managing Challenge in Treatment of HAP'.

Risiko terjadinya VAP meningkat sekitar 20 kali lipat pada pasien-pasien dengan alat ventilator. Sedangkan HAP diperkirakan mencapai 25% terjadi pada infeksi ICU dan lebih dari 50% mendapatkan terapi antibiotik. Menurut Prof. Hadiarto, masalah HAP/VAP di Indonesia disebabkan beberapa hal, antara lain kontroversi dalam menentukan

diagnosis, pemberian antibiotik, strategi eskalasi, pemeriksaan mikrobiologi (yang memakan waktu) dan pemberian antibiotik yang terlambat. Mengenai patogen penyebab HAP, yang timbul lebih dari 5 hari (*late onset*), biasanya adalah pseudomonas, acinetobacter, dan MRSA.

Biasanya VAP dikaitkan dengan gram negatif. Mortalitas yang disebabkan oleh klebsiella biasanya lebih ringan dibandingkan akibat pseudomonas. "Maka bila terapi atasi pseudomonas tidak tepat maka angka kematian akan lebih tinggi dibandingkan dengan penyebab lainnya, seperti *S aureus* dan acinetobacter."

Bila dicurigai kemungkinan adanya VAP, perlu dilakukan pemeriksaan mikrobiologis (kultur dan pewarnaan) dan pengobatan antibiotik empirik (berdasarkan faktor risiko). Bila hasil mikrobiologis

gram positif atau MRSA, terapi dengan anti-MRSA. Namun bila gram negatif (misalnya *A baumannii*) diberikan karbapenem dan jika pseudomonas spp dapat diberikan antipseudomonas. Jika hasilnya tidak menunjukkan keduanya, dapat diberikan antibiotik dan berdasarkan epidemiologi setempat. Kesemua langkah ini perlu dievaluasi selama 48-72 jam.

Karbapenem, lanjut Prof Hadiarto, merupakan terapi inisial pada pasien yang berisiko terkena MDR terutama yang baru saja rawat inap, dirawat di *nursing home*, dan pasien rawat lama. Sebelum memutuskan penggunaan ventilator pada pasien PPOK, perlu dilakukan pengukuran terlebih dahulu. Lalu lihat pola resistensi antibiotik serta tetap harus mengikuti panduan klinis. 

Epilepsi, apa yang perlu diketahui?

Hardini Arivianti

Penyebab epilepsi seringkali dipertanyakan. Menurut dr. Lyna Soertidewi, SpS (K), MEpid, penyebab primernya idiopatik (77%) dan simtomatik (23%). Yang simtomatik dapat berupa serebrovaskular (5%), neoplasma susunan saraf pusat, malformasi kongenital SSP, trauma, infeksi SSP, lainnya (metabolik dan toksik), dan asfiksia lahir. Sedangkan berdasarkan etiologi dan usia, dr. Lyna menjelaskan, beberapa kategori epilepsi sebagai berikut cedera perinatal (saat lahir), defek metabolik, malformasi kongenital, infeksi (bisa sampai usia 20 tahun), epilepsi genetik (biasanya timbul pada usia sekitar 5 tahun-an), trauma

post-natal (bisa muncul sampai usia 20 tahun), tumor otak (20 tahun ke atas) dan penyakit vaskular (usia lanjut).

Epilepsi akan timbul bila terjadi bangkitan (*seizure*) yang bersifat intermiten, tiba-tiba dan berlebihan pada neuron serebral korteks. Karakteristik bangkitan/*seizure* tersebut onset tidak terduga misalnya saat tidur dan episode berulang dengan gambaran stereotipe. "Bila bangkitan itu terjadi pada kedua hemisfer akan terjadi gangguan kesadaran dan rekaman EEG nya tampak abnormal," tukasnya lebih lanjut.

Ada 2 prinsip kegiatan listrik dalam otak yaitu pembangkit (eksitatorik) dan penahan (inhibitorik) agar bangkitan listrik terjadi secara normal. Penyebab

timbulnya bangkitan di otak antara lain perubahan konsentrasi elektrolit (Na, K, Ca), asam amino eksitatorik (asam glutamat), asam amino inhibitorik (asam butirat), koneksi interneuron ireguler, dan koneksi struktur kortikal aferen (diensefalon, talamus, batang otak) yang abnormal. Semuanya ini diperlukan agar bangkitan listrik di otak berjalan dengan normal.

Jenis *seizure* dibedakan menjadi umum dan parsial. *Seizure* umum terdiri dari absensi, mioklonik, tonik-klonik, tonik, klonik dan atonik. Sedangkan *seizure* parsial terdiri dari simpel, kompleks dan umum sekunder. Serangan umum (primer) biasanya mengenai kedua belahan otak. Pada serangan umum sekunder, cetusan epilepsi pada mulanya lokal lalu menyebar yang mengakibatkan serangan umum. Bila terjadi hanya lokal saja, akan timbul serangan parsial.

Epilepsi katamenial

"Pada wanita dengan epilepsi bila mengonsumsi pil kontrasepsi, harus dikonsultasikan dengan dokter terlebih dahulu," tukas dr. Lyna. Obat anti epilepsi (OAE) yang terbaik bagi wanita dengan epilepsi adalah lini pertama dan monoterapi. Ada beberapa OAE yang merupakan *inducer* (atau inhibisi enzim P450) yang dapat berinteraksi dengan estrogen/progesteron. Progesteron adalah antikonvulsif dan estrogen adalah prokonvulsif.

Katamenial epilepsy dialami oleh wanita dengan epilepsi yang mengonsumsi pil kontrasepsi. Biasanya *seizure* terjadi secara eksklusif pada saat siklus menstruasi. Agar dokter mengetahui hal ini, wanita dengan epilepsi diminta untuk



membuat catatan kapan serangan itu datang. Hal ini disebabkan oleh hormonal terutama estrogen dan progesteron.

Bila wanita dengan epilepsi ingin hamil, dianjurkan untuk mengoptimalkan pengobatan sebelum terjadinya pembuahan dan harus dimonitor sebelum, selama dan sesudah kehamilan. Selama proses reproduksi dan kehamilan berlangsung, dapat diberikan asam folat ($> 0,4$ mg/hari).

Selama hamil, OAE perlu dievaluasi terutama karbamazepin, valproat dan divalproex dengan memeriksakan kadar alfa protein serum (minggu 14-16) dan USG pada minggu 16-20 biasanya dilakukan amniosentesis. Pada semester pertama dan akhir kehamilan perlu dimonitor ketaatan minum obat dan dapat diberikan vitamin K 10mg/hari pada akhir semester.

Pada anak

"Anak dikatakan epilepsi bila pernah mengalami kejang secara spontan 2 kali atau lebih. Kejang yang terjadi ini

disebabkan oleh aliran listrik pada otak. Saat aktivitas listrik pada sel-sel otak muncul secara berlebihan, maka akan terlihat gejala sebagai kejang,” jelas dr. Hardiono D Pusponegoro, SpA(K). Penyebabnya diperkirakan tidak diketahui, bisa berupa infeksi saat kehamilan, misalnya toksoplasmosis, CMV.

Selain kejang, aktivitas listrik itu juga menimbulkan gejala penyerta lainnya, seperti perubahan tingkah laku, perubahan kesadaran dan perubahan lainnya yang hilang timbul, baik terasa atau terlihat. Hal ini berbeda pada usia remaja yang tidak pernah memiliki riwayat sebelumnya, dengan sakit kepala hebat yang berlangsung lama dan tidak sembuh-sembuh, kemungkinan hal ini disebabkan oleh tumor pada otak.

Kejang demam berbeda dengan epilepsi. Kejang demam atau yang dikenal dengan ‘step’ ini, didahului oleh demam dan hanya terjadi pada anak-anak hingga usia 5 tahun.

Pengobatan

Bila terjadi kejang sekali – walau spontan – belum dapat dikatakan/didiagnosis sebagai epilepsi, dan biasanya tidak diberikan obat kecuali ada hal-hal tertentu. Namun bila kejang sudah 2 kali pun dengan jarak lebih dari 6 bulan, juga seringkali tidak diberikan pengobatan karena sulit menilai efek obat tersebut.

Menurut dr. Hardiono, dengan memberikan sedikit obat maka makin bagus hasilnya. Pemberian monoterapi, diperkirakan 70% bebas serangan dan 30% perlu tambahan bila kejang masih terjadi setelah diberikan pengobatan. Politerapi ini memberikan peluang perbaikan pada 40% dan peluang sembuh

lebih kecil.

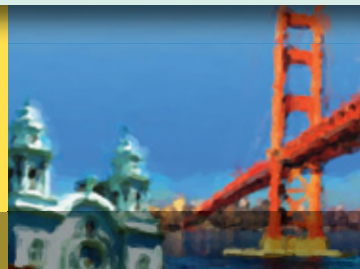
Obat lini pertama adalah Fenobarbital (dengan efek samping berupa hiperaktif), fenitoin (efek samping kosmetik, bila gigi tidak dirawat dengan baik makan akan timbul penebalan gusi, ataksia), karbamazepine (efek samping pada awal pengobatan timbulkan alergi berat), dan valproate (pemberiannya tidak boleh digerus karena tablet ini bersifat hidroskopis, nafsu makan meningkat, dan diberikan 2-3x/hari, gangguan hati)

Obat lini pertama ini efeknya bagus dan efek sampingnya lebih mudah dikontrol. Pada epilepsi yang menimbulkan gejala kelojotan, hampir semua obat sama baiknya, hanya saja dipertimbangkan dari segi harga dan efek samping. Sedangkan pada epilepsi parsial, pilihannya adalah karbamazepin. “Untuk pilihan ini sebenarnya dilihat dari ketersediaan obat, ada tidaknya efek samping, dan harga,” lanjut dr. Hardiono.

Bila setelah pengobatan dalam waktu 2-3 tahun anak bebas kejang, maka obat dapat dihentikan dan diperkirakan 70% tidak kejang kembali. Namun penghentian obat ini ada syaratnya, obat dikurangi secara perlahan dan tidak boleh berhenti mendadak, karena anak dapat mengalami serangan kejang yang hebat. Kurangi perlahan-lahan dalam waktu 3 bulan. Setelah obat dihentikan, 60-75% anak tetap bebas kejang dan 25-40% kejang lagi (50% dalam 6 bulan pertama dan 60-80% dalam 1 tahun). Bila kejang terjadi lagi, maka obat akan diberikan lagi. Anak dengan epilepsi perlu pantang 2 hal, tukas dr. Hardiono, yaitu tidak boleh berenang dan naik sepeda di jalan raya tanpa pengawasan.

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Tel : 021-70726355, 4705684,
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Email : pipkraparu@yahoo.com

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Sekr : Divisi Endokrinologi
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Dalam UnSyiah/RSUD
Dr. Zaenal Abidin

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Fax : 0651-26090

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Niacin trial sparks controversy



The AIM-HIGH trial raises more questions about the benefits of niacin in heart patients.

Radha Chitale

Large doses of extended-release niacin, a lipid agent shown to increase “good” high-density lipoprotein (HDL) cholesterol levels, had no effect on cardiovascular events or stroke in patients with stable chronic heart disease who were already on statin therapy in the AIM-HIGH* trial.

Unexpectedly, patients treated with niacin had a higher rate of ischemic stroke compared with a placebo group (1.6 percent versus 0.9 percent, respectively) over 32 months of follow-up.

Consequently, the trial was deemed futile and discontinued 18 months earlier than scheduled after a mean 3 years of follow-up.

“If you are able, as a patient with stable,

nonacute cardiac disease, to maintain the levels of [low density lipoprotein, LDL] control that we did in the study, ie, in the low 60s, then there is not evidence from this trial to support continued use of niacin for the purpose of reducing further clinical events,” said lead AIM-HIGH researcher Dr. William Boden of the State University of New York at Buffalo in New York, US.

The AIM-HIGH trial included 3,414 patients with established cardiovascular disease (CVD), well-controlled LDL cholesterol levels (less than 180 mg/dL) and low baseline HDL who were randomized to receive 1500-2000 mg/day niacin or placebo, plus 40-80 mg/day simvastatin with 10 mg ezetimibe per day as necessary to maintain low LDL cholesterol levels. [*N Engl J Med* 2011 Nov 15. Epub ahead of print]

A majority of patients in the AIM-HIGH trial had taken statins prior to trial entry and 20 percent had taken niacin previously.

Patients in the niacin arm improved their HDL, LDL and triglyceride levels compared to patients on placebo (25 percent increase, 12 percent decrease and 28.6 percent decrease versus 9.8 percent increase, 5.5 percent decrease and 8.1 percent decrease, respectively).

But composite primary endpoints – death from coronary heart disease, nonfatal myocardial infarction, ischemic stroke, hospitalization for acute coronary syndrome or symptom-driven coronary or cerebral revascularization – occurred at nearly identical rates between the niacin- and placebo-treated groups (282 [16.4 percent] versus 274 [16.2 percent], $P=0.79$ by the log-rank test).

The researchers also reported a non-significant trend towards ischemic stroke among niacin-treated patients compared to placebo (27 patients, 1.6 percent versus 15 patients, 0.9 percent; $P=0.11$), some of which occurred between 2 months and 4 years after discontinuing niacin.

There is no previous evidence for an association between niacin and stroke.

The AIM-HIGH trial raises larger questions about the relevance of niacin therapy for cardiovascular disease in general.

Since the description of its favorable effects on lipid levels in the 1950s, no contemporary research has shown added benefits of niacin in heart patients in the wake of therapies such as aspirin, beta-blockers, statins and defibrillators that are proven to reduce morbidity and mortality after heart attack.

However, there is no definitive evidence

against niacin therapy either.

Discussant Dr. Philip Barter of the University of Sydney in Australia was “[disturbed] greatly” that the design and power of the AIM-HIGH trial was insufficient to determine the effects of niacin.

“The trial probably would have needed to go on for 15 to 20 years to be able to draw any conclusions,” he said, citing the ambitious 25 percent reduced event rate goal.

In an accompanying editorial, Dr. Robert Giugliano noted that the “disappointing” results of the AIM-HIGH trial fail to support the expenses of an add-on therapy of uncertain benefit in chronic CHD patients with well-controlled LDL. [*N Engl J Med* 2011 Nov 15. Epub ahead of print]

However, cardiologists are not in favor of discontinuing niacin therapy, which may have some merits, in patients who need it. Barter said that it would be in the public’s health disinterest to assume that a lack of evidence for niacin’s efficacy to reduce cardiac events indicates that it has no benefits.

Giugliano noted that it would be prudent to await results from larger trials designed and powered to answer questions about the benefits of niacin, particularly the Heart Protection Study 2: Treatment of HDL to Reduce the Incidence of Vascular Events (HPS2-THRIVE) trial, results from which are expected in 2012, before altering treatment strategies.

“I do not believe our practice should change until we see the results of this much larger [HPS2-THRIVE] trial,” Barter said. “[However], if that trial doesn’t show a positive effect, niacin is finished.”



**AIM HIGH: Atherothrombosis Intervention in Metabolic Syndrome with Low HDL/High Triglycerides: Impact on Global Health*

FDA approves new indication for rivaroxaban

Elvira Manzano

The US Food and Drug Administration has approved new anti-clotting drug rivaroxaban (Xarelto®) for use in the prevention of stroke in patients with non-valvular atrial fibrillation (AF) or abnormal heart rhythm.

The approved dose is 20-mg once daily, or 15-mg once daily for patients with moderate to severe renal impairment, taken with the evening meal.

The approval is largely based on the results of the ROCKET-AF* trial which showed that rivaroxaban was non-inferior to warfarin in preventing stroke and non-central nervous-system embolism in patients with AF.

AF is one of the most common types of abnormal heart rhythm. The condition can lead to formation of blood clots which can break off and travel to the brain and block blood flow, resulting in stroke.

"This approval gives doctors and patients another treatment option for a condition that must be managed carefully," said Dr. Norman Stockbridge, director of the Division of Cardiovascular and Renal Products in the FDA's Center for Drug Evaluation and Research.

The FDA however warned that, as with other anti-clotting drugs, rivaroxaban can cause bleeding that can lead to death in rare instances. Bleeding was the most common adverse event patients reported in the ROCKET-AF trial. Although there were less intracranial and fatal bleeding events with rivaroxaban, more bleeding into the stomach and intestines was reported.

As a safety concern, the FDA said the drug's label will include a boxed warning that people should not discontinue taking rivaroxaban



Rivaroxaban is now FDA approved for stroke prevention in non-valvular AF patients.

without talking to a healthcare professional. Discontinuing the drug can increase the risk of stroke.

The agency also requires the drug manufacturer to include a medication guide describing the risks and adverse reactions associated with rivaroxaban.

Moreover, advisors for the European Medicines Agency (EMA), the Committee for Medicinal Products for Human Use (CHMP), has also issued a positive opinion for rivaroxaban in the prevention of stroke and systemic embolism in non-valvular AF.

In July this year, rivaroxaban was approved for use in the prophylaxis of deep vein thrombosis (DVT) and pulmonary embolism in patients undergoing knee or hip replacement surgery. It is one of the three new oral anti-coagulants developed in recent years as an alternative to warfarin which has been around for 60 years. Dabigatran is FDA-approved while apixaban will be submitted for approval this year.

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**ROCKET-AF: Rivaroxaban Once Daily Oral Direct Factor Xa Inhibitor Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation*



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Higher blood clots risk with drospirenone pills

Rajesh Kumar

Regular use of drospirenone-containing oral contraceptives is linked to a higher risk of deep vein thrombosis and pulmonary embolism, according to research.

An analysis of data from 329,995 women in Israel aged 12 to 50 years who received oral contraceptives between January 2002 and December 2008 identified a total of 1,017 thrombotic events in 431,223 total use episodes over a follow-up period lasting until 2009. [CMAJ 2011. DOI:10.1503/cmaj.110463]

“The use of drospirenone-containing combined oral contraceptives was associated with a significantly increased risk of venous thrombotic events (deep vein thrombosis and pulmonary embolism) but not arterial thrombotic events (transient ischemic attack and cerebrovascular accident), relative to use of second or third-generation combined oral contraceptives,” said lead author Dr. Naomi Gronich of the pharmacoepidemiology and pharmacogenetics unit at the Clalit Health Services headquarters in Tel Aviv, Israel.

The risk was the highest in the early months of use.

All oral contraceptives are associated with a higher risk of blood clots, but the information about the risk of adverse events with drospirenone has been conflicting.

The prescribing of drospirenone-containing pills is on the rise as these pills are marketed as causing less weight gain and edema than other birth control pills. The authors said it is therefore important to raise awareness of the increased, albeit small, risk of venous thromboembolism compared to



the third-generation pills, especially among those who are older or obese.

“The study adds further evidence of a higher relative risk of venous thromboembolism among women taking this type of oral contraceptive, relative to the alternatives of either third- or second-generation oral contraceptives,” said Dr. Susan Solymoss of McGill University, Canada, in a related commentary.

Recent studies of drospirenone have shown a higher risk of blood clots compared with earlier articles that did not identify an elevated risk, Dr. Solymoss noted.

Older age, high blood pressure, high cholesterol, cancer and obesity were also risk factors for blood clots.

Earlier this year, a study funded by the US Food and Drug Administration (FDA) warned of the increased risk of blood clots linked to the same contraceptive pills. The FDA was scheduled to discuss the risks and benefits of these contraceptives at a meeting of the reproductive health drugs advisory committee and the drug safety and risk management advisory committee on Dec. 8. [<http://tinyurl.com/3fwbd22>]

Diabetes causes decline in cognitive function

Leonard Yap

The brain is not usually thought to play much of a role in diabetes, but recent research is debunking this perception, says an expert.

Insulin receptors in the brain serve many functions; some have a role in glucose transport, but many are thought to be involved in cognitive processes. It is suggested that cognitive decline is a consequence of reduced insulin action in the brain. In individuals without diabetes, poor glucose regulation has been associated with poorer outcomes in cognitive assessment, especially in the elderly, said Dr. Harold E. Lebovitz, a professor of medicine, division of endocrinology, State University of New York Health Science Center, Brooklyn, US. [*Diabetes Care* 2009;32(2):221-6]

New studies indicate that the brain possesses its own insulin receptors, located on the surface of brain cells, and that they play a bigger role in normal glucose control than once believed, said Lebovitz, at the Diabetes Asia 2011 Conference organized by the National Diabetes Institute recently.

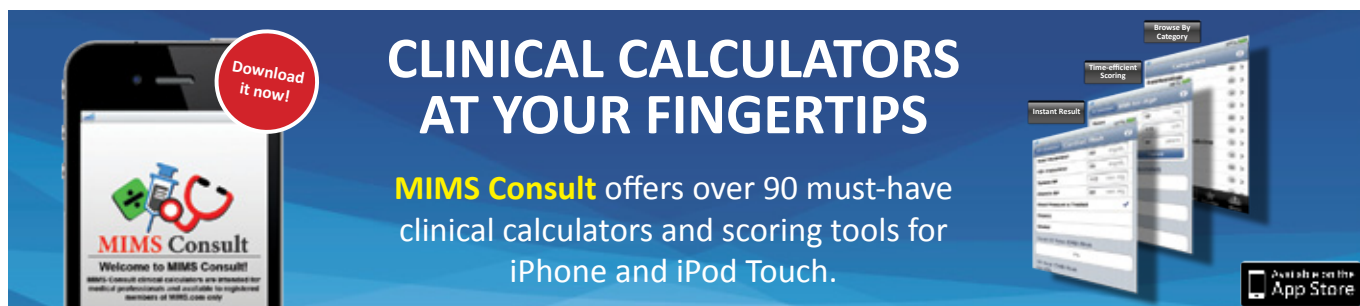
The Action to Control Cardiovascular Risk in Diabetes-Memory in Diabetes

(ACCORD-MIND) trial found a statistically important age-adjusted association between HbA_{1c} levels and cognitive test scores, with a significant reduction in cognitive function for every 1 percent increase in HbA_{1c}. The study also found that fasting plasma glucose levels did not affect performance in the cognitive tests. [*Diabetes Care* 2009;32(2):221-6]

Diabetes has been shown to be associated with moderate cognitive deficiencies, and displays significant structural and neuronal changes in the brain, best described as accelerated brain aging. The risk of dementia in the elderly is increased significantly if they have diabetes. [*Eur J Pharmacol* 2002;441(1-2):1-14]

“Chronic hyperglycemia causes progressive loss of brain function ... therefore, we have another reason why we want tight control of diabetes,” he said. “We know that one of the major problems in our society is the number of older people who have dementia. The cost to society for taking care of people with dementia is enormous ... therefore, anything that we can do to improve the quality of brain function in this very large population of diabetics is indeed critical.”

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Individualized approach to mammography screening recommended in Asia

Elvira Manzano

Although screening with mammography has been shown to reduce breast cancer deaths in western countries, its utility in Asia remains a challenge, says one expert.

“Several issues including high interval cancer, poor sensitivity, overdiagnosis and low cost-effectiveness hamper breast cancer screening in Asia,” said Professor Hsiu-Hsi Chen from the Institute of Epidemiology and Preventive Medicine, National Taiwan University in Taiwan. “To solve these problems, it may be appropriate to shorten inter-screening interval from 3 years to 2 years or from 2 years to 1 year, start screening at an early age or use multiple detection modalities.”

Many studies support the use of multiple detection modalities and intensive screening to reduce interval cancer and advanced breast cancers. In a US study, adding a single screening ultrasound to mammography yielded an additional 1.1 to 7.2 cancers per 1,000 high-risk women but substantially increased the number of false positives in women with heterogeneously dense breast tissue. [*JAMA* 2008; 299:215-2163]

In a multicenter study in the UK, screening with both contrast enhanced magnetic resonance imaging (CE MRI) and mammography was able to diagnose 35 cancers in women with strong family history of breast cancer. In this

study, CE MRI is more sensitive than mammography in detecting cancer ($P=0.01$). [*Lancet* 2005;365:1769-78]

The incidence of breast cancer in Asian countries is low compared to western countries. “This makes mass screening costly,” Chen said. “The threshold of annual incidence rate is 2 for every 1,000 person-years given the willingness to pay (WTP) at around \$20,000.”

Another issue, Chen said, is the age to commence screening. The majority of breast cancer cases happen to women older than 50 and the evidence does not support routine screening in younger women who may be forced to undergo unnecessary procedures because of a false-positive test.

However, the incidence of breast cancer in Asian women younger than age 40 appears to be higher than their western counterparts. In Taiwan, 29.3 percent of oriental women with breast cancer were under age 40 while in Singapore, 13.6 of women with breast cancer were younger than 40. [*Breast Cancer Res Treat* 2000;63:213-223; *Singapore Cancer Registry Report* 1999; no.5]

The American Cancer Society recommends yearly mammograms starting at age 40 and continuing for as long as a woman is in good health. Clinical breast exam (CBE) every 3 years for women in their 30s and 20s and every year for women 40 and older is also recommended. Breast self-exam (BSE)

is an option for women in their 20s. For women with strong family history of breast cancer or genetic tendency, screening with MRI in addition to mammogram, is advised.

As mammography is costly, the World Health Organization (WHO) however recommends CBE as an early detection strategy for low-and middle-income countries.

In Taiwan, the breast cancer screening policy has evolved from selective mammographic screening within a high-risk group to a mass screening with physical examination by public health nurses, and finally to a two-stage screening with a risk assessment followed by mammography for

moderate-to-high-risk group. “Two-stage mammography screening had the most favorable results compared with the two previous screening regimes. This suggests that the two-stage model is appropriate in a low to medium risk country such as Taiwan,” Chen said.

Early detection to improve breast cancer outcome and survival is the cornerstone of breast cancer control. “Mammography is beneficial. Multiple detection modalities and intensive screening may detect advanced cancer, however it may not be cost-effective in Asian countries,” Chen said. “Individually-tailored screening is therefore recommended,” he concluded. 

Second phase of ACTION study launched

Elvira Manzano

The George Institute for Global Health, an internationally-recognized health research institution, recently launched Phase II of the ASEAN CoTs In Oncology (ACTION) study on the economic and social impact of cancer in eight ASEAN member states.

To mark the launch, 120 investigators, physicians and nurses from across the region will participate in a 2-day field training, to be followed by patient recruitment from each of the eight participating ASEAN countries – Malaysia, Cambodia, Indonesia, Laos, Myanmar, Philippines, Thailand and Vietnam.

The study will involve 10,000 cancer patients. Follow-up period is 1 year.

Participants will be given a set of questionnaires and a cost diary to assess the economic impact of the disease on households, management and costs of treatment, and the social and quality of life impact on patients.

“The ASEAN Foundation recognizes the impact of cancer on the economic and social health and wellbeing on households, communities and countries. We are pleased The George Institute for Global Health is acting now to implement Phase II of the ACTION study,” said Dr. Makarim Wibisono, executive director of the ASEAN Foundation, during the launching which follows from the ASEAN Cancer Stakeholders Forum co-organized by the ASEAN Foundation, George Institute and Roche in Singapore recently. 

Poly pharmacy linked to ED



The more medications a man takes, the higher the potential risk and severity of ED.

Rajesh Kumar

Poly pharmacy can lead to erectile dysfunction (ED), the incidence and severity of which increases with the number of medications, according to a study.

Researchers analyzed pharmacy record data of 37,712 ethnically diverse men aged 46 to 69 from California, US, who were on three or more medications between 2002 and 2003. [BJUI 2011. Nov 15. DOI: 10.1111/j.1464-410X.2011.10761.x]

They found that the more medications the patients were taking, the higher the incidence and severity of their ED. Of the 16,126 men taking up to two medications, the rate of ED was 15.9 percent across all age groups, increasing to 30.9 percent among 4,670 men who were taking 10 or

more medications.

A dose-response relationship was observed, in which worsening degrees of ED were seen when a greater number of medications were taken, regardless if they were prescribed or over-the-counter, said lead author Diana Londoño, urologist at Kaiser Permanente Los Angeles Medical Center in Los Angeles, California, US.

“A crucial step in the evaluation of ED would be to review the current medications the patient is taking and their potential side effects. When appropriate, decreases or changes in the amount or type of medication should be considered,” said Londoño, while explaining the clinical relevance of the findings for GPs.

Singapore urologist Dr. Peter Lim said the link between poly pharmacy and ED severity is already well-established, but agreed it may get overlooked due to the time constraints of a busy general practice. The study, therefore, serves as a reminder to GPs, said Lim.

The most common medications associated with ED included antihypertensives (beta-blockers, thiazides, and clonidine) and psychogenic medications such as selective serotonin reuptake inhibitors, tricyclic antidepressants, lithium, monoamine oxidase inhibitors, and any medication which can interfere with testosterone pathways.

ED was also associated with older age, higher body mass index, diabetes, high cholesterol, hypertension, depression, and being a current or past smoker. Even after taking these conditions into account, the relationship between multiple medications and ED persisted.

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Drinking any amount of alcohol detrimental to the gut

Rajesh Kumar

Drinking alcohol even in moderation may cause gastrointestinal symptoms including bloating, gas, abdominal pain and diarrhea associated with bacterial overgrowth in small intestines, according to a new study.

The findings put a damper on previous research highlighting moderate alcohol drinking's cardioprotective effects, at least in middle-aged men.

The retrospective study, which reviewed the charts of 198 patients who underwent lactulose hydrogen breath testing (LHBT), found that any current alcohol consumption was significantly associated with small intestinal bacterial overgrowth (SIBO). The findings were recently presented at the American College of Gastroenterology's 76th annual scientific meeting held in Washington, DC, US.

Of the 198 patients in the study, 95 percent drank just one or two drinks a day (sometimes less than one drink per day), said lead researcher Dr. Scott Gabbard, a fellow at the Dartmouth-Hitchcock Medical Center and the Mayo Clinic in Lebanon, New Hampshire, US.

The findings indicate consumption of even the slightest amount of alcohol could have an impact on gut health, said Gabbard, adding that any alcohol consumption is a strong predictor of a positive LHBT and SIBO. Smoking or the use of proton pump inhibitors were factors not associated with an increased risk.

Similar earlier studies have focused on



Alcohol cessation may be therapeutic for patients with SIBO who cannot absorb sufficient nutrients in their gut.

alcoholics with gastrointestinal symptoms who were found to have high rates of SIBO, but it is the first time the researchers have looked at the relationship between moderate alcohol consumption and this potentially harmful condition.

SIBO is a condition where abnormally large numbers of bacteria proliferate in the small intestine and use up many of the body's nutrients for their own growth. As a result, a person with SIBO may not absorb enough nutrients and become malnourished. The breakdown of nutrients by the bacteria in the small intestines can produce gas and lead to a change in bowel habits.

"While typical treatment for SIBO has been antibiotics, probiotics or a combination of the two, the question now becomes what is the exact association between moderate alcohol consumption and SIBO and whether alcohol cessation can be used as a treatment for [SIBO]," said Gabbard.

Video games help improve lazy eye

Amblyopia, or lazy eye, can be improved in many older children if they regularly play shooting and car racing video games keeping only their affected eye open, alongside standard treatment, according to a study.

The findings challenge the current wisdom that if amblyopia is not diagnosed and corrected before the child reaches school age, it is difficult or impossible to correct.

The study involved 100 patients aged between 10 and 18 years equally divided in four groups, who followed a basic treatment plan involving eyeglasses that blocked the stronger eye for at least 2 hours a day. During this time, they practiced exercises using the weaker eye.

Group 1 followed only this basic plan and served as the control group. Meanwhile, groups 2, 3 and 4 received additional treatments in the form of an antioxidant for good vision, at least 2 hours of shooting and car racing video games daily using only the weaker eye, or citicoline, a supplement believed to improve brain function.

A year later, nearly 30 percent of participants had achieved significant vision gains and about 60 percent showed at least



Two hours of playing video games daily improved eye muscle strength in children with amblyopia.

Orlando, Florida, US.

The US-based Pediatric Eye Disease Investigation Group (PEDIG) earlier reported significant vision gains in 27 percent of older children. Ghosh said this prompted him to

“ The cooperation of the patient is very important, maybe even crucial, to successful treatment of amblyopia

some improvement, said lead researcher Dr. Somen Ghosh of Dr. Ghosh's Clinic in Calcutta, India.

Significant gains were more likely in children in groups 3 or 4. Also, improvement was more likely in children younger than 14, said Ghosh. The findings were released at the 115th Annual meeting of the American Academy of Ophthalmology recently held in

test new approaches and learn what might be particularly effective for them.

“The cooperation of the patient is very important, maybe even crucial, to successful treatment of amblyopia,” said Ghosh. “We should never give up on our patients, even the older children, but instead offer them hope and treatment designed to help them achieve better vision.”

— RK 

No cell phone-brain cancer link, study finds

Elvira Manzano

Recent research out of Denmark suggests that cell phones do not increase the risk of brain cancer.

No link between central nervous system tumors or brain cancer and the long-term use of mobile phones was detected in the 17-year study. In fact, people using mobile phone for 13 years or more faced the same cancer risk as non-subscribers. This finding is consistent with a growing body of evidence from many large trials that even heavy cell phone users do not get cancer. [*BMJ* 2011 Oct 19; 343:d6387. doi: 10.1136/bmj.d6387]

“There was no indication of dose-response relation

either by years since first subscription for a mobile phone or by anatomical location of the tumor – that is in regions of the brain closest to where the handset is usually held to the head,” said lead author Dr. Patrizia Frei from the Institute of Cancer Epidemiology, Danish Cancer Society, Copenhagen, Denmark.

The study comes on the heels of a report released by the World Health Organization’s International Agency for Research on Cancer which found that mobile devices may increase the risk of developing glioma, a type of brain cancer. Although the report did not claim cell phones cause cancer, the scientists

called for more research to draw conclusions about its health effects. [*Lancet Oncol* 2011;12:624-6]

Still, epidemiologists have said that the bulk of the evidence has shown that cell phone use does not cause cancer. Earlier results from the Danish study found no increased risk of brain cancer or any type of cancer among cell phone subscribers from 1982, the year mobile phones were introduced in Denmark, until 1995.

Although the recent trial data are reassuring, the investigators noted that the study focused on cell phone subscriptions rather than actual cell phone use, thus debates on cell phone safety are unlikely to settle. Another weakness of the study is that they excluded corporate subscriptions. All these factors could have diluted any association between cell phone use and cancer risk and limit the interpretation of the findings.

Moreover, as a small-to-moderate increase in risk of cancer among heavy users of cell phones for 10 to 15 years or longer “cannot be ruled out,” further studies with large study populations are warranted, said the authors.

Meningioma, the most common type of primary brain tumor, accounts for approximately 30 percent of all tumors. About 85 percent of meningiomas are benign and can be removed entirely by surgery, though, rarely, a meningioma may be malignant. Gliomas, on the other hand, are rarely curable and the prognosis for patients with high-grade gliomas is generally poor.

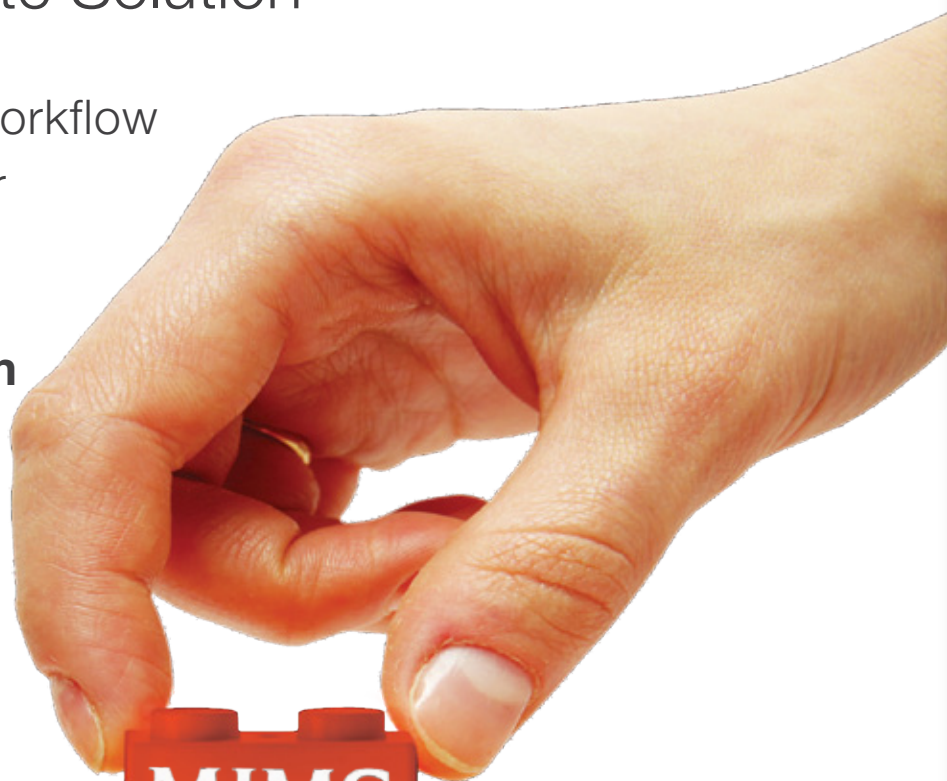
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High-dose statins impress in SATURN

Elvira Manzano

Rosuvastatin and atorvastatin are both significantly effective in reversing the progression of coronary artery disease, when administered at high doses, suggests new data from the SATURN* study.

In this large-scale multi-center trial which involved 1,385 patients, rosuvastatin 40 mg/day or atorvastatin 80 mg/day produced similar regression in the buildup of cholesterol plaques in the coronary artery walls (atherosclerosis) after 24 months of treatment.

Clinic Coordinating Center for Clinical Research, Cleveland, Ohio, US. There were few adverse events observed during the study and no patients experienced serious muscle injury.

“Doctors have been reluctant to use high doses of statins but in this study, the drugs were safe, well-tolerated and had a profound impact on lipid levels, the amount of plaque in vessel walls and the number of cardiovascular events,” he added.

Nicholls said that while statins have consistently reduced cardiovascular events in large

“ I see the removal of the disease from the artery wall that ultimately causes the clinical event as a very reassuring extra benefit

Patients who received rosuvastatin had lower low-density lipoprotein (LDL) cholesterol levels and higher high-density lipoprotein (HDL) cholesterol levels compared with patients treated with atorvastatin (62.6 versus 70.2 mg/dL, $P < 0.001$; 50.4 versus 48.6 mg/dL, $P = 0.01$ respectively). These differences however did not result in a significant incremental effect on disease regression, as assessed according to the primary intravascular ultrasonographic end point (PAV).

Intravascular ultrasound (IVUS) showed a 0.99 percent decrease in plaque burden with atorvastatin and a 1.22 percent decrease with rosuvastatin, with no statistically significant differences between the regimens ($P = 0.17$).

“The differences between the two drugs were modest and the difference in HDL levels was less than we were anticipating based on previous studies,” said Dr. Stephen Nicholls, cardiovascular director of the Cleveland

randomized controlled trials, no study has compared the effects of maximal dosages of statin regimens on progression of coronary atherosclerosis. This prompted researchers to conduct the SATURN trial.

“SATURN demonstrates that the highest doses of the most effective statins currently available is safe, well-tolerated and produces marked plaque regression,” said Nicholls. “If you’re looking for benefit, I see the removal of the disease from the artery wall that ultimately causes the clinical event as a very reassuring extra benefit for the doses of these agents.”

The finding that nearly one-third of patients continue to progress however supports the need to develop additional anti-atherosclerotic therapies, he added.

Meanwhile, discussant Dr. Darwin Labarthe, from the Northwestern University Feinberg School of Medicine, Chicago, Illinois, US said the results of SATURN were inconclusive.

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While IVUS showed a regression of atherosclerosis, he said the direct implication for clinical practice is unknown.

MT

**SATURN: Study of Coronary Atheroma by Intravascular Ultrasound: Effect of Rosuvastatin versus Atorvastatin*

ATLAS trial: Low-dose rivaroxaban reduces mortality rate in ACS patients

Adding low-dose rivaroxaban, a direct factor Xa inhibitor, to standard therapy after a myocardial infarction or unstable angina significantly reduced the risk of a repeat heart attack, stroke or death, according to the results of the ATLAS ACS TIMI 51* study.

In the trial, patients treated with rivaroxaban 2.5 mg twice daily were 34 percent less likely to die from cardiovascular disease (CVD) than patients in the placebo group (HR 0.66; 95% CI 0.51 to 0.86; $P=0.002$) and 32 percent less likely to die from any cause (HR 0.68; 95% CI 0.53 to 0.87, $P=0.002$), a survival benefit not seen with the twice-daily 5 mg dose.

Both doses were associated however with increased rates of bleeding. "Compared with placebo, the two doses of rivaroxaban increased the rates of major bleeding and

bleeding were similar for both groups.

In each case, however, bleeding rates were lower in the 2.5 mg group than in the 5 mg group (0.1 percent versus 0.4 percent, $P=0.04$).

The study involved more than 15,000 patients with a recent heart attack or unstable angina randomized to twice daily doses of either 2.5 mg or 5 mg of rivaroxaban or placebo for a mean of 13 months and up to 31 months. [*N Engl J Med* 2011 Nov 13; Epub ahead of print]

Many large trials have shown rivaroxaban's ability to reduce stroke in atrial fibrillation patients but its use in patients with ACS has had mixed results. As patients are often on other anti-clotting medications, the bleeding risk has been very high.

"Our findings are important because

66 Blocking the production of thrombin is an important new way to improve coronary syndrome patients' long-term risk of death

intracranial hemorrhage, without a significant increase in fatal bleeding," the authors said.

Major bleeding rate not related to coronary artery bypass grafting (CABG) was 2.1 percent for rivaroxaban versus 0.6 percent for placebo (HR 3.96; 95% CI 2.46 to 6.38; $P<0.001$); intracranial hemorrhage rate was 0.6 percent vs 0.2 percent (rivaroxaban vs placebo, $P=0.009$), whereas rates of fatal

blocking the production of thrombin is an important new way to improve coronary syndrome patients' long-term risk of death, stroke and heart attack after being hospitalized with an ACS," said principal investigator Dr. Michael Gibson, from the Harvard Medical School, Cambridge, Massachusetts, US.

Patients with ACS experience chest pain that radiates to the left arm and the left

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angle of the jaw, diaphoresis, nausea and vomiting, and shortness of breath. Some may report palpitations, anxiety or a sense of impending doom and a feeling of being acutely ill. Despite best efforts at treatment following heart attack or unstable angina, patients still face a 10 percent or higher risk of a repeat heart attack, stroke or death 1 year later, said Gibson.

“The addition of very low-dose

anticoagulation [rivaroxaban 2.5 mg bid] to anti-platelet therapies represents an effective new treatment strategy to reduce cardiovascular events in patients with a recent ACS,” he concluded.

– EM 

**ATLAS ACS TIMI 51 = Anti-Xa Therapy to Lower Cardiovascular Events in addition to Standard Therapy in Subjects with Acute coronary Syndrome*

Vorapaxar not ready for use in heart patients

Radha Chitale

A first-of-its class oral antithrombotic agent failed to reduce serious cardiovascular events in patients with non-ST-segment elevation acute coronary syndrome (NSTEMI ACS) while significantly increasing the risk of major bleeds in a large, multinational trial.

The Thrombin Receptor Antagonist for Clinical Event Reduction in Acute Coronary Syndrome (TRACER) trial was halted in January 2011 after an unplanned safety evaluation showed increased intracranial bleeding in stroke patients treated with vorapaxar compared to placebo.

Following analysis, ACS patients treated with the protease-activated receptor-1 inhibitor experienced a 35 percent increase in the relative risk of intracranial bleeding compared to placebo. [*N Engl J Med* 2011 Nov 13. Epub ahead of print]

The drug did not reduce the risk for any of five primary endpoints: cardiovascular death, myocardial infarction, stroke, recurrent ischemia with rehospitalization and urgent coronary revascularization.

“The addition of vorapaxar to standard therapy... is not a viable strategy as was used in the trial,” said Dr. Robert Harrington, director of the Duke Clinical Research Institute in Durham, North Carolina, US and chair of the TRACER steering committee. “The efficacy effect appears present but seems to be outweighed by the bleeding risk.”

The researchers were particularly surprised by the results for the drug, for which they had high hopes since its mechanism of action is different from other antithrombotics such as warfarin and clopidogrel, and it performed well in earlier stage trials.

The trial, funded by Merck, Sharp & Dohme, randomized 12,942 ACS patients from 37 countries to receive 40 mg loading dose of vorapaxar followed by a daily 2.5 mg dose, or placebo, plus standard therapy, usually aspirin and clopidogrel.

Over a median follow-up of 502 days, at least one of the five primary cardiovascular endpoints occurred in about one-fifth of both vorapaxar and placebo treated patients – 18.5 percent and 19.9 percent, respectively ($P=0.07$).

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Moderate and severe bleeds occurred in 7.2 percent of vorapaxar patients compared to 5.2 percent of placebo patients. Intracranial bleeds occurred in 1.1 percent of vorapaxar patients and in 0.2 percent of placebo patients ($P < 0.001$ for both).

There was a statistically significant improvement in the secondary endpoints – CV death, stroke and MI – with vorapaxar compared to placebo (14.7 percent versus 16.4 percent), but the researchers did not consider this sufficient to deem the trial a success.

There were questions about whether the

trial was underpowered. But study leader Dr. Ken Mahaffey, of the Duke Clinical Research Institute, said consistent results for primary and secondary endpoints as well as bleeding across geographic regions, including Asia, Europe and South America, meant they could have confidence in the overall results when faced with patient questions.

A companion trial was not halted and Harrington said results from that trial, which should be available this year, might provide some context to understand and improve upon the TRACER results. 

Abused girls more prone to CVD later in life

Elvira Manzano

Adult women who were physically or sexually abused during childhood have higher risks of heart attack, heart disease and stroke than women who were not, suggests new research.

A study of 67,102 American nurses aged 43 to 60 found that women who had repeated episodes of forced sex before the age of 18 had a 62 percent higher risk of cardiovascular disease (CVD) as adults. Moreover, women who reported severe physical abuse as children or teens had a 45 percent increased risk of cardiovascular events.

“The associations were stronger for sexual abuse than they were for physical abuse and surprisingly, they were stronger for stroke than they were for heart disease,” said lead author Janet Rich-Edwards, Sc.D., M.P.H., associate professor in the department of medicine at Brigham and Women’s

Hospital in Boston, Massachusetts, US. “The single biggest factor explaining the link between severe child abuse and adult cardiovascular disease was the tendency of abused girls to have gained more weight throughout adolescence and into adulthood.”

Mild to moderate physical or sexual abuse was however not associated with increased risk.

“Half of the association we saw between severe child abuse and adult cardiovascular disease in women was explained by the established cardiovascular risk factors – body mass index, alcohol use, hypertension and diabetes – that we know how to prevent and treat. So this is good news,” said Rich-Edwards. “This means women who have had a history of severe abuse in childhood have access to preventive care that could reduce their risk by as much as 40 to 50 percent. That would be lifestyle interventions, reducing smoking, reducing

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weight, getting more activity... generally taking care of themselves.”

In the study, 11 percent of women reported forced sexual activity before age 18, and 9 percent reported severe physical abuse.

“Child abuse is really prevalent. However, it’s hidden. It is something we don’t like to talk about but both national surveys and our study showed that about half of women have reported some forms of childhood physical or sexual abuse. We need to daylight this. If we can’t talk about it, we can’t begin to do anything about it,” Rich-Edwards said.

Primary health care health professionals should consider the child abuse stories of their patients. “By talking about it, we begin to normalize the experience and make it more possible for women to take a look at what has happened and consider whether it’s affecting their current health,” she said. “We need to learn more about specific psychological, lifestyle, and medical interventions to improve the health of



Physicians should make an effort to know the child abuse stories of their patients.

abuse survivors.”

However, she said further research is needed to identify new pathways to prevent CVD in a large number of abused women.

Her message to women: “Although your body may have been abused as a child, you can take good care of it as an adult and make a big difference to your health.” 

Tripling clopidogrel dose overcomes genetic resistance

Patients with stable cardiovascular disease and genetic resistance to clopidogrel achieved similar levels of antiplatelet activity when their daily dosage was increased threefold.

The standard dose for the common anti-clotting agent, indicated for patients with prior heart attacks or stents, is 75 mg/day, but about one-third of patients do not respond to treatment.

The results of the ELEVATE-TIMI 56*

trial showed that boosting the dosage to 225 mg/day was enough to overcome resistance to clopidogrel’s anti-clotting activity in patients with one loss-of-function allele in the CYP2C19 gene – CYP2C19*2. [JAMA 2011 Nov 16. Epub ahead of print]

However, patients with two loss-of-function alleles were unable to achieve similar results even when their daily dose was quadrupled to 300 mg.

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"If I knew someone's genotype, I would feel uncomfortable treating them with standard doses of clopidogrel," said lead researcher Dr. Jessica Mega, of Brigham and Women's Hospital in Boston, Massachusetts, US.

The trial included 335 patients who had a prior heart attack or surgery to unblock arteries and who were already taking 75 mg clopidogrel each day. After blinded genotyping, 86 allele variant carriers were randomized to four 14-day maintenance dose periods of either 75 mg, 150 mg, 225 mg or 300 mg of clopidogrel.

Twenty-four percent of all the patients carried one variant and 2 percent carried a double variant, which is representative of the general population.

Non-carriers were randomized to 14-day maintenance dose periods of 75 mg or 150 mg of clopidogrel, twice each. Platelet function was tested at the end of each maintenance period.

CYP2C19*2 allele variant carriers receiving 75 mg/day showed significantly higher platelet reactivity compared to non-carriers receiving the standard daily 75 mg dose. However, this reactivity decreased with the 225 mg dose to match that of non-carriers on standard treatment and dropped below non-carrier reactivity at 300 mg ($P < 0.001$ for all).

On average, 52 percent of allele variant carriers did not respond optimally to clopidogrel at 75 mg, 26 percent did not respond optimally at 150 mg and 10 percent did not respond optimally at 225 mg and 300 mg.

No significant adverse events occurred in any groups and the data suggests

higher doses of clopidogrel may be efficacious in patients with certain genotypes.

Importantly, the trial was racially limited as 88 percent of the study population was Caucasian and 75 percent were male.

Dr. Lawrence Lesko, of the University of Florida in Gainesville, Florida, US, said future trials should include a wider variety of gene variants which are more common in different ethnic groups. For example, 10 percent of Asians carry CYP2C19*3 allele variants, although he said such patients likely would respond similarly to CYP2C19*2 patients.

In addition, a variety of other factors including age, weight, sex, the presence of diabetes and other comorbidities can affect platelet reactivity and patients unresponsive to clopidogrel are candidates for alternative anticlotting therapies such as prasugrel, ticagrelor or cilostazol.

However, clopidogrel may be the preferred drug based on cost as it is slated to be available as a generic drug this year.

Currently, genotyping is expensive and inconvenient to be available for each patient, but Lesko said that doctors may want to consider it for high-risk patients such as those who are on several types of blood thinners at once.

"The needle moves towards the direction of greater consideration of adoption [for genetic testing]," he said. — **RC** 

**ELEVATE-TIMI 56: Dosing Clopidogrel Based on CYP2C19 Genotype and the Effect on Platelet Reactivity in Patients With Stable Cardiovascular Disease*

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- Recommendation of Nutrition Screening for Children and Adult Patients Care
- COPD
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Day 2 on Sunday, February 19th 2012

- Nutrition in Neurologic Disorders
- The Role of Antioxidant in Wellness and Antiaging Program
- Cardiovascular Diseases
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Anticoagulant regimens show similar efficacy in post-MI setting

Rajesh Kumar

Two anti-clotting regimens – abciximab+heparin and bivalirudin – were similarly effective in preventing death, subsequent heart attack or need for further revascularization in post-myocardial infarction (MI) patients undergoing intracoronary stenting, a study has found.

The double-blinded ISAR-REACT 4 study* randomized 1,721 patients with non-ST-segment elevation MI (non-STEMI) undergoing percutaneous coronary intervention (PCI), which includes balloon angioplasty and intracoronary stenting, to receive one of the two regimens.

Death, any recurrent MI or urgent target vessel revascularization occurred in 12.8 percent (110/861) patients in the abciximab+heparin group versus 13.4 percent (115/860) patients in the bivalirudin group (relative risk: 0.96 [0.74 to 1.25], $P=0.76$). Major bleeding occurred in 4.7 percent (40 patients) in the abciximab+heparin group and 2.6 percent (22 patients) in the bivalirudin group (relative risk: 1.84 [1.10 to 3.07], $P=0.02$).

The researchers also noticed that compared with bivalirudin, the dual treatment of abciximab+heparin significantly raised the risk of major bleeding.

Both of the regimens tested in this study are widely used in non-STEMI patients but have not previously been compared directly in a large, randomized setting, said lead researcher Dr. Adnan Kastrati



Anti-clotting regimens were similarly effective in the ISAR-REACT 4 trial.

of the German Heart Center in Munich, Germany.

“Understanding which treatment works better is important because non-STEMI heart attack patients are in danger of further cardiovascular problems,” said Kastrati. “The results of PCI in these patients are strongly dependent on the efficacy and safety of the anti-clotting drugs used during the procedure.”

Dr. Deepak Bhatt, chief of cardiology at VA Boston Healthcare System and associate professor of medicine at Harvard Medical School, Boston, Massachusetts, US, cautioned that an important limitation of the study was that patients who took part had been pre-treated with aspirin+clopidogrel 600 mg. Therefore, he said, the results may not apply to others not pre-treated as such. **NI**

* ISAR-REACT 4: Intracoronary Stenting and Antithrombotic Regimen: Rapid Early Action for Coronary Treatment study.

Catheter ablation outperforms drug therapy in AF

Rajesh Kumar

Radiofrequency catheter ablation performs better than antiarrhythmic drugs in treating patients with paroxysmal atrial fibrillation (AF), but with slightly more side effects, according to the MANTRA-PAF* trial.

Researchers randomized 294 drug-naïve paroxysmal AF patients (mean age 55 years, 206 males) to receive either radiofrequency catheter ablation ($N=146$) or antiarrhythmic drug therapy ($N=148$) for up to 24 months.

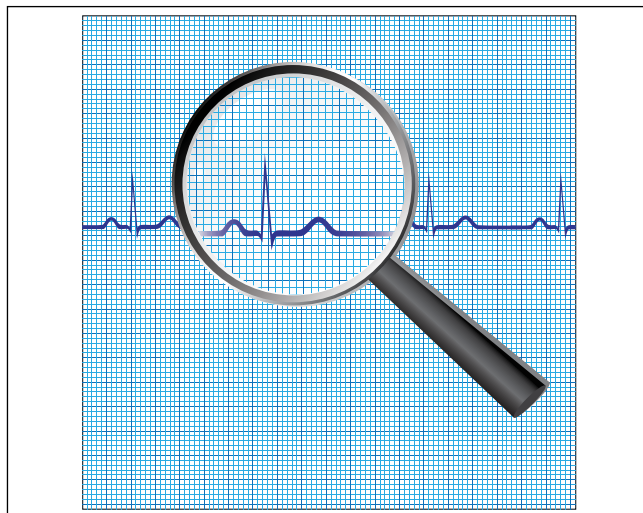
No significant difference was seen in the amount of time the patients in the two treatment groups experienced AF, nor in the cumulative AF burden at 3, 6, 12 and 18 months. However at 24 months, the ablation group had significantly less AF burden than the drug-treated patients ($P=0.007$).

In the radiofrequency ablation (RFA) group, 22/146 patients (15 percent) had AF compared to 43/148 (29 percent) treated with drugs ($P=0.004$). Ten ablation patients (7 percent) had symptomatic AF episodes compared to 24 (16 percent) in the drug group.

Serious adverse events were recorded in 19 ablation recipients and 15 patients who received drug therapy. Occurrence of atrial flutter did not differ between the two groups.

These data support RFA as a first-line treatment in patients with PAF, the study concluded.

"Ablation therapy is at least as good and tends to be better than drug therapy at preventing episodes of atrial fibrillation," said lead researcher Dr. Jens Cosedis Nielsen, professor



RF reduced AF better than drug therapy in the MANTRA-PAF trial on drug-naïve paroxysmal AF patients.

of cardiology at Aarhus University Hospital in Denmark.

Of the patients primarily treated with ablation, 13 needed supplementary drugs and 54 patients who didn't improve with drugs underwent supplementary RFA.

"Not every patient should be offered ablation, but this research should be discussed with patients when a physician feels it is a viable treatment option," said Nielsen.

"Considering the relative safety of the technique when performed by experienced operators, ablation may be considered as an initial therapy in selected patients," commented Dr. William Stevenson of the Brigham and Women's Hospital at Harvard Medical School in Boston, Massachusetts, US

The MIT logo, consisting of the letters "MIT" in white on a red square background.

**MANTRA-PAF: Medical Antiarrhythmic Treatment or Radiofrequency Ablation in Paroxysmal Atrial Fibrillation*

American Heart Association Scientific Sessions 2011, 12-16 November, Orlando, Florida, US

Surgical ablation superior to catheter ablation in correcting AF

Elvira Manzano

Minimally invasive surgical ablation appears to work better than catheter-based ablation in correcting drug refractory atrial fibrillation (AF), researchers have found.

In the FAST* trial, which involved 124 patients with AF, 65.6 percent of patients randomized to surgical ablation ($N=61$) achieved freedom from atrial arrhythmias lasting >30 seconds without anti-arrhythmic agents compared with 36.5 percent of patients randomized to catheter ablation

Netherlands. This, he added, is “at the cost of a higher procedural serious adverse event rate.”

Adverse events during the procedure and the 1-year follow-up were significantly higher for surgical ablation (34.4 percent) than for catheter ablation (15.9 percent); $P=0.027$, caused mainly by procedural complications – pneumothorax (6 cases in the surgical ablation group) and major bleeding.

“These findings may be used by physicians and patients to guide optimal invasive therapy,” Boersma said. “The risk of the procedure accompanying the chance for greater

““ These findings may be used by physicians and patients to guide optimal invasive therapy

($N=63$) [$P<0.0022$]. In this study, 66 percent of patients had paroxysmal AF or sporadic AF and 34 percent had persistent AF. [*Circulation* 2011 Nov 14; Epub ahead of print]

When anti-arrhythmic drugs were used, 12-month freedom from AF was achieved in 78.7 percent of patients who underwent surgery compared with only 42.9 percent of catheter ablation recipients ($P<0.0001$).

“The results indicate that in atrial fibrillation patients with dilated left atrial and hypertension or failed prior catheter ablation, surgical ablation is superior to catheter ablation in achieving freedom from left atrial arrhythmias after 12 months of follow-up,” reported Dr. Lucas Boersma from the St. Antonius Hospital, Nieuwegein, The

success needs to be carefully weighed.”

Discussant Dr. A. Marc Gillinov, a staff cardiothoracic surgeon at the Cleveland Clinic, Ohio, Cleveland, US, said that patients might go for the catheter procedure because it does not rule out a surgical operation if fibrillation recurs. He noted that 38 of the 63 catheter patients had been treated previously with a catheter procedure and 73.8 percent of those getting surgery were seeking treatment following an unsuccessful catheter procedure.

“In these more difficult patients, surgical ablation is more effective,” Gillinov said. “It had greater morbidity, however.”

MI

*FAST: Atrial Fibrillation Catheter Ablation Versus Surgical Ablation Treatment

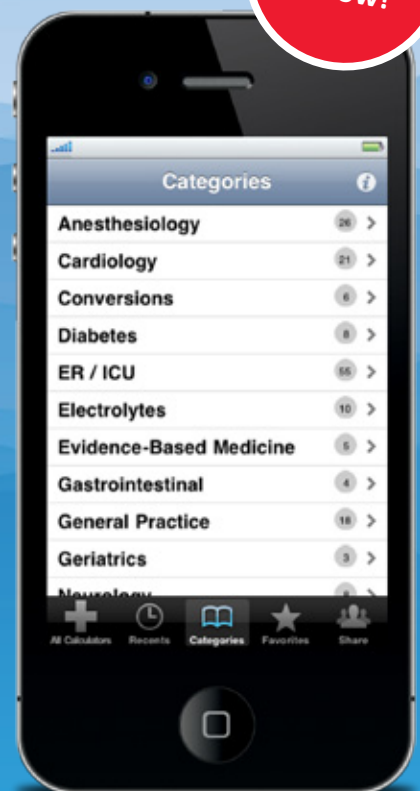
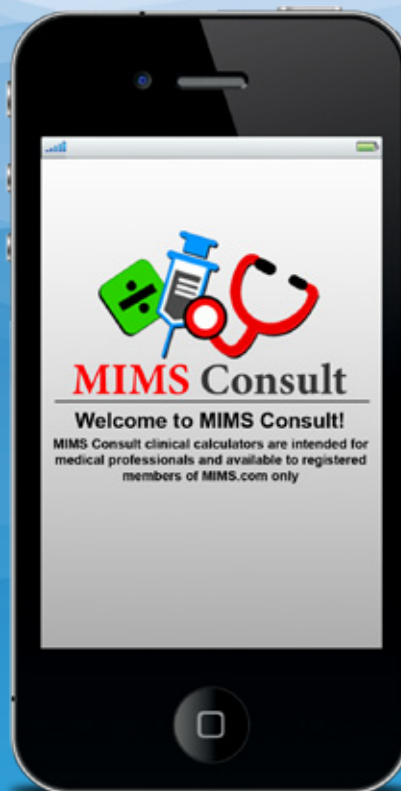
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Personal Perspectives



- “ I look at cardiovascular disease risk in women with type 1 diabetes. I thought there was more of an emphasis on women’s cardiovascular health at this meeting, not only the Go Red for Women session but in other large sessions, which is always nice to see.

*Dr. Janet Snell Burgeon
University of Colorado, Denver, US*



- “ Percutaneous valves are going to be game changers. It’s going to change the way we take care of aortic valve disease. [That], along with the world of new anticoagulants, questions about which are just starting to be answered, are the big things here I think are exciting.

*Dr. Vincent Bufalino
Chairman/CEO, Midwest Heart Specialists, Chicago, Illinois, US
AHA Spokesperson*



- “ To me the most interesting study was the AIM HIGH study. I also enjoyed the Saturn study looking at rosuvastatin and atorvastatin on IVUS since atorvastatin is going generic, and there wasn’t a dramatic difference between the two.

*Dr. Roger Blumenthal
Johns Hopkins University, Baltimore, Maryland, US*



- “ There was a poster showing the number of publications in a specific journal and how much of that research was not funded or only partially funded. It really demonstrates how hard it is to get funding but how passionate people are who are managing to do it anyway. As a junior investigator that’s something I’m struggling with and it’s nice to see someone highlight that.

*Dr. Amy Alman
University of Colorado, Denver, US*

Apixaban, enoxaparin comparable in preventing VTE

A 30-day low-dose oral regimen of the new anticoagulant apixaban has been shown to be as effective as a standard 1- to 2-week course of intravenous therapy with enoxaparin in preventing venous thromboembolism (VTE).

The Apixaban Dosing to Optimize Protection from Thrombosis (ADOPT) trial involved more than 6,500 patients aged ≥ 40 years who were randomly assigned to either twice-daily 2.5 mg apixaban tablets orally for 30 days or 40 mg IV shots of enoxaparin daily for 6 to 14 days. All patients had restricted mobility and were hospitalized for at least 3 days with congestive heart failure, acute respiratory failure or other conditions that increase risk of VTE.

Among the 4,695 patients for whom effectiveness data could be evaluated, 2.7 percent of those given apixaban experienced a VTE event (death, deep vein thrombosis or pulmonary embolism), compared to 3.1 percent of patients given enoxaparin, a difference that was not statistically significant. [*N Engl J Med* 2011 Nov 13. Epub ahead of print]

While rates of major bleeding were statistically higher with apixaban compared to enoxaparin (0.47 percent versus 0.19 percent, respectively, $P=0.04$).

Although enoxaparin's current recommended use is for 6 to 14 days, many patients receive a shorter course because the treatment is discontinued when their hospitalization ends. Thus, conclusions about the drug comparison should be withheld, said Goldhaber.

"ADOPT may not be applicable to typical

populations of hospitalized patients because routine screening for VTE is not ordinarily undertaken at the time of hospital discharge," said lead researcher Dr. Samuel Goldhaber, director of the Venous Thromboembolism Research Group at Brigham and Women's Hospital in Boston, Massachusetts, US.

The differences between apixaban and enoxaparin also begin to separate well after the final dose of enoxaparin, suggesting there might have been a more positive study outcome if researchers had extended apixaban for more than 30 days, he said.

Considering longer-term preventive treatment beyond hospital discharge is important for patients at risk for VTE, the researchers added.

"Risk factors for VTE may actually increase after hospital discharge as patients may become more immobile when they are no longer prodded and encouraged to mobilize by hospital nurses and therapists," said Goldhaber. The research did not assess mobility after discharge.

Discussant Dr. Mary Cushman, professor of medicine and pathology at the University of Vermont College of Medicine, Burlington, Vermont, US, said the risk of VTE extends to 3 months after hospital discharge and half of all the events occur after discharge, due to which the post-discharge treatment and follow-up should be continued.

Cushman stressed the need to develop validated risk models to include only high-risk patients in trials and the use of treatment with lowest bleeding risk, in addition to continued follow-up of patients. — **RK** 

Intracoronary abciximab administration promising in heart failure

Administering the anti-platelet agent abciximab directly into a blocked coronary artery was just as good as delivering it intravenously for improving overall health outcomes in heart failure patients undergoing percutaneous coronary intervention (PCI).

Importantly, fewer patients receiving the drug by the intracoronary route suffered another heart failure.

This was a key finding of the AIDA-STEMI* trial, in which 2,065 patients with ST-elevation myocardial infarction (STEMI) who underwent PCI between July 2008 and April 2011 were randomized to receive abciximab intracoronary (IC) or intravenous (IV). Within 90 days, 7 percent of those receiving the drug IC had another heart attack or developed new heart failure, compared to 7.6 percent of those receiving it by the IV route.

“Neither therapy arm was superior to the other in the primary endpoint,” said lead researcher Dr. Holger Thiele, deputy director of the department of internal medicine (cardiology) at the University of Leipzig Heart Center in Leipzig, Germany. “However, we found a lower rate of heart failure in the intracoronary patients.”

Only 2.4 percent receiving the dose IC were diagnosed with heart failure within 90 days, compared to 4.1 percent receiving the IV dose (22/935 versus 38/932 patients; $P=0.04$), a statistically significant difference.

Earlier research had suggested the IC delivery during PCI could boost



Intravenous abciximab was as effective as delivering it to a blocked coronary artery.

concentration of the drug at the treatment site, limit heart tissue damage and improve blood flow. But researchers found no difference between the two study groups in blood flow or infarct size.

“Intracoronary administration of abciximab is safe, with no significant increase in bleeding or other problems,” said Thiele.

AIDA-STEMI is the first trial addressing important questions regarding efficacy

American Heart Association Scientific Sessions 2011, 12-16 November, Orlando, Florida, US

and safety of IC versus IV abciximab bolus administration during primary PCI in patients with STEMI. Its results will impact the route of glycoprotein IIb/IIIa-inhibitor (anti-platelet) administration, the researchers concluded.

Discussant Dr. Alice Jacobs, professor of medicine at Boston University Medical Center, Boston, Massachusetts, US, said it was unclear whether the lack of a difference in outcomes was due to the

enrolment of lower risk patients, more rapid distribution of IV abciximab, or dual anti-platelet therapy.

Whether IC abciximab should be limited to patients with large infarcts and thrombus burden and/or no reflow will require further study, said Jacobs. – **RK** 

**AIDA STEMI: Abciximab Intracoronary versus Intravenously Drug Application in ST-Elevation Myocardial Infarction.*

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Managing peripheral arterial disease in primary care



Associate Professor Peter Ashley Robless
Head and Senior Consultant, Division of Vascular and Endovascular Surgery
Department of Cardiac, Thoracic and Vascular Surgery
National University Heart Centre
Singapore

Legs for life

Peripheral arterial disease (PAD), or peripheral atherosclerotic occlusive disease, is a common yet serious condition. It typically affects the arteries of the lower limbs, resulting in gangrene, ulceration or amputation. In Singapore, about 700 major amputations are performed annually due to diabetes and PAD. It is estimated that up to 70 percent of leg amputations occur in people with diabetes. The World Health Organization (WHO) estimates that every 30 seconds, a leg is lost to diabetes.

While PAD occurs most often in the leg arteries, it can also affect the arteries that go to the aorta, the brain, the arms, the kidneys and the gut. The hardened arteries in patients with PAD are a sign that

Asia, diabetes, hypertension and hyperlipidemia are the most common causes of PAD. The WHO has projected diabetes cases to hit 12 percent by 2025 in Singapore, but at the onset of 2012, it was already nearing its mark (11.9 percent). In our population, one in 10 people has diabetes and this has been a rising trend over the last two decades.

While the disease is more common in men, we are also seeing an increasing trend in women. The problem is compounded by an increasingly ageing population.

Diagnosing PAD

Ninety percent of patients with PAD are asymptomatic, 9 percent have symptoms

“ Primary care physicians are likely to detect a lot of asymptomatic patients who do not need urgent referral to a specialist

arteries to the brain and heart may be also hardened and narrowed, making them at high risk for heart attack or stroke.

PAD is markedly predominant in the elderly, with a peak of incidence after age 60. The risk factors are the same as those observed in patients with coronary atherosclerosis. In western countries, smoking appears to be more associated with PAD than other risk factors. However in

of claudication or pain in the calf muscles when they walk, and a proportion of patients develop ulceration or gangrene of the lower limb.

In large polyclinics and within GP practices, diabetic foot screening is being done by podiatrists who examine the intensity of lower limb pulses. They perform clinical assessment of the feet. The symptoms to watch out for, aside from leg pain when

walking or exercising, are numbness, tingling or coldness in the lower legs or feet, sores, deformity, skin changes, callous formation and early ulceration. They also assess the circulation, temperature and color of the feet.

Once PAD is suspected, our screening tool is the ankle-brachial pressure index (ABI) or toe-pressure index (TBI). The assumption is that the ratio between the highest ankle pressure and the brachial pressure should be at least 1.0. A blood pressure reading in the ankle which is lower than that in the arm indicates a narrowing or blockage in the lower limb artery. An ABI ratio of <0.9 is consistent with PAD, 0.8 means moderate disease with symptoms, and <0.5 means the patient is at risk of serious complications. The ABI has been shown to be an accurate predictor of amputation, as well as cardiovascular mortality in this group of patients. It is a good global indicator of vascular disease burden.

If the ABIs are abnormal, a Duplex ultrasound may be used to determine the extent of atherosclerosis.

In diagnosing PAD, primary care physicians are likely to detect a lot of asymptomatic patients who do not need urgent referral to a vascular specialist. All they need is risk factor modifications such as regular exercise, smoking cessation, anti-platelet therapy, statin therapy and blood pressure control. However, since 1 in 5 patients with moderate PAD may need intervention by specialists, they may refer patients for routine assessment and monitoring.

Clinical practice guidelines

Several consensus clinical guidelines



The vascular specialists work in multidisciplinary teams with other physicians and podiatrists, wound care nursing specialists and rehabilitation specialists to prevent amputation.

are in place. One is the Trans Atlantic Society Consensus (TASC) II guidelines which stratify patients according to the severity of the disease and recommended treatments. The most recent guidelines are from the PAD coalition, a consensus statement guideline of all North American societies dealing with PAD including the American College of Cardiology (ACC), American Heart Association (AHA) and the Society for Vascular Surgery (SVS). There is little difference between the guidelines in terms of recommendations for clinical practice. Both suggest aggressive control of HbA1c to a target of <7.0 percent and recommend aggressive medical management for patients with PAD.

In Singapore, we use the recommended standard of care. However, the obstacle frequently lies in the patients' access to a PAD specific program. In the past, it was not clear as to who treats patients with PAD. Is it the GPs, the endocrinologists or the vascular surgeons? New paradigms have emerged with various specialties

such as angiologists and vascular medicine specialists taking ownership of this problem. At the National University Heart Centre (NUHCS), we have started a vascular medicine and therapy program that focuses on patients with PAD. We have a comprehensive one-stop clinic staffed by trained physicians and offering non-invasive duplex assessment, podiatric foot care and supervised exercise programs. We have incorporated nurse educators, patient information leaflets and a resource website for patients who may have PAD. The program has a simple mantra: to accept all patients and provide one last chance to those facing a major limb amputation.

Treatment of PAD

Standard medical treatment for PAD consists of antiplatelet medication (aspirin, clopidogrel, ticlopidine) where there is no contraindication, cholesterol lowering drugs, use of HMG coenzyme-A reductase inhibitor (statin), diabetes control and anti-hypertensive therapy. Cilostazol is also used for intermittent claudication in the absence of heart failure.

However, in the Reduction of Atherosclerosis for Continued Health Care (REACH) registry which looked at 60,000 patients globally – 10,000 from Asia and 881 from Singapore – proven therapies were found to be consistently underused in all patient types. Data for Singapore showed a high proportion of diabetes (57 percent), hypertension (80.6 percent) and hypercholesterolemia (80.1 percent). One in 5 patients had a major CV event (CV death, MI or stroke) or were hospitalized within a year. However, patients were undertreated with antiplatelet agents



PAD can lead to ulceration, gangrene and amputation of lower limbs.

(71.9 percent) and statins (76.2 percent). This means that established atherosclerosis risk factors are common in Singapore patients, but most of these risk factors remain suboptimally controlled.

Other strategies include supervised exercise (at least half an hour three times a week at a moderate level) and smoking cessation. Supervised exercise training is actually recommended as an initial treatment modality and has been shown to be as effective as pharmacotherapy.

In more difficult cases – with gangrene or infected non-healing wounds – a wide armamentarium of treatment is needed to achieve limb salvage. Some patients have disease that is amenable to local treatment by angioplasty or arterial bypass surgery to prevent amputation. Current generation tibial drug eluting balloons are frequently used to achieve the desired patency and healing rates. In situations where multiple segments of the artery are

affected by atherosclerotic plaque, endarterectomy or bypass surgery is performed to improve blood flow to the foot.

Once revascularization has been achieved and the infection is controlled, soft tissue debridement and closure is required. Biosurgery or maggot therapy (blowflies) is frequently used to debride the devitalized tissue in the wounds before closing them with a vacuum assisted closure (VAC) dressing. The process can take up to a few weeks in a hospital. For more complex wounds, a plastic surgeon is called in to provide flap coverage. With this strategy, we have been able to achieve amputation-free survival rates of over 70 percent at 1 year.

A multidisciplinary approach

With PAD and limb salvage, it takes a whole village to save feet. We the vascular specialists, work in multidisciplinary teams with other physicians and podiatrists, wound care nursing specialists and rehabilitation specialists to prevent amputation. We work together with the same objective in mind – to provide comprehensive evidence based care to PAD patients. Limb salvage is everybody's responsibility. That includes the GPs, the patients themselves and their families. **MI**

Online Resources:

PAD Coalition

www.padcoalition.org/

Heart Healthy Women

www.hearthealthywomen.org/

American Diabetes Association

www.diabetes.org/

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January

ASCO – 2012 Gastrointestinal Cancers Symposium

19/1/2012 to 21/1/2012

Location: San Francisco, California, US
Info: American Society of Clinical Oncology
Tel: +1 703 449 6418
Email: giregistration@jspargo.com
Website: gicasymposium.org/Home.aspx

World Cancer Immunotherapy Conference

25/1/2012 to 26/1/2012

Location: San Diego, California, US
Info: Arrowhead publishers and conferences
Tel: +1 312 244 3703
Email: enquiries@arrowheadpublishers.com
Website: www.cancervaccinesconference.com

February

6th Asia Pacific Congress of Heart Failure (APCHF)

3/2/2012 to 5/2/2012

Location: Chiang Mai, Thailand
Info: Asia Pacific Congress of Heart Failure
Tel: + 66 (0) 2940 2483
Fax: + 66 (0) 2940 2484
Email: apchf2012@lawson-marsh.com
Website: www.apchf2012.com

7th Congress of the World Institute of Pain

4/2/2012 to 6/2/2012

Location: Miami, Florida
Info: Kenes International/WIP 2012
Tel: +41 22 908 0488
Fax: +41 22 906 9140
Email: wip@kenes.com
Website: www2.kenes.com/wip/pages/Home.aspx

70th Annual Meeting of the American Academy of Dermatology

4/2/2012 to 8/2/2012

Location: San Diego, California, US
Info: American Academy of Dermatology
Tel: + 847 240 1280
Fax: + 847 240 1859
Website: www.aad.org/

22nd Conference of the Asia Pacific Association for the Study of the Liver

16/2/2012 to 19/2/2012

Location: Taipei, Taiwan
Info: Asian Pacific Association for the Study of the Liver
Tel: +886 2 8502 7087 Ext.31
Fax: +886 2 8502 7025 |
Email: secretariat@apasl2012taipei.org
Website: www.apasl2012taipei.org/

20th Regional Conference of Dermatology

20/2/2012 to 23/2/2012

Location: Manila, Philippines

Info: Philippine Dermatological Society
Tel: +632 727 7309; 723 0101 loc 2015
Telefax: +632 727 7309
Email: rcd2012@pds.org.ph
Website: www.pds.org.ph/rcd-2012/

Upcoming

13th Pan American Congress of Neurology

5/3/2012 to 8/3/2012

Location: La Paz, Bolivia
Info: World Federation of Neurology
Tel: +56 2 946 2633
Fax: +56 2 946 2645
Email: pcn2012@kenes.com
Website: www2kenes.com/pcn2012/pages/Home.aspx

15th Ottawa Conference on Assessment of Competence in Medicine and the Healthcare Professions

9/3/2012 to 13/3/2012

Location: Kuala Lumpur, Malaysia
Info: Secretariat
Tel: +603 425 29100
Fax: +603 425 71133
Email: ottawa2012@aosconventions.com
Website: www.ottawaconference.org

61st American College of Cardiology Annual Scientific Sessions

24/3/2012 to 27/3/2012

Location: Dubai, UAE

Info: American College of Cardiology
Tel: +202 375 6000 Ext. 5603
Fax: +202 375 7000
Email: resource@acc.org
Website: accscientificsession.cardio-source.org/ACC12.aspx

15th World Congress of Anesthesiologists

25/3/2012 to 30/3/2012

Location: Buenos Aires, Argentina
Info: WFSA World Congress of Anesthesiologists
Email: wfsahq@anaesthesiologists.org
Website: www.wca2012.com

9th European Congress on Menopause

28/3/2012 to 31/3/2012

Location: Athens, Greece
Info: European Menopause and Andropause Society
Tel: +41 22 908 0488
Fax: +41 22 906 9140
Email: emas@kenes.com
Website: www2.kenes.com/emas/pages/default.aspx

American Thoracic Society International Conference 2012 (ATS 2012)

18/5/2012 to 23/5/2012

Location: San Francisco, California, US
Info: American Thoracic Society
Tel: +1 212 315 8652
Email: conference@thoracic.org
Website: www.thoracic.org/go/international-conference

TORONTO

Where Different Cultures Meet

Yen Yen Yip

For a long time, Toronto's name was mistakenly attributed to the Huron word *toronton*, "place of meetings." Canadian historians clarified that the city's name actually originated from a Mohawk term, *tkaronto*, meaning "where there are trees standing in the water." This referred to the stakes used in native Indian fishing weirs at Lake Simcoe, north of present day Toronto. Though erroneous, "place of meetings" stuck – because it aptly describes the hyper-diverse city which housed 267,855 immigrants between 2001 and 2006. That's about one-quarter of all the immigrants to Canada (more than 1.1 million) during that period.

The influx of immigrants used to be dominated almost exclusively by applicants from the UK and Europe. This was reflective of the immigration policy during the early-to mid-1900s, which excluded migrants from other parts of the world. But this all changed from the 1960s when the country introduced important regulatory changes. Today, Canada is known worldwide for its broad policy. Asia contributes the highest number of immigrants, especially China, Hong Kong, and India. Of all the immigrants to Canada, a significant proportion sought



TORONTO

asylum in the country for humanitarian reasons. In 2004, 13.9 percent of those admitted were from the refugee class.

Metropolitan Toronto has a population of about 2.5 million, of which half were born outside of Canada. While the city represents about 8 percent of Canada's population, it is home to 30 percent of all recent immigrants. Interestingly, data from a 2006 survey showed that Chinese was the most commonly spoken language after English and French, followed by Italian, Punjabi, Tagalog and Portuguese. With a motto, "Diversity Our Strength", the city prides itself on its wide range of cultures, languages, food and arts. Just stroll through the various neighborhoods of the city and the city's eclectic culture will become apparent. In certain historical districts, such as the Annex on Bloor Street in downtown Toronto, shops cater to conventional North American tastes. South of the Annex lies Little Italy on College Street, an enclave of Italians who started migrating to Canada in the 1950s to find work in city development projects. The area is profuse with sidewalk cafes,

charming trattorias, restaurants and nightclubs. As the sky grows dark, cars ferrying long-haired fashionistas start appearing on the roads, throbbing to the beat of dance music. Good food and vibrant night life in the area has made it a favorite hangout of young people.

Chinatown, hugging Spadina Avenue, is lit up by ubiquitous neon shop signs above shop houses selling fresh fruits and vegetables, stocking exotic herbs and Canadian ginseng. Bubble tea shops, hot pot diners and dim sum restaurants display lengthy menus and lunch specials at their shop fronts. Acupuncture centers and massage therapists, dollar stores and herbal shops are incongruously sited beside restaurants. Chinatown is not limited to Chinese food. One can tuck in to pho soup and banh mi baguette sandwiches at Vietnamese noodle houses. Koreatown, west of the city, is similarly bustling and crowded with eateries, bakeries, karaoke lounges and other businesses catering to the Korean community.



TORONTO

Little India – represented by the Gerrard India Bazaar on Gerrard Street – clusters to the east, a marketplace of shops, restaurants and grocery stores displaying the sights, music, aromas and taste of south Asia. South Asians make up about 12 percent of the Toronto population. The merchandise sold here – from fashion and jewelry, to spice, groceries and kitchenware – allows them to maintain their cultural and religious traditions.

Caribbean culture offers another vibrant slice of the city. In Toronto, Caribana has become an eagerly anticipated summer event, an annual street festival showcasing Caribbean music, food and masquerade costumes. Attracting about 1 million participants annually, it is one of the largest Caribbean festivals in North America. The highlight is the street parade, where masqueraders (“mas players”), dressed up in outlandish, colorful costumes and headgear, dance to the beat of calypso and reggae music blasted from 18-wheeler trucks.

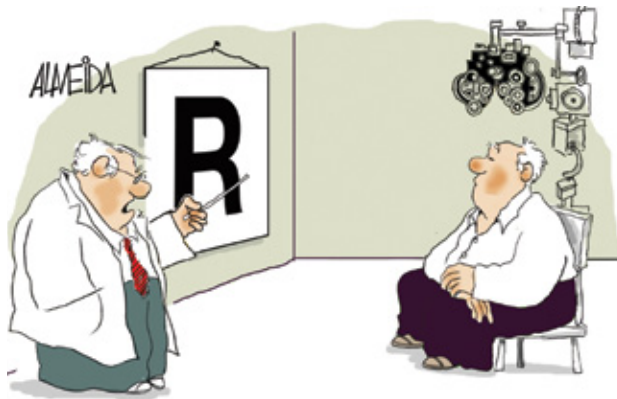
Various neighborhoods – such as

Greektown, Little Jamaica, Roncesvalles (a Polish district) – demonstrate the diversity of the city, each a showcase of ethnic identity featuring unique cuisine and culture. Significant populations of other visible minorities include, but are not limited to, Filipinos, Columbians, Guyanese, Lebanese, Iranians, Russians and Somalis. The Canadian federal government had predicted that visible minorities will make up the majority of Toronto population by 2012.

While recent reports have indicated that visible minorities are still under-represented in leadership roles and in the workplace, Toronto residents generally remain open and stay positive when it comes to immigrants. A study published by a Canadian research organization, the Institute for Research on Public Policy recently showed that a majority of Canadians – including those in Toronto – are pro-immigration, believing in the economic benefits that immigrants bring and taking pride in their country’s distinctive multicultural image.

MI





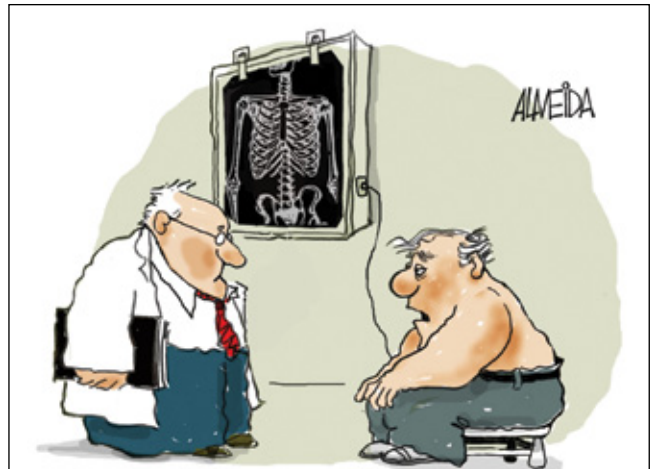
"This is your last chance."



"Me? Why can't YOU make the pain disappear?"



"My doctor said I don't pay attention to what my body is trying to tell me. Anyway, that's what I think he said!"



"How much longer do I have before I quit smoking and drinking?"



"There were some complications during the operations, but the good news is, I found my cell phone!"



"You're a genius, Dr Flunk! This is by far the best artificially flavored orange juice I have ever tasted!"

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