Poster Board 1
Design of Clinical Trials in the New Era

Response Rate with Chlorambucil and Bevacizumab in Advanced Heavily Treated Solid Tumors, an Old Drug with a New Anticancer Agent

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Background: Advanced cancer is an especial entity of medicine, incurability, pain, poor quality of life, cost and economical problem and psychological impact on family and society and side effects of new anticancer agents and finally short time to death.

As a way to find affecting this natural course ,chlorambucil-bevacizumab selected for this intervention. Chlor*ambucil is a safe and cost effective and interesting dr*ug and known for its broad anticancer pow*er* to control diverse tumors, selected in this trial combined with tumor antiangiogenesis agent bevacizumab to control and modulate the activity of advanced tumors to find a better natural course.

Objective: To evaluate the response rate and characterizing the patterns of clinical course of the patients with this combination to control the activity of cancer affecting the quality of life.

Method: A total of thirty-three cases with advanced solid tumors considered for this trial, seventeen patients with breast cancer, ten cases with advanced ovarian cancers and six with refractory Hodgkins lymphoma were in this study.

Dosage of the Chlrorambucil was four to six milligram per day and bevacizumab six mg per kg every four weeks for six months to have the least side effects related to cancer management.

Data Collected based on response rate and response duration and quality of life.

Results: The overall response rate in this study was thirty-six percent and duration of response was four months and no major side effects seen to affect the quality of life of the patients.

Conclusion: Using chlorambucil and bevacizumab with a safe toxicity profile in advanced solid tumors can be suggested as a challenging option in advanced cancers to improve the quality of and reminding us not to forget the old drugs in current time of battling with cancer.

Poster Board 2
Design of Clinical Trials in the New Era

Model to Study Rare Diseases to Make Progress and Improve Outcomes

Denise Reinke

President and CEO, SARC, USA

Background: Increasingly drug development is targeted to smaller and smaller patient populations as a result of molecular characterization and identification of rarely occurring mutated targets. However, while this is true in some subtypes of sarcoma (GIST), we have learned that histologic subtypes are a major determinant of drug efficacy. Therefore, an efficient method to study rare subtypes of sarcomas is needed to make progress.

Objective: Improve outcomes for patients with sarcoma through efficient clinical trial mechanisms.

Methods: SARC, a non-profit academic research consortium, was formed 15 years ago to study patients with sarcoma. From the first of its 30 trials, SARC was able to show that histologic subtypes specific investigation is more important than combining sarcomas into broad groups of soft tissue and bone. The SARC consortium consists of the major sarcoma programs in the US who have dedicated sarcoma experts in pathology, imaging, medicine, pediatrics, surgery and radiation which in turn attracts a sizable population of patients with these uncommon diseases. When necessary and feasible, SARC has invited international sites including Europe to aide in rapid completion of accrual. SARC conducts phase 1, 2 and 3 trials. Trials are primarily investigator initiated but also include collaborative registration trials.

Results: SARC has completed 24 studies with 6 ongoing. Nearly 2800 patients have been accrued. A repository has been created that includes biospecimens, imaging and clinical data. Illustrative of the success of our approach is a study of single agent pembrolizumab. Surprising activity was seen in dedifferentiated liposarcoma and undifferentiated pleomorphic sarcoma. This trial completed accrual of 80 patients in 11 months demonstrating the benefit of a committed collaborative consortium.

Conclusion: SARC has established collaborations with academia, biotech companies and the pharmaceutical industry for the efficient conduct of clinical research. SARC continues to be committed to reducing morbidity and mortality for patients with sarcoma through research.

Poster Board 3
Design of Clinical Trials in the New Era

Vitamin D and Calcium Supplementation and Mammographic Density: A Randomized, Placebo-controlled, Double-blinded Clinical Trial among Premenopausal Chinese Women

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Background: Breast cancer is the most commonly diagnosed female cancer in Hong Kong, and the risk increases substantially among Chinese women aged between 40-49 years. Among premenopausal women, the majority of observational studies reported that higher intakes of vitamin D and calcium were associated with a reduced risk of breast cancer. Mammographic density is a strong risk factor of breast cancer, and higher intakes of vitamin D and calcium are associated with lower mammographic density among premenopausal women in several cross-sectional and longitudinal studies. Therefore, epidemiological evidence suggests that intakes of vitamin D and calcium may reduce breast cancer risk through decreasing mammographic density among premenopausal women. However, no randomized controlled trial has been conducted to directly assess the effect of vitamin D and calcium supplements on breast density in this population.

Objective: This project aimed at investigating the effect of vitamin D and calcium supplements on mammographic density among premenopausal Chinese women in Hong Kong.

Methods: Women aged 40-49 years were randomly assigned to either the supplement or the placebo group. The supplement group took a daily dose of 800 IU vitamin D and 1000 mg calcium. Each group had approximately 148 participants. The duration of intervention was one year and both groups received baseline and one-year follow-up mammograms. The effect of the supplements was estimated by comparing the changes of mammographic density between the two groups using intention-to-treat analysis.

Conclusion: The findings of this trial will offer new insights on the current debate about the role of vitamin D and calcium in breast cancer etiology and prevention among premenopausal women. If the protective effect can be established, it will have important implications by providing a safe, modifiable, and inexpensive way for breast cancer prevention.

Poster Board 4
Design of Clinical Trials in the New Era

Biosimilars Clinical Trials Design and Execution: Challenges from Sponsor Perspective

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Biological products represent 20% of the global pharmaceutical market with a $200.000 mill value, expecting to grow up to 70% in the upcoming 2 decades. It implies an enormous spending for the patients and health systems. Currently 146 biosimilar molecules are in research under 642 clinical studies that will help the accessibility and sustainability of the health system. The main area of application will be Oncology (36%).

Biosimilar drugs have become an effective and economical option to approach oncology treatments. Regulatory Agencies, sponsors and investigators should make an effort to adapt their working methods to the development of alternative drugs that will change the oncology panorama treatment within the next years.

Biosimilar clinical development projects face a number of unique operational challenges related to executing clinical trials. Key Performance Indicators and data collected in two biosimilar Oncology studies were studied: Rituximab biosimilar (RTXM83 - 256 Non-Hodking Lymphoma patients, 88 sites, 13 countries) and Bevacizumab biosimilar (BEVZ92 - 140 colon cancer patients, 15 sites, 5 countries).

Designing global clinical studies, selecting the population needed according to the different regulatory requirements due to lack of harmonized biosimilar guidelines, reference medicinal product suppliers selection, difficulties in purchasing and obtaining support documents, poor scientific motivation and sometimes insufficient investigators' biosimilar knowledge, patients´ low interest to participate depending on reference medicinal product accessibility and complete treatment price are some of the main challenges that a sponsor needs to face when it comes to developing a biosimilar clinical trial.

Consequently, sponsors have to reinvent the clinical trial approach and strategy turning upside down former tactics. Design, study set-up, country and site selection, executing and monitoring and controlling processes have been completely shifted to respond to major changes in needs or context.

Poster Board 5
Personalized Cancer Medicine

Clinical Trials for Cancers of Unknown Primary in the Tumor Profiling and Immunotherapy Era.

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Background: There have been a limited number of clinical trials in patients with cancers of unknown primary over the past 20 years. Many of the original studies focused on the use of broad-spectrum chemotherapeutic agents. More recently trials have been developed to investigate the use of newer imaging techniques to localize a possible primary site. Few studies have been published on the use of molecularly targeted treatments or immunotherapy for cancers of unknown primary.

Objective: To review clinical trials in cancers of unknown primary and determine areas for future research.

Methods: A PubMed search was performed to find published clinical trials for cancers of unknown primary from 1996 - 2016. Trials were excluded if they involved treatment of patients with specific primary sites. Therapeutic and non-therapeutic studies were reviewed.

Results: Sixty-six clinical trial publications were identified. (Table 1) Most of the trials involved the use of chemotherapeutic agents including paclitaxel, platinum compounds and gemcitabine. Few published studies have explored the use of targeted therapies or immunotherapies. Some trials involved the use of radiation or supportive care.

Conclusions: Despite the availability of next generation sequencing, targeted therapies and immunotherapies, there have been relatively few trials on cancers of unknown primaries specifically involving newer technologies. Results from a Foundation Medicine study are awaited and the NCI-MATCH study is ongoing, but neither is specific for cancers of unknown primary. There remains a need for more specific studies for patients with cancers of unknown primary.

	Paclitaxel or Docetaxel Chemotherapy	Non-Taxane Chemotherapy	Chemotherapy plus a targeted agent	Targeted Therapy Alone	Gene Expression Based
Number of trials	22	25	3	1	3

Poster Board 6
Personalized Cancer Medicine

Capecitabine Metronomic Chemotherapy in Metastatic Breast Cancer Patients after Prior Systemic Therapy for Metastatic Disease– A Single-Arm Phase II Study

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Purpose: The aim of this study is to investigate efficacy and toxicity of Capecitabine metronomic therapy preceded by prior treatment with at least one drug regimen for metastatic disease.

Methods: Between June 2013 and February 2015, 38 women with pathologically proven metastatic breast cancer (MBC) with at least one significant lesion, who had received prior chemotherapy for metastatic disease, were enrolled. Patients received oral Capecitabine (Xeloda) metronomic therapy (750 mg/m^2, twice every day). The primary endpoints of this study were progression-free survival (PFS) rates and safety profile. Secondary end points were tumor response and overall survival (OS).

Results: Objective response was observed in 23.7% of patients (9/38), and tumor control rate was 84.2% (32/38). Complete response was observed in 2 patients (5.3%) following treatment. The estimated median PFS and OS were 9 and 18 months, respectively. The 1-year OS and PFS rates were 73.6% and 42.1%, respectively. Treatment-related adverse events were manageable with only 2 patients (5.3%) suffered from Grade 3/4 hand-foot syndrome and another 2 patients (5.3%) suffered from Grade 3 diarrhea. No Grade 3/4 hematologic toxicity was recorded. All patients received full doses of Capecitabine and dose reduction was not required in any of our patients throughout the study.

Conclusions: Capecitabine metronomic therapy in MBC patients after prior chemotherapy in metastatic setting offered a promising clinical benefit and simple way to be administered in outpatients, to the degree that makes it not only feasible, but also may be surpassed by the patients.

Key words: Metastatic breast cancer, capecitabine metronomic therapy

Poster Board 7
Personalized Cancer Medicine

IL-8 mRNA expression level difference in poor prognostic histologic type of advance gastric adenocarcinoma predict the outcome for chemotherapy treatment

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Background: Recently, the author reported the significantly higher level of IL-8 mRNA expression as a genetic risk in case controlled study for Thai advance gastric cancer patients. However, it's not well understood for prediction of cancer treatment outcome.

Aim: The author aimed to measure tissue *IL-8 mRNA* expression levels and search for the correlation of expression between at tumor position and internal control normal mucosal position in clinical response and survival

Methods: The author designed analytic experimental study in prospective non-randomized clinical trial for advance stage gastric adenocarcinoma treatment. Gastric tissue biopsies were investigated the *IL-8* mRNA expression by Real time RT-PCR (relative quantification real time reverse transcription polymerase chain reaction). Tissue samples were taken from 2 sites of normal lessor curvature and tumor position by endoscopic biopsy in 102 new advance gastric cancer patients who were underwent surgery and adjuvant chemotherapy or neoadjuvant chemotherapy by FOLFOX IV regimen during year 2011 to 2015.

Results: Demographic data results is not difference between group of adjuvant chemotherapy or neoadjuvant chemotherapy by age, gender, cancer stage, positive lymph node if surgery, histologic type, alcohol drinking, and smoking. There is no difference *IL-8* expression level between positive or negative lymph node metastasis or between stage III and IV, but resulted in level and survival difference among histologic type. Prolong survival is found on diffuse type cancer who has higher Raw RQ level more than 100 or log10 more than 2 in sub group analysis at non- tumor site. Although, there is no statistically significant difference at time analysis, there is trend of convert correlation of expression level between 2 positions.

Conclusion: This results provide an additional new information that may lead to personalized cancer treatment and followed up, and help for new drug search for gastric cancer patients in nearby future.

Poster Board 8
Personalized Cancer Medicine

Liquid/Tissue Rebiopsy for II Line Treatment Choices in EGFR-MUT NSCLC

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After the beginning of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKIs) therapy, within 10 to 16 months, approximately 60% non–small cell lung cancer (NSCLC) tumors develop treatment resistance. T790M mutation is the most common cause of acquired resistance to EGFR-TKIs, being found in up to 50% of patients treated with these drugs; several next-generation EGFR-TKIs, (irreversible T790M mutant–specific EGFR-TKI), have been developed to overcome such resistance. Nevertheless, the performance of a second biopsy to assess T790M mutation status can be difficult depending on tumor size and location, possibly requiring invasive procedures. Liquid biopsy (LB), a non-invasive means to detect cancer cell DNA in blood, has the potential to allow detection of cancer, tumor burden measurement, and evaluation of drug sensitivity /resistance. In our experience, a total of 80 patients was recruited between January 2016 and November 2016 at two centers, all tested by LB for detecting T790M; in 44 of these, T790M mutation was positive; 11 patients underwent simultaneous tissue biopsy: results of liquid and tissue biopsy were concordant in 8/11 patients; only 3patient tested negative for T790M on peripheral blood and positive on tissue biopsy. In 29.5% and 70.5% of patients, sensitizing L858R and delection of 19 exon mutation detected on tissue at diagnosis, were also detected upon LB at the time of progression. Most patients (63.6%) received afatinib as first line TKi treatment, 35.4% gefitinib. The median progression free survival on first line therapy was 18 months (range 9-63). 44 patients, positive for T790M mutation, were enrolled in the Astris trial (NCT02474355) and treated with Osimertinib. A similar benefit from third-generation EGFR TKI therapy regardless of how T790M mutation is detected was observed. Prospective studies on molecular monitoring of response/progression by quantitative LB are warranted.

Poster Board 9
Personalized Cancer Medicine

Preliminary results of capecitabine metronomic chemotherapy in operable triple-negative breast cancer after standard adjuvant therapy – A single- arm phase II study

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Purpose: The aim of this study is to investigate efficacy and toxicity of 1 year of capecitabine metronomic therapy preceded by standard adjuvant chemotherapy in triple-negative breast cancer (TNBC) patients.

Methods: Between June 2010 and February 2012, 19 women with pathologically proven operable TNBC, who had received standard adjuvant chemotherapy before were enrolled. Patients received 1 year of oral capecitabine metronomic therapy (650 mg/m2, twice every day), after standard adjuvant chemotherapy and radiotherapy if indicated. The primary endpoints of this study were disease-free survival rates (DFS) and safety profile. Secondary end point was overall survival (OS).

Results: The maximal follow-up was 46.6 months with a median of 30.1 months ±11.525 (95% CI; 28.5–33.5 months). The median DFS was 41.7 months ±2.7 (95% CI; 36.5–46.9). No one developed locoregional recurrence. The actuarial rate of DFS was 88.8% and 82.05% at 2 and 3 years, respectively. At the time of the analyses, no patients had died and the median OS was not reached. Treatment-related adverse events were manageable with only 1 patient (5.3%) suffering from Grade 3/4 hand-foot syndrome and another 1 patient (5.3%) suffering from Grade 3 diarrhea. No Grade 3/4 hematologic toxicity was recorded. All patients received full doses of capecitabine throughout the study and dose reduction was not required in any of our patients.

Conclusion: One year of capecitabine metronomic therapy preceded by standard adjuvant chemo-therapy, is active and well-tolerated in TNBC patients previously treated with standard adjuvant chemotherapy.

Poster Board 10
Personalized Cancer Medicine

Ventilation series similarity: a study for ventilation calculation using deformable image registration and 4DCT to avoid motion artifacts

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Ventilation distribution calculation using deformable image registration (DIR) and 4DCT is a recent development which can be applied in personalized radiotherapy treatment planning and treatment evaluation. The major problem involved in this technique is the possible motion artifacts which can introduce errors in registration and consequently in the derived ventilation distribution. This study is to investigate the ventilation similarity among the derived data from the different phases in a 4DCT data set. Since in some cases only a few phases have the mushroom motion artifacts, the ventilation distribution can be then calculated using the other phases that do not have the obvious mushroom artifacts, if the ventilation series similarity is fair. A total of 10 lung cancer cases were analyzed in this study. In each case, DIR was performed between the end-expiration phase and all other phases. Ventilation distributions were then calculated using the deformation matrices. Similarity was compared between the one based on end-expiration and end-inspiration and the ones based on end-expiration and all other phases. Spearman correlation coefficient (SCC) was employed in the similarity comparison using the 3D ventilation distributions. The correlation between the phases was reasonably good, with average SCC values between 0.27 and 0.71 for the original data, 0.27 and 0.76 after smoothing. The better correlation between the neighboring phases, with average SCC values between 0.59 and 0.71 for the original data, revealed the non-linear property of the dynamic ventilation. To reduce errors introduced to ventilation distributions calculated using the 4DCT data with motion artifacts, phases in the 4DCT that without serious mushroom artifacts may be used. To minimize the effect of the non-linear property in dynamic ventilation, the phase used in the calculation should be as close to the end-inspiration as possible, when the mushroom artifacts are present in the end-inspiration phase.

Poster Board 11
Immuno-Oncology - End Point with Immunotherapy

The Prognostic Role of Tumor-Infiltrating Lymphocytes CD8 and Foxp3 and their Impact on Recurrence in Breast Cancer Patients.

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Background: The presence of tumor- infiltrating lymphocytes (TIL) within tumor epithelium or stroma of breast cancer is a surrogate of an immune response to cancer development, but their significance remains controversial. We conducted this study to evaluate the correlation of CD8+ (cytotoxic T) lymphocyte infiltration and Foxp3+ Tregs and tumor characteristics and their impact on recurrence in patients with invasive breast cancers.

Patients and methods: CD8+ T cells and Foxp3+ Tregs were detected by immunohistochemistry using the paraffin-embedded tumor tissues from 68 patients with stage (I to III) breast cancer. Clinicopathological data including patient's age, tumor size and grade, stage, lymph node metastasis, estrogen and progesterone receptor status, Ki-67, and human epidermal growth factor receptor-2/neu, and recurrence were reviewed.

Results: The decreased mean number of CD8+ T cells was significantly associated with tumors with lymph node metastasis (P=0.02), and immune-positivity of Ki-67 (P=0.00). The increased number of Foxp3+ Tregs was significantly correlated with tumors with lymph node metastasis (P=0.01) higher stage (stage III, P=0.03), and immune-positivity for Ki-67 (P=0.02). Further analysis of the correlation using CD8+ T-cell/Foxp3+ Treg ratio showed significant correlation with tumors with lymph node metastasis(P=0.01), and immune-positivity of Ki-67 (P=0.00). Also, there were significant correlations between the increased Foxp3+Treg /CD4+ T-cell ratio and lymph node metastasis (P=0.00), and immune-positivity of Ki-67 (P=0.02).

Conclusions: Data showed that lymph node metastases, tumor stage, immunopositivity of Ki67, and nontriple-negative tumors were associated with high regulatory T-cell infiltration. The prognostic role of immunologic balance as a marker for recurrence must be evaluated more clearly in a larger study.

Poster Board 12
Immuno-Oncology - End Point with Immunotherapy

Breast Cancer Stem Cell-Derived RNA Activates Dendritic Cells for Cell-Mediated Tumor Killing

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Breast cancer is the most common cancer in women worldwide including Thailand. Although the treatment of breast cancer patients are very well developed for decades, drug resistance and cancer recurrence exist. Dendritic cell-based immunotherapy has been developed as an alternative choice for the treatment of cancer. This study aims to investigate the efficiency of dendritic cell activation by total protein or total RNA from cancer cells to effectively activate tumor cell cytotoxic lymphocytes. The protein and total RNA from the in-house Thai breast cancer patient-derived cell line, BCA55-121, were utilized to activate PBMC-derived dendritic cells. CD11c, CD40, CD80, CD83, CD86, and HLA-DR expressions were detected by flow cytometer to confirm the activated dendritic cells. Total lymphocytes were activated then by these antigen-primed dendritic cells. The different ratio between tumor cells and activated lymphocytes were co-cultured and tumor cell apoptosis was detected by Annexin V. The results showed the superiority of the total RNA antigen to prime dendritic cells in activating tumor-specific lymphocytes with significant cytotoxicity compared to those primed with tumor cell proteins. In addition, $CD44^{+}CD24^{-}$ breast cancer stem cells were isolated from the whole culture of BCA55-121 by fluorescence-activated cell sorter. The stemness properties were confirmed by stem cell-related gene expression level by real-time PCR and proliferation capability by colony formation assay. The efficiency of total RNA from these breast cancer stem cells in priming dendritic cells and activating tumor-specific T cells were reported. The conclusion from our study elicited the potential of patient-derived breast cancer stem cell total RNA in maximizing the efficacy of dendritic cell-based breast cancer immunotherapy in clinical trials.

Poster Board 13
Monitoring of Trials and Statistics

Association between Phase II Trials Design and Successful Subsequent Phase III Trials

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Background: The process of developing drugs is a challenge often leading to a resource consumption contributing to determine the high costs of the few molecules that gain the approval. Besides costs also ethical aspects have to be considered during drug process because of patients waiting for the development of effective drugs. So phase II design is crucial to foreseen the results of a phase III trial.

Objective: To investigate phase II features associated with subsequent phase III successful trials in advanced/metastatic solid tumors.

Methods: We systematically reviewed through MEDLINE literature from 2011 to date searching for phase III trial on novel (targeted or immuno) therapies or new drug combination or new indication. Once phase III trials were selected according to established criteria the preceding phase II trials were retrieved. Features of phase II studies considered in the analysis included primary endpoint, randomization, number of participating centers, sample size, follow-up length and sponsor type. Association was measured with chisquare test and logistic model.

Results: We selected 232 trials, 122 with Overall Survival (OS) as primary endpoint, 107 with Progression Free Survival (PFS), three trials were designed with alternative endpoints. A positive result was found in 102 trials (43.9%), 45 (44.1%) designed on OS and 57 (55.9%) on PFS. Negative studies were 130, 77 (59.2%) considered OS as the primary endpoint. Analysis on the association of these results with phase II trial is still ongoing.

Conclusion: In a phase III setting the choice of primary endpoint and effect size is crucial. OS is considered the gold standard but can be biased by subsequent therapies and crossover effect. A well designed multicenter phase II trial can help to avoid time and resources consumption during drug development.

Poster Board 14
Regulations – Survival Based Medicine

All-oral combination of lapatinib and letrozole as first-line therapy in patients with hormone receptor–positive HER2-positive metastatic breast cancer.

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Purpose: The aim of this study is to investigate efficacy and tolerability of the combination of letrozole plus lapatinib (LL) as first-Line therapy in hormone receptor–positive (HR positive), HER-2 positive metastatic breast cancer (MBC).

Patients and Methods: Between January 2013 and January 2015, 21 postmenopausal patients with pathologically proven HR –positive HER2+ –positive MBC, were included. Sixteen patients (76.19%) progressed after prior adjuvant hormonal treatment and 5 patients (23.81%) were hormonal -naïve for MBC. Patients received lapatinib 1500 mg once daily every morning continuously and letrozole 2.5 mg once daily continuously. Twelve patients (57.1%) initially treated by trastuzumab-based regimens in either adjuvant or neoadjuvant setting of disease. No patients had received prior lapatinib and/or letrozole. End-points were response rate (RR), progression free survival (PFS), overall survival (OS) and toxicity.

Results: The overall response rate (ORR) was 28.6% (6⁄21) and all were partial response. Median PFS was 9 months. For patients received prior adjuvant hormonal treatment and hormonal -naïve patients the median PFS was 9.00 months and 13.00 months respectively. Median OS was 33 months. Treatment-related adverse effects were tolerable. Grade 3–4 toxicities were diarrhea (9.5%), nausea/vomiting (4.7%), and rash (4.7%).

Conclusion: The oral combination of LL well-tolerated and effective treatment in patients with HR –positive HER2+ –positive MBC.

Key words:

Hormone receptor–positive, HER2+ –positive breast cancer, metastatic breast cancer, letrozole, lapatinib.

Poster Board 15
Regulations – Survival Based Medicine

Azacytidine in Elderly Patients with Acute Myeloid Leukemia (AML) and Myelodysplastic Syndromes (MDS): A Single Centre Experience.

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Background: Myelodysplastic syndrome (MDS) is more prevalent in elderly population. According to risk of transformation to AML and survival data it is subdivided into Low risk, Intermediate risk and high risk categories as per International Prognostic Scoring System (IPSS). National Institute of Clinical Excellence (NICE) recommends role of Azacytidine in Intermediate and high risk MDS patients who are unfit for intensive chemotherapy. Azacytidine works as DNA hypomethylation agent as well as cytotoxic agent.

Objectives: MDS intermediate and high risk patients and elderly AML or relapsed AML received Azacytidine chemotherapy. We assessed improvement in blood counts, remission, partial remission, stable disease and survival.

Methods: Patients n=22, males (n=15), females (n=7). Mean age 72.2 years (range 51 to 83 years). High risk MDS, n=10, intermediate risk n=6; denovo AML n=3, post-allo BMT relapse AML n=1, post-intensive chemotherapy relapse AML n=2. Schedule: Azacytidine 75mg/m^2 subcutaneously daily Day 1-7 repeated every 4 weeks.

Results: On this on-going treatment, 63% have received upto 6 Azacytidine cycles, 27% more than 6 cycles upto 12 cycles and 13% less than 3 Azacytidine cycles. Responses to Azacytidine showed stable disease and reduction in blood product support. AML patients: 2/6 died after 8 months with cardiac condition. 4/6 66% have stable disease for 8-12 months. MDS patients: 1/16 high risk MDS with monosomy 7 progressed after 2 cycles. 1/16 had good response for 12 cycles and then progressed. 1/16 died due to progression to AML after 6 months and 11/16 (68%) have stable disease with Azacytidine therapy for 8-12 months.It is of interest that post intensive chemotherapy and BMT relapsed AML responded to become stable disease for 1 year

Conclusion: Azacytidine therapy improves quality of life (QoL) and indicative of prolonged survival. Role of Azacytidine should be explored further in larger number of elderly AML patients.

Poster Board 16
Regulations – Survival Based Medicine

Chronic Myeloid Leukemia (CML) bcr-abl Molecular Response Monitoring with Failure, Warning and Optimal Response Signals and Indications for Changing Therapy.

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Background: Tyrosine kinase inhibitor (TKI) including Imatinib, Nilotinib, Dasatinib, Bosutinib and Ponatinib has revolutionised targeted therapy in cancer medicine. Challenge remains regular monitoring of molecular response, optimal response and deep molecular response. European Leukemia Net (ELN) assessment tool is used to monitor optimal response. Reports show that 8000 out of 14,500 bcr-abl-pos patients in 2016 had intolerance or resistance.

Objective: To assess optimal and deep bcr-abl molecular response and look at the warning signs for early introduction of 2nd or third line treatment. In addition deep molecular response patients given choices for treatment break with regular bcr-abl monitoring.

Methods: bcr-abl ratio was assessed as per international score (10%=1log, 1%=2log, 0.1%=3log, 0.01%=4log, 0.001%=5log,0.0001%=6logs). 3-log reduction (0.1%) also called Major Molecular Response(MMR). Patients details n=23, female 6, Male 17. Average age 50.7 years (range19-82 years) !st line treatment Imatinib n=16, Nilotinib n=4, Dasatinib n=3(Spirit-2). Follow up 60-months.

Results: Imatinib first line showed 86.7% MMR. Nilotinib was used second line showing 50% MMR but follow-up is short, Dasatinib spirit 2 patients are in MMR. Regular bcr-abl monitoring revealed n=18 optimal response, n=3 warning which were changed to 2nd line treatment. One had 2nd line Dasatinib failure and developed mutation T315I. This patient transformed to AML and undergoing AML-type therapy and Ponatinib therapy. Computer based CML tool uses traffic light system green, yellow, red signals for early warning in treatment failure and appropriate change of TKI and early mutations analysis. It also highlights MMR and deep molecular response. We were able to stop treatment in patient and reduce TKI dosage in other patient.

Conclusion: Computer-based CML monitoring tool is using simple warning signals for assessment of CML patients. It highlights patients achieving optimal bcr-abl response with appropriate TKI therapy. CML tool also identifies non-adherence and suboptimal response patients.

Poster Board 17
Ethics and Patients' Rights

Knowledge and Attitudes of Cancer Patients and Their Relatives on Clinical Trials: A Pilot Study

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Background: Defining the attitudes and lack of knowledge of the participants regarding clinical trials may address to develop an effective intervention to increase awareness of clinical trials and to decrease the pre-existing fears and concerns resulting in a rise in clinical trial accrual.

Objective: The purpose of this study was to understand cancer patients' and their relatives' knowledge and attitudes regarding clinical trials in a developing country, Turkey.

Methods: Qualitative, in-depth questionnaires were conducted face-to-face with existing patients and patient relatives who had not been offered a clinical trial before, during November 2016. Three comprehensive medical oncology clinics in Istanbul, Turkey, accepted as a representative of general population were selected to collect data. The questionnaire included demographic information such as age, sex, education etc. and two parts evaluating both knowledge and attitudes regarding clinical trials. All questions were close-ended and all participants were asked to pick one of the five categories for each question (1.definitely agree, 2.agree, 3.neither agree nor disagree, 4.disagree, 5.definitely disagree).

Results: A total of 110 participants filled out the questionnaires. Median age was 51(20-83). 54%(n=59) were patients and 46%(n=51) were their relatives. Education levels were grouped as:1.Primary school 2.Secondary and high school 3.University with a distribution of 40%, 34% and 26%, respectively. The questionnaire demonstrated sufficient internal consistency (Croncbach` s alpha:0.737). Knowledge score had no significant relationship with education level, age, sex, being patient or patient relative. However, higher knowledge level was associated with higher education level (p=0.003). Increase in attitude score (meaning higher disagreement) was found if the education level increased (p=0.036) or age decreased (p=0.002).

Conclusions: High education level and young age had an unexpected relationship with high attitude score. Older participants or ones with lower education level seemed to prefer questioning lesser and accepting to participate in clinical trials more.

Poster Board 18
Side Effects

Applying MASCC index score for identifying febrile neutropenia patients at high risk of complications at a tertiary care hospital in Pakistan

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Background: Febrile Neutropenia (FN) is a medical emergency which requires hospitalization and antibiotics. Multinational Association of Supportive Care of Cancer (MASCC) index score is a clinical tool to predict outcomes in FN patients. This risk index score has been validated in international trials however local data is not available. Our aim was to determine hospital based incidence rate of serious complications in admitted chemotherapy induced febrile neutropenia patients presenting to a tertiary care hospital. Also, we compared proportions of serious complications in patients having MASCC score < 21 or ≥21 hence substantiating MASCC score usage in our population.

Methods: A hospital based prospective close cohort study was designed and conducted at the Oncology wards of The Aga Khan University from February to August 2014. Total of 88 patients, aged 16 and above, with chemotherapy induced febrile neutropenia were identified. They were divided on basis of MASCC Score into low or high risk {exposure} groups. Outcome was assessed in terms of development of serious complications.

Results: Hospital based incidence rate of febrile neutropenia admission was 5.98% , 95%CI [4.88%-7.08%] and hospital based incidence rate of serious complications was 18.2%, 95%CI[11.5%-25%]. Out of 88 patients with chemotherapy induced febrile neutropenia 85.2% patients were in the high risk group and 14.8% in the low risk group. Serious complications were found in 21.33% and no patients in high and low risk group respectively. Age > 60, MASCC score <15 and an albumin <2.5 mg/dl was associated with a higher chance of developing serious complications. Sensitivity, specificity, positive and negative predictive value of MASCC score in accurately predicting risk of serious complications was 21.33%, 100%, 100% and 18.06% respectively.

Conclusion: MASCC risk-index score is a useful tool to identify patients at low risk of complications. Our hospital based incidence rate of serious complications was 18.2%.

Poster Board 19
Side Effects

Nd-YAG laser therapy in patients with non-operable malignant obstructive endobronchial lesions after prior chemotherapy and/or radiotherapy

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Background: Nd-YAG laser has long been used to treat cancers within the tracheobronchial tree. It offers the advantages of a relatively short duration of treatment, a low side effect profile, and a relatively low risk in patients with non-operable malignant obstructive endobronchial lesions. We report the first successful use of Nd-YAG laser as palliative management of non-operable malignant obstructive endobronchial lesions at Tanta University Hospital in cooperation with National Institute of Laser Enhanced Sciences, Cairo University and German University in Cairo.

Patients and methods: A series of 16 patients with non-operable malignant obstructive endobronchial lesions after prior chemotherapy and/or radiation therapy at Clinical Oncology Department, Faculty of Medicine, Tanta University Hospital were treated with laser therapy at Chest Department, Tanta University Hospital, in cooperation with National Institute of Laser Enhanced Sciences, Cairo University and German University, in Cairo during the period between January 2011 and October 2013. Endpoints were response rate (RR) and safety.

Results: The mean age was 50.2 ± 9.7 years old. Malignant primary lung cancer was reported in 62.5% of the cases; and in 37.5% of the patients the diagnosis was metastatic tumors. All patients had obstructive pneumonitis at time of start of Nd- YAG laser therapy, while dyspnea was, reported in 93.75% of the patients followed by cough (87.5%) and hemoptysis (81.25%). Response rate was 81.4% with a significant improvement of clinical signs and symptoms, arterial blood gas indices and spirometric results, however, complete response (CR) occurred only in 2 (12.5%) patients. Progressive disease (PD) was recorded in 3 (18.75%) patients. Complications of the Nd- YAG laser therapy occurred in 8 of 16 cases (50%), included; bleeding in 31.25%, and respiratory failure in 6.25%.

Conclusion: Nd-YAG laser is well-tolerated, and provides prompt and durable palliation in unresectable patients with malignant obstructive endobronchial lesions.

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Side Effects

Radiofrequency Ablation Combined with Chemotherapy Compared to Chemotherapy Alone in Patients with Liver Metastases from Primary Colorectal Cancer

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Purpose: The aim of this study is to investigate the therapeutic index of radiofrequency ablation (RFA) in patients with colorectal liver metastases.

Methods: Between June 2013 and June 2014, 40 patients with pathologically proven colorectal liver metastases, in Clinical Oncology Department, Tanta University Hospital and Clinical Oncology Department, Faculty of Medicine, Menoufia University Hospital were enrolled. Patients divided into two groups; Group A (20 patients) treated by RFA & systemic chemotherapy, and Group B (20 Patients) treated by systemic chemotherapy alone. The primary endpoints of the study were tumor response and tolerability of treatment. Secondary end point was the progression-free survival (PFS).

Results: For group A, the overall response rate (ORR) was observed in 65% of patients (13/20) and complete response was observed in 10 patients (50%) following treatment. For group B the ORR was 15% with no one has developed complete response. The estimated median PFS for group A and group B were 9 and 7 months, respectively (p value <0.001). Treatment-related adverse events with RFA for group A, were mild to moderate. The most common adverse reactions among those patients were wound infection in 30% of patients. Grade III/IV hepatic dysfunction developed in 20% of patients and hemorrhage was noted in 10% of patients and these adverse reactions were manageable.

Conclusion: Chemotherapy with selective use of RFA in patients with colorectal liver metastases appeared to offer an acceptable clinical profile in patients who are not suitable to surgical resection. Such an approach is the current standard of care.

Poster Board 21
Side Effects

Weekly dose-dense paclitaxel and carboplatin in recurrent ovarian carcinoma: A phase II trial

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Purpose: The aim of this study was to investigate efficacy and toxicity of the dose-dense weekly paclitaxel (T) and carboplatin (C) in the management of platinum-resistant/sensitive recurrent epithelial ovarian cancer (EOC) previously treated with 3- weekly paclitaxel/carboplatin.

Methods: Thirty two patients with recurrent EOC who had received 3 weekly TC before were enrolled. Nine patients relapsed within 6 months (platinum-resistant), 13 patients relapsed after 12 months (platinum-sensitive) and in 10 patients recurrence occurred between 6 and 12 months) intermediate platinum-sensitive). Weekly (T) at a dose of 80 mg/m^2 followed by weekly (C) AUC 2 on day 1, 8, and 15 of a 28-day cycle for 6 planned cycles were administrated. End-points were overall response rate (ORR), progression free survival (PFS), overall survival (OS) and toxicity**.**

Results: The ORR was 62.5%. For the platinum-resistant, intermediate platinum-sensitive and platinum-sensitive patients the ORR was 44.4% (4/9), 60% (6/10) and 76.9% (10/13), respectively, and 1 (11.1%), 2 (20%) and 5 (38.46%) patients, respectively had CR. PFS was 9.1 months (6.13, 9.1 and 12.17 months, for the 3 groups, respectively) (P< 0.001). OS was 14 months (9.17, 15.2, and 19.23 months, for the 3 groups, respectively) (P< 0.001). Treatment-related adverse events were manageable with only 1 patient (3.1%) suffering from grade 4 neutropenia. Grade 3 hematological and non-hematological toxicities were neutropenia in 8 (25%), and peripheral neuropathy in 4 (12.5%) patients, respectively.

Conclusion: Weekly TC is active and well-tolerated in platinum-resistant and platinum-sensitive patients with recurrent EOC previously treated with TC given every 3 weeks.