

year changes in the ratio were beneficially affected by lifestyle factors, but only to a modest degree. It is concerning that obesity at baseline contributes to a significant worsening of the ratio whereas a report of exercise only slightly improves the ratio.

1202-88 Cholesterol Screening of Adults in the US: Role of Socio-demographic Factors

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Background: The National Cholesterol Education Program (NCEP) II & Expert Panel Adult Treatment Panel III (ATPIII) guidelines recommend a cholesterol screen every 5 years for all adults ≥20 yrs age. No information regarding the role of socio-demographic factors on US adult cholesterol screening has been published.

Methods and Results: Data were extracted from the 1999 CDC Behavioral Risk Factor Surveillance System (BRFSS) survey. The BRFSS telephone surveyed 159,000 US adults regarding cholesterol screening within the last 5 years. Data were stratified by age, gender, ethnicity, income, education, level of insurance and the ability to afford health care. Overall 69% adults were screened within the last 5 yrs, which is below the Healthy People 2000/2010 goals of 75% & 80% respectively. However 85% adults >65 years were screened. Adults aged ≥45 years were 3.7 times more likely to receive cholesterol screening. Those with health insurance were 2.4 times more likely to receive screening. High school graduates or those with some college were 1.5 times more likely to be screened. Women were 1.2 times more likely to be screened. Those with an income ≥\$20K/yr were 1.4 times more likely to receive screening. The socio-demographic variables had a compounding influence on cholesterol screening. For example, the individual <45 yrs age, who was less educated, with a lower economic status and had no health insurance was the least likely to report having received cholesterol screening within the last 5 years (29%).

Conclusion: Socio-demographic factors play an important role in cholesterol screening. This information may be used for targeted future cholesterol screening interventions.

1202-89 Contemporary Awareness and Understanding of Cholesterol as a Risk Factor: Results of an American Heart Association National Survey

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Public awareness and understanding of risk factors for atherosclerotic vascular disease are essential for successful primary and secondary prevention. The American Heart Association conducted a national telephone survey to assess public knowledge of the link between cholesterol and heart disease and the specifics of cholesterol management in April 2001. A national probability sample of 1114 adults age 40 years and older was interviewed by trained personnel using a structured format. Good regional distribution was achieved; 29% of respondents were over age 65, 56% were women and 87% were white. Most (55%) were employed and of those, 70% identified themselves as white-collar workers. Over 90% had at least a high school education and over 30% completed college. Although 91% stated that it was "important to them personally to have a healthy cholesterol level" (77% extremely or very important), 51% did not know their own level. Only 40% were aware of national guidelines for cholesterol management, and 52% could not identify the correct desirable total cholesterol level for a healthy adult. More people selected HDL than LDL as the most important lipid fraction to control (22% vs 16%). When asked what sources of information they rely on the most, 67% identified physicians and 13% stated magazines were their principal sources, while only 4% rely primarily on the internet.

Conclusion: public awareness of the importance of cholesterol as a risk factor for cardiovascular disease is high, but specific knowledge of cholesterol management is poor. Patients overwhelmingly identify physicians as their primary source of information. Therefore, physicians have an important opportunity to improve public understanding and management of lipid abnormalities.

1202-90 Lowering LDL Cholesterol With Simvastatin, an HMG-CoA Reductase Inhibitor, Does Not Affect Luteal Function in Women

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Background: Cholesterol is the precursor of all steroid hormones, therefore cholesterol-reducing drugs could theoretically disrupt gonadal function in premenopausal women.

Methods: This double-blind, randomized, placebo-controlled study was conducted to evaluate the effects of simvastatin treatment in premenopausal women. Normally cycling women (n=86) with elevated baseline LDL cholesterol (LDL-C) levels (130-250 mg/dL) were studied over six menstrual cycles. At the end of the screening phase (cycle #1), participants received placebo for the second menstrual cycle, and subsequently were randomized to receive either placebo (n=44) or simvastatin 40 mg/day (n=42) for the next four menstrual cycles (cycle #3-6). The second and sixth menstrual cycles were considered baseline and treatment cycles, respectively. Participants kept a menstrual diary throughout the study, recording onset and duration of bleeding, and provided daily first-void urine samples (cycles #2 and 6). Urine samples were assayed for luteinizing hormone (LH) and pregnanediol glucuronide (PdG), the chief urinary metabolite of progesterone. The primary endpoint was change in luteal phase duration as defined by the day of the urinary LH peak to the day preceding the onset of menstruation. The primary hypothesis was that there would not be a clinically significant decrease (4 days) in luteal phase duration between the treatment groups.

Results: Simvastatin lowered LDL-C and triglycerides by 34.3 (p<0.001) and 14.7%

(p<0.001), respectively, and raised high-density lipoprotein cholesterol by 4.9% (p<0.050). Simvastatin treatment had no clinically relevant effect on luteal phase duration, peak PdG concentration, or integrated luteal phase PdG concentration compared to the placebo group. Furthermore, the number of women experiencing anovulatory cycles or abnormal cycle lengths did not differ between the treatment groups.

Conclusion: Treatment with simvastatin 40 mg/day was safe and effective at lowering LDL-C and did not adversely affect the hypothalamic-pituitary-gonadal axis in premenopausal women.

ORAL CONTRIBUTIONS

873 Venous Thromboembolism: Prevention and Treatment

Tuesday, March 19, 2002, 4:00 p.m.-5:00 p.m.
Georgia World Congress Center, Room 255W

4:00 p.m.

873-1 Lack of Association of Celecoxib With an Increased Risk of Thromboembolic Events

Gerald Faich, I. E. Allen, S. D. Ross, James B. Lefkowitz, *Pharmaceutical Safety Assessments, Inc., Narberth, Pennsylvania, Metaworks, Inc., Medford, Massachusetts.*

Background: It has been hypothesized that COX-2 specific inhibitors may increase the risk of cardiovascular (CV) thromboembolic events because of their inhibition of vascular prostacyclin synthesis and lack of an effect on platelet aggregation.

Methods: Data from the celecoxib clinical trial database were analyzed to determine the incidence of serious thromboembolic events (cardiac, cerebrovascular and peripheral vascular events) using a methodology derived from a recent FDA cardiorenal review (NDA 21-042, S-007). Since aspirin use for CV prophylaxis (<325 mg/d) was permitted, the analysis was performed for all patients and patients not taking aspirin.

Results: The incidence rates, patient exposure and relative risk (RR) for the long term safety trial CLASS (duration 12-15 mo.), 15 controlled arthritis trials (durations 3-6 mo.) and the open label long term safety trial (duration 24-36 mo.) for celecoxib and NSAIDs (naproxen, diclofenac, ibuprofen) are shown in the following table (unadjusted for differences in study demographics and cardiac risk factors).

Conclusion: These data suggest that celecoxib is not associated with an increased incidence of serious thromboembolic events when compared to NSAIDs and thus do not support the hypothesis of a class effect of COX-2 specific inhibitors on CV events.

Disclosure: Sponsored by Pharmacia Corporation and Pfizer Inc.

	Celecoxib	NSAIDs	RR (95% CI)
CLASS	Rate/100 pt-yrs (total patient exposure)		
All Patients	2.24 (2,320)	2.22 (2,203)	1.01 (0.67-1.52)
Non-ASA	1.39 (1,804)	1.34 (1,715)	1.03 (0.56-1.91)
Arthritis Trials			
All	1.41 (2,845)	1.59 (1,445)	0.88 (0.52-1.55)
Non-ASA	0.73 (2,587)	1.21 (1,325)	0.61 (0.30-1.26)
Open Label Trial			
All	1.37 (7,024)	--	--
Non-ASA	0.80 (5,720)	--	--
Combined Trials (CLASS, Arthritis, Open Label)			
All	1.59 (11,693)	1.97 (3,648)	0.81 (0.61-1.07)
Non-ASA	0.92 (9,677)	1.28 (3,040)	0.72 (0.49-1.07)

4:15 p.m.

873-2 Ominous Prognostic Implications and Inadequacy of Heparin Alone for Right Heart Thrombi in Patients With Acute Pulmonary Embolism: Analysis of Baseline Characteristics, Echocardiograms, Treatment, and Clinical Outcomes in the International Cooperative Pulmonary Embolism Registry

Adam Torbicki, **Samuel Z. Goldhaber,** Nazzareno Galié, Anna Covezzoli, Marisa De Rosa, on behalf of the ICOPER Study Group, *Institute of Tuberculosis and Lung Disease, Warsaw, Poland.*

Background: Management of right heart thrombi (RHTh) in acute pulmonary embolism (PE) is controversial, because most reports have been small case series. Therefore, we analyzed 2,454 consecutive acute PE patients enrolled in International Cooperative Pulmonary Embolism Registry (ICOPER).

Methods: Of the 2,454 patients, 1,143 underwent baseline echocardiography. We compared the 42 patients with versus 1,071 without RHTh.

Results: Patients with RHTh had lower systolic blood pressure (116.0±28.0 versus 125.7±25.0 mmHg, p=0.008), especially < 90 mm Hg (14% versus 5%, p=0.012), and more frequent right ventricular hypokinesis (64% versus 40%, p=0.002). However, they were similar at admission with respect to age (62.9 versus 62.5 years), arterial oxygen pressure (71.3±26.0 versus 69.5±30.5 mmHg), and prevalence of cancer (14% versus 19%). The overall mortality rate at 14 days and at 3 months was twice as high in patients with RHTh (21% versus 11%, and 29% versus 16%, respectively, p<0.05) and remained so after the exclusion of patients with right heart catheters and electrodes potentially pro-

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