nausea and vomiting by the physicians. Strickingly, 44% of the patients had received information about mucositis, 43% about altered taste, and 59% about loss of appetite by the nurses only.
Conclusions: It seems that oncological patients are given scant or little information on malnutrition during their chemotherapy. On the contrary, it may be extremely important for the nurses to provide information and advice on this subject mostly because he/she is the one who is more in contact with the patients themselves. The literature shows that family members of cancer patients are not prepared to support their relative with cancer, so it is very important that the nurse can assist the patient and his family at the same time. In this way their nutritional status improve and consequently their quality of life.

4274 POSTER

Comparison of the Effectiveness of Glutamine and Triple Gargle for Prevention of Mucositis Development in Patients Who Have Undergone Bone Marrow Transplantation

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Background: Musocitis is one of the most frequent side effects seen in patients receiving chemotherapy, and presence of the microflora in mouth and the oral mucosa deteriorating following bone marrow transplantation makes the development of mucositis easier. This study was designed as an experimental study to show the affect of glutamine use in addition to the oral care protocol applied in patients undergone bone marrow transplantation(BMT) to prevent mucositis development.
Material and Method: Universe of the study consists of the inpatients of the medical oncology clinic of a university hospital in Turkey who have undergone BMT.An explanation of the study was given to patients. The Ethics Committees of the two hospitals approved the study. Patients were divided into two equal groups as experiment and control groups according to age, gender, diagnosis and the treatment protocol applied. Data collection form and oral evaluation guide were used to collect data. Standard oral care protocol was used in the control group to prevent mucositis development (two ampoules of sodium bicarbonate in 500 cc water+500 cc normal saline+triflucan suspension − to be used one measuring cup in mornings and evenings). In patients of the experiment group, however, glutamine was used in addition to this protocol (two sachets in the morning, noon and evening, total 30 g). All patients used gargles every two hours in daytime and every six hours in nighttime. Patients washed their mouths with gargles containing normal saline and sodium bicarbonate and then spitted out, and swallowed triflucan suspension. Patients in the experiment group, however, added Glutamine into 200cc water, kept it in their mouths for one minute, and then swallowed.
Oral mucositis grading system of WHO was used in the study to evaluate mucositis, and evaluation of mucositis was performed by the nurse of the patient (0, 5, 10 and 15 days).
Results: In the day 5 following BMT, it was observed that mucositis did not develop in 53.8% and Grade 1 mucositis developed in 46.2% of the patients that glutamine serum was applied. Grade 2 mucositis developed in 9.1% of the patients that triple gargle was applied. In the day 10 following BMT, it was observed that mucositis did not develop in 69.2%,Grade 2 mucositis developed in 7.7% of the patients that glutamine serum was applied. However, mucositis did not develop in 54.5% and Grade 1 mucositis developed in 45.5% of the patients that triple gargle was applied. No statistically significant differences were seen between trial and control groups as regards mucositis development ($p > 0.05$). Mucositis development of the patients were compared with age, daily oral fluid amount and leukocyte and platelet values, and it was seen that there were no statistically significant differences ($p > 0.05$).
Conclusion and Recommendations: Performing studies with larger samples to determine the effects of glutamine us for the prevention of mucositis development after BMT will be beneficial.

4275 POSTER

The Evaluation of Infections Related to the Internal Diseases and Hematology Patients Observed at Intensive Care Service at Akdeniz University

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Introduction: Infections related to the medical care service (SBHII) indicate the quality of a treatment institution. Increasing the duration of staying at hospital due to the infections related to the medical care service brings out the problems such as increasing mortality and morbidity and treatment duration. It is possible to control such infections by surveillance the infection results and comparing these result to the other hospitals'.
Purpose: In this study, infections related to the medical care services, their frequencies, causes, and effects on treatment duration were studied at oncology/hematology internal intensive medical care service patients at Akdeniz University Hospital (AUH).
Material and Methodology: In this study, infection diagnosis patients at internal intensive medical care services are taken into account at AUH between the intervals January 2008-December 2010. Study was performed by the surveillance system based on both prospective patient and laboratory. Infections are diagnosis by taking the criteria of Center for Disease Control and Prevention (CDC) into account. Statistical analyses were performed by the National Hospital Infections Control Unit (UHESKB) and data of the rates of infections were compared by the data of National Nosocomial Infections Surveillance (NNIS) and UHESKB.
Diagnosis: 4243 patients were observed at internal intensive medical care service between January 2008-December 2010. 105 SBHII was obtained 55% of all patients. In detail, 21(%6.05) in 11 oncology patient, 13 (%7, 15) in 7 hematology patient, 71 (%14.85) in other 27 patients, SBII was increased. When we have a closer look to the distribution of infections, pnömoni (%25.75), bakteremi (%16.06), urinar sistem (%11.07) were observed respectively. On the other hand, most frequent causes were the Acinetobacter baumani (%30.30), Pseudomonas aeruginosa (%15.15), Enterococcus faecium (%12.12) respectively. In most of the patients (%88.2), there were more than one invasive attempt making easier the formation of infection. Their lining times in hospital were changing from 7 to 60 days. Patients lining in the hospital more than 7 days are more likely to have a quick infection formation rate.
Result: The rates of hospital infections in internal intensive medical care services are in an increasing regime and this creates a serious problem. Increase in lining time at hospital, grouped patients, and increased number of patients per a nurse increases the frequency of infections.

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Oral Presentations (Sun, 25 Sep, 09:00−11:05)
Breast Cancer − Advanced Disease

5000 ORAL

Long-term Outcome of HER2-positive (HER2+) Metastatic Breast Cancer (MBC) Patients (pts) Achieving Durable Complete Remission (DCR) After Trastuzumab (T)-containing Chemotherapy (CT)

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Background: CR following a T-containing CT is reported throughout all phase II and III clinical trials of first-line CT plus T but there is lack of data about clinical features and long-term outcome of these pts. Moreover the optimal duration of maintenance T following CR remains undefined.
Material and Methods: We performed a retrospective review of pts with HER2+ MBC treated with a T-containing CT at our two Institutions and identified all cases who achieved DCR. HER2 positivity was defined as 3+score at immunohistochemistry and/or amplification at FISH test. DCR was defined as a CR according to RECIST 1.0 criteria lasting $\geqslant$36 months. Pts were identified by systematical cross-match of the datasets of Medical Oncology, Pathology and Pharmacy Departments.
Results: We identified 120 pts with HER2+ MBC treated from May 2000 to April 2011. Eleven pts (9%) had a DCR. Their characteristics are as follows: median age: 59 yrs (range 30−65), stage at diagnosis: M0 54%/M1 46%, histology: ductal 82%/mixed ductal-lobular 9%/unknown 9%, tumour grade: G3 54%/G2 27%/unknown 19%, oestrogen receptors (ER): negative 64%/positive 36%, metastatic disease: liver only visceral disease 55%/liver and/or other visceral metastases 18%, soft tissues only metastases 27%, T regimen: T+docetaxel+carboplatin 64%/T+taxane 27%/T+capecitabine 9%. All pts were T-naïve. Median follow-up time is 6.5 yrs (range 4–10.9). Median duration of T was 63 months (17–121+). Maintenance T was stopped in 7 pts: 2 at disease relapse (after 74 and 83 months from

commencement of T respectively), 5 without disease relapse. Only 1 pt relapsed (with local in-breast recurrence) after T discontinuation. Eight pts are still alive and in CR (4 still on maintenance T). These pts are: ER negative 75%, liver only visceral disease 63%.
Conclusions: This is the largest series so far analysing long-term outcome of HER2+ MBC pts with DCR following T-containing CT. A small group of pts who show no further relapse at long-term FU can be identified. They are more frequently ER negative and have metastatic disease confined to liver. Our data suggests that in selected cases of CR lasting ⩾36 months maintenance T can be safely discontinued with very low risk of subsequent relapse. The molecular profile of this subset of pts should be specifically investigated to allow early identification of pts who are more likely to achieve DCR on T+CT.

5001 ORAL

Trastuzumab Emtansine (T-DM1) Vs Trastuzumab Plus Docetaxel (H+T) in Previously-untreated HER2-positive Metastatic Breast Cancer (MBC): Primary Results of a Randomized, Multicenter, Open-label Phase II Study (TDM4450 g/BO21976)

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Background: T-DM1 is a HER2-targeted antibody-drug conjugate in development for the treatment of HER2-positive cancer. It provides intracellular delivery of the cytotoxic agent DM1 while maintaining the antitumour activities of trastuzumab. We previously presented preliminary data from the first randomized phase II study of T-DM1 vs. H+T as first-line treatment in patients with HER2-positive MBC (Perez, et al. ESMO 2010, LBA3; TDM4450 g/BO21976; NCT00679341). Here we present the primary efficacy and updated safety results.
Methods: Patients (N = 137) were randomized 1:1 to T-DM1 3.6 mg/kg IV q3w, or H 6 mg/kg IV (8 mg/kg in cycle 1) + T 75 or 100 mg/m^2 IV q3w, until disease progression or unacceptable toxicity. Primary objectives were investigator-assessed progression-free survival (PFS) and safety. Results are based on a clinical data cutoff date of 15 November, 2010.
Results: Baseline characteristics were similar between groups. In the H+T arm, most patients (74.2%) initiated T at 75 mg/m^2. Median durations of follow-up were 13.5 mos (H+T) and 13.8 mos (T-DM1). Among safety evaluable patients, the most common adverse events (AEs) were alopecia (66.7%), neutropenia (63.6%), diarrhea (45.5%), and fatigue (45.5%) in the H+T arm; and fatigue (49.3%), nausea (47.8%), increased AST (39.1%), and pyrexia (39.1%) in the T-DM1 arm. Consistent with previously reported results, grade ⩾3 AEs were reported less frequently in the T-DM1 arm (46.4% vs 89.4%) as were treatment discontinuations due to AEs (7.2% vs 28.8%). Serious AEs occurred less frequently in the T-DM1 arm (18.8% vs 25.8%). One patient in each arm had an AE that resulted in death. At the data cut-off, 43.3% of patients were continuing T-DM1 vs 21.4% who were continuing H+T. Efficacy data, summarized in the table below, are notable for a significant improvement in PFS in the T-DM1 arm (14.2 vs 9.2 months, HR = 0.59, p = 0.035).
Conclusion: First-line treatment of HER2-positive MBC with T-DM1, compared to H+T, provided a significant improvement in PFS with a favorable safety profile. These results demonstrate the feasibility of T-DM1 in HER2-positive MBC.

	H+T	T-DM1
PFS	n = 70	n = 67
Median PFS (mos)	9.2	14.2
HR (95% CI), *P*-value	0.59 (0.36, 0.97), 0.035	
Objective Response	n = 69	n = 67
ORR, n (%), (95% CI)	40 (58.0), (45.5, 69.2)	43 (64.2), (51.8, 74.8)
Complete response, n (%)	3 (4.3)	7 (10.4)
Partial response, n (%)	37 (53.6)	36 (53.7)

5002 ORAL

Complications Associated With Chemotherapy in Patients With Metastatic Breast Cancer

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Background: Treatment with chemotherapy has been associated with significant rates of adverse events which may lead to expensive care or changes and delays in provided treatment. This study estimates the prevalence of chemotherapy-related complications in patients receiving chemotherapy for the treatment of metastatic breast cancer (mBC) in a real world setting.
Materials and Methods: The PharMetrics® Integrated Database (2004–2009) was used to select patients with mBC treated with chemotherapy and/or anti-HER2 targeted therapies. Episodes of mBC chemotherapy treatment with single-agent or combination of agents for a course of at least 30 days were identified. Complications were identified using medical claims with a diagnosis for one of the following events of interest: anemia, alopecia, arthralgia, bilirubin elevation, dehydration, dyspnea, infection, leukopenia, and neutropenia.
Results: A total of 1551 patients with 3157 eligible episodes of treatment met the inclusion criteria. The mean age of women was 57 years. The complication rates for the commonly used agents including anti-HER2 (i.e., trastuzumab and lapatinib), docetaxel, paclitaxel, gemcitabine, vinorelbine, and doxorubicin, are reported in the table.
Conclusions: Anemia, bilirubin elevation, and leukopenia were the most common complications during an episode of treatment, with substantial variations across types of regimen to treat mBC. Further research assessing the total impact (clinical, humanistic, and financial) of chemotherapy-related complications is required. There is a need for agents providing clinical efficacy without incurring significant toxicities.

	All episodes of treatment	Anti-HER2[1]	Trastuzumab + Vinorelbine[2]	Trastuzumab + Docetaxel[2]	Docetaxel[3,4]	Paclitaxel[3,4]	Gemcitabine[3,4]	Vinorelbine[3,4]	Doxorubicin[3,4]
Number of patients	1551	510	160	84	228	175	234	197	123
Number of episodes of treatment	3157	1157	172	90	264	188	240	207	133
Average by patient	2.0	2.3	1.1	1.1	1.2	1.1	1.0	1.1	1.1
Average duration (days)	131	158	169	141	118	115	94	107	95
Number of episodes with complications									
Anemia	51%	51%	70%	60%	55%	52%	70%	65%	50%
Arthralgia	12%	15%	18%	16%	9%	11%	9%	12%	10%
Bilirubin elevation	26%	29%	35%	31%	22%	31%	20%	21%	19%
Dehydration	10%	11%	14%	17%	11%	7%	10%	10%	13%
Dyspnea	19%	17%	24%	19%	21%	22%	24%	19%	20%
Infection	19%	20%	22%	22%	23%	14%	21%	16%	12%
Leukopenia	25%	18%	38%	20%	36%	23%	33%	46%	28%
Neutropenia	18%	13%	30%	14%	27%	15%	21%	30%	15%

[1]Based Regimen; Monotherapy or combination.
[2]Based Regimen; Including combination with anti-hormone therapy.
[3]Excluding anti-HER2-agents.
[4]Based regimen; Monotherapy or combination with anti-hormone therapy.

5003 ORAL

Inhibition of HER2 Positive Breast Cancer Cells by Drug Screening

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Background: About 20% of all breast cancers have an amplicon in 17q12−21 resulting in over-expression of the human epidermal growth factor receptor 2, *ERBB2*/*HER*-2. HER-2 is a receptor tyrosine kinase, belonging to the epidermal growth factor receptor (EGFR) family of proteins. Phosphorylation of the HER2 tyrosine domain activates downstream pathways like PI3K/Akt and MAPK that are involved in regulation of cell growth, survival, migration and proliferation. In the clinic, HER-2+ patients are treated with Trastuzumab (Herceptin), a monoclonal antibody targeted