

Quality of Life of Patients Under Anticoagulant Therapy Compared to Patients Treated with Antiplatelet Therapy

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ABSTRACT

Introduction: Health-related quality of life (HRQoL) includes the physical, functional, social, and emotional well-being of an individual. The most important and frequently used generic HRQoL assessment is Short Form- 36 (SF-36). The objective of this study was to analyze the HRQoL of patients under chronic use of oral anticoagulants in a specialized stroke unit.

Methods: One hundred and twenty-six stroke patients from our stroke clinic between April 1, 2014 and June 1, 2014 were included in this cross-sectional study. The inclusion criteria included only patients whose Rankin score was "0" and were on oral anticoagulant or antiplatelet treatment for ≥ 1 year. Questionnaire SF-36 was used for the study. The patients' age, sex, comorbidities, medical treatments, modified Rankin Scores, bleeding complications, emergency polyclinic admissions, and hospitalization were also noted.

Results: Seventy-five of them were men. The median age was 55.67 \pm 14.23 years. Seventy-seven of the patients were on anticoagulant therapy. Being on anticoagulation therapy did not influence the domains of HRQoL. All of the domains presented the lowest scores in female group. The domains of general health, physical function, and vitality had the lowest scores among hypertensive patients. The domains of physical function, role function, vitality, and mental health had significantly lower scores in the diabetic group. Bodily pain scores were lowest in patients having recurrent stroke attacks. Stroke patients taking more than 3 drugs were found to have worse QoL scores.

Conclusion: Patients under chronic treatment with oral anticoagulants had no negative perception of QoL when attending an anticoagulation specialized outpatient clinic.

Keywords: Quality of life, stroke, anticoagulant therapy, antiplatelet therapy

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INTRODUCTION

Atherothrombosis is a progressive and generalized pathological process that affects the vascular system. The mainstay for prevention includes risk factor management through lifestyle modifications and treatment of the underlying disease. Guidelines have recommended treatment with antiplatelet agents for secondary prevention of stroke and atherothrombosis (1). Meanwhile, for patients who present with cardioembolic stroke, oral anticoagulation (OA) is the recommended treatment. However, a therapy with coumarinic agents might be complicated due to the variability of the biological effects, narrow therapeutic index, and potential occurrence of thrombotic or bleeding effects when compared to long term use with oral antiplatelet agents. Recent literature has suggested that stroke patients might have a worse quality of life (QoL) when compared to the general population (2, 3, 4). The reasons responsible for a worse QoL for stroke patients include disability after stroke, concomitant diseases, and other medical treatments. As the use of coumarinic agents requires a special diet and routine follow-ups with blood tests, it might have a negative impact on the patients' lifestyle when compared to treatment with antiplatelet agents.

The World Health Organisation (WHO) defines QoL as "an individual's perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards, and concerns" (4). Health-related QoL (HRQoL) is composed of parameters including physical, functional, social, and emotional well-being of an individual. HRQoL is a patient-reported outcome that is usually measured with carefully designed and validated instruments such as questionnaires or semi-structured interview schedules. These assessments are increasingly important when evaluating the benefits and harms of new treatments being tested in clinical trials. The most important and frequently used generic HRQoL assessment is the Short Form-36 (SF-36).

The objective of this study is to analyze the HRQoL of patients on OA, compare this group with patients on antiplatelet therapy, and further evaluate additional factors, comorbidities, and concomitant medical treatments.

METHODS

Patient Recruitment

In this cross-sectional study, follow-up stroke patients from our stroke clinic between April 1, 2014 and June 1, 2014 were included. The inclusion criteria included only patients whose Rankin score was "0" and were on OA or antiplatelet treatment for ≥ 1 year. The exclusion criteria included patients who were not able to answer and complete the HRQoL questionnaire due to disability, including possible cooperation or speech problems. The patient records were reviewed and age, sex, comorbidities, medical treatments, modified Rankin Scores (mRS scores), bleeding complications, emergency admissions, and hospitalizations after the initial stroke were all noted. This study was submitted and approved by the local ethics committee of Bakirköy Education and Training Hospital of Neurology, Neurosurgery, and Psychiatry. Informed consent was obtained from each patient.

Assessment of QOL

Data collection was conducted through application of SF-36. This multipurpose short-form health survey is comprised of 36 questions that provide an eight-scale profile of functional health and well-being scores (physical function, role function, bodily pain, general health, vitality, social functioning, emotional well-being, and mental health) as well as composite physical and mental health summary measures, and a preference-based health utilities index (HUI) (5). It is a multidimensional questionnaire and each aspect of SF-36 varies from 0 to 100, with 0 regarded as "the worse" and 100 as "the best" QoL for each domain (6). SF-36 was modified to suit a Turkish population in 1995 by Bölüktaş et al. for chronic diseases including cardiological, renal, and diabetic patients (7).

Statistical Analysis

All statistical analyses were conducted using the Statistical Package for the Social Sciences (SPSS Inc; Chicago, IL, USA) version 16.0. Statistical significance was set at $p < 0.05$. The difference in SF-36 scores was assessed using an independent Student's t-test and ANOVA.

RESULTS

One hundred and twenty-six patients were included into the study, 51 were females (40%) and the median age was 55.50 years. The characteristics of the patients are listed in Table 1. When treatments were reviewed, 77 (61%) patients were on OA and 49 (39%) patients were on antithrombotic therapy. 69.8% of the patients had comorbidities including: hypertension (HT) (48.4%), diabetes mellitus (DM) (24.6%), hyperlipidemia (30.2%), coronary artery disease (CAD) (19%), and recurrent stroke (1.6%). The scores for each component of SF-36 are presented in Table 2. When treatment effects on QoL were compared, being on OA or antithrombotic therapy did not influence the domains of HRQoL (Table 2). When sex effects on QoL were reviewed, there were statistically significant differences among all the SF-36 parameters in females [physical functions (PF) ($p=0.00$), physical role

Table 1. Patient characteristics

	Oral anticoagulant	Antithrombotic
Age (years)	54±14.43	57±13.78
Female (%)	37.7	44.9
Existence of comorbidities (%)	62.3	81.6
Use of drugs in addition to an anticoagulant (%)	70.1	81.6
Treatment length (years)	4.13	1.78
Existence of bleeding (%)	14.3	2
Required Emergency care (%)	22.1	12.2
Hospitalization after treatment (%)	5.2	2

Table 2. Mean score of the domains in the QoL Scale SF-36 under anticoagulant and antithrombotic treatments

	Oral anticoagulant		Antithrombotic		p
	Mean deviation	Standard	Mean deviation	Standard	
Physical functioning	62.28	26.81	53.97	27.42	0.098
Physical role	54.62	45.47	46.93	46.66	0.098
Bodily pain	74.44	24.28	66.18	25.52	0.074
General health	53.25	18.82	52.89	19.19	0.917
Vitality	54.87	20.94	48.09	20.04	0.072
Social functioning	63.12	25.35	60.71	21.80	0.572
Emotional functioning	52.00	45.04	51.02	44.15	0.905
Mental Health	65.33	17.50	61.30	18.31	0.223

Table 3. Results of SF-36 domains for Turkish stroke patients

SF-36	Male	Female	p
Physical functioning	65.9±27.2	48.96±24.1	0.00
Physical role	59.66±46.2	39.82±43.0	0.015
Bodily pain	76.30±25.2	63.76±22.9	0.005
General Health	57.28±18.5	47.00±17.7	0.002
Vitality	57.62±19.8	44.31±19.6	0.019
Emotional role	58.22±45.2	41.90±42.0	0.00
Social functioning	66.14±25.3	56.37±20.6	0.04
Mental Health	67.46±17.3	58.33±17.4	0.005

Data are presented as mean±standard deviation

functions (PR) ($p=0.015$), bodily pain (BP) ($p=0.005$), general health (GH) ($p=0.002$), social functioning (SF) ($p=0.01$), vitality (VT) ($p=0.00$), emotional role (ER) ($p=0.04$), and mental health (MH) ($p=0.005$)] (Table 3).

When the effects of comorbidities on the QoL were assessed, patients were reviewed as follows:

- 1) Hypertensive patients had the lowest scores among GH, PF, and VT ($p=0.038$, $p=0.037$, and $p=0.038$, respectively).
- 2) Patients with diabetes mellitus had significantly lower scores among PF, RF, VT, and MH ($p=0.039$, $p=0.005$, $p=0.015$, and $p=0.023$, respectively).
- 3) BP scores were significantly lower in patients having recurrent stroke attacks ($p=0.00$) (Table 4).

Table 4. Comorbidities that influence the domains of SF-36

SF-36	Hypertension	Diabetes	Hyperlipidemia		
			CVD	CAD	P
Physical functioning	0.03	0.03	0.08	0.71	0.71
Physical role	0.33	0.005	0.32	0.66	0.97
Bodily pain	0.31	0.06	0.09	0.49	0.00
General health	0.03	0.30	0.49	0.19	0.47
Vitality	0.03	0.01	0.41	0.50	0.54
Emotional role	0.31	0.27	0.57	0.48	0.97
Social functioning	0.67	0.13	0.90	0.95	0.86
Mental health	0.37	0.02	0.31	0.09	0.91

CAD: coronary artery disease; CVD: cerebrovascular disease

The PF and VT domains of the QoL had the lowest scores in patients on antihypertensive therapy ($p=0.027$ and $p=0.043$, respectively). The PF, RF, BP, VT, and MH domains of the SF-36 questionnaire also had significantly lower scores in patients on antidiabetic therapy ($p=0.047$, $p=0.010$, $p=0.035$, and $p=0.016$, respectively). PF scores were also lowest in patients on antilipidemic therapy ($p=0.03$).

Stroke patients taking more than three drugs were found to have worse QoL scores in the PF domain of the questionnaire ($p=0.003$).

DISCUSSION

Stroke might be responsible for affecting the QoL because of disability after stroke, concomitant diseases, medical treatments, long term use of OA, and necessary routine work-up required in this patient group. Current data about QoL of stroke patients has been insufficient and only a few previous studies have evaluated the QoL in patients on long term OA treatments. Treating patients with OA therapy has challenges because patients would be followed up with routine work up for INR with the requirement of routine visits to the stroke center. The perceived reduction in QoL is an important factor that may influence a physician's treatment strategies and treatment compliance to warfarin therapy. Bleeding complications, together with the inconvenience of anticoagulation monitoring, might be responsible for worse QoL scores. Conversely, patients may also be more averse to the potential consequences of stroke and less bothered by the side-effects of antithrombotic and anticoagulant treatment. In an observational study, when the risk perception of patients with a high risk of stroke were compared to their treating physicians, it showed that patients placed more value on the avoidance of stroke when compared to warfarin complications (8). However, when patients with previous bleeding complications were assessed, they had more negative perceptions of QoL (5). In another study, Lancaster et al noted that patients who had a prior bleeding episode showed a significant decrease of health perception, but concluded that the warfarin therapy overall was not associated with a significant QoL reduction (9). However, Casais et al showed that the negative perceptions related to anticoagulant treatment was more evident in patients worrying about bleeding risks, but bleeding episodes were not associated with negative QoL perceptions (10). Similarly, our study showed that previous bleeding episodes did not influence the QoL of stroke patients on OA. Additionally, emergency care or hospitalization required due to warfarin complications showed no effect on the health perception domain.

When the existence of comorbidities, including HT, DM, and dyslipidemia were reviewed, the data showed that they might also be responsible for a negative perception of QoL in stroke patients. HT and DM are the most frequent comorbidities seen in stroke patients. In our study, the results showed that both these diseases lead to a negative perception of QoL in the patient group.

When the parameters of SF-36 were reviewed, HT seemed to have negative perceptions on VT, GH, and PF while diabetes had negative perceptions on PF, VT, and MH. When patients with recurrent stroke were reviewed, the only negative domain was the BP aspect in SF-36 in our study. But it should be noted that the study group included patients with "0" Rankin scores; therefore, they did not have physical disability influencing other aspects of QoL. When daily life activities were affected in a patient group, physical disability was also noted. Being hypertensive also seemed to promote patients to be more prone to immobilization and physically inactive even if they had a Rankin score of 0. Additionally, lifestyle changes including a strict diet, exercise, and additional chronic medications also had negative perceptions in hypertensive and diabetic patients (11). The idea of having a chronic illness can cause anxiety and depression in some patients and affect mental health. All of these reasons

can be crucial confounders playing an important role leading a negative perception of these domains in the SF-36 questionnaire. In our study, when the effect of multidrug therapies on QoL was assessed, patients on multidrug regimens (≥ 3 drugs) showed a negative perception on the PF domain of the SF-36 questionnaire. The existence of comorbidities would lead stroke patients to use multidrug regimens. As these patients were also mostly hypertensive and diabetic, this result was interpreted to the existence of these chronic diseases also leading to negative scores in the SF-36 domains. When the effect of sex on the QoL was evaluated, our study showed that females had worse outcomes when compared to males, in accordance with previously reported studies (12, 13). Even though men had a higher risk of stroke than women, because of higher rates of positive risk factors such as age, the lifetime risk of stroke becomes higher in women and the functional outcomes of stroke are often worse in females (14).

In our stroke unit, patients were followed up with routinely at least every 3-6 months for neurological exams and had monthly blood-checks including INR. Patients were followed up by our stroke neurologist closely, and thus, interrater variability was avoided. Patients were able to reach their physicians in any need and receive necessary information from our medical caregivers about anticoagulation and its side effects. Being followed up closely by their stroke neurologist and being able to reach emergency services when in need can positively influence the QoL of the patients. Similarly, in the study by Almeida et al, positive perceptions were more present in patients followed by a specialized anticoagulation stroke unit and by the same doctor (5). Thus, it is important for stroke patients on chronic medications to be followed in a stroke unit setting by their established physician as this eliminates any anxiety that may be caused in times of an emergency.

In conclusion, our study showed that patients under chronic treatment with OA had no negative perception of QoL when compared to patients on antithrombotic therapy while being followed up in a stroke outpatient clinic. The existence of comorbidities and treatment with multiple medications showed negative perceptions in most of the domains of the questionnaire. When the sex effect was assessed, females seemed to have more negative results, and thus, physical and emotional rehabilitation support should be given these patients in need. While assessing QoL with SF-36, this questionnaire seemed to be a valuable self-explanatory questionnaire that was cost effective, easy to use, and required a short time for assessment. SF-36 might be a valuable tool in stroke centers to assess patients.

One of the limitations of the study is that it is a cross-sectional study over a short time period. 2 months of follow-up may not be enough to make a statement about all of the stroke patients taking OA. Long term follow-up studies are warranted.

Committee Approval: Ethics committee approval was received for this study from the ethics committee of Bakırköy Education and Training Hospital of Neurology, Neurosurgery and Psychiatry.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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