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### PHS5

## THE ASSOCIATION BETWEEN LDL LEVELS AND CVD WITHIN THE COMMUNITY: AN OBSERVATIONAL STUDY

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OBJECTIVES: Evidence from recent studies on statin treatment intensity for secondary prevention supports targeting lower low-density lipoprotein (LDL) levels through higher intensity statin treatment. This study aims to assess whether achievement of the lower LDL threshold is associated with a reduction in cardiovascular outcomes. METHODS: Retrospective cohort study of adult members of a large health fund with pre-existing ischemic heart disease (IHD) treated with statins for at least one year during 2006-2010, and with a routine, fasting serum LDL test measures. The incidence of the composite Major Adverse Cardiac Events (MACE) was compared between three patient groups according to their achieved LDL: (>70-1-100mg/dl (Moderate) vs. >100·1-130mg/dl (High), and >70·1-100mg/dl (Moderate) vs. ≤70mg/ dl (Low)). **RESULTS:** Of 52,177 patients treated with statins, 11,647 had an achieved LDL (post-statin treatment) of 70mg/dl or below, 29,097 between 70.1-100mg/dl and 11,433 between 100·1-130mg/dl. Mean follow-up time from achieved LDL to MACE was 3.6 years (±1.5), with 10,955 subjects incurring a MACE during follow-up. LDL levels 70·1-100mg/dl compared to 100-130mg/dl were associated with a significant 8% reduction in the incidence of MACE (hazard ratio [HR]=0.92 [95% CI, 0.88-0.97; p=0·001]), while  $\leq$ 70 mg/dl compared to 70·1-100mg/dl was not (HR=0·98 [95% CI,  $0\cdot 93\text{-}1\cdot 03;\, p = 0\cdot 374]).\,Results\, remained\, consistent\, in\, propensity\, score-adjusted\, Cox$ regression, a sensitivity analysis, and in a sub-group analysis, with no demonstrated advantage in MACE outcomes for achieved LDL levels ≤70mg/dl. **CONCLUSIONS:** Among a real-world population of IHD patients adherent to their statin treatment, achieving LDL levels below 100mg/dl is associated with significant clinical benefit, whereas no additional benefit is gained by achieving LDL levels below 70mg/dl.

# NATURAL HISTORY OF METASTATIC PROSTATE CANCER IN CLINICAL PRACTICE $\label{eq:continuity} \begin{tabular}{l} Ulcickas Yood $M^1$, Cheng $S^2$, Wells $KE^3$, Casso $D^4$, Woodcroft $KJ^3$, Ukropec $J^2$, $\underline{Zyczynski}$ $T^2$ in EpiSource, LLC, Newton, MA, USA, $^2$Bristol-Myers Squibb Company, Princeton, NJ, USA, $^3$Henry $L^2$ in EpiSource, LLC, Newton, MA, USA, $^3$ in EpiSource, LLC,$ Ford Health System, Detroit, MI, USA, 4Formerly of EpiSource, LLC, Newton, MA, USA

OBJECTIVES: To describe the natural history of metastatic prostate cancer in patients treated with androgen deprivation therapy (ADT) or orchiectomy in clinical practice. METHODS: Newly diagnosed prostate cancer patients (2004-2010) treated with ADT/orchiectomy were identified from the Henry Ford Health System tumor registry. Patients were followed through July 31, 2012. Data on disease progression (rising prostate-specific antigen [PSA] and presence of metastases) were collected from medical records and automated data. Time from initial diagnosis to metastases was determined by Kaplan-Meier analyses. RESULTS: We identified 702 patients; 58% ≥70 years and 50% African American; 56% of patients were initially diagnosed at stage II, 10% at stage III, 22% at stage IV, and 12% had missing/unknown stages. Three percent received orchiectomy; 97% received ADT. Comprehensive data on testosterone levels were not available. During followup, an additional 8% of patients progressed to metastatic disease (N=207): 52% (107) had evidence of postcastration disease progression (17% rising PSA, 28% presence of ≥2 new bone metastases, 55% met both criteria). Bone was the most common site, occurring in 74% of metastatic patients; 59% of metastatic patients developed bone mestastases to spine. Other metastatic sites included distant lymph nodes (12%), lung (8%), central nervous system (7%), and other (14%). Mean follow-up time was 3.8 years. Kaplan-Meier analysis indicated that by 5 years after initial diagnosis, 13% of stage II and 36% of stage III patients developed metastases. CONCLUSIONS: While the incidence of cancer is routinely collected via registries, information on progression or recurrence is sparse. This study is one of few to present information on the natural history and disease progression of ADT/orchiectomy-treated prostate cancer in a clinical setting. In this study, we found 30% of patients were diagnosed with or progressed to metastatic disease. This assessment of medical need may inform future resource planning.

## THE DIAGNOSTIC AND CLINICAL VALUE OF ANTI-MUTATED CITRULLINATED VIMENTIN ANTIBODIES IN RHEUMATOID ARTHRITIS

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OBJECTIVES: Objective To assess the diagnostic and clinical value of anti-mutated citrullinated vimentin (anti-MCV) antibody for rheumatoid arthritis (RA) via comparing with rheumatoid factors (RF) and anti-cyclic citrullinated peptide antibodies (anti-CCP). METHODS: Anti-MCV and anti-CCP were determined using enzymelinked immunosorbent assay (ELISA), and meanwhile, the RF was detected in 88 patients with RA and 16 patients with other rheumatic diseases. Receiver operating characteristic (ROC) curve was operated to calculate the areas under the curve of RF. anti-CCP and anti-MCV, the max Youden indexes were also calculated to determine the optimum testing threshold and the corresponding sensitivity and specificity, the diagnostic significance of RF, anti-CCP and anti-MCV in RA were analyzed. The correlation of erythrocyte sedimentation rate (ESR) and anti-MCV, and C reactive protein (CRP) and anti MCV were evaluated by linear-regression analysis. RESULTS: The areas under the curve of RF, anti-CCP and anti-MCV were 0.775, 0.847 and 0.873, respectively. The  $\max$  Youden indexes of RF, anti-CCP and anti-MCV were 0.534, 0636 and 0.71, respectively, and the corresponding sensitivity and specificity were 78.4% and 75%, 63.6% and 100%, and 77.3% and 93.7%, respectively. A correlation between ESR and anti-MCV antibody, and CRP and anti-MCV antibody levels was observed. CONCLUSIONS: The sensitivity of anti-MCV is higher compared to anti-CCP and is comparable to RF, and its specificity is higher than that of RF. Consequently, anti-MCV can be served as a diagnostic index for RA and its expression is associated with disease activity of RA.

### PHS8

## SURVIVAL ANALYSIS FOR GASTRIC CANCER DETECTED BY ENDOSCOPIC SCREENING

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OBJECTIVES: The effectiveness of endoscopic screening for gastric cancer has been continually evaluated; however, only a few studies have reported its effectiveness. Notably morality reduction from cancer screening has not yet been rigorously evaluated in survival analyses, but an important requirement for cancer screening is improving survival. We performed survival analysis for gastric cancer detected by endoscopic screening and compared the results with those of survival analysis for gastric cancer detected by radiographic screening and outpatients. METHODS: The subjects of our study were selected from gastric cancer cases registered in 4 cities in the Tottori Cancer Registry from 2001 to 2006. The target age group was defined as the age in which gastric cancer was diagnosed from 40 to 79 years. Follow-up was continued from the date of diagnosis to the time death from gastric cancer or up to December 31, 2011. The survival of 3 groups at 5 and 10 years were compared using the Kaplan-Meier method with the log-rank test. **RESULTS:** There were 347 subjects selected for endoscopic screening, 166 for radiographic screening, and 980 as outpatients. The 5-year survival rates were follows: 91.2 ± 1.5% (95% CI: 87.6-93.8) for endoscopic screening, 84.3 ± 2.9% (77.7-89.1) for radiographic screening, and 66.0  $\pm$  1.6% (62.8-68.9) for outpatients. The 10-year survival rates were follows: 88.5  $\pm$  2.0% (83.9-91.9) for endoscopic screening, 80.1 ± 3.6% (71.9-86.2) for radiographic screening, and  $64.6 \pm 1.6\%$  (61.3-67.6) for outpatients. The survival rates were significantly different in the 3 groups (P < 0.001). **CONCLUSIONS:** The survival rate was higher for endoscopic screening than those for radiographic screening and outpatients. Since a high survival rate is mainly affected by lead-time bias, the effectiveness of endoscopic screening should be further evaluated in term of mortality reduction by conducting large-scale and reliable studies.

## SCREENING FOR TYPE 2 DIABETES: A METHODOLOGICAL REVIEW AND COST ANALYSIS

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OBJECTIVES: Screening for type 2 diabetes (DM) has peaked as a controversial issue given the publication of the recent Canadian guidelines and since the clinical trial evidence for the effectiveness of DM screening is lacking. METHODS: A two-step evidence-based analysis was performed: 1) narrative review of international guidelines 2) systematic review of primary studies. MEDLINE, EMBASE, CINAHL, Wiley Cochrane, and Centre for Reviews and Dissemination (2008-2012) were used to identify primary studies comparing the effectiveness of DM screening to usual care. Randomized controlled trials and observational studies meeting inclusion criteria were meta-analyzed and the quality of evidence was evaluated using GRADE. A cost analysis was developed using Ontario claims data and estimating the downstream health care costs in Canadian dollars of screening in Ontario. RESULTS: Eight guidelines and six studies from 2,780 citations were identified. The recommendations for universal screening or screening for low to moderate risk individuals were heterogeneous, not shown for high or very high risk individuals. The guidelines consistently recommended screening for the latter. Screening was associated with a lower likelihood of retinopathy (RR: 0.54, 95% CI: 0.32-0.92) and lower absolute % HbA1c (MD: -0.32, 95% CI: -0.53, -0.11). Screening was not linked to increased anxiety or false reassurance. One large RCT showed no beneficial effect of screening on long-term mortality outcomes. Two observational studies meta-analyzed showed no beneficial effect of screening for neuropathy and nephropathy. The quality of evidence was moderate to very low. Estimated cost savings is \$150.4 million dollars using established parameters, with a range of cost savings as low as \$16.7 up to \$280.4 million dollars in sensitivity analysis. **CONCLUSIONS:** Despite its widespread acceptance, the evidence for the long-term effectiveness of DM screening is lacking. Further clinical and cost analysis in Canada is needed for short-term outcomes to help clarify the issue.

## OUALITY OF PHARMACIST-MANAGED ANTICOAGULATION THERAPY IN LONG-TERM AMBULATORY SETTINGS: A SYSTEMATIC REVIEW

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OBJECTIVES: To perform a systematic review to evaluate the quality of anticoagulation control in outpatient pharmacist-managed anticoagulation services (PMAS) compared to routine medical care (RMC). METHODS: We searched MEDLINE, SCOPUS, EMBASE, IPA, CINAHL, Cochrane CENTRAL, with language restriction to English. Two authors independently reviewed each study and extracted data for all outcomes using a standardized form, with any disagreement resolved by a third author. The primary outcome was the quality of warfarin-related anticoagulation management using time in therapeutic range (TTR) as an indicator. Warfarin-related bleeding, thrombotic events and resource utilization were assessed as secondary outcomes. RESULTS: Of 155 articles identified, 23 articles met the criteria for final review. Of these, three studies were RCTs and twenty were observational studies. Most studies were conducted between year 2000 to 2013 (N=18, 78%), and study follow-up ranged from six to twelve months (N=13, 57%). Among studies that reported patients' age, the average age ranged from 46 to 80.5 years, and was similar between PMAS and RMC groups. The majority of patients were treated for atrial fibrillation and venous thrombosis. Quality of anticoagulation control was better in the PMAS group compared to RMC, as indicated by higher TTRs in the majority of the studies (N=21, 91%). Clinical outcomes were also favorable in the PMAS group as evidenced by lower risk of major bleeding (N=10 of 14, 71%) or thromboembolic