

POSTER PRESENTATION

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# Development of a core outcome set based on Case Report Form (CRF) to assess laboratory biomarkers and clinical parameters in Onco-Hematology area

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## Background

The number of cases, the crude and age-standardized incidence, mortality rates and the prevalence proportions estimated by the Italian Association of Cancer Registries (AIRTUM) presently providing the epidemiological indicators for the major cancers used in ICD-O-3.1 [1-3]. By 2012, the breast cancer incidence in women (age 25±over 85 years) was about 29%; trends for stomach and colorectal cancer were about 5% and 14% for both genders (age 35/45±over 85 years); the lung cancer incidence rates was about 15% in men (age 45±over 85 years) and 6% in women (age 40±over 85) in 2009 [4,5]. From 2011 onwards the tendency changed: the female rates (20 per 100,000) increased much more rapidly than the male rates [6].

Aim of this study is to examine the relationships among the incidence of genera-cancer-associated risk factors and routine laboratory in cancer patients through CRF.

## Materials and Methods

The CRF database has been developed by a dedicated working group using Delphi process. It contain anonymous records on patient characteristics (gender, age, alcohol and smoking history, height, body weight, performance status measured using the Eastern Cooperative Oncology Group-ECOG PS, chronic comorbidities weighted by the Charlson Comorbidity Index-CCI, type and stage of tumor) (Figure 1) [7-9] and one set of

biomarker laboratory data identified in several variables (Table 1) [10,11].

## Results

Between 2012 and 2014, 1373 cancer patients were enrolled at three Italian Oncological Institutions after informed consent. Among these patients, 36% were men and 64% were women (mean age 71±45 years) (Figure 2) and breast was the most frequent type cancer (43%) followed by lung (29%), colon-rectum (18%) and stomach (9%). 72% (n=85) of the lung, 67% (n=24) of the stomach, 33% (n=25) of the colon-rectum, 4% (n=7) of the breast cancer patients had comorbidities weighted with 3 point and above (Age Unadjusted Charlson-Comorbidity-Index $\geq$ 4; HR=6.38; 99% CI [3.07,13.24]) [12,13] (Figure 3). Multivariate analysis determined that comorbidity was highly associated with cancer type, stage and ECOG PS (p=0.01) (Figure 4). Evaluation between cardiovascular

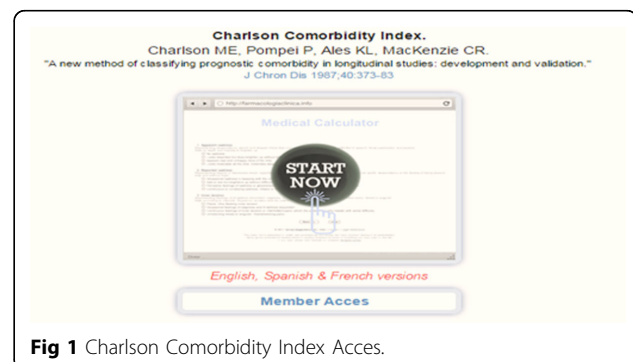


Fig 1 Charlson Comorbidity Index Acces.

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**Table 1. Multivariate Analyses of cancer type, comorbidity score and biomarkers laboratory**

Comorbidity	Breast p	Colon-rectum p	Stomach p	Lung p
HCT_cod	0.105	0.708	0.387	0.078
Hb_cod	0.035	0.775	0.466	0.351
RBC_cod	0.564	0.343	0.194	0.448
WBC_cod	0.292	0.172	0.930	0.583
PLT_cod	0.167	0.535	0.401	0.332
<b>CCI_SCORE ≥4</b>	<b>0.495</b>	<b>0.029</b>	<b>0.092</b>	<b>0.381</b>

cancer type: breast, colon-rectum, stomach and lung; biomarkers laboratory: HCT, Hb, RBC, WBC, PLT;

disease, risk of bleeding, deep-vein thrombosis and colon-rectum cancer stage (p=0.01), breast (p=0.03), lung (p=0.01) compared into comorbidities (Figure 5). The other tested variables: Hgb level, neutrophil and platelet count had the strongest relationship with breast, lung cancer stage (p=0.02), stomach (p=0.002) and colon-rectum (p=0.1) [14,15].

**Conclusions**

The appropriateness of results could be useful to better describe the role of CRF and biomarkers recorded in patient charts as well as the other variables could allow nurses to identify patients at risk for shorter survival time following hospitalization [16,17].

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**Correction**

1. Corrected 7/2014 (based on 1996 paper)
2. Age-based scoring starts at age 50 years (not age 40 years)

**Scoring**

1. Age <50 years: 0 points
2. Age 50-59 years: 1 points
3. Age 60-69 years: 2 points
4. Age 70-79 years: 3 points

**Fig 2** CCI and their respective point scores.

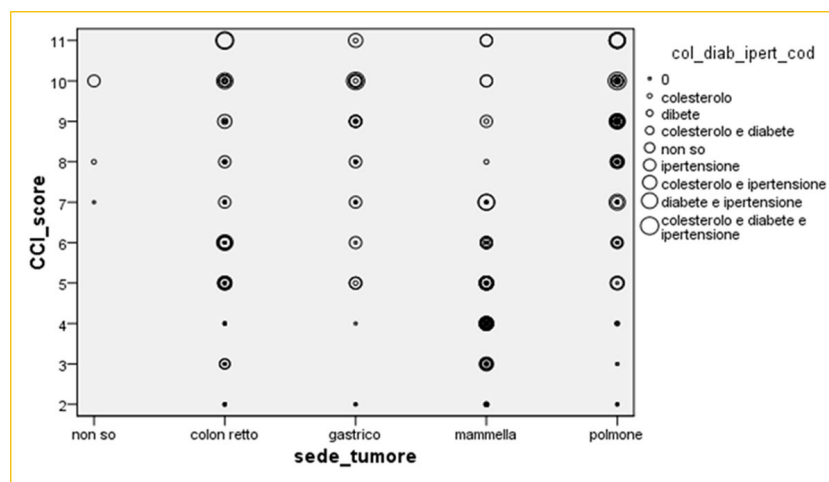
Points	1	2	3	6
Morbidity	MI CCF PVD COPD DM (without end-organ damage) Cerebrovascular disease Dementia Ulcers Connective tissue disease Mild liver disease	Hemiplegia Moderate-severe CRF DM (with end-organ damage) Malignancy Leukaemia Lymphoma	Moderate-severe liver disease	Metastatic solid tumour AIDS

Abbreviations: MI, myocardial infarction; CCF, congestive cardiac failure; PVD, peripheral vascular disease; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; CRF, chronic renal failure.

**Fig 3** CCI and their respective point scores.



**Fig 4** Multivariate Analysis and the comorbidities of CCI with IBM SPSS Italian version 21 statistical software.



**Fig 5** Multivariate Analysis and the comorbidities of CCI with IBM SPSS Italian version 21 statistical software.

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