perceptions about the use of biological therapy in five countries in Central America

Methods: Through November 2008 to April 2009 cancer specialists were invited to complete a survey evaluating demographic variables, practice characteristics, and opinion about target therapy in theirs clinical setting. Results: 68 physician were surveyed. 44 males and 24 females. medical oncologists (50%), 15 (22%) surgical oncologists and 19 (28%) gynecologist oncologists. Median age was 46 ± 8.4 years. 85% do both public and private practice. While 28% of patients in private practice frequently ask about biological therapy only 7% of patients in public practice do (p < 0.001). 93% of oncologists acknowledge the patient's right to be inform regardless the inequities of the system. 43 (63%) physicians comment about biological therapy to patients with clinical indication and 20 (37%) hysicians do not comment unless the patient ask. There were no differences between the physicians characteristics and tell or not to tell about the biological therapy. Not having the biological therapy available for patient produce some degree of stress in 70% of physicians (p = 0.001). 68% of physician whom would not tell the patient about the biological therapy consider that raising the topic would only produce anxiety in patients and their families versus 32% whom disagree (p = 0.023). In a situation without budget deficit 97% and 95% of physicians would use trastuzumab in adjuvant and palliative setting (p < 0.001), 86% erlotinib after chemotherapy failure in metastatic lung cancer (p < 0.001), 91% first line monoclonal antibodies in metastatic colorectal cancer (p < 0.001), 96% sunitinib in metastatic renal carcinoma. Only 37% agree the use of trastuzumab beyond progression (p = 0.038) and 30% would use monoclonal antibodies beyond progression in metastatic colorectal cancer (p = 0.007). 70% of physician use NCCN treatment guidelines and 10% ESMO recommendation, but 79% refer that clinical guidelines do not consider cost-effectiveness issues.

Conclusion: Facing decision about biological therapy in public health system in low and middle income countries involve ethical and social dilemma for doctors and patients. A balance between information and realistic option is recommended.

3032 POSTER

Dermatological side effect interventions for targeted cancer treatment untangled: a systematic review

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Significance & Background: Dermatological side effects, such as papulopustular rash, xerosis, pruritus, periungual inflammation and ocular changes, often occur during cancer treatment with Targeted Therapy. Patients are hindered in their daily activities and cannot maintain privacy about their illness because of these visible side effects. These circumstances can lead to a decreased health related quality of life (HRQoL) and to discontinuation of treatment. Conceptual Framework: At present, clear terminology of the dermatological symptoms and evidence of the effectiveness of the management options about the side effects are lacking. Both, guidelines and assessment tools to collect relevant data are little used in current daily practice.

Methods & Analysis: A very specific search strategy was constructed thoroughly. The literature research was performed in Medline through Pubmed, Embase and CINAHL, following the guidelines of the Cochrane Collaboration. All papers about management of dermatological reactions caused by Targeted Therapy were included. Different categories were developed in advance and all data were analyzed accordingly (a. patient education, b. assessment tools, c. guidelines, d. pharmacological agents, e. interventions not otherwise specified, f. effect on the seriousness of the dermatological reactions, g. HRQoL, and h. treatment compliance). Two reviewers independently assessed the papers and extracted the data.

Findings & Implications: 135 articles were included. Inconsistent advices on management strategies and their influence on the seriousness of the dermatologic reactions were found. The results indicate that for rash topical immunomodulators and oral antibiotics seem to be more effective than topical antibiotics, antibacterials and retinoids.

The review suggests that interventions like baseline assessment, patient education and measurement of HRQoL and treatment compliance can help managing the rash. The assessment tools FACT and SKINDEX-16 can be worthwhile to use.

033 POSTER

Health-related quality of life (HRQL) of family members and cancer patients undergoing chemotherapy – final results

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Background: It was observed that although cancer patients undergoing chemotherapy had better mental component parameters, they faired worse in physicalcomponent parameters. In order to confirm the initial results we extended our survey to a higher sample population.

Methods: 212 family members (133 women) of mean age 48.9 and 212 cancer patients undergoing chemotherapy (119 women) of mean age 57.3 completed the SF-36 health survey by personal interview. The SF-36 health survey contains 36 questions covering functional health status and general health and has been validated in a Greek general population. The questions are summarized into eight scales measuring physical functioning (PF), role physical (RP), bodily pain (BP), general health perception (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH), with higher scores (0–100 range) reflecting better-perceived health. Two component summary scores capture the overall physical and mental health (Physical Component Summary or PCS and Mental Component Summary or MCS).

Data analysis was performed with SPSS version 13.0 while statistical analysis was performed with Wilcoxon signed ranks test. Significance was set at 0.05.

Results: Table 1 summarizes the final results of our study. As it was expected the physical component parameters were higher in the family members of the patients (p < 0.001). Indeed, the mental component of the family members was lower than the cancer patients; statistically significant in MH and MCS.

Conclusions: The final results, with double the surveyed population, confirmed the preliminary findings of our study. Although the mental component parameters were significantly higher in cancer patients undergoing chemotherapy, the physical component ones were significantly higher in their family members. Supportive programs for both the patients and the family members seem mandatory.

Table 1

	PF	RP	BP	GH	VT	SF	RE	МН	PCS	MCS
Patients	68.9*	31.2	64.9	55.0	61.6	67.7	60.2	67.6	40.7	47.6
	(30.4)	(39.5)	(35.9)	(23.4)	(24.5)	(35.9)	(41.7)	(20.0)	(11.6)	(11.8)
Family members	93.3	83.0	88.2	72.6	67.1	65.6	55.9	60.3	57.0	40.1
	(15.7)	(33.5)	(23.0)	(18.5)	(25.6)	(32.7)	(41.1)	(23.4)	(8.0)	(13.6)
p	<0.001	<0.001	<0.001	<0.001	0.024	0.305	0.408	0.001	<0.001	<0.001

^{*} Mean score and (1Standard Deviation) is described.

3034 POSTER

CORRECT, a web-based, observational study, showing that darbepoetin alfa is effective in treating chemotherapy-induced anaemia and improves quality of life in patients with breast or colorectal cancer

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Background: Clinical studies have shown that darbepoetin alfa (DA) therapy is effective in treating chemotherapy-induced anaemia (CIA) in patients (pts) with non-myeloid cancer, resulting in improved haemoglobin (Hb) levels, reduced transfusion requirements and better quality of life (QoL). Less is known about the response to DA treatment in daily clinical practice.

Methods: This prospective, multicenter observational study evaluated the efficacy of DA in treating CIA in pts with breast cancer or colorectal cancer (CRC) in routine clinical use. A web-based registry was used to collect data on therapies, Hb levels, transfusions and QoL.

Results: The present analysis is based on data from 574 breast cancer pts and 222 CRC pts. Physicians' treatment objectives for DA included prevention of red blood cell (RBC) transfusions (81% of breast cancer pts vs 18% of CRC cancer pts), fatigue (36% for breast cancer pts vs 61%

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for CRC cancer pts) and prevention of a Hb decrease (67% for breast cancer vs 46% in CRC pts). Hb levels significantly increased in both cancer groups (see table). In 20% of the breast cancer pts and in 18% of the CRC pts, the treatment was discontinued due to patient Hb levels \geqslant 13 g/dl. Approximately 20% of the pts received RBC transfusions.

QoL improved in about half of the examined pts as judged by the physicians and emphasized by significant changes in FACIT-F and LASA scores (see table).

Conclusions: CRC and breast cancer pts with CIA receiving DA treatment experienced significant increases in Hb levels. In these patients, QoL also significantly improved as measured by the physicians' judgement and objective QoL scores. These data further support the effectiveness of DA treatment for CIA.

	Breast cancer (N = 574)		CRC (N = 222)	
Hb level (g/dl, mean±SD)				
Baseline	10 ± 0.9		9.7 ± 0.7	
End of correction phase	11.3 ± 1.4		11.3 ± 1.5	
Hb increase	1.3±1.4**		1.6±1.4**	
Treatment				
DA treatment duration (in weeks, mean±SD)	6.2±5.1		7.5±5.1	
Number of pts receiving RBC transfusions during treatment	100 (17%)		54 (24%)	
Number of pts receiving iron supplementation (intravenous and/or oral)	157 (27%)		78 (35%)	
QoL (mean±SD)	FACIT-F	LASA	FACIT-F	LASA
Baseline	97.6±28.1	46.1±26.4	95.9±25.5	44.2±25.2
End of treatment phase	104.8 ± 26.9	39.1 ± 24.2	101.0±28.2	38.1±24.1
Difference	$7.3\pm21.5**$	-7.2±23.4**	$5.8 \pm 17.4^{**}$	-6.1±20.7

^{*}P < 0.01; **P < 0.0001 (Wilcoxon, paired).

This observational study was conducted by Amgen GmbH.

3035 POSTER Distress Thermometer (DT) in multidisciplinary management of cancer patients (pts): quality of life and quality of care

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Background: Cancer involves all areas of patient's life and his family. To detect patients' needs at diagnosis is important to take care of him, recognize areas of major discomfort to improve his quality of life. The NCCN guidelines suggested the use of the DT since 2006, although others have questioned the real efficacy of this tool (Jacobsen JCO 25; 452–6; 2007). Patient and Methods: Since 2007, 320 pts at diagnosis have filled in a self-evaluation thermometer that analyzes the distress through a numeric graduating scale (0–10). Five areas were explored to identify the causes for distress, according NCCN DT: physics, psychological, social, family and spiritual. If score was of 3 or more, pts were referred to an operator to whom was shown the cause of major distress observed. Median age of pts was 63 yrs (range 18–93), 55% female; 28% affected by gastrointestinal cancer, 18% breast, 18% genitourinary tract, 11% gynecologic, 8% lung, and 17% others.

Results: Average grade of distress has been 5. There haven't been observed substantial differences among the two genders, cancer type and comparative analysis between pts age < or >65 yrs, except for the prevalence of the second aspect: emotional in men (9%) and social in women (5.3%). Table shows the areas and the main aspect of distress in each areas.

PHYSICAL	51%	EMOTIONAL	33%	SOCIAL	10%
Gastrointestinal disorder	13%	Worry	35%	Transportation	33%
Fatigue	12%	Anxiety	21%	Financial	20%
Pain	9%	Sadness	16%	Housing	18%
Sleep	7%	Fear	15%	Child care	17%
Others	59%	Depression	13%	Others	12%
SPIRITUAL	3%			FAMILY	3%

Eighty-two% of pts has pointed more than one areas of distress (40% two, 27% three, 11% four and 4% five).

Conclusions: Our experience suggests that the DT is able to detect more than 45% of the pts' discomfort at diagnosis which is not detectable with a medical checkup. The inclusion of a psychologist and a social worker into the medical staff could guarantee a preliminary action in order to facilitate the therapeutic path. We have started a new randomized study in which the DT will be repeated after 3 and 6 months from the first time in order to evaluate whether supportive action has or not improved the distress.

POSTER

G-CSF use and neutropenic events in patients with breast and lung tumours: data from routine clinical practice (IMPACT Solid study)

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Background: EORTC guidelines recommend primary prophylaxis with granulocyte colony stimulating factors (G-CSFs) for cancer patients at high overall (≥20%) risk of febrile neutropenia (FN) due to chemotherapy (CT) and other risk factors, as well as to support dose dense regimens. We aim to assess G-CSF prophylaxis in clinical practice and its impact on neutropenic events and CT delivery.

Methods: This prospective, observational study (Clinicaltrials.gov: NCT00883181), is planned to include ~1300 patients with solid tumours (breast cancer, non-small cell lung cancer [NSCLC], small cell lung cancer [SCLC] and ovarian cancer) receiving any myelotoxic CT, who are judged to be at ≥20% risk of FN per EORTC guidelines. The primary outcome measure is the incidence of FN in relation to G-CSF use.

Results: This descriptive interim analysis includes 202 patients recruited from Dec 2007, who completed CT by Dec 2008. The most common CT regimens in breast cancer were docetaxel (Doc)/doxorubicin (A)/ cyclophosphamide (C) (22%), fluorouracil (F)/epirubicin (E)/C-Doc (18%) and A or E/Doc (17%), as was cisplatin + etoposide or vinorelbine in lung cancer (46%). G-CSF prophylaxis and FN events are shown below (see table)

Conclusions: This interim analysis suggests that many breast cancer patients considered at high FN risk are receiving aggressive adjuvant CT, often with G-CSF primary prophylaxis. The low proportion of elderly breast cancer patients suggests that few receive aggressive CT. Lung cancer patients may be at high FN risk due to older age and advanced disease. G-CSF primary prophylaxis was less common in this group, where FN and CT dose reductions were more frequent. Guidelines on G-CSF use may not be routinely applied in the non-curative setting. This ongoing study will help to better describe neutropenia management in clinical practice.

Breast Cancer (N = 129)	NSLC (N = 39)	SCLC (N = 22)
50 (28-82)	65 (41-83)	62 (43-79)
17 (13%)	20 (51%)	6 (27%)
19 (15%)	34 (87%)	14 (64%)
128 (99%)	29 (74%)	16 (73%)
79 (61%)	3 (8%)	1 (5%)
11 (9%)	5 (13%)	4 (18%)
14 (11%)	7 (18%)	1 (5%)
11 (9%)	5 (13%)	0
33 (26%)	10 (26%)	6 (27%)
16 (12%)	9 (23%)	4 (18%)
	(N = 129) 50 (28-82) 17 (13%) 19 (15%) 128 (99%) 79 (61%) 11 (9%) 14 (11%) 11 (9%) 33 (26%)	(N=129) (N=39) 50 (28-82) 65 (41-83) 17 (13%) 20 (51%) 19 (15%) 34 (87%) 128 (99%) 29 (74%) 79 (61%) 3 (8%) 11 (9%) 5 (13%) 14 (11%) 7 (18%) 11 (9%) 5 (13%) 33 (26%) 10 (26%)

*From cycle 1; initiated by day 7 if CT given on Day 1 only or by day 11 if CT given on Day 1+8. †Stage IV (breast cancer), IIIb-IV (NSCLC) or extensive disease (SCLC). Ovarian cancer not shown (N = 12).

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3037 POSTER

Development of the Analgesic Quantification Algorithm (AQA): a new scale to assess changes in analgesic use

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Background: Approximately two-thirds of patients with advanced cancer experience pain and, of these, more than one-third rated their pain as moderate or severe. Consequently, assessing changes in pain has become an important focus for clinical trials of medications for cancer treatment that are expected to have an impact on pain. In order to better understand the