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ARAŞTIRMA RESEARCH ARTICLE

Our results on SF-36 quality of life scale in patients diagnosed with drug allergy

İlaç allerjisi tanılı hastalarımızda SF-36 yaşam kalitesi ölçeği sonuçlarımız

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ABSTRACT

Objective: Drug allergies are drug-hypersensitivity reactions that are assumed to be seen frequently in practice and affect quality of life considerably. The aim of this study is to investigate the effect of drug-allergy on quality of life.

Materials and Methods: A total of 100 patients, between 18-70 years of age, who referred to our center with drug allergy were evaluated prospectively. During assessment of patients, a questionnaire including socio-demographic characteristics and a Short Form-36 (SF-36) Quality of Life Scale were used.

Results: Of our patients 76% were women, 24% were males and mean age was 38.56 ± 11.03 years. The physical, social and emotional role components of SF-36 were found to be decreased in all areas in women. When the score dispersion of quality of life subscale according to education level was examined, the "physical function" subscale was found lower only in elementary school and lesser education areas.

Conclusion: In present study it was observed that drug allergy had affected the quality of life of both

ÖZ

Giriş: İlaç allerjileri pratikte sıklıkla karşılaşılan ve yaşam kalitesini oldukça etkilediği tahmin edilen ilaç hipersensitivite reaksiyonlarıdır. Bu çalışmanın amacı, ilaç allerjisinin yaşam kalitesi üzerine etkisini araştırmaktır.

Gereç ve Yöntem: İlaç allerjisi nedeniyle merkezimize başvuran 18-70 yaş arası 100 hasta prospektif olarak değerlendirildi. Hastaların değerlendirilmesinde sosyodemografik özelliklerini içeren soru formu ve Kısa Form-36 (SF-36) Yaşam Kalitesi Ölçeği kullanıldı.

Bulgular: Hastalarımızın %76'sının kadın, %24'ünün erkek, yaş ortalamasının 38.56 ± 11.03 yıl olduğu gözlendi. SF-36'nın fiziksel, sosyal, duygusal rol bileşenlerinin kadın hastalarda tüm alanlarda düştüğü saptandı. Eğitim durumuna göre yaşam kalitesi alt ölçek puan dağılımı incelendiğinde yalnızca ilköğretim ve altı eğitim alanlarda "fiziksel fonksiyon" alt ölçeği düşüktü.

Sonuç: Bu çalışmada ilaç allerjisinin her iki cinsiyette de yaşam kalitesini etkilediği, fakat bu etkilenmenin kadınlarda daha belirgin olduğu görüldü.

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genders; however its influence over women was more prominent.

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INTRODUCTION

All reactions that occur against a drug used for diagnosis and treatment of a disease and that can not be predicted are called "drug hypersensitivity reactions". "Drug allergy" which makes up a substantial portion of drug reactions is an immunological reaction that develops with the formation of specific antibodies or sensitive lymphocytes against the drug or its metabolites. These reactions are frequent in practice. In a study, it was reported that 20% of hospitalized patients and 7% of outpatients had drug sensitivity[1]. The true incidence is believed to be higher due to the failures in reporting and identification of cases. Drug reactions result in serious problems not only in relation with occurrences, but also in terms of being an important cause of morbidity and mortality, and their costs. These reactions can be life threatening or may be seen with a mild clinical course involving one or few organs. The discomforts, social and physical limitations of these symptoms on patients may impact the quality of life by impairing the status of emotional and mental health.

Quality of life is a general "well being" which includes being happy and satisfied with life. It is a concept that reflects the personal responses to diseases and physical, mental and social impacts of daily life[2]. The World Health Organization defined the quality of life as "individuals' perception of their position in life in the context of the culture and value systems". The quality of life concept covering the aims, expectations, standards and interests of individuals in where they live includes physical health, mental health, level of independence, social relationships, environmental factors and personal beliefs on a subjective ground[3]. The quality of life scales are used to identify the special needs, determine the psycho-social status, monitor the improvements and decide on the treatment of the patients.

Measurement methods for quality of life should be reliable, validated and sensitive. There are two types of quality of life scales, being generic and specific, used in medical science. Generic scales can be used in all fields of health. The most preferred scales are Nottingham Health Profile (NHP), Short Form-36 (SF-36) and Sickness Impact Profile (SIP)[4,5]. Also, scales specific for various diseases are available.

SF-36 scale is a generic measurement tool being short and easily applicable which enables a comprehensive measurement[6].

In this study, we intended to have a different approach to drug allergy by identifying the changes in quality of life of the patients via SF-36 scale for drug allergy, which we frequently encounter in clinical practice.

MATERIALS and METHODS

A hundred patients aged between 18 and 70 who applied to our polyclinic due to drug allergy were prospectively evaluated. After a detailed questioning was performed on patients, drug allergy and conditions likely to be encountered excluded through physical examination and laboratory tests. During referral hospital records were examined. In vivo and in vitro drug tests were performed when necessary.

A questionnaire prepared by the investigators, covering socio-demographic characteristics such as age, gender, occupation and level of

education, and SF-36 quality of life scale were used for data collection. The approval of scientific ethics committee and consent of the patients were obtained for this study.

SF-36 was developed and introduced by Rant Corporation in 1992. It has been used in researches on health and can be adapted for differences in various countries. Eight domains of health including physical function capacity (PFC), physical role limitation (PRL), emotional role limitation (ERL), social function, pain, vitality, mental health and perception of general health (PGH) are evaluated via 36 questions. Moreover, there were items related to the perception of change in health during the last four weeks and the last week. Subscales evaluate health in a score range of 0 to 100 with the increase in scores showing improvement in quality of life related to health[6-9]. The studies of validity and reliability of the Turkish version were conducted by Kocyiğit et al.[10]. Since control group was not used in study comparison was made using the dimensional scores of validity study of SF-36 scale in Turkish population and results were shown in Table 1.

"SPSS, 15 Evaluation" package program was used in the statistical analysis of the data and "Student's t-test" was used for intra-group comparisons. $p< 0.05$ was considered statistically significant in all assessments.

RESULTS

Socio-demographic characteristics of our patients are shown in Table 2, while SF-36 results in Table 3 and the relation of some socio-demographic characteristics to subscales in Table 4.

When socio-demographic characteristics of our patients were investigated in Table 2; it was found that 76% of the patients were female and 24% were male with a mean age of 38.56 ± 11.03 years. 50% of the patients were housewives and 55% were graduated from primary school.

In Table 3; total scores from quality of life subscales of our patients were examined and the highest mean (73.10 ± 23.79) were found in the PFC subscale, while the lowest (50.26 ± 20.92) were in the PGH subscale.

In Table 4, the relation of some socio-demographic characteristics to subscales was examined. When SF-36 subscales were observed for gender, "physical function" was 67.69 ± 23.21 in female patients and 90.20 ± 16.64 in male patients. A statistically significant difference was found between gender and mean scores of "physical function" ($p< 0.001$), "physical role impairment" ($p= 0.005$), "general health" ($p= 0.001$), "vitality" ($p< 0.001$), "social function" ($p< 0.001$), "emotional role impairment" (p=

Table 1. The relationship between the results of patients in research group according to SF-36 and quality of life in Turkish population

Characteristic dimensions of SF-36	Patients (means ± SD)		Scope (means ± SD)		T Table values	p
Physical function	73.10	23.79	86.6	25.2	-5.67	< 0.001
Difficult in role (physical)	60.25	44.39	89.5	29.6	-6.58	< 0.001
Pain	61.72	22.82	86.1	20.6	-10.68	< 0.001
General health	50.26	20.92	73.9	17.5	-11.29	< 0.001
Vitality (energy)	52.15	20.97	67.0	13.8	-7.07	< 0.001
Social function	66.75	23.71	94.8	14.2	-11.82	< 0.001
Difficulty in role (emotional)	63.00	45.16	94.7	20.9	-7. 01	< 0.001
Mental health	58.20	15.92	73.5	11.6	-9.60	< 0.001

Table 2. Socio-demographic characteristics of the study group

Characteristic	n	%
Gender		
Female	76	76.0
Male	24	24.0
Age		
Under 20	7	7.0
20-29	13	13.0
30-39	35	35.0
40-49	28	28.0
50 and above	17	17.0
Total	100	100.0
Mean 38.56 ± 11.03 (18-66 years)		
Housewife	50	50.0
Student	4	4.0
Officer	10	10.0
Self employed	14	14.0
Retired	6	6.0
Other	16	16.0
Education level		
Non-literate	1	1.0
Primary education	55	55.0
High school	24	24.0
College	20	20.0

0.004), "mental health" (p= 0.006) subscales. It was found that the mean scores were decreased in all domains among women (Table 4).

When score distribution of quality of life subscale was examined in relation to patients' education level, a statistically significant difference was found between the mean scores of "physical function" subscale (p= 0.019) only in those having education at the level of primary school or less, while no difference of any statistical significance was found for the other mean scores of subscales (Table 4).

Since control group was not used in study comparison was made using the dimensional scores of validity study of SF-36 scale in Turkish population and results were shown in Table 1. As seen in Table 1, the mean scores of patients in the research group are statistically significantly lower in all subdimensions than the mean of scope[10,11].

DISCUSSION

Adverse reactions due to drugs are one of the leading iatrogenic diseases and are an important health problem encountered in practice. 6-7% of adults have drug allergy. The increasing drug use due to the rapid improvements in diagnosis and treatment of disease leads to an increase in the frequency of drug allergy. As new drugs are introduced, several adverse drug reactions will occur[12-15].

Table 3. Assessment results of patients according to SF-36

	n	Minimum	Maximum	Mean	SD
Physical function	100	10.00	100.00	73.10	23.79
Role impairment (physical)	100	0.00	100.00	60.25	44.39
Pain	100	10.00	100.00	61.72	22.82
General health	100	0.00	97.00	50.26	20.92
Vitality (energy)	100	5.00	100.00	52.15	20.97
Social function	100	0.00	100.00	66.75	23.71
Role impairment (emotional)	100	0.00	233.33	63.00	45.16
Mental health	100	24.00	96.00	58.20	15.92

Table 4. Relation of some socio-demographic characteristics with subscales

Variable	Physical function (mean ± SD)	Role impairment Physical (mean ± SD)	Pain (mean ± SD)	General health (mean ± SD)	Vitality (mean ± SD)	Social function (mean ± SD)	Role impairment Emotional (mean ± SD)	Mental health (mean ± SD)
Gender								
Female (76)	67.69 ± 23.21	53.28 ± 45.33	59.30 ± 23.81	46.53 ± 20.61	46.44 ± 18.82	61.67 ± 23.03	55.70 ± 46.63	55.78 ± 15.6
Male (24)	90.20 ± 16.64	82.29 ± 33.36	69.37 ± 17.67	62.04 ± 17.54	70.20 ± 17.03	82.81 ± 18.36	86.11 ± 30.95	65.83 ± 14.8
p	**0.000**	**0.005**	**0.059**	**0.001**	**0.000**	**0.000**	**0.004**	**0.006**
Education								
Primary school or lower (56)	68.21 ± 25.92	56.69 ± 45.69	59.64 ± 21.02	47.05 ± 22.72	50.62 ± 21.88	54.09 ± 23.64	58.33 ± 48.92	58.42 ± 17.5
High school or higher (44)	79.31 ± 19.30	64.77 ± 42.90	64.36 ± 24.92	54.34 ± 17.80	54.09 ± 19.83	69.88 ± 23.70	68.93 ± 39.63	57.90 ± 13.9
p	**0.019**	0.369	0.306	0.083	0.414	0.243	0.245	0.872

In our out-patient follow-ups, we observed that patients with drug allergy were affected in terms of physical, psychological and social aspects. The impact of drug allergy on quality of life is not known.

The number of female patients was found higher (76%) in our study (Table 2). When literature was researched for drug allergy, it was found that previous studies reported high prevalence of multi drug allergy, sensitivity to non-steroidal drugs in females[16-18].

When the relationship between gender, one of the socio-demographic characteristics of our patients, and quality of life was examined, it was found that quality of life in female patient group was significantly impaired in all domains compared to males (Table 4). There is no study in literature investigating quality of life in drug allergy. However, considering the studies on quality of life in various diseases, it was reported that the pain perception was more intense in female patient group than male patient group and thus, quality of life values of pain domain and other domains were lower in women[8,19-21]. Our findings are consistent with these results. This may be explained by the difference in perception of the quality of life concept due to the differences in psycho-social characteristics between females and males. The difference in perception of pain, which was identified in our study by SF-36 in female patients with drug allergy compared to males, may also result from this characteristic.

When the relationship between educational status and quality of life were examined, a statistically significant difference in physical function subscale was identified only in those having education at the level of primary school or less (Table 4). Nevertheless, our patients had the greatest score in PFC. Some studies on quality of life in allergic diseases also reported that the PFC mean score was the highest[20-23]. This suggests that patients may not have serious problems in their physical functions because drug allergy is not always a disease with severe symptoms and usually does not result in persistent organ or extremity damage. The reason for the lowest score to be in

PGH may be due to the presence of other health problems necessitating drug use with drug allergy and the obligation to continue these drugs.

As seen in Table 1, the mean scores of subdimensions of patients in research group were found statistically significantly lower in all subdimensions than the mean of scope. Although a control group was not used in study, when dimensional scores of validation study of community-based SF-36 scale in Turkish population were used it can be said that drug allergy affected the quality of life.

In patients who participated in our study and diagnosed with drug-allergy the quality of life had been affected. This effect was more prominent in women. For patients who referred with drug-allergy, we feel that physical, social and emotional changes, as well as treatment of disease, should be evaluated with quality of life measures.

The restricting and deficient aspect of this study is that the effect on quality of life has not been planned according to drug groups and severity of allergic reaction. Further studies are needed in this subject.

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