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ΔΙΑΒΑΣΤΕ ΣΕ ΑΥΤΟ ΤΟ ΤΕΥΧΟΣ:

Έργο της ΕΛΕΝΗΣ ΖΟΥΝΗ

Αγαπητοί αναγνώστες - φίλοι και μέλη της ΕΛΕΦΙ,

Χρόνια Πολλά και Καλή Χρονιά.

Ευχόμαστε σε όλους υγεία και ακμαία, δημιουργική πορεία τη Νέα Χρονιά!

Το Δ.Σ. και η συντακτική επιτροπή του περιοδικού της ΕΛΕΦΙ θα είμαστε κοντά σας το 2015 με ενδιαφέροντα άρθρα, ενημερώσεις και νέα σχετικά με τη Φαρμακευτική Ιατρική.

Επιδίωξή μας να ανταποκριθούμε στις απαιτήσεις των επιστημονικών και θεσμικών εξελίξεων του κλάδου μας και συστηματικά να προωθήσουμε τη συνεχιζόμενη ιατρική εκπαίδευση και τις καλές πρακτικές στην άσκηση της εξειδίκευσης της Φαρμακευτικής Ιατρικής στην Ελλάδα.

Σε αυτήν την προσπάθεια σας προσκαλούμε να συνεισφέρετε στην ύλη του περιοδικού άρθρα με τις απόψεις σας, τις έρευνές σας και τις προτάσεις σας.

Εκ μέρους του Δ.Σ. και της συντακτικής επιτροπής

Με συναδελφικούς χαιρετισμούς και πολλές καλές ευχές.

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* Στην ΕΛ.Ε.Φ.Ι. συμμετέχουν ως μέλη ιατροί, φαρμακοποιοί ή πτυχιούχοι βιολογικών επιστημών, οι οποίοι ασχολούνται με κλινικές μελέτες (έρευνα), φαρμακοεπαγρύπνηση, εγκρίσεις φαρμάκων και με άλλους τομείς της Φαρμακευτικής Ιατρικής.

Ανασκόπηση της Βιβλιογραφίας - Ενδιαφέροντα άρθρα

Βαρβάρα Μπαρούτσου

Αγαπητοί συνάδελφοι,

μοιράζομαι μαζί σας κάποια σημαντικά κατά την άποψη μου άρθρα, κείμενα και ενημερώσεις και ειδικότερα τα θέτω προς συζήτηση και ανταλλαγή απόψεων μεταξύ μας

a. **Good Pharmaceutical Medical Practice** – μια πρώτη απόπειρα Ορθής Πρακτικής Φαρμακευτικής Ιατρικής από το Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom November 2014
Source: https://www.fpm.org.uk/policypublications/gpmp2014

b. **Sharing and Reporting the Results of Clinical Trials** interesting viewpoint published in JAMA on NIH proposed policy aiming to increase transparency/disclosure of NIH funded research.
Source: https://jama.jamanetwork.com/article

c. **Medical Researchers fears over data protection rules.** Researchers call on the EU to provide the legal framework for research so it can deliver reliable answers as rapidly and cost effectively as possible. The Scientific community is deeply concerned over the risks that Europe's new data privacy rules present to research.
Source: www.europeanvoice.com

d. **Horizon 2020 INFO DAY ICT-SCI: E Health & Ageing**
On December 2014 the European Commission organised a Horizon 2020 information day on the topic ICT-SC1 (Societal Challenge 1), for funding of projects in the domain of ICT for health, wellbeing and ageing. The presentations that took place have been made available online and can be accessed in the below link.
Source: EC: Digital Agenda for Europe

e. **IMI Launches E 115 M Calls for Proposals.**
Innovative Medicines Initiative (IMI) has now launched its 3rd and 4th Calls for proposals under IMI 2, with topics on remote assessment, type 2 diabetes, neuropsychiatry, vaccine manufacture, perysis vaccines, patient engagement and adaptive pathways.
Source: Innovative Medicines Initiative

f. **Adaptive pathways: A Future approach to bring new medicines to patients.**
«Adaptive pathways should be the preferred approach in the near future to bring new medicines to patients». A number of scientists, including members of the European Medicines Agency (EMA) and its scientific Committees take this position in a co-authored article published in Clinical Pharmacology and Therapeutics. The concept of adaptive pathways foresees an early approval of a medicine for a restricted patient population based on small initial clinical studies. The first approval is followed by progressive adaptations of the mar-

keting authorisation to expand access to the medicine to broader patient populations based on data gathered from its use and additional studies.
Source: EMA

g. **Shaping science policy in Europe.**
The Lisbon Strategy was adopted by the Heads of State and Government of the European Union (EU) in 2000. By moving science into a central position for the development of a European knowledge-based economy and society, its adoption at political level seems to have been a powerful catalyst for the increased involvement of scientists in science policy in the EU. The European biomedical community has recently proposed the creation of a strategic action plan for health research (the European Council of Health Research; EuCHR), provisionally translated at present into a Scientific Panel for Health (SPH) research in Horizon 2020, the EU's research-funding programme for the period 2014-2020. The creation of such Scientific Panel should be viewed as an important contribution by the biomedical community as a major political agreement has been reached on the need for a comprehensive and long-term scientific strategy to accelerate research and facilitate innovation at EU level. It is our belief that describing and analyzing the process leading to the creation of the ERC and SPH (2002-2014) should be widely shared with the research community in general, as this may contribute to the understanding of the evolving relations between scientists and science-policy making.
Source: Celis JE
Gago JM Mol Oncol. 2014 May;8(3):447-57. molonc.2014.03.013. Epub 2014 Mar 21.

Μελέτη QUARTET*

Evaluation of Quality of Life of patients with unresectable, locally advanced or metastatic Non-Small Cell Lung Cancer during and after the completion of 1st line therapy with Docetaxel in combination with cisplatin

Abstract

Introduction-Aim: Non-small cell lung cancer (NSCLC) is frequent solid tumor accounting for high mortality rates. It is mostly diagnosed in stages III and IV, reducing the treatment options that can be offered to patients. Chemotherapy offered to patients with advanced disease is primary palliative and therefore the influence of Quality of Life (QoL) parameters should be seriously considered. This prospective observational study was conducted to evaluate the tolerability of a first line Docetaxel-based chemotherapy and to assess QoL for unresectable, locally advanced or metastatic NSCLC patients.

Methods: Adults patients with histologically or cytologically proven locally advanced or metastatic NSCLC that have already initiated treatment with Docetaxel/Cisplatin as first line treatment, with ECOG PS under 2, and patients who have signed the ICF were included in this study. Disease characteristics were monitored alongside with clinical and QoL evaluations (EuroQol five-Dimensional questionnaire [EQ-5D], Visual Analogue Scale [VAS] and Lung Cancer Symptom Scale [LCSS] for patients and health providers), were performed at the beginning and at the completion of the study.

Results: 126 patients administered the Docetaxel/Cisplatin regimen were enrolled in 8 sites. This chemotherapy proved to be well tolerated, with manageable toxicity, without deteriorating the Quality of patients' Life parameters with the exception of appetite and daily activities that might be linked to the disease progression and increasing ECOG-PS that were also observed. At the completion of the study, the patients achieved overall response rates of 17.1% and stable disease of 22.2%.

Discussion: Chemotherapy regimen based in Docetaxel proved not to deteriorate the QoL parameters in patients enrolled for this study, whereas overall responses and stable disease were achieved for 39.3% of the study population.

Keywords: Non-small cell lung cancer (NSCLC), quality of life (QoL), chemotherapy regimens.

Introduction:

Lung Cancer is one of the most common and lethal cancers in all over the world [1]. It is one of the most frequent cancers being first for male and third for female with 14.1 million new cases in 2012 worldwide. It is the first cancer in terms of mortality with 8.2 million deaths worldwide. The last decade, the incidence increased by 25% in male and 70% in female population suggesting that both the incidence and mortality rates among the two sexes tend to equilibrate. In Greece, the incidence of lung cancer for both sexes is 6.884 according to 2012 data, placing lung cancer as the most frequent cancer in male and the third in female population, whereas the differences between the two sexes show a different to global trend to equilibrate (male to female ratio is 4.7:1) [2]. However, it should be mentioned that a local Pathologist Analysis evaluated all solid tumors in Hospital Laboratories in 2009 and 2010 [3] and reports a decreased incidence of lung cancer compared to Globocan 2012

estimation. This is explained by the fact that advanced or metastatic lung cancer is not usually biopsied. Taking into consideration that the majority of lung cancer cases are diagnosed in an advanced stage, this leads to a possible underestimation of lung cancer incidence.

Numerous causes for lung cancer have been identified including but not limited to tobacco use, exposure to radiation and environmental and occupational exposure primarily asbestos workers [4 - 7]. The clinical features of lung cancer are generally divided into anatomic regions since this generally parallels the extent and the spread of the disease. Local symptoms include cough, dyspnea, hemoptysis, recurrent infections and chest pain, whereas symptoms secondary to distant metastasis include organ related pain (liver, bone, brain, pleura) and general symptoms, mainly weight loss and fatigue [6 – 7].

There are two types of lung cancer. The variant known as small cell lung cancer (SCLC) accounts for 20% of cases, while the rest 80% of cases are non-small cell lung cancer (NSCLC). There are three major types of NSCLC, with each type to have a different incidence and pattern of occurrence by age, sex, race, and geographical area [8]. Squamous cell carcinoma represents 30% of all cases, it is most commonly found in men, it is closely correlated with smoking and it consists of layers of epithelial cells that secrete keratin, and therefore often present as obstructing tumors in the bronchi. Adenocarcinoma is the most common type in women, and non-smokers and it is characterized by high level of expression of small airway or immunologically associated proteins [9] and K-ras mutations are frequently reported [10]. Large cell carcinoma has a high tendency to metastasize, its lesions are mostly peripheral and it comprises of undifferentiated cells [11].

More than 70% of NSCLC is diagnosed at stages III & IV (according to WHO classification) and it is too advanced to be cured by surgery including lobectomy, pneumonectomy and mediastinal lymph node dissection which are usually treatment options for early stages. Neoadjuvant chemotherapy is used in early stages to decrease the risk of distant metastases, to induce higher rates of responses, although the survival improvement is questionable. Adjuvant treatment is also administered in early stages post-operatively since survival benefit has been proved in clinical trials and it is now a standard for stages IB and II.

For locally advanced NSCLC, chemotherapy is usually combined with radiotherapy, whereas in metastatic disease various chemotherapy regimens are administered so as to customize therapy. Unfortunately, in unresectable, locally advanced and metastatic NSCLC, first line chemotherapy is only effective for a few months and NSCLC responds poorly to agents used second line. Despite the progress from new treatments in terms of survival, the prognosis is poor and the survival at 5 years is 3-7% for stage IIIb [12] and less than 2% for stage IV, whereas the 1 year survival for stage IV is highest in patients with bronchioloalveolar adenocarcinoma (29.1%) and lowest in those with large cell tumors (12.8%) [13]. Taking into consideration that the role of chemotherapy in advanced disease is primary palliative, the influence of patients' QoL is an important consideration in determining the true value of any therapy [1]. Additionally, the impact on various everyday patients' life aspects is considered to be of great importance.

The parameter of Health Related Quality of Life (HRQoL) is now evaluated as an important outcome measure in lung cancer clinical trials. However few studies have incorporated the measure of QoL. Disease specific lung cancer questionnaires have been developed and validated predominantly in patients with more advanced lung cancer and often those undergoing chemotherapy or radiotherapy in the clinical trial setting. On the other hand, HRQoL in

Conflict of Interest

Anna Tziraki is an employee of Sanofi working as Medical Scientific Liaison for Greece.

Authors contributions

SI, PC, SE, VI were principal investigators and provided editorial support for the manuscript. AT was study-sponsor coordinator. All other study investigators conducted the study and collected the data.

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long term survivors of lung cancer or those with early stage disease who have undergone surgery has usually been evaluated using generic HRQoL instruments [14].Today, disease-specific and generic validated tools for the evaluation of HRQoL are available. The availability of the new instruments enables clinicians to have some choice in the way that they analyze HRQoL in their clinical trials. HRQoL encompasses issues such as pain, mobility, symptoms, social health and psychological health [15].

In order to monitor QoL measurements in the population diagnosed with advanced or metastatic NSCLC, relevant measures are used.

1. One of the measures that is frequently used, EQ-5D, is a generic measure of health status developed by an international research group, the EuroQol Group. The general EuroQol five-dimensional questionnaire (EQ-5D) was developed to address the fact that the outcome measures need to encompass a broad range of different disease areas, specialties and types of care and to provide a single index that can be linked to cost. Most clinical researchers use the EQ-5D self-report questionnaire, which asks respondents to classify and rate their own health according to five dimensions: mobility, self-care, daily activities, pain/discomfort and anxiety/depression. For each dimension, patients had to mark which condition best applies to their case on a scale from 1 to 3, with 1 related to lack of symptom, 2 related to moderate symptom and 3 related to serious manifestation of symptom. The resulting health state can therefore be also defined by a five digit number by combining one level from each of the five dimensions [16].
2. In parallel, Visual Analogue Scale (VAS) is used to enable the respondent to provide an overall self-rating of his/her own health fluctuating on a 0 to 100 scale, with 0 related to worst condition and 100mm related to best condition. Respondents draw a line to the point on the scale that indicates their overall health status assessment [16].
3. A third evaluation of the QoL, is represented by the use of the Lung Cancer Symptom Scale (LCSS). This is a disease- and site-specific instrument, particularly designed for clinical trials and clinical practice focusing on the dimensions most likely to be affected by treatment. The LCSS consists of two instruments, one for patients and a counterpart, optional one, for health professionals as observers [17].

   a) The patient scale comprises of nine dimensions: six measuring main symptoms for lung malignancies and three summation items related to total symptomatic distress, activity status and overall quality of life. All items are measured by visual analogue scales using 100mm lines to determine the intensity of patient responses to appetite loss, fatigue, cough, dyspnea, hemoptysis, pain, symptoms of lung cancer, activity levels and quality of life. The patient is asked to focus on describing lung cancer symptoms given the time frame, the last 24 hours. Zero corresponds to lowest rating and 100 represents the highest rating, that is 0 stands for negative symptom presence (positive evaluation) and 100 stands for positive symptom presence (negative evaluation) [17].

   b) The observer scale is an ordinal level scale measuring six common lung cancer symptoms: appetite loss, fatigue, cough, dyspnea, hemoptysis and pain. Response categories are 100 for no symptom, 75 for mild, 50 for moderate, 25 for marked and 0 for severe symptoms. Although the scoring system is the reverse of the patient scale, it is similar to performance scales used in oncology [17]. Although observer LCSS is an optional scale, it is of major importance since the estimation of the quality of life is often different between the physicians and their patients. For example, the pain is often underestimated by the physicians, while it consists one of the main concerns for the cancer patients.

In general, QoL is related to tolerability of chemotherapy. Toxicities of chemotherapy lead to low tolerability and poor compliance. Not all patients receive all of the planned cycles of chemotherapy or they receive lower dose of drug. Patients that do not complete the planned chemotherapy are classified as having failed to complete therapy due to patient refusal, toxicity, disease progression, comorbidities or death.

In this context, we decided to conduct a post authorization, non-interventional, local, multicentre, prospective product registry, in order to evaluate the tolerability of Docetaxel-based chemotherapy, the compliance of patients with unresectable, locally advanced or metastatic NSCLC treated with Docetaxel regimen as first line chemotherapy and the related Quality of Life of these patients. The evaluation of QoL was assessed by the EQ-5D and the LCSS in patients included in the study with stages III and IV NSCLC. In addition, this study was important for Greek physicians to realize the significance of QoL assessment for such an indication and to familiarize them with QoL evaluation. Additionally, the use of these QoL instruments will involve the patients and allow them to express their feelings about their illness and treatment. This study was approved by the Hospital Scientific Committees and the National Organization for Medicines from February 2008 to July 2013.

Methodology:

Patients and treatment:

This study was planned to enroll 320 patients in up to 25 sites selected after The specific inclusion and exclusion criteria defined in the study protocol (DOCET_L_3284/QUARTET) included adult patients with histologically or cytologically proven locally advanced or metastatic NSCLC that were administered Docetaxel/Cisplatin regimen and had received at least one cycle of chemotherapy prior to inclusion in the study. In addition, patients should have a ECOG PS under 2, they should not participate in another study at the time of inclusion, they should also comprehend and respond to the questions asked in the multiple questionnaires and have signed the ICF.

Statistical Considerations for sample size:

To estimate the sample size for this study based on the primary outcome as this was defined above, a 5% level of significance (i.e., type I error = 0.05) and a power of 80% (1-β = 0.80) was assumed. The comparison between baseline and the last available measure of QoL will be based on a paired t-test. For the estimation of sample size, the expected mean difference in QoL and the expected standard deviation of the difference in QoL between baseline and last available measurement should be known. Taking into consideration that these values were not available, these values were estimated based on results from the literature [18]. We have hypothesized a range of mean differences from 1 unit to 9 units and a range of standard deviations from 10 to 50.

Safety Reporting:

All participating investigators had to report all adverse events (AE) having occurred during the conduction of this non interventional study within appropriate timelines according to Good Pharmacoepidemiology Practices (GPPs). The AE reporting was initiated from signing the informed consent form (ICF) until performing the last visit or finalizing patient's follow up. All AE, serious and non-serious, were followed up until their resolution.

Data Analyses:

For the implementation of the statistical analysis, descriptive statistics were used. Statistical measures used were frequencies and distribution percentages

for discrete variables and descriptive measures (mean, median, maximum, minimum, standard error of the mean) for continuous variables. Statistical tests among discrete variables were implemented by using the statistical test Chi-Square. For statistical tests of discrete variables with two categories each (2x2 tables) the Fisher Exact Test was used. Also, the statistical Student's T-test was used for the comparison of values of continuous variables between two categories of discrete variables and the statistical Anova F-Test for the comparison among more than two categories of discrete variables. For comparisons of quantitative variables between two points in time the paired t-test was used while an Ancova model was set so as to check whether changes in quality of life indicators differ between groups of patients.

Additionally, the relationship between quantitative variables was studied with the use of Pearson Correlations. Mc Nemar test was also used to study the change in time of dichotomous variables.

All statistical analyses were implemented at a significance level of $\alpha=0.05$ (2-sided) by using the statistical package SPSS version 16.0.

Results:

Although 21 sites were initiated, only 8 sites recruited a total of 126 patients between 09.06.2008 and 10.08.2012, according to specific inclusion and exclusion criteria defined in the study protocol (DOCET_L_03284/QUARTET). Baseline patient demographics of the study population and characteristics of the disease are shown in Table 1.

The majority of the patients participating in the study had a tumor stage III/IV during the first visit (95.2%). The physicians also reported that 45.2% of the patients had a tissue diagnosis of adenocarcinoma, 15.9% of epithelial cancer and 2.4% of large cell carcinoma. Other tissue diagnoses were recorded to 19.8% of all patients (mainly squamous cell carcinoma).

The majority of patients (79.4%) had not received any treatment other than 1st cycle of chemotherapy prior to the baseline visit, while 13.5% had undergone radiotherapy and 7.9% were operated. No significant difference in previous treatments was detected with regards the age (p-value=1.00) or the gender of patients (p-value=0.56).

As concern as the presence of comorbidities, 66.7% of the study population-was disease-free, while 22.2% had confirmed heart disease and 9.5% endocrine ones. The existence of comorbidities was related to the age of respondents (p-value<0.01) with older respondents having higher probability of presenting a comorbidity.

Thirty four percent of included patients did not receive any supportive treatment during the first cycle Docetaxel/Cisplatin regimen administration. Main other treatments that were administered were Filgrastim (20.6%), Ondaserton (19.0%), Dexamethasone (17.5%), Aprepitant (15.9%) and Palonosetron (14.3%).

Quality of life (QoL) evaluation at the beginning of the first cycle

The Quality of life was investigated with the use of three QoL questionnaires for the patients and one for their treating physicians.

As shown in table 2, at baseline and as reported in EQ-5D scale 53.2% of all patients had no difficulties in mobility, 80.2% were lacking self-care problems and 50.0% were performing without problems all daily activities. In addition, 46.8% were lacking any pain/discomfort problems, while a 56.3% experience moderate anxiety/depression.

As shown in table 3, at baseline visit and as reported in patients LCSS scale, the overall average assessment as calculated by the values of the nine parameters scored at 30/100. Taking into consideration that this is an inverted scaling, this evaluation was not strongly differentiated from the EQ-5D assessments of the quality of life described above. Patients scored better with regards to the presence of hemoptysis (14/100), dyspnea (23/100) and pain (24/100). Relatively moderate were the assessments with regards to appetite (26/100) and coughing (28/100). The evaluations were more negative for fatigue (33/100), symptoms presence (36/100) and effect on daily activities (36/100).

With respect to age, younger patients (≤ 65 yo) had a better EQ-5D scaling score of 77.8 vs 69.6 for ages >65 yo (p-value=0.03). There has not been any age differences with respect to self-assessment 1-100 VAS scale (p-value=0.10) or the LCSS recorded quality of life (p-value=0.15).

In addition, strongly significant differences in quality of life indicators are recorded between the two ECOG groups. More specifically, EQ-5D scaling for patients with ECOG=0 was 84.2 vs 66.4 for patients with ECOG=1 (p-value<0.001). Furthermore, the quality of life score at the VAS scaling 1-100 for patients with ECOG=0 was 72.8% vs 58.7% for patients with ECOG=1 (p-value<0.001), while the respective score of the LCSS recorded quality of life was 19/100 for patients with ECOG=0 vs 36/100 for patients with ECOG=1 (p-value<0.001) (table 4).

In addition to the above, the physicians were also asked to give a subjective evaluation of the quality of life of their patients (observers LCSS). The doctors evaluated six parameters of quality of life (loss of appetite, fatigue, cough, dyspnea, hemoptysis and pain) on a scale from 0 to 100 where 0 referred to severe symptoms and 100 to lack of symptoms. Table 5 summarizes the results of the baseline measurement. 73% of the doctors completed the respective observers´ LCSS scale at the first cycle. The physicians average evaluation of hemoptysis was 91/100, followed by dyspnea 85% and loss of appetite as well as pain (both 84/100). More severe evaluations received the fatigue factor (74/100) and the coughing one (79/100). All above evaluations were significantly correlated with the respective evaluations of the patients at the first cycle (table 6).

Patients´ status at the completion of the study

40.5% of the patients received all 6 chemotherapy cycles, 19.1% received 4-5 cycles, while 40.4% received less than 4 cycles (table 19). 56.6% of these patients had a ECOG Performance Status of 1, while 18.9% had a value of 0, 17.2% a value of 2, and the remaining 7.4% higher ECOG values. In one case, the supervising doctor continued the therapy beyond the 6th cycle (8 cycles in total).

The majority did not have any change in coughing symptoms as shown in table 8.

With respect to the tumor's stage at the completion of the study, 72.8% of patients were at stage IV, 22.8% at stage III and the remaining 4.4% at lower stage. For 34 patients, this info was not recorded (27%). At the completion of the study, the response to chemotherapy was recorded. 3.4% of patients achieved complete response and 13.7% partial response, summing up to a total response rate of 17.1%. 22.2% of patients achieved stable disease (disease control rate of 39.3%). However, response rate was unknown for 10.3% of the study population.

At 89.6% of all recorded visits, the Docetaxel treatment continued without any change, 4.2% continued with dosage change while at 6.3% of all visit cases the treatment was interrupted. Out of those cases, where a Docetaxel interruption

reason was given, 40% attributed the interruption to the change of therapy due to disease progression, 17% mentioned that this was a physician's choice while 17% referred to hematologic toxicity.

Similarly at 89.8% of all recorded visits, continued the cisplatin treatment without any change, 3.6% continued with dosage change while at 6.8% of all visit cases the treatment was interrupted. Out of those cases, where a cisplatin interruption reason was given, 41% attributed the interruption to the change of therapy due to disease progression, 16% mentioned that this was a physician's choice while 16% referred to hematologic toxicity.

Also, out of the patients who were found to have disease progression 36.7% were at cycle 6, 23.5% at cycles 4 or 5 and 39.7% at previous cycles.

Moreover, 51 patients out of all 126 patients completed all six therapy cycles (40.5%). For 48 of those (94%) the final outcome has been recorded. 6.3% achieved complete response, 29.2% partial response (overall response rate of 35.5%), 25.0% stable disease and 37.5 disease progression. At 2.1% of cases the response info was unknown.

Changes in QoL indicators

Table 9 summarizes the evaluations of patients at the completion phase with regards the EQ-5D scaling. As also shown in table 10, there has not been any strongly significant change in the EQ-5D evaluations in times as these are denoted by the percentage of patients declaring any problem. The only exception has been the self-care parameter, where there has been a significant increase in the above metric (from 20% to 32% at the completion of the study, p-value<0.01).

In addition, the self-assessment (VAS) of the quality of life in the 1-100 scaling received a mean score of 62.4% at the completion of the study vs 63.8% at the baseline stage. The above difference was not statistically significant at 5% (p-value=0.34).

Furthermore, similar quality of life evaluations were recorded with the usage of the LCSS booklet by the patients at the completion stage. No significant differences between completion and baseline stage were found at the significance level of a=5% with the exception of appetite (p-value=0.02) and daily activities (p-value=0.02). Both parameters had a poorer score at the completion stage in terms of quality of life. Appetite received an average score of 31/100 (vs 26/100 at the baseline phase) and daily activities a score of 41/100 (vs 36/100 in baseline, at the scale 0 positive to 100 negative). However the overall evaluation of all quality of life items as these were recorded at the LCSS booklets ranged from 30/100 (baseline) to 32/100 (completion), a change which was not found to be significant (p-value=0.13). Also, there has not been any significant change in the physicians' evaluations between baseline and final measurement.

In order to investigate possible interactions between the quality of life performances per ECOG grouping, an ANCOVA model was set using initial assessments as covariates. The interactions between ECOG groups and EQ-5D scaling was not found to be significant (p-value=0.14). Similarly, the interaction between ECOG groups and self-assessment at the 1-100 VAS scaling was not found to be strongly significant (p-value=0.05) and the same for the interaction with the LCSS self-evaluation (p-value=0.27).

Report of Adverse Events

Docetaxel-emergent adverse events reported frequency was 27.8% and Cisplatin-emergent adverse events frequency was 31.0% in the study population (Table 17). 45 Non Serious Adverse Events (NSAE) were reported

in 36 (28.6%) patients, whereas 67 serious adverse events (SAE) were captured in 35 (27.8%) patients of the study population. 23 out of the 67 SAE were related to chemotherapy, whereas 18 out of the 45 NSAE were also related to chemotherapy.

Table 11 summarizes the incidence at all grades of the most frequently reported adverse events. Adverse events were documented to be fatal in 9.8% (11 patients). Three of the 11 fatal events were related to chemotherapy. More analytically, one SAE of acute renal failure resulting in death was related to cisplatin, one SAE of cardiopulmonary arrest resulting in death was related to Docetaxel and one SAE of patient with fever and positive sputum culture resulting in pulmonary insufficiency, hypercapnic coma and eventually death was related to both Docetaxel and Cisplatin. All other 8 cases were not related to chemotherapy regimen administration and include cases of bowel perforation, respiratory distress syndrome, cardiac arrest and hyperventricular tachyarrhythmia, whereas one patient died at home after one administration of the chemotherapeutic regimen and no autopsy was performed.

Tables are provided in appendices.

Discussion:

As the role of chemotherapy in advanced NSCLC is essential palliative, it is recognized that we need to add on the effect of the treatment, the effect on symptom relief. In this aspect, QoL assessments are of major importance. The TAX 326 randomized trial, demonstrated that patients treated with Docetaxel platinum regimens generally experienced an improvement in their QoL versus Vinorelbine treatment [18].

In this local conducted study, the study population was diagnosed mainly (95.2%) with an advanced tumor stage (III and IV). The physicians also reported that 45.2% of the study population was diagnosed with adenocarcinoma, 15.9% with epithelial cancer and 2.4% with large cell carcinoma, whereas other tissue diagnoses were recorded to 19.8% of all patients (mainly squamous cell carcinoma). It should be mentioned though that according to WHO classification, epithelial cancer may be adenocarcinoma or squamous cell carcinoma and accordingly this 15.9% should be further allocated to the 45.2% of the patients with adenocarcinoma and the 19.8% of the patients with squamous cell carcinoma. Large cell carcinoma may be also of epithelial of endocrine origin and accordingly this also alters the initial percentages reported by the treating physicians. This kind of clarification was beyond the scope of this study and no further assessments were required.

The comparison for NSCLC stages and ECOG-PS at baseline and at last treatment assessment showed that there had been deterioration in terms of disease and performance status evaluations in the study population. As described in various articles, NSCLC is diagnosed mostly in an advanced stage when the chemotherapy is effective for a few months and then the disease progresses. At these stages, chemotherapy is not curative, but mostly palliative, and primarily its influence in patients QoL parameters should be considered. QoL assessments for the late stages NSCLC patients need to be evaluated to determine the value of any therapeutic manipulation.

In this context, this local product registry evaluated the tolerability, compliance and QoL indicators to Docetaxel/Cisplatin regimen administered as first line chemotherapy treatment to patients diagnosed with unresectable locally advanced or metastatic NSCLC.

The chemotherapeutic regimen was well tolerated taking into consideration that 40.5% of the included patients were administered all 6 cycles with

one of these patients to have been administered a total of 8 cycles as per summary of product characteristics indication and dosage [19]. The dose of the regimen was not altered in approximately 90% of the patient population. The activity of this combination resulted in a clinical benefit accompanied by an expected increase in adverse events, attributable to the chemotherapy regimen and NSCLC. Some of the common adverse events reported were anemia, leucopenia, diarrhea, fatigue, fever and dyspnea. This implies that both Docetaxel and Cisplatin safety profiles are manageable. No new safety signal was reported, as well.

At the completion of the study, the response to chemotherapy was reported. 3.4% of the study population had complete response and 13.7% had a partial response, summing up to a total response rate of 17.1%. At the same time point, the disease was stable for 22.2% of the patients, whereas for 50.4% progressed. It is also important that from the 40.5% of the included patients that were administered all 6 cycles of the regimen, 35.5% responded either completed or partially to the Docetaxel/Cisplatin combination, whereas 25.0% had their disease stabilized. Taking together with the trend described above on disease deterioration as described in ECOG-PS and stage evaluations, it is suggested that the chemotherapy administered to the patient population suffering mainly from late stages of a rapid progressive neoplasm, it is well tolerated and it shows efficacy for a high percentage of patients.

A direct evaluation of the QoL indicators was performed with various assessment instruments. As per EQ-5D patients' evaluation, it was shown that mobility, performance of daily activities, pain and anxiety/depression parameters were not different when baseline reports were compared to end of study ones. The only parameter that significantly differs between the start and end of patients' evaluation was the improvement in self-care. However, the overall VAS self-assessment of the EQ-5D did not differ within the patients at baseline and end of study visit. Similar quality of life evaluations were recorded with the completion of the LCSS booklet by the patients. No significant differences between completion and baseline stages were found with the exception of appetite and daily activities that showed to have had a poorer score at the completion stage. It is also of value to highlight that the LCSS observers' evaluations were positively correlated to the QoL assessment performed by their patients, implying the close monitoring of their patients disease status. No significant differences between completion and baseline stage were found in the LCSS observers' evaluation, too.

Although, we have to highlight that the study did not succeed to include the planned number of patients, the QoL evaluations, tolerability and compliance available data, imply that the Docetaxel/Cisplatin regimen administered to patients suffering from this lethal neoplasm was well tolerated, with manageable toxicity and without deteriorating their QoL parameters. At the same time, complete response in 3.4% and partial response in 13.7%, summing up to a total response rate of 17.1% was observed in the study population. We should also highlight that a total response rate in 14% and a stable disease in 8% was observed in patients administered all 6 cycles of the Docetaxel-containing regimen.

Conclusion:

The present study indicates that the Docetaxel/Cisplatin regimen administered to mainly late stages NSCLC patients is well tolerated, with manageable toxicity, without deteriorating the Quality of patients' Life parameters, while at the completion of the study, the patients achieved overall response rates of 17.1% and stable disease of 22.2% (disease control rate of 39.3%).

Appendix I-Tables and Figures

Table 1: Baseline Patient Characteristics

Characteristic	n	%
Gender		
Male	106	84.1
Female	20	15.9
Total	**126**	
Age (years)		
Median	67	
Range	42-91	
≤65 years old	49	38.9
>65 years old	77	61.1
Smoking		
Smoker	49	40.8
Ex-smoker	65	54.2
Non smoker	6	5.0
ECOG PS		
0	45	35.7
1	81	64.3
BMI		
Normal	54	42.9
Overweight	54	42.9
Obese	18	14.3
Primary metastatic site*		
None	60	47.6
Adrenal glands	9	7.1
Liver	17	13.5
Brain	12	9.5
Bones	21	16.7
Lungs	22	17.5
Soft tissue	2	1.6
Other	7	5.6
Tumor stage		
I	1	0.8
II	5	4.0

Characteristic	n	%
III	43	34.7
IV	75	60.5
Previous treatment*		
None	100	79.4
Radiotherapy	17	13.5
Surgery	10	7.9
Comorbidities		
Yes	42	33.3
No	84	66.7

Table 2: EQ-5D evaluation at the beginning of the 1st cycle

EQ-5D (beginning of 1st cycle)		No problems	Moderate problems	Serious problems	Total
Mobility	%	53.2%	44.4%	2.4%	100.0%
Self-care	%	80.2%	16.7%	3.2%	100.0%
Daily problems	%	50.0%	42.1%	7.9%	100.0%
Pain/discomfort	%	46.8%	49.2%	4.0%	100.0%
Anxiety/depression	%	29.4%	56.3%	14.3%	100.0%

Table 3: Mean assessment of the 9 parameters of QOL evaluated on a scale 0 (positive) to 100 (negative) at the initial stage of the study

Factors assessed-booklets	Mean	Median
Appetite	26	20
Fatigue	33	30
Coughing	28	23
Dyspnea	23	14
Blood	14	5
Pain	24	15
Symptoms	36	30
Daily activities	36	32
QoL overall	47	45
Average assessment	30	28

Table 4:
Quality of life assessments between ECOG groups at the initial stage of the study

QOL Factors assessed	ECOG=0	ECOG=1
EQ-5D Scaling (0 negative -100 positive) (p-value<0.001)	84.2/100	66.4/100
VAS Self-reported (0 negative – 100 positive) (p-value<0.001)	72.8%	58.7%
LCSS average scoring (0 positive-100 negative) (p-value<0.001)	19/100	36/100

Table 5: Mean assessment of the 6 parameters of physicians' LCSS booklet

Factors assessed-booklets	Mean	Median
Loss of appetite	84	100
Fatigue	74	75
Coughing	79	75
Dyspnea	85	100
Hemoptysis	91	100
Pain	84	100

Table 6:
Correlations between LCSS (patients) and LCSS (physicians) booklets' at the beginning of the study (the negative sign refers to positive correlation due to inverted scales)

Factors assessed-	Correlations
Loss of appetite	-0.59**
Fatigue	-0.62**
Coughing	-0.71**
Dyspnea	-0.67**
Hemoptysis	-0.63**
Pain	-0.63**

**significant at level 0.01

Table 7: Flow of patients during the various stages of the study

Study stage	No of patients participating	%
Cycle 1	126	100%
Cycle 2	108	85.7
Cycle 3	94	74.6
Cycle 4	75	59.5
Cycle 5	56	44.4
Cycle 6	51	40.5
Follow up visit 1	36	28.6

Table 8: Symptoms change evaluation at the completion stage

Symptoms	Improvement	No change	Deterioration
Coughing	10.3%	63.2%	26.5%
Dyspnea	11.1%	53.8%	35.0%
Pain	13.7%	60.7%	25.6%

Table 9: EQ-5D evaluation at the completion phase

EQ-5D (completion phase)		No problems at all	Moderate problems	Serious problems	Total
Mobility	%	44.0%	51.2%	4.8%	100.0%
Self-care	%	68.0%	25.6%	6.4%	100.0%
Daily problems	%	48.0%	42.4%	9.6%	100.0%
Pain/discomfort	%	47.6%	47.6%	4.8%	100.0%
Anxiety/depression	%	28.6%	56.3%	15.1%	100.0%

Table 10: Patients with any problems at the EQ-5D scaling at baseline and at the completion of the study

Factors assessed	Baseline %	Completion %	p-values
Mobility	47%	56%	0.052
Self-care	20%	32%	<0.01
Daily problems	50%	52%	0.85
Pain/discomfort	53%	52%	1.00
Anxiety/depression	71%	71%	1.00

Table 11: Incidence at all grades of the reported adverse events

Adverse Event	AE Cases	Percentage	NSAE	SAE
Anemia	27	24.1%	25	2
Neutropenia	8	7.1%	6	2
Disease progression	6	5.4%	0	6
Death	8	7.1%	0	8
Diarrhoea	5	4.5%	3	2
Leukopenia	4	3.6%	4	0
Nausea/Vomiting	4	3.6%	2	2
Fatigue	6	5.4%	0	6
Renal Failure	2	1.8%	0	2
Dehydration	2	1.8%	0	2
Loss of hearing	2	1.8%	1	1
Hypocalcemia	1	0.9%	0	1
Fever	4	3.6%	0	4
Anorexia	3	2.7%	1	2
Dyspnea	4	3.6%	0	4
Dysphagia	1	0.9%	0	1
Allergic skin reaction	1	0.9%	0	1
Hemoptysis	1	0.9%	0	1
Cough	1	0.9%	0	1
Hypercalcemia	1	0.9%	0	1
Muscle weakness	1	0.9%	0	1
Hyperemesis	1	0.9%	0	1
Urine infection	1	0.9%	0	1
Pneumonia	1	0.9%	0	1
Multiple organ failure	1	0.9%	0	1
Atrial fibrillation	1	0.9%	0	1
Bowel perforation	1	0.9%	0	1
Chest pain	1	0.9%	0	1
Prerenal azotemia	1	0.9%	0	1
Febrile pericarditis	1	0.9%	0	1
Abdominal pain	1	0.9%	0	1
Sputum culture positive	1	0.9%	0	1
Hyperventricular arrhythmia	1	0.9%	0	1
Superior vena cava syndrome	1	0.9%	1	0
Lung inflammation	1	0.9%	0	1
Neurotoxicity	1	0.9%	1	0
No response to therapy	1	0.9%	0	1
Pain	1	0.9%	1	0

Adverse Event	AE Cases	Percentage	NSAE	SAE
Pain	1	0.9%	1	0
Pleural effusion	1	0.9%	0	1
Respiratory distress	1	0.9%	0	1
Tremor of limbs	1	0.9%	0	1
TOTAL	112	100%	45	67

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Results from the PROMETHEUS-ACS Registry

Aspects of the Current Clinical Practice in Administering, Antiplatelet and Anticoagulant Therapies to Medically Treated Patients with Acute Coronary Syndromes in Greece.

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Introduction: Management of Acute Coronary Syndromes (ACS) has been rapidly evolving during the last decades. Despite the interventional treatment, the percentage of the medically treated patients with ACS is still considered to remain high. Furthermore, antiplatelet and anticoagulant therapies have progressively established a cornerstone role in acute and long-term management of ACS patients.

Objectives: The aim of PROMETHEUS-ACS Registry was to reflect the main clinical practice trends in antithrombotic and anticoagulant treatments for medically managed patients with ACS, as well as to provide data regarding the cardiovascular (CV) events' rate in non-invasively treated ACS patients over 6 and 12 months after the initial hospitalization, and the medication compliance rates at hospital discharge.

Patients and Methods: The study enrolled 386 adult patients presented with ACS (Unstable Angina, Myocardial Infarction with [STEMI] or without [non-STEMI] ST-interval elevation) from 16 cardiology departments in state hospitals throughout Greece, with subsequent non-interventional management in the period from August 2009 to November 2010. After hospital discharge, patients were followed-up for one-year period. The study protocol had been reviewed and approved by the relevant Hospital Scientific Committees and Institutional Review Boards and accepted by the National Medicines Organization – EOF.

Results: A total of 386 patients were recruited (mean age±SD:73.5 ± 11.1 years), of which 62.4% were men and 74% were overweight or obese. The majority of the patients presented with non-STEMI (40.7%), whereas 30.8% had Unstable Angina and 28.5% of the patients had - STEMI. ACS type was associated with dyslipidaemia (p=0.001), diabetes (p=0.049) - or vascular diseases (p=0.004).

Non-interventional therapeutic strategy for the management of ACS was related with the advanced age of the patients (23.6%), particularly above the age of 80 years, as well as with non-availability of haemodynamic (catheterization) laboratory (23.1%).

Regarding medical treatment, 43.5% of patients were taking **antiplatelet treatments** [Acetyl-Salicylic Acid (ASA)75%, Clopidogrel 54.2%] before the onset of ACS symptoms for a mean 5 -year duration. Only 4 out of 10 ACS patients (40.2%) received a loading dose of antiplatelets at the beginning of ACS management in a mean time span of 6 hours after the symptoms onset. The main antiplatelet loading clopidogrel doses administered were 300mg (56.8%).

The majority of hospitalized ACS patients (91.5%) were treated with antiplatelet drugs in maintenance doses during their hospitalisation. Antiplatelet therapy included ASA 100 mg (in 84.4% of patients), and Clopidogrel 75mg

(50.7%). Furthermore, 86.3% of ACS patients were considered suitable to receive **anticoagulant treatment**, particularly 78.2% of patients with Unstable Angina, 93.6% of patients with STEMI and 87.3% of patients with Non-STEMI. Anticoagulants were administered with a mean of 10 hours (median 5 hours) after the onset of symptoms. Anticoagulant drugs were Enoxaparin (in 48.9% of patients, with main doses 60mg [44.8%], 40mg [24.5%] and 80mg [17.2%]) and Fondaparinux 2.5mg (in 39.9% of patients), while unfractionated heparin was administered to 4.2% of patients and Tinzaparin to 3.0% of patients.

In the first follow-up visit at 6 months post hospital discharge, 298 out of 374 patients (79.7%) did not have a cardiovascular event, while 76 patients (20.3%) had the following events: 15 patients suffered myocardial infarction, 19 patients underwent urgent reperfusion therapy and 3 patients had ischemic stroke and 39 patients diagnosed with other ACS. In total 44 patients (57,9%) with cardiovascular events died at 6 months after discharge.

Regarding treatment non-compliance rates, 22.6% of the patients were non-compliant with the medication, mainly because of the patients' initiative (13%) or due to side effects (7.2%). No significant differences in the cardiovascular events rate were recorded between compliant and non-compliant to therapy patients, as 88.6% and 91.3% were free of events in 6 months respectively among the total of 305 ACS patients.

In the **second follow-up visit at 12 months post hospital discharge**, 297 out of 322 patients (92.2%) did not have a cardiovascular event, while 25 patients (7.8%) presented with myocardial infarction (8%) or an urgent reperfusion therapy (32%). At the same time, 60% of the patients with cardiovascular events died at 12 months after discharge.

The compliance with the medication prescribed at hospital discharge was recorded in 279 out of the total 386 patients (72.3%) at 12 months. Among patients with reported compliance, 27.2% did not comply with the doctors' instruction. One year after hospitalization for ACS, no significant differences in the cardio-vascular events rate were recorded between compliant and non-compliant to therapy patients, as 97.5% and 96.1% were free of events in 12 months respectively among the total of 279 ACS patients.

☐**Conclusions:** Preliminary data from PROMETHEUS-ACS Registry in Greece show that non-invasive, medical therapeutic strategy was reserved mainly for ACS patients with advanced age in cardiology departments with limited access to interventional centers.

The compliance to treatment, recommended at discharge, did not seem to influence the rate of CV events either in 6 or in 12 months after the Acute Coronary Syndrome.

Data are confirming the results of recent Greek studies, which showed that mortality rates remain high 12 months after hospitalization for ACS compared to in-hospital mortality.

Διαδικασία και προκλήσεις μιας μη φαρμακευτικής προσέγγισης: Η περίπτωση της προσωποκεντρικής ψυχοθεραπείας

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Η προσωποκεντρική προσέγγιση

Η προσωποκεντρική προσέγγιση στην ψυχοθεραπεία, η οποία έχει επίσης ονομαστεί και «μη κατευθυντική», «πελατο-κεντρική», «ανθρωπιστική» ή «ροτζεριανή», αναπτύχθηκε από τον Carl Rogers την δεκαετία του 1950. Η εμφάνισή της ήρθε ως εναλλακτική λύση στις άλλες δύο θεωρητικές προσεγγίσεις την ψυχανάλυση και τον συμπεριφορισμό και φέρει την επιρροή των φιλοσοφικών κινημάτων του υπαρξισμού και της φαινομενολογίας.

Ο σκοπός αυτής της προσέγγισης δεν είναι να λύσει συγκεκριμένα προβλήματα, αλλά να βοηθήσει το άτομο να αναπτυχθεί έτσι ώστε να μπορέσει να αντιμετωπίσει τα προβλήματά του. Βασίζεται στην εσωτερική τάση του ατόμου προς την προσαρμογή και την ανάπτυξη. Τονίζει τα συναισθηματικά στοιχεία και την παρούσα κατάσταση του ατόμου. Δίνει έμφαση στην ίδια την θεραπευτική σχέση ως μια αναπτυξιακή εμπειρία.

> “Η εμφάνιση της προσωποκεντρικής προσέγγισης ήρθε ως εναλλακτική λύση στις άλλες δύο θεωρητικές προσεγγίσεις την ψυχανάλυση και τον συμπεριφορισμό και φέρει την επιρροή των φιλοσοφικών κινημάτων του υπαρξισμού και της φαινομενολογίας”

Η προσωπικότητα στην προσωποκεντρική θεωρία

Σύμφωνα με την προσωποκεντρική προσέγγιση, τα άτομα είναι από τη φύση τους δημιουργικά και αξιόπιστα, και έχουν ανάγκη για αυτο-αποδοχή και αυτο-εκτίμηση και για αγάπη και αποδοχή από τους άλλους, ενώ τείνουν προς την αυτο-πραγμάτωση (actualizing tendency) δηλαδή τη διατήρηση, την ενίσχυση και τη διαφοροποίηση της προσωπικότητάς τους.

Όταν το άτομο δεν γίνεται αποδεκτό από τους άλλους στο περιβάλλον του (οικογενειακό, κοινωνικό) παρά μόνο άν ανταποκρίνεται σε όρους τους οποίους θέτει και αξιολογεί ως κυρίαρχο το περιβάλλον, τότε το άτομο αρχίζει να μην αποδέχεται ούτε να αναγνωρίζει ακόμα και σημαντικές εμπειρίες, να διαστρεβλώνει ή να αρνείται πλευρές του οργανισμικού εαυτού του. Αυτό συμβαίνει λόγω της εξάρτησης του ατόμου από την αποδοχή των άλλων και έχει ως αποτέλεσμα να δημιουργείται διάσταση ή ασυνέπεια ανάμεσα στην πραγματικότητα και τον «κατασκευασμένο» εαυτό (self): το άτομο βρίσκεται σε κατάσταση «ασυμβατότητας» και είναι ευάλωτο. Οι όροι αξίας με τους οποίους το άτομο γίνεται αποδεκτό από το περιβάλλον του, ενδοβάλλονται, με αποτέλεσμα να αποτελούν πλέον μέρος της αυτο-εικόνας του (self-concept). Όταν αυτά τα άτομα κάνουν αξιολογήσεις και επιλογές για τη ζωή τους, καθοδηγούνται περισσότερο από τους εξωτερικούς όρους αξίας που έχουν ενδοβάλλει παρά βασίζονται στην δική τους ανάγκη ή εμπειρία. Η σύγκρουση που δημιουργείται μεταξύ του οργανισμικού αξιολογικού συστήματος του ατόμου (πραγματικός εαυτός) και των ενδοβλημένων όρων αξίας (αντίληψη του ιδανικού εαυτού) και η ανάδυση μηχανισμών άμυνας (προκειμένου οι προσλαμβανόμενες εμπειρίες να γίνουν λιγότερο απειλητικές για την αυτοεικόνα) οδηγούν σε σύγχυση, άγχος και δυσπροσαρμοστική συμπεριφορά.

Τα χαρακτηριστικά ενός πλήρως λειτουργικού ατόμου είναι να διαμορφώνει αντίληψη της πραγματικότητας σύμφωνα με τη δική του θέληση, να έχει εμπιστοσύνη στην δική του οργανισμική διαδικασία αξιολόγησης, να διαθέτει την ικανότητα να βιώνει όλα του τα συναισθήματα χωρίς να τα φοβάται, να είναι ανοιχτός στην εμπειρία, να ζει στο παρόν, να έχει αίσθηση της ελευθερί-

ας και να διακρίνεται από δημιουργικότητα σαν φυσική απόρροια της τάσης πραγμάτωσης που τον κατευθύνει, ζώντας μια πιο καλή και πλούσια ζωή.

Η ψυχοθεραπεία με την προσωποκεντρική προσέγγιση

Για την μεγάλη πλειοψηφία των ανθρώπων οι οποίοι δεν είχαν μια ιδανική ανάπτυξη με μία άνευ όρων αποδοχή από το περιβάλλον τους αλλά γινόντουσαν αποδεκτοί υπό όρους, η προσωποκεντρική προσέγγιση θεωρεί ότι η προσωπικότητά τους μπορεί να αλλάξει και να αναπτυχθεί μέσα από τη θεραπευτική διαδικασία, η οποία στοχεύει στο να επιλυθούν οι προερχόμενες από τους όρους αξίας συγκρούσεις, να επιτευχθεί συμφωνία του εαυτού με την εμπειρία και να αποκατασταθεί η οργανισμική διαδικασία αξιολόγησης του πραγματικού εαυτού.

Στην προσωποκεντρική ψυχοθεραπεία η σχέση ανάμεσα στο ψυχοθεραπευτή και τον θεραπευόμενο είναι ο πιο σημαντικός παράγοντας. Η σχέση αυτή θεωρείται από μόνη της θεραπευτική. Η αλλαγή και ανάπτυξη του θεραπευόμενου υποκινείται από την ενδογενή τάση πραγμάτωσης. Για να μπορέσει να λειτουργήσει η τάση πραγμάτωσης, είναι απαραίτητη η δημιουργία ενός περιβάλλοντος ασφάλειας όπου το άτομο τιμάται, γίνεται αποδεκτό και κατανοητό χωρίς όρους και προϋποθέσεις.

Οι αναγκαίες και επαρκείς συνθήκες της θεραπευτικής αλλαγής στην προσωποκεντρική ψυχοθεραπεία, έχουν περιγραφεί ως εξής:

Τα δύο πρόσωπα βρίσκονται σε ψυχολογική επαφή, ο ονομαζόμενος «πελάτης» ο οποίος τελεί σε κατάσταση ασυμβατότητας, είναι ευάλωτος ή αγχωμένος και ο θεραπευτής ο οποίος τελεί σε κατάσταση συμβατότητας, είναι αυθεντικός ως προς τον εαυτό του.

Ο θεραπευτής βιώνει άνευ όρων θετική αποδοχή για τον πελάτη σαν άνθρωπο, ενσυναισθητικά κατανοεί το εσωτερικό πλαίσιο αναφοράς του πελάτη και επικοινωνεί αυτή την κατανόηση, ενώ τα παραπάνω προσλαμβάνονται σε ένα βαθμό από τον πελάτη.

Οι προσωποκεντρικοί ψυχοθεραπευτές δεν λειτουργούν σαν να είναι ειδικοί στη ζωή των πελατών τους. Δεν συνάδει με την θεραπευτική διαδικασία η παροχή συμβουλών. Αυτό ισχύει ακόμα και για την συμβουλευτική που αποτελεί μία θεραπευτική διαδικασία πιο περιορισμένης έκτασης σε πλάτος και σε βάθος από την ψυχοθεραπεία. Ακόμα και στην συμβουλευτική οι πελάτες βοηθούνται να εκφράσουν αυτά που τους απασχολούν, να συνειδητοποιούν τι τους συμβαίνει, να ενδυναμώνονται ψυχολογικά και να αναλαμβάνουν με τις εσωτερικές τους δυνάμεις να αντεπεξέρχονται στις δυσκολίες της ζωής.

Ζητήματα και μέθοδος της ψυχοθεραπευτικής διαδικασίας

Ο θεραπευτής απαιτείται να συγκεράσει τις εκπαιδευτικές - θεωρητικές του καταβολές με τις ανάγκες της διεξαγωγής της θεραπευτικής διαδικασίας. Χρειάζεται να συνδιαλέγεται και να βρίσκεται σε θεραπευτική σχέση με τελείως διαφορετικούς ανθρώπους, με μία ευρεία γκάμα προσωπικοτήτων και συμπεριφορών. Χρειάζεται ο θεραπευτής στον ψυχισμό του και τη στάση του να είναι εξαιρετικά σταθερός, με ισχυρό εγώ και όρια, για να μπορεί να σταθεί στη σχέση του με τον πελάτη, να μπορεί να αντικατοπτρίζει τον εσωτερικό κόσμο του πελάτη και να υποστηρίζει την ανάπτυξή του. Ο θεραπευτής έχει τακτική επαφή με τον δικό του επόπτη επαρκούς κατάρτισης, οποίος λειτουργεί σαν δεύτερη γραμμή υποστήριξης και ελέγχου τόσο του θεραπευτή όσο και των πελατών που παρακολουθεί.

Το αγαθό της ψυχοθεραπείας είναι περισσότερο αναγκαίο με την οικονομική κρίση η οποία δοκιμάζει τις ανθρώπινες σχέσεις και πολλαπλασιάζει τον αριθμό των ανθρώπων που βρίσκονται σε κρίση και έχουν ανάγκη υποστήριξης. Ο θεραπευτής καθορίζει τη διαδικασία μιας μακρόχρονης θεραπείας, ακολουθώντας πιστά τους κανόνες επαγγελματικής ηθικής. Επιλαμβάνεται ζητημάτων που αφορούν σε πελάτες που δεν είναι έτοιμοι για ψυχοθεραπεία, που προσέρχονται ίσως επειδή κάποιος άλλος τους πίεσε, σε πελάτες που είναι δύσκολοι στο να ανοιχτούν ή να εκφραστούν, σε άτομα με σοβαρή συνοδό ψυχοπαθολογία τα οποία ίσως πρέπει να τύχουν ψυχιατρικής παρακολούθησης. Επίσης ο θεραπευτής χρειάζεται να εξισορροπήσει σχετικά θέματα όπως οικογενειακά, πολιτισμικά, φυλετικά, φύλου και ηλικίας του πελάτη.

Δεν υπάρχουν εγχειρίδια ή οδηγοί θεραπευτικών σχεδίων ή παρεμβάσεων. Το ποιός είναι ο θεραπευτής, το πώς είναι διαμορφωμένος ο ψυχισμός του καθορίζει τον τρόπο του. Ο εαυτός του είναι το εργαλείο της δουλειάς του και απαιτείται ο θεραπευτής να είναι ο εαυτός του. Το πόσο αυθεντικός είναι καθορίζει τη σχέση του με τον πελάτη. Ο ίδιος χρησιμεύει ως μοντέλο για την προσωπική ανάπτυξη του πελάτη. Ο θεραπευτής για να είναι αποτελεσματικός με τους πελάτες του, χρειάζεται και στο δικό του ιδιωτικό περιβάλλον να λειτουργεί αυθεντικά, συμβατά με τον πραγματικό του εαυτό. Η εξέλιξή του είναι μία διαρκής πορεία που απαιτεί επαφή και επεξεργασία των επαγγελματικών εμπειριών και των επιστημονικών εξελίξεων τόσο της προσωποκεντρικής όσο και των άλλων θεραπευτικών προσεγγίσεων.

> “Εξ ορισμού οι πελάτες είναι προσωπικότητες που βρίσκονται σε ευάλωτη θέση με δυσκολίες στο τρόπο που αλληλεπιδρούν και σχετίζονται, άρα αυτές αναπαράγονται και με τους θεραπευτές”

Εξ ορισμού οι πελάτες είναι προσωπικότητες που βρίσκονται σε ευάλωτη θέση με δυσκολίες στο τρόπο που αλληλεπιδρούν και σχετίζονται, άρα αυτές αναπαράγονται και με τους θεραπευτές. Υπάρχουν περιπτώσεις όπου ο πελάτης μπορεί να παρεξηγήσει τη διαδικασία, να πληγωθεί, ή να εκφράσει αρνητικά συναισθήματα όπως αποδοκιμασία, θυμό, απόρριψη ή και μίσος, ή αντίθετα να παρεξηγήσει την αποδοχή και την οικειότητα του θεραπευτή και να επιδείξει προσκόλληση, αγάπη, φυσική ή σεξουαλική έλξη. Ο θεραπευτής επιλύει τέτοια ζητήματα από την αρχή θέτοντας όρια με φυσικό τρόπο, προσέχοντας να μην αναστείλει το άνοιγμα του πελάτη στη διαδικασία, και φροντίζοντας τις προϋποθέσεις για την εγκατάσταση εμπιστοσύνης του πελάτη προς τον ίδιο. Εξισορροπεί την κατάσταση ώστε να μην υπάρχει άσκηση εξουσίας από αυτόν αλλά ισοτιμία και ίση αξία με τον πελάτη. Ο θεραπευτής αφουγκράζεται συνέχεια τη θεραπευτική σχέση, πως αυτή εξελίσσεται, πως βιώνεται, πως αισθάνονται αυτός και ο πελάτης του και τι ο πελάτης του μεταβιβάζει μέσα από αυτή. Πρέπει συνέχεια να διερωτάται για τη ποιότητα της θεραπευτικής σχέσης, και να επικοινωνεί διεξοδικά για τα αίτια τόσο με τον πελάτη όσο και με την εποπτεία του.

Ο θεραπευτής χρειάζεται να είναι συνέχεια παρών για τον πελάτη στο εδώ και τώρα της διαδικασίας. Πρέπει να έχει θετική αποδοχή χωρίς όρους για τον πελάτη του σαν άνθρωπο. Άνευ όρων θετική αποδοχή σημαίνει, χωρίς επηρεασμό από τις συμπεριφορές του και χωρίς προκαταλήψεις, ενδιαφέρον, εκτίμηση, επιβεβαίωση της αξίας και θετική αποτίμηση της προσωπικότητας κάθε πελάτη ως ανθρώπου. Αυτή η αποδοχή είναι θεραπευτική για τον πελάτη.

Ο θεραπευτής δεν επεξεργάζεται θεωρίες ή επεξηγήσεις σχετικές με τον ψυχισμό του πελάτη, αλλά προσπαθεί να εξερευνήσει διαφορετικούς θεραπευτικούς τρόπους απόκρισης για να φέρει στην επιφάνεια το κόσμο του πελάτη. Η ενσυναισθητική κατανόηση και η επικοινωνία της προς τον πελάτη μοιάζει με τη λειτουργία ενός καθρέφτη στη θέση του οποίου είναι ο θεραπευτής βιώνει την κατάσταση σαν να ήταν ο ίδιος ο πελάτης και την αντικατοπτρίζει πίσω προς αυτόν. Ο θεραπευτής προσπαθεί να καταλάβει τα συναισθήματα, τις σκέψεις και το γιατί ενεργεί και πράττει όπως πράττει ο πελάτης. Επικοινωνεί τι βαθύτερα καταλαβαίνει, τι αισθάνεται από τη συμπεριφορά του πε-

λάτη και τι συναισθήματα του γεννούνται σε σχέση με αυτόν. Οι αποκρίσεις του είναι γνήσιες και βοηθούν στο να προωθηθεί η συνειδητοποίηση και η επεξεργασία από τη μεριά του πελάτη τι του συμβαίνει. Ο θεραπευτής είναι ο πραγματικός του εαυτός στις αποκρίσεις του. Όμως, συγκεντρώνεται στην ιδιαίτερη γλώσσα του πελάτη και στο τι σημαίνει η εκάστοτε συμπεριφορά του πελάτη για αυτόν τον ίδιο. Προσπαθεί επίσης να συγκρατεί εκτός της διαδικασίας οποιαδήποτε απόκριση δεν είναι βοηθητική για τον πελάτη σε δεδομένο χρόνο.

Θεραπευτικές προκλήσεις

Ο ψυχοθεραπευτής χρησιμοποιεί τον ψυχισμό του για να στηρίξει τη θεραπεία άλλων ανθρώπινων ψυχών που βρίσκονται σε ανάγκη. Οι πελάτες γίνονται αποδεκτοί και εκτιμούνται άνευ όρων σαν άνθρωποι για όλες τις πλευρές της προσωπικότητάς τους, συνειδητοποιημένες ή κρυφές, βοηθούνται στο να αυξάνουν την αυτο-συνειδητοποίηση, να τακτοποιήσουν τις συγκρούσεις μεταξύ των εσωτερικών τους <<θέλω>> και των περιβαλλοντικών <<πρέπει>> και με τη δράση του εσωτερικού τους δυναμικού να αναπτυχθούν ως άτομα. Η πορεία ανάπτυξης των πελατών γίνεται με κριτήρια δικά τους και δεν εξαρτάται από προσωπικά πιστεύω ή προκαθορισμένους θεραπευτικούς στόχους από τον θεραπευτή.

Καθοριστικοί παράγοντες στην αποτελεσματικότητα της ψυχοθεραπευτικής διαδικασίας αναδεικνύονται το μέγεθος της αυθεντικότητας του θεραπευτή και οι βαθμοί αυτογνωσίας και αυτοαποδοχής που τον χαρακτηρίζουν. Η εμπειρία του θεραπευτή, ιδιαίτερα το κατά πόσο ο ίδιος έχει ψυχοθεραπευτικά επεξεργαστεί και ξεπεράσει τους προσωπικούς του βαθείς φόβους, ανασφάλειες και άγχη είναι κριτήριο για το κατά πόσο αποτελεσματικός είναι μέσα στη θεραπευτική σχέση. Ο τρόπος που έχει επεξεργαστεί και επιλύσει σημεία του χαρακτήρα του ώστε να οδηγηθεί στο να αισθάνεται σιγουριά, είναι ο κόσμος μέσα στον οποίο μπορεί να βρει πατήματα, δρόμους και γέφυρες προς την αντίστοιχη εμπειρία του πελάτη. Αυτά τα δυνατά σημεία έχει στη διάθεσή του ώστε να τα εκμεταλλευτεί προχωρώντας τόσο σε πλάτος όσο και σε βάθος στη θεραπεία. Αυτές οι παράμετροι φαίνεται ότι καθορίζουν τη δυσκολία και τις προκλήσεις στην εξάσκηση του ψυχοθεραπευτικού λειτουργήματος.

Η όσον το δυνατόν μεγαλύτερου βαθμού αυτογνωσία επιτρέπει στον θεραπευτή την αποφυγή τυφλών σημείων στη θεραπεία του πελάτη. Ο ψυχοθεραπευτής χρειάζεται να φέρει στην επιφάνεια όλες τις όψεις του εαυτού του πελάτη που βρίσκεται αγχωμένος και διαταραγμένος λόγω της ασυμφωνίας μεταξύ τους. Πρέπει να τις προσέξει όλες εξίσου ώστε ο πελάτης να τις αναγνωρίσει και αυτός να τις επανατοποθετήσει και να επιλέξει μεταξύ τους με λειτουργικό τρόπο. Προχωρώντας σε βάθος στη θεραπεία, ο θεραπευτής ανταποκρίνεται όχι μόνο σε αυτά που του παρουσιάζει ο πελάτης αλλά φθάνει και σε αυτά που διαφαίνονται βαθύτερα. Δεν είναι μόνο λήπτης αλλά και εκφραστής αυτών των κρυμένων κομματιών. Η θεραπευτική του στάση πρέπει να ανταποκρίνεται σε όλες αυτές τις διαφοροποιήσεις της προσωπικότητας του πελάτη.

Υπάρχουν πάντοτε νέες παράμετροι και δεδομένα τα οποία αντιμετωπίζει ο θεραπευτής. Πολλές φορές ο πελάτης μπορεί να τον δοκιμάζει ή να μην τον αποδέχεται. Μπορεί να προσβάλει τις προσωπικές αξίες και την ψυχολογία του. Ο θεραπευτής χρειάζεται να μην αυτοαναιρείται μπροστά σε αυτο-προστατευτικές διαδικασίες άμυνας του πελάτη, μπροστά σε καταστροφικές και αυτοκατοστροφικές συμπεριφορές του, μπροστά σε υφέσεις και υπαναχωρήσεις. Ο θεραπευτής γνωρίζει ότι απαιτείται να μην υποχωρεί και να μην κλονίζεται η άνευ όρων αποδοχή του προς τον πελάτη. Οποιαδήποτε αποστροφή νιώσει προς τις συμπεριφορές του πελάτη ανάγεται σε δικά του

θέματα και είναι δική του η ευθύνη να την επιλύσει ίσως και στο επίπεδο της εποπτείας του.

Ενίοτε, ο θεραπευτής μπορεί να αντιμετωπίζει το ζήτημα της αποτελεσματικότητας της θεραπείας. Θεωρητικά, υπάρχει η σκέψη ότι με τη διαδικασία της ψυχοθεραπείας, η ασυμβατότητα και η διαταραχή που παρουσιάζει ο πελάτης θα μειωθούν και θα υπάρξει αλλαγή προς μία αναπτυξιακή πορεία. Όμως, αυτό δεν είναι πάντα σίγουρο. Ο πελάτης μπορεί να οπισθοδρομήσει σε προηγούμενα στάδια και να επιδείξει μία αμετάκλητη άρνηση προς το θεραπευτή και τη θεραπευτική πορεία. Σε τέτοιες περιπτώσεις ο θεραπευτής δεν μπορεί αλλά και δεν πρέπει με κανένα τρόπο να προσπαθήσει να ελέγξει παρεμβατικά ή πόσο μάλλον συγκρουσιακά τον ψυχισμό του πελάτη. Προσωποκεντρική προσέγγιση σημαίνει ο πελάτης εκτιμάται θετικά ακόμη και αν οδηγείται σε πορεία ανάπτυξης αντίθετη από αυτή που προσωπικά ο θεραπευτής θα θεωρούσε σωστή. Σε κάθε περίπτωση εκφράζεται η βαθιά πίστη των λειτουργών της προσωποκεντρικής προσέγγισης στον άνθρωπο, στο αναπτυξιακό δυναμικό του και στην ελευθερία εκλογής στη ζωή.

Ο ψυχοθεραπευτής συνεχώς αντιμετωπίζει και ξεπερνά τους δικούς του φόβους οι οποίοι αναβιώνουν μέσα από το λαβύρινθο του ψυχισμού του πελάτη. Οι συγκρούσεις της θεραπευτικής διαδικασίας τον αναγκάζουν συνεχώς να επεξεργάζεται πτυχές του δικού του εαυτού και προκαλούν μία δοκιμασία της δικής του αυτο-αποδοχής. Κατά ένα παράξενο τρόπο φαίνεται ότι ο ψυχοθεραπευτής αναμετράται με τον εαυτό του. Οι προκλήσεις αυτές συμβάλλουν σε μία δική του αέναη πορεία αυξανόμενης αυτογνωσίας και ανάπτυξης σαν θεραπευτής και σαν άνθρωπος.

Αναφύεται η σοφία των αρχαίων ρητών:

“Γνώθι σ’αυτόν”
“Γηράσκω αεί διδασκόμενος”

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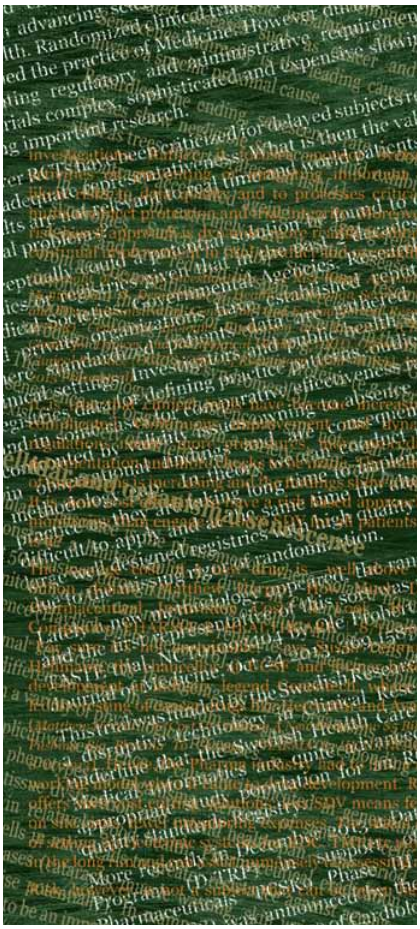

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