Among the publications that provided this information, no patients were given neo-adjuvant chemotherapy. Twenty-one publications (42%) reported if adjuvant chemotherapy was given to patients. Tumour size and depth were reported in twenty (40%) and nine (18%) publications respectively. Twenty-nine publications (58%) specified the location of the tumour. Tumour histological type was reported in eighteen publications (36%). Tumour grade or TNM stage were reported in twenty-seven publications (54%).

Conclusions: The reporting of baseline data in gastric cancer surgery trials is markedly inconsistent. A consensus-based approach is required to identify a standardised minimum set of baseline data which should be reported by all trials examining therapeutic surgical interventions for gastric cancer.

No conflict of interest.

1332A POSTER
The biological role of AKT serine/threonine kinase 2 in lung cancer
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Background: Lung cancer, also known as carcinoma of the lung or pulmonary carcinoma, is a malignant lung tumor characterized by uncontrolled cell growth in tissues of the lung. Primary lung cancers, are carcinomas derived from epithelial cells. The main primary types are small-cell lung cancer (SCLC), and non-small-cell lung cancer (NSCLC). The closely follow-up of patients having the predisposing disorders can yield an increase in the rates of early diagnosis and curative treatment modalities. Protein kinase B (PKB), also known as Akt, is a serine/threonine-specific protein kinase that plays a key role in multiple cellular processes such as glucose metabolism, apoptosis, cell proliferation, transcription and cell migration. AKT is an important signaling molecule in the insulin signaling pathway. It is reported to induce glucose transport. Akt isoforms are overexpressed in a variety of human tumors, and, at the genomic level, are amplified in gastric adenocarcinomas (Akt1), ovarian, lung, pancreatic and breast (Akt2) cancer.

Emerging evidence confirms a central role of Akt in cancer. To evaluate the relative contribution of deregulated Akt and their clinicopathological significance in lung carcinomas, overexpression, activation of AKT gene increases were investigated.

In the current study, we aim to determine the serum levels of AKT-2 verified lung cancer patients. The results are compared with the controls by using statistical tests.

Material and Methods: The serum samples of the 60 consecutive patients with lung cancer who referred to Istanbul University Institute of Oncology from 2015 to 2016 were obtained. The healthy control group consisted of 20. AKT-2 protein assay employs ELISA. The colored reaction product was measured using an automated ELISA microplate reader at 450 nm. Results: AKT-2 (P = 0.00) protein levels were significantly higher in patients with lung cancer than the healthy controls. However, known clinical variables including response to adjuvant chemotherapy were not found to be correlated with serum AKT-2 concentrations (P > 0.05). A significant relationship between other clinicopathologic variables including localization of lung (P = 0.04), presence of metastasis (P = 0.01), vascular invasion (P = 0.02).

Discussion: We think this parameter will be important in serum samples of patients with lung cancer diagnosis and disease follow-up. AKT-2 is important in lung cancer targeted therapy.

No conflict of interest.

1333 POSTER SPOTLIGHT
Setting international standards in analyzing patient-reported outcomes and quality of life endpoints data for cancer clinical trials (SISAQOL consortium)
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Background: With patient-centered care garnering a more central role in oncology, patient-reported health-related quality of life (HRQL) is also increasingly being identified as an important source of data to help describe clinical benefit in cancer randomized controlled trials (RCTs). However, the various ways HRQL endpoints are currently defined, analyzed and interpreted make it difficult to compare results across cancer RCTs. To respond to this problem, the Setting International Standards in Analyzing Patient-Reported Outcomes and Quality of Life Endpoints Data for Cancer Clinical Trials (SISAQOL) initiative was established.

This: international multidisciplinary Consortium steered by the European Organization for Research and Treatment of Cancer (EORTC) was assembled to standardize the analysis of HRQL data from RCTs. Methods: We present the steps undertaken to form the SISAQOL initiative: an open discussion among various stakeholders regarding current needs, and the assembly of an international and multidisciplinary Consortium, the preparation of a work plan and planning of future steps. Results: The Consortium is composed of over 40 leading international experts including: HRQL researchers and statisticians, key individuals from various international oncolgy and medical societies, pharmaceutical industry, regulatory and advisory bodies (US Food and Drug Administration, European Medicines Agency, Health Canada, Institute for Quality and Efficiency in Health Care), academic societies (International Society for Pharmacoeconomics and Outcomes Research, International Society for Quality of Life Research, Multinational Association of Supportive Care in Cancer), cancer institutes (National Cancer Institute, Mayo Clinic, EORTC) and patient organizations (International Brain Tumour Alliance). We met in March 2017 to the members. There was a clear consensus that a standardised way of analyzing HRQL data is urgently needed. A work plan was developed to a) examine current statistical methods and challenges in interpreting HRQL in cancer RCTs, and b) consider general methodological guidelines proposed by different regulatory bodies and academic societies. These reports will be collated and a formal consensus will be set up to deliberate on how to resolve these issues.

Conclusions: RCTs cost time, money and effort; and patients, in the interest of improving their situations and helping others, voluntarily give their time to complete HRQL questionnaires for these trials. Therefore, the data from these trials must be exploited to the full, with appropriate and standardized statistical analyses. The aim of SISAQOL is to develop clear, internationally standards for the analysis of HRQL data from RCTs. We anticipate that the availability of guidelines will lead to more reliable findings, stemming from use of higher quality statistical methods.

Conflict of interest: Other Substantive Relationships: An unrestricted education grant was received from Boehringer Ingelheim GmbH to initiate this work.

1334 POSTER
Development of biosensor for non-invasive oral cancer detection
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Background: Oral cancer occurs due to uncontrolled growth of cells in the mouth most is currently the sixth most common cancer. If undetected at an early stage, it can metastasizes in the whole body leading to death. The conventional methods currently used for detection and monitoring of the oral cancer are time consuming, labour-intensive, expensive and require expensive equipment. Therefore, an affordable and accessible technique that can be used for rapid detection of oral cancer. In this context, biosensors are considered to be attractive and cost-effective technique that can be used for detection of oral cancer. Recently, there are several biomarkers such as IL-8, IL-6, VEGF, HER2, TP53 and EGFR that have been used in the oral cancer detection. But these biomarkers are secreted in very low concentration (<1ng/mL) in biological fluids. So it requires ultrase nsitive technique for its detection, that make the whole process very complex. Besides this, these biomarkers are secreted in serum/blood samples and hence the detection is invasive. Detection via salivary biomarker is a promising non-invasive approach for detection of oral cancer. Interestingly, the CYFRA-21-1 antigen is known to be over-secretated in saliva. In normal subjects, the CYFRA-21-1 level is found to be 3.8 ng/mL whereas in oral cancer patients it increases to 17.46±1.46 ng/mL. The aim of this study was to fabricate nH2O2 based efficient, that cover the whole physiological range of CYFRA-21-1 biomarker secreted in saliva sample of oral cancer patients.

Material and Methods: The nH2O2 was synthesized through one step hydrothermal process and further functionalized with 3-aminopropyl triethoxysilane (APTES) via low temperature sialation process. Indium tin oxide (ITO) coated glass electrode was used as a substrate for fabrication of biosensing platform. Functionalized nH2O2 (APTES/nH2O2) was electrophoretically deposited onto ITO electrode. Next, anti-CYFRA-21-1 biomolecules was further immobilized onto APTES/nH2O2/ITO electrode through EDC/NHS chemistry. BSA was used for the blocking of non-specific binding sites. Unstimulated saliva of ten patients were used to diagnostic oral cancer.

Results: Fabricated immunoelectrode i.e. BSA/anti-CYFRA-21-1/APTES/nH2O2/ITO shows linearity range 2 to 16 ng/mL (with regression
coefficient 0.988), high sensitivity 9.28 u/mL ng·cm⁻² with acceptable lower detection limit of 0.21 ng·cm⁻². The obtained results show good correlation with gold standard technique for protein biomarker detection i.e. enzyme linked immunosorbent assay (ELISA).

Conclusions: The results are considered to be attractive and cost-effective technique that can be used for detection of oral cancer. We have fabricated a label free, non-invasive and efficient biosensor, which can be used in the detection of oral cancer.

No conflict of interest.

1335 Systematic registration of outcome in a radiotherapy institute

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Background: Over the last years there has been an increasing focus on registration and national audits of quality indicators, since it is assumed that insight in the quality of a certain treatment will increase quality. Two important indicators of quality of radiotherapy (RT) are (1) the incidence and severity of RT-related acute and late side-effects, and (2) the incidence of locoregional control. However, in many RT institutes, patients receive their follow-up after RT in the referring hospitals, thereby hampering the recording of outcome by radiation-oncologists (RTOs). Therefore, the aim of the current project was to set up a systematic tumor and toxicity outcome data collection, to be presented in dashboards. In the present part of the project we first focussed on obtaining data on radiation-induced toxicity.

Material and Methods: For RT-induced toxicity, we discriminate Patient Reported Outcome Measures (PROMs) and Doctor Reported Outcome Measures (DROMs), the latter referring to medical sources in its broadest sense. During intake, baseline patient variables, such as age, sex, and WHO-score, are recorded in the electronic medical record (EMR). Acute toxicity is scored in the EMR during and directly after RT according to CTC-AE4 criteria. Baseline questionnaires are personally handed to the patient during intake, follow-up PROMs are sent to the patient by regular mail at 3 weeks, 3 and 6 months, and 1 year after RT, and thereafter annually for at least 5 years. Returned PROMs are digitalized and linked to the EMR and to our data warehouse. From the data warehouse, the toxicities are presented to the tumor workgroups using dashboards. DROMs with scores of Grade 3 are immediately sent to the treating RTO, to ensure adequate treatment of the patient.

Results: Acute DROMs are being recorded for all tumor groups; late DROMs are systematically being recorded for Gynaecology, Urology, and Head and Neck Cancer. PROM questionnaires for both acute and late toxicity are sent out for nine tumorgroups: Gynaecology, Urology, Gastro-Intestinal (lower), Gastro-Intestinal (upper), Breast, Lung, Head and Neck, Neurology, Palliation. Preliminary analyses of the response rates showed promising figures: for Head and Neck patients 84% of the baseline PROM questionnaires were returned.

Conclusions: We have been able to set up a robust system to acquire data on acute and late RT-induced toxicity, and to present this in interactive dashboards. Further effort will be put in adding data on case-mix and treatment-mix, to allow proper benchmarking.

References


No conflict of interest.

1336 POSTER SPOTLIGHT

Health-related quality of life in adolescent and young adult (AYA) cancer patients: a longitudinal study

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Background: The aim of this study was to examine changes in health-related quality of life (HRQoL) and its predictors over the first two years after initial cancer diagnosis in adolescent and young adult (AYA) cancer patients.

Material and Methods: A multicenter, longitudinal, prospective study was conducted among a diverse sample of AYA cancer patients aged 14–39 years. One hundred seventy-six patients completed a self-report measure of HRQoL (Short-Form-36 [SF-36]) within the first four months of diagnosis and again 12 and 24 months later. Linear mixed models with random intercept and slope estimated changes in QoL.

Results: Recently diagnosed AYA cancer patients had significantly worse physical component scores (PCS: 38.7 vs. 52.8; p<0.001) and mental component scores (MCS: 42.9 vs. 48.9; p<0.001) when compared to population norms. Significant improvements in PCS and MCS from baseline to 24-month follow-up were observed; however, these increases were largest during the first 12 months. At 24-month follow-up, AYAs still had significantly lower PCS (48.0 vs. 52.8; p<0.001) and MCS (45.8 vs. 48.9; p=0.002) when compared to population norms. Multivariate analysis revealed that improvements in PCS and MCS were primarily a function of being off-treatment and being involved in school or work. PCS but not MCS was worse for AYAs diagnosed with cancers with poorer prognoses, suggesting a substantial psychological impact even in the context of malignancies with relatively good prognosis.

Conclusion: Although improved over time, HRQoL was still compromised 24 months after primary diagnosis. Given relatively little observed into Danish and validation among Danish patients of an American PROMs, AYA patients may benefit from (psychosocial) support interventions administered during the second year following diagnosis.

No conflict of interest.

1337 POSTER

Translation and validation of PREM-questionnaire

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Background: Several questionnaires to measure patient reported outcomes (PROs) exist within the health care system and have become an increasingly popular source to gather information on various aspects of the patient condition. A number of these, mainly Patient Reported Outcome Measures (PROM) questionnaires, are used in clinical routine care such as EORTC-QOL-30. While the health care system gains significant knowledge of e.g. patients’ symptoms and QOL from extracting information, little is known, however, on how patients perceive filling out these questionnaires. To get more knowledge on patient perception of PROMs, a standardized Danish Patient Reported Experience Measures (PREM) questionnaire was needed. Despite thorough research, it was not possible to find a Danish PREM. This study describes the translation and validation among Danish patients of an American PREM feedback form ‘Patient Feedback Form’. The form consists of 13 questions.

Material and Methods: Having gained permission from the original developer of the form, Claire Snyder Associate Professor of Medicine at Johns Hopkins School of Medicine, the first phase of the process began. The translation and cultural adaption process was carried out according to existing guidelines with forward and backward translation, consensus meetings and cognitive interviewing. Hereafter, cognitive interviewing with seven cancer patients (48–86 years; men 2, women 5) and again 12 and 24 months later. Linear mixed models with random intercept and slope estimated changes in QoL.

Results: Recently diagnosed AYA cancer patients had significantly worse physical component scores (PCS: 38.7 vs. 52.8; p<0.001) and mental component scores (MCS: 42.9 vs. 48.9; p<0.001) when compared to population norms. Significant improvements in PCS and MCS from baseline to 24-month follow-up were observed; however, these increases were largest during the first 12 months. At 24-month follow-up, AYAs still had significantly lower PCS (48.0 vs. 52.8; p<0.001) and MCS (45.8 vs. 48.9; p=0.002) when compared to population norms. Multivariate analysis revealed that improvements in PCS and MCS were primarily a function of being off-treatment and being involved in school or work. PCS but not MCS was worse for AYAs diagnosed with cancers with poorer prognoses, suggesting a substantial psychological impact even in the context of malignancies with relatively good prognosis.

Conclusion: Although improved over time, HRQoL was still compromised 24 months after primary diagnosis. Given relatively little observed into Danish and validation among Danish patients of an American PREM, AYA patients may benefit from (psychosocial) support interventions administered during the second year following diagnosis.

No conflict of interest.