

patients from 2000 to 2007 were matched 1:10 by age and gender to cancer-free controls selected from the PHARMO RLS with date of diagnosis as the index date for both RCC patients and their controls. TE events were defined as any venous TE event or arterial TE event requiring hospitalization in the 12 months before or after index date. **RESULTS:** A total of 973 RCC patients were included, 6% of whom underwent nephrectomy. The proportion of patients with any TE event was similar before (2.0%, 95% CI: 1.2–3.0%) and after (1.4%, 95% CI: 0.8–2.4%) RCC diagnosis. Arterial TE events were more common prior to diagnosis (1.6%, 95% CI: 0.9–2.7%) than post-diagnosis (0.5%, 95% CI: 0.2–1.2%), whereas venous TE events were less common prior to diagnosis (0.3%, 95% CI: 0.1–0.9%) than post-diagnosis (0.9%, 95% CI: 0.4–1.8%). Compared to cancer-free controls, RCC patients were more likely to have had a pre-diagnosis (odds ratio = 2.7, 95% CI: 1.6–4.4) or post-diagnosis (hazard ratio = 2.1, 95% CI: 1.2–3.7) TE event. **CONCLUSIONS:** In this population-based study, RCC patients were twice as likely to develop TE events compared to cancer-free controls, although frequency of events was low. These results emphasize the need for careful observation of RCC patients after diagnosis.

PCN6

A COMPARISON OF CLINICAL EFFICACY AND SAFETY OF LENOGRASTIM AND FILGRASTIM IN THE STEM CELL MOBILIZATION

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OBJECTIVES: TO compare efficacy and safety of lenograstim and filgrastim in stem cell mobilization in healthy donors (allogenic transplantation) and in oncological patients (autologous transplantation). **METHODS:** Comparison was based on randomized controlled trials (RCTs) identified by means of systematic review, carried out according to the Cochrane Collaboration guidelines. The most important medical databases were searched (EMBASE, MEDLINE, CENTRAL). Two reviewers independently selected trials, assessed their quality and extracted data. Meta-analysis of head-to-head trials was performed to compare lenograstim and filgrastim in stem cell mobilization in healthy donors and oncological patients. **RESULTS:** The results of 4 RCTs in healthy donors and 3 RCTs in oncological patients were included in the analysis. For healthy donors mobilization with lenograstim resulted in higher number of CD34+ cells harvested than mobilization with filgrastim (WMD = 0.66×10^6 per kg of body weight [0.05; 1.26]). No differences between lenograstim and filgrastim were found in the number of donors requiring second apheresis (RR = 0.91 [0.62; 1.35]). Adverse events rates were similar in both arms. Most common adverse events including bone pain and arthralgia. For oncological patients no differences in the number of patients that gained target CD34+ cells ($>2 \times 10^6$) were found (RR = 0.72 [0.33; 1.55]). Results for hematological recovery are inconsistent. No significant differences in the incidence of neutropenia were noted (RR = 0.72 [0.50; 1.03]) whereas platelet transfusions were more frequent in filgrastim treated patients than in lenograstim group (RR = 0.16 [0.04; 0.67]). The length of hospital stay after transplantation was similar in both groups. No significant differences regarding safety outcomes were reported. **CONCLUSIONS:** In healthy donors lenograstim is more potent than filgrastim in stem cell mobilization into peripheral blood and no differences in safety profiles between two drugs were noted. In oncological patients both drugs has similar impact on stem cell mobilization while lenograstim decreases the risk of platelet transfusion. **Acknowledgements:** This analysis was supported by Sanofi-Aventis.

PCN7

A COMPARISON OF CLINICAL EFFICACY AND SAFETY OF PERIPHERAL BLOOD STEM CELL TRANSPLANTATION AFTER MOBILIZATION WITH LENOGRASTIM AND FILGRASTIM

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OBJECTIVES: This study compared efficacy and safety of allogenic peripheral blood stem cell transplantation (PBSCT) after mobilization with either lenograstim or filgrastim. **METHODS:** Comparison was based on randomized controlled trials (RCT) identified by means of systematic review, carried out according to the Cochrane Collaboration guidelines. The most important medical databases were searched (EMBASE, MEDLINE, CENTRAL). Two reviewers independently selected trials, assessed their quality and extracted data. Since head-to-head trials were not found, indirect comparison using Bucher's method was performed. **RESULTS:** The results of 2 RCTs for PBSCT after lenograstim mobilization and 7 for PBSCT with filgrastim were included. In all trials PBSCT was compared with bone marrow transplantation (BMT). No significant differences between lenograstim and filgrastim were found in mortality rate (RR = 0.84 [0.49; 1.42]) and relapse rate (RR = 0.69 [0.19; 2.49]). PBSCT after mobilization with lenograstim comparing to BMT does not increase the risk of acute graft versus host disease (GvHD) (RR = 1.06 [0.73; 1.53]) whereas PBSCT after filgrastim use is associated with higher risk of acute GvHD than BMT (RR = 1.19 [1.03; 1.37]). However indirect comparison results in similar incidence of acute GvHD (RR = 0.89 [0.60; 1.32]). There was also no difference between lenograstim and filgrastim in respect to chronic GvHD (RR = 1.33 [0.84; 2.11]). Lenograstim and filgrastim in PBSCT resulted in similar mortality rate due to GvHD (RR = 0.55 [0.19; 1.59]), treatment related mortality (RR = 1.11 [0.60; 2.04]). No differences in hospital admissions for donors mobilized with lenograstim and filgrastim were identified (RR = 1.04 [0.60; 1.79]). **CONCLUSIONS:** Indirect comparisons indicate similar efficacy and safety of PBSCT after mobilization with lenograstim and PBSCT after mobilization with filgrastim. **Acknowledgements:** This analysis was supported by Sanofi-Aventis.

COMORBIDITIES IN PATIENTS WITH METASTATIC COLORECTAL CANCER

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OBJECTIVES: To describe the prevalence of comorbidities in the newly diagnosed mCRC population. **METHODS:** The study used a large US claims database. Patients aged ≥ 18 with newly diagnosed mCRC between January 2005 and June 2008 were selected using the ICD-9 diagnosis codes (CRC: 153.x [excluding 153.5], 154.0, 154.1, 154.8; distant metastasis: 196.0, 196.1, 196.3, 196.5, 197.x [excluding 197.5], 198, 199.0). The initial mCRC diagnosis date was defined as the index date. One-year continuous medical and drug benefit coverage prior to the index date was required. Medical diagnoses and medication treatments were examined. All comorbidities were estimated during 1-year except for traumatic conditions which were assessed for 30-day prior to the index date. **RESULTS:** Based on the selection criteria, 12,648 patients were included with mean (\pm standard deviation) age of 66.3 (± 13.0) years, 54% male, and 70% with colon primary. Distribution of metastases included liver (40%), lung (14%), bone (6%), and brain (3%). The most prevalent comorbidity was cardiovascular disease (CVD) (62% of patients) including hypertension (41%), coronary artery disease (17%), congestive heart failure (7%), dysrhythmias (14%), arterial thromboembolism including ischemic heart disease (18.6%), and venous thromboembolism (6%). Over 10% of patients had a major surgery, bone fracture, or open wound 30 days prior to mCRC diagnosis; 31% had a history of bleeding; and nearly 12% of patients were treated with anticoagulant and 6% with antiplatelet agents. Additionally, 19% of patients had diabetes, 8% had renal failure or insufficiency, and 5% had skin disorders. Patients ≥ 65 years old had a significantly higher CVD prevalence (73%; $p < 0.001$). **CONCLUSIONS:** Comorbid medical conditions are common in patients with mCRC. CVD is the most prevalent comorbidity and affects approximately $\frac{3}{4}$ of patients over age 65. It is important to assess comorbidities in all patients with mCRC since their presence may impact treatment decision making.

PCN9

DEVELOPMENT OF SERUM TESTS FOR COLORECTAL CANCER SCREENING

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OBJECTIVES: Current options for colorectal cancer (CRC) screening include imaging procedures such as colonoscopy and flexible sigmoidoscopy, guaiac fecal occult blood tests (gFOBT), and fecal immunochemical tests (FIT). Compliance with screening for CRC guidelines remains low among average-risk adults, at least partly because of low patient acceptance of available tests due to their invasiveness, inconvenience, and perceived safety risks. Serum tests are noninvasive, convenient, and safe, and may improve compliance. We systematically reviewed the literature to assess the current status of serum tests and other screening tests for CRC. **METHODS:** We analyzed studies of CRC screening tests identified in a search of English-language MEDLINE-indexed articles published in the 3 years prior to March 2009 and non-MEDLINE-indexed sources such as organization websites, meeting abstracts, and government publications. **RESULTS:** We identified 123 primary studies from MEDLINE and 45 from non-MEDLINE sources for a total of 168 pertaining to tests or biomarkers for early diagnosis of CRC. Serum biomarkers being evaluated include tumor associated antigens, cytokines, anti-apoptotic and pro-growth factors, and hypermethylated DNA. Biomarkers under development have significantly higher sensitivity for CRC than for adenomatous polyps, making them more effective for cancer detection than prevention. CRC sensitivity and specificity of certain serum biomarkers and serum biomarker panels under development are better than those of the existing test gFOBT and equivalent or better than those of FIT. However, most biomarkers in development are common to other cancers and diseases, reducing their specificity for CRC. **CONCLUSIONS:** Several serum biomarkers show promise in detecting CRC, but require testing in large, average-risk populations. Unless biomarkers are identified that are more specific for adenomas and/or CRC than currently known, and because of the heterogeneity of CRC, the approach most likely to be successful would involve the combination of multiple serum biomarkers to create a distinctive CRC biomarker profile.

PCN10

MALIGNANT GASTROINTESTINAL STROMAL TUMORS TREATED WITH IMATINIB IN FRANCE: EFFICACY IN REAL LIFE

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OBJECTIVES: GISTs are rare tumors of the GI tract. In France, their incidence is estimated to be 9–12/10⁶ inhabitants/year. Imatinib has been approved to treat unresectable and/or metastatic Kit-positive GISTs since 2002, but information on routine use, safety and efficacy in unselected “real life” setting is lacking. An observational cohort (EPIGIST) in France was designed to provide data on survival, safety and treatment patterns and quality of life. **METHODS:** EPIGIST is a nationwide