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Original Article

The Assessment of Adherence to the Treatment Regimen in Patients with Percutaneous Coronary Intervention

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Abstract

Background: Cardiovascular diseases are one of the world's most important causes of mortality. Despite the reduction in mortality, these patients are forced to adherence is a particular therapeutic regimen to prevent further complications. This cross-sectional study was conducted on 110 patients four to six weeks following Percutaneous Coronary Intervention (PCI).

Methods: The questionnaire involved seven areas: attention in treatment, willingness to participate in treatment, ability to adapt, treatment integration with life, adherence to treatment, commitment to treatment, and doubt in implementing treatment.

Results: Findings showed that the standardized mean score of total treatment adherence was 91.39. According to the results, gender, age, marital status, place of residence, underlying disease, smoking, use of cardiac drugs, patient condition and the number of vessels involved did not affect the score of treatment adherence ($p>0.05$). Further analysis revealed that with increasing hospitalization days, treatment adherence increases ($p<0.05$).

Conclusion: The present survey indicated that patients' treatment adherence was favorable. Based on the findings, treatment adherence, one of the fundamental factors for reducing the mortality rate of patients undergoing PCI, is satisfaction level. Further investigations are highly recommended to consider other risk factors for reducing the mortality rates in these patients.

Keywords: Attention, Cardiovascular diseases, Cross-sectional studies, Percutaneous coronary intervention, Personal satisfaction, Risk factors, Smoking, Surveys and questionnaires

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Introduction

Coronary syndromes are the most mortality causes of cardiovascular diseases. Despite progression in cardiovascular disease management, the mortality rate of heart failure increases gradually, especially in less developed, lower-income countries (1). Annually, more than 7 million subjects are diagnosed with acute coronary syndrome around the world (2). Recently, it was demonstrated the increasing acute coronary syndromes in patients without Standard modifiable cardiovascular risk factors such as diabetes, obesity, hypertension, hyperlipidemia, and smoking (2). Primary Percutaneous Coronary Intervention (PCI) within two hours following ST-segment elevation myocardial infarction reduces mortality from 9 to 7% (2). The main goal of coronary syndrome treatment is decreasing adverse events and increasing survival and treatment efficacy, which caused the proliferation of considerable literature. In this line, it was found that elective coronary revascularization plus medical therapy can improve the final outcome compared with medical therapy alone (3). In addition to conducting the most appropriate treatment strategy, self-care and collaboration of patients in the therapy period are deniable.

Behavioral management of patients with life-threatening disorders such as cardiovascular disease, renal failure, and rheumatoid arthritis is critical in disease management. In this regard, treatment adherence has recently taken the attention of researchers to reduce mortality and morbidity rates. The rate of adherence to long-term treatments for chronic diseases in developed countries is 50%, and this rate is even lower in developing countries. The prolonged treatment period in chronic diseases was the most common reason between reports for continuous reduction of treatment non-adherent during treatment. Several factors were proposed for non-adherent treatment, which was between nationalities. In China, a recent investigation reported that low information about the importance of drugs, their usage time, patients' sociodemographic characteristics, and health status influences treatment adherence. In a study by Spedale *et al*, it was demonstrated in patients with Heart Failure (HR) that sleep quality influences patients' self-care (4). It was demonstrated that following myocardial infarction, the adherence to the treatment regimen reduces to 65% in three months follow-ups, which is affected by independent factors such as education degree, place of residence, economic status and marital status (5).

According to the definition by the World Health Organization, the extent of a person's behavior includes taking medicine, following a diet, or implementing changes in lifestyle in accordance with the recommendations provided by health care personnel (6). Three terms, compliance, concordance and adherence, are used to describe compliance with treatment. Adherence means compliance and is considered the primary goal (6). The word compliance means following and includes the result of this process. Finally, the word concordance means the definition of conformity and the process used to apply this head, and it indicates how far the patient follows the doctor's orders (6,7).

The last published report was about the treatment adherence rate in patients with Heart Failure (HF), but the sample size was very low (8). Hence, conducting further investigations in various countries with different study designs is necessary to improve adherence to treatment regimens and, finally, increase clinical outcomes and quality of life for patients. On the other side, patients undergoing PCI face a noticeable change in their lifestyle after angioplasty; therefore, this study aims to investigate compliance with the treatment regimen of angioplasty patients.

Materials and Methods

The current research is a cross-sectional descriptive study. The treatment compliance of the patients was investigated four to six weeks after angioplasty.

Study population

The inclusion criteria included the following: willingness to cooperate and participate in the research by the research units, the patients treated between four and six weeks (the importance of paying attention to the treatment regimen in the first months after angioplasty), performing angioplasty for the first time (have no previous experience), age over 18 years, absence of dementia or any other acute and chronic mental illness based on the patient's medical record and history; patients should be able to speak and understand Persian. The exclusion criteria were

considered as the following: refusal to continue participating in the research. Sampling was done using the available method to evaluate 110 patients with the inclusion criteria.

Data collection strategy

The data collection tool in this research included two parts. The first part of the questionnaire was demographic characteristics and information related to the disease. The validity of this tool was determined through the content validity method by surveying cardiologists. The research tool was first designed by reviewing the relevant literature and considering the factors affecting treatment adherence. In the next stage, it was evaluated and approved by several cardiologists.

The second tool was the treatment compliance questionnaire in chronic patients, published by Seyed Fatemi *et al* in 2018. This questionnaire has 40 items in seven areas of attention in treatment (9 items): willingness to participate in treatment (7 items), ability to adapt (7 items), integration of treatment with life (5 items), adherence to treatment (4 items), commitment to treatment (5 items) and doubt in implementing treatment (item). This week, the range covered 48.51% of the variance. The reliability of the questionnaire was obtained with Cronbach's alpha internal consistency equal to 0.92. Answers to the questions of this questionnaire are in the form of a seven-item Likert scale (completely disagree, somewhat disagree, slightly disagree, have no opinion, somewhat agree, somewhat agree, completely agree). The questionnaire scores will be standardized on a scale of 100 after completion. Scores between 75 and 100 were classified as perfect adherence, 50 to 74 as good, 26 to 49 as moderate, and 0 to 25 as poor. The researcher extracted information such as the condition of the disease, the use of heart medication, the underlying disease, *etc*.

An experienced interventional cardiologist conducted the PCI. All the patients received anti-platelet and anti-coagulant therapies. A semi-structured interview was used to assess adherence to treatment by a nurse (PhD candidate). Before starting the study, a pilot interview was carried out to improve the quality. The interview takes 15-30 *min*.

Statistical analysis

Descriptive statistics of the qualitative and quantitative variables were shown as frequency (percentage) and mean±Standard Deviation (SD), respectively. The chi-square test and trend chi-square test were used to evaluate the association between qualitative variables and Influenza vaccination status. The $p<0.05$ was regarded as a significant statistical difference. Data analysis was done using SPSS 23 (IBM Corp., Armonk, NY, USA).

Results

Based on the inclusion criteria, 110 patients with an average age of 58.36 years and 6.02 days of hospitalization were selected. 66.4% of the participants were male, and 33.6% were female. 36.4% of the patients had secondary education, followed by 25.5% with university educations, diplomas (21.8%), and illiterate (16.4%). Only 2.7% of the patients were single (Table 1). Diabetes was

Table 1. The demographic information of the included patients

Variables		Results
Age (year) (mean±SD)		58.36±10.47
Hospitalization days (mean±SD)		6.02±6.16
Gender (%)	Male	73(66.4)
	Female	37(33.6)
Education (%)	Illiterate	18(16.4)
	High school	40(36.4)
	Diploma	24(21.8)
	University	28(25.5)
Marital status (%)	Single	107(97.3)
	Married	3(2.7)
Underlying disorders (%)	None	15(13.6)
	High blood pressure	31(28.2)
	Diabetes	35(31.8)
	High fatty blood	39(26.4)
Smoking (%)	Yes	39(35.5)
	No	71(64.5)
History of cardiac drug usage (%)	Yes	57(51.8)
	No	53(48.2)
Type of cardiac involvement (%)	Infarction	68(61.8)
	Acute syndrome	24(21.8)
	Chronic syndrome	18(16.4)

the most common underlying disease, followed by high blood pressure (28.2%) and high blood lipids (26.4%) (Table 1). 64.5% of the participants had no smoking history, and 48.2% had no history of taking cardiac drugs. In data collection related to patient assessment, 97.3% were collected face to face, and only 2.7% were in communication with each other through the Internet. In terms of the type of cardiac involvement, the most common disorders were cardiac infarction (61.8%), acute coronary syndrome (21.8%), and chronic coronary syndrome (16.4%), respectively (Table 1). 40% of the patients had ≥3 vessels involved.

The average score of the treatment compliance was 255/27, with a standard deviation of 10/47. Based on the comparison of the standardized scores, the areas of doubt in the implementation of treatment (97.09), willingness to participate in treatment (95.51), and integration of the treatment with life (91.97) had the highest scores, respectively. The total compliance score with the treatment of patients who underwent angioplasty four to six weeks ago was obtained as 91.39, which is within the range of excellent compliance (Table 2).

The results showed no correlation between age and the number of days of hospitalization with the total score of commitment to treatment and its dimensions. Only commitment to treatment was positively associated with the number of days of hospitalization (p=0.041) (Table 3).

Table 2. The mean and standard deviation of the total score of treatment adherence

Variable	Area score				Standardized area score	
	Minimum	Maximum	Mean	SD	Mean	SD
Treatment attention	46	62	56.11	3.26	89.07	5.19
Willingness to treatment participate	42	49	46.80	1.53	95.51	3.13
Ability to adapt	37	49	44.15	2.92	90.11	5.96
Combining treatment with life	25	35	32.19	2.41	91.97	6.90
Treatment adherence	15	28	23.93	3.54	85.48	12.64
Treatment commitment	19	35	31.68	4.26	90.51	12.19
Doubt in the treatment implementation	3	21	20.39	2.28	97.09	10.87
Total score	231	278	255.27	10.47	-	-
Total score (divided by 40)	5.78	6.95	6.38	0.26	-	-

Table 3. Correlation between the areas of adherence to treatment and its total score with age and number of days of hospitalization

Variable	Hospitalization days		Age	
	p-value	Correlation coefficient	p-value	Correlation coefficient
Treatment attention	0.386	-0.083	0.648	0.044
Willingness to treatment participate	0.105	0.155	0.453	-.0.072
Ability to adapt	0.856	-0.017	0.342	-0.091
Combining treatment with life	0.085	0.165	0.483	-0.068
Treatment adherence	0.697	0.037	0.692	0.038
Treatment commitment	0.041	*0.196	0.404	-0.080
Doubt in the treatment implementation	0.260	0.108	0.308	-0.098
Total score (divided by 40)	0.128	0.146	0.411	-0.079

This means that with the increase in the number of hospitalization days, people's commitment to their treatment also increases. It was also found that there is no difference between the two sexes on the level of treatment adherence (p=0.959) (Table 4).

Additionally, no significant difference was found between people who live alone and married people for adherence to treatment (p=0.467) (Table 4). Also, no difference was found between the level of education and adherence to treatment (p=0.974) (Table 4).

Table 4. Comparison of the mean of the total score of adherences to treatment according to gender and Marital status

Variable	Gender		p-value
	Male (mean±SD)	Female (mean±SD)	
Treatment attention	56.32±3	55.73±3.75	0.372
Willingness to treatment participate	46.74±1.42	46.92±1.75	0.563
Ability to adapt	44.12±3.04	44.22±2.71	0.877
Combining treatment with life	32.11±2.23	32.35±2.77	0.626
Treatment adherence	23.79±3.65	24.22±3.35	0.551
Treatment commitment	31.81±4.35	31.43±4.15	0.662
Doubt in the treatment implementation	20.42±1.87	20.30±2.96	0.820
Total score	255.32±10.80	255.19±9.95	0.959

Variable	Marital status		p-value
	Single (mean±SD)	Married (mean±SD)	
Treatment attention	56.07±3.29	58±3.1	0.328
Willingness to treatment participate	46.79±1.55	47±1.3	0.864
Ability to adapt	44.17±2.94	43.67±2.75	0.753
Combining treatment with life	32.18±2.45	32.67±2.1	0.719
Treatment adherence	23.92±3.58	24.67±3.3	0.708
Treatment commitment	31.65±4.30	32.67±4.5	0.643
Doubt in the treatment implementation	20.38±2.31	20.67±1.38	0.807
Total score	255.16±10.59	259.33±10.46	0.467

Variable	Education (mean±SD)				p-value
	Illiterate	High school	Diploma	University	
Treatment attention	56.56±3.97	56.50±2.41	55.67±3.5	55.68±3.7	0.646
Willingness to treatment participate	46.28±1.78	46.72±1.43	47.13±1.68	46.96±1.37	0.379
Ability to adapt	44.33±2.17	44.10±2.97	43.37±3.09	44.79±3.11	0.313
Combining treatment with life	32.06±2.82	32.35±2.12	31.96±2.80	32.25±2.3	0.908
Treatment adherence	25.50±1.69	26.63±3.95	22.88±4	24.29±3.13	0.094
Treatment commitment	30.61±5.51	31.58±3.78	32.75±3.33	31.61±4.75	0.467
Doubt in the treatment implementation	19.39±4.84	20.58±0.75	20.96±0.2	20.29±2.11	0.183
Total score	254.72±10.10	255.45±11.67	254.71±8.56	255.86±10.92	0.974

Contd. table 4.

Variable	Underlying disorders (mean±SD)				p-value
	Without underlying disorder	Hypertension	Diabetes	Hyperlipidemia	
Treatment attention	55±3.70	57.35±2.52	55.46±3.35	56.17±3.17	0.052
Willingness to treatment participate	46.87±1.51	46.55±1.67	47.09±1.40	46.69±1.58	0.534
Ability to adapt	44.20±3.19	43.68±3.25	44±2.74	44.83±2.63	0.487
Combining treatment with life	31.60±2.85	31.61±2.80	32.54±2.41	32.69±1.51	0.200
Treatment adherence	23.60±4.45	23.32±3.94	24.29±3.22	24.34±2.97	0.622
Treatment commitment	31.40±4.79	30.52±4.31	32.77±3.22	31.76±4.89	0.198
Doubt in the treatment implementation	19.87±2.83	20.68±0.65	20.37±3.07	20.38±2.04	0.739
Total score	252.53±10.59	253.71±11.55	256.51±9.41	256.86±10.47	0.416

Variable	Smoking (mean±SD)		p-value
	Yes	No	
Treatment attention	56.08±3.85	56.14±2.93	0.922
Willingness to treatment participate	46.77±1.60	46.82±1.51	0.877
Ability to adapt	44.05±2.83	44.21±2.99	0.785
Combining treatment with life	32.33±2.30	32.11±2.49	0.649
Treatment adherence	23.51±3.84	24.17±3.37	0.355
Treatment commitment	32.44±3.82	31.27±4.47	0.171
Doubt in the treatment implementation	20.56±1.77	20.30±2.53	0.558
Total score	252.74±10.23	255.01±10.67	0.729

Variable	Taking cardiac medication (mean±SD)		p-value
	Yes	No	
Treatment attention	56.02±3.36	56.23±3.20	0.739
Willingness to treatment participate	46.75±1.65	46.85±1.42	0.749
Ability to adapt	43.88±3.10	44.45±2.71	0.304
Combining treatment with life	31.93±2.49	32.47±2.33	0.242
Treatment adherence	23.70±3.58	24.19±3.51	0.474
Treatment commitment	31.54±4.27	31.83±4.30	0.727
Doubt in the treatment implementation	20.46±2.44	20.32±2.13	0.758
Total score	254.28±10.85	256.34±10.06	0.305

Further investigations showed that the underlying disorders (p=0.416), smoking (p=0.729), and history of taking cardiac medication did not influence the patient's adherence to treatment (p=0.305) (Table 4).

Discussion

Despite the high education and prevention, the incidence of heart disease in Iran has been increasing and has been reported as the first cause of death (9).

Among the essential factors in reducing the mortality rate in these patients, there are various methods to assess the level of treatment adherence and create strategies to increase its efficiency. Direct methods are based on laboratory and clinical tests, which are generally expensive. In indirect methods, the primary role of the patient is used in evaluating adherence to the treatment. Treatment adherence is a two-way process in which the performance of the patient and the treatment team plays a prominent role.

Contrary to the popular belief, increasing adherence and changing patient behavior significantly leads to an increase in patient life quality, reduction in mortality and costs of treatment (10). The results of the present study showed that diligence in treatment (89/07), willingness to participate in treatment (95/51), ability to adapt (90/11), integration of treatment with life (91/97), adherence to treatment (85/48), commitment to treatment (51/90) and finally doubt in the implementation of treatment (97/09), which according to the placement in the range of 75 to 100 indicates very good compliance of the studied community. According to the results of this research, gender of the disease, marital status of the disease, place of residence of the disease, underlying disease, smoking, use of cardiac drugs, patient's condition, and the number of vessels involved do not affect the score of adherences to the treatment and its areas, and the average adherence to the treatment regimen has been excellent in contributors.

The results of the present study showed that 66.4% of the patients were male, but no significant relationship was observed between the level of adherence to the treatment and the gender of the patients. Contrary to the findings of the present study, Amininasab *et al*, by examining 300 patients with HF in 2018, showed that factors such as literacy level, number of children, disease severity, underlying diseases, and the number of pills taken per day have a direct effect on treatment adherence (11). According to the results of this research, the areas of doubt in the implementation of treatment, desire to participate in treatment and integration of treatment with life obtained the highest scores, respectively, which are dimensions related to patients' understanding. However, it should be kept in mind that a person's mental state and motivation can affect all the mentioned aspects. Cardiac patients, due to reduced quality of life, high costs, loneliness, old age, and lack of efficiency after complete recovery, reduce the motivation to adhere to treatment, which is not affected by factors such as gender, education level, and social status.

In addition, depression and anxiety play a role in HF's development and progression, and even with complete adherence to treatment, the desired outcome is not achieved. For this purpose, it is strongly recommended that the patient's depression and life expectancy be considered when examining adherence to treatment. On the other hand, there is an overlap between HF symptoms and depression and anxiety (12). It has been suggested to use serotonin reuptake inhibitors for these patients (13). In addition, it has been determined that the emotional burden of HF patients directly affects their adherence to treatment, and this interference increases with age (14,15). On the other hand, the present study's findings showed that the commitment to treatment increases with the increase of hospitalization days, which can be due to more communication and training of nursing and the treatment team. Due to its simplicity, adherence assessment in the form of questions and answers may not determine its importance for the patient. The results of Dinh Ha *et al* further highlight the importance of this issue. In a systematic review, they showed that the use of the teach-back method increases the understanding of patients with HF about the importance of adherence to treatment (16). There are many cases where the patient gives false information due to negative feedback from their doctor and caregivers. In some cases, this issue can even lead to a wrong change in the course of treatment (17). In order to avoid underreporting and non-adherence to avoid disapproval, it is recommended that the doctor collects the information he needs through clinical interpretation indirectly so that the patient does not understand. Although the best and easiest thing is to create a sense of confidence at the beginning of the treatment in the patient to express his adherence honestly. The study's results by Kim *et al* showed that adherence to long-term treatment in newly diagnosed type 2 diabetic patients leads to the prevention of Cardiovascular Disease (CVD) and HF (18). However, one of the main challenges in the long-term treatment of chronic diseases is the

availability of medicine and its cost. In high-income and developed countries, they use the prescription of generic drugs to minimize treatment costs. However, according to the results published by the American Heart Association, patient non-adherence to treatment in the case of using generic drugs is more due to less confidence in their effectiveness (19,20). On the other hand, in developing countries with lower income, the main problem is drug costs rather than the type of manufacturing company (19). Side effects are one of the main issues contributing to reducing patient adherence to treatment. In 2019, Rodriguez *et al*, reviewing a cohort study with a large population, stated that adherence to atorvastatin therapy alone was very low due to high complications and showed that therapy with this drug alone effectively reduces the mortality rate of CVD patients (21).

In this regard, a study was conducted by Roshandel *et al* in Iran, in which they compared several drug combinations under the title polypill strategy in low-income and middle-income countries compared to minimal non-drug combinations for the prevention of cardiovascular diseases (22). Polypill strategy treatment was a combination of 4 drugs, including hydrochlorothiazide 12.5 *mg*, aspirin 81 *mg*, atorvastatin 20 *mg*, and enalapril 5 *mg*. The results of this study demonstrated that there was no difference in mortality between the two groups, but the side effects were significantly less in the polypill group. Also, the adherence rate in the study subjects selected from the rural population was similar to the results of the present study (80.5%) (22). The measurement method and tools used in evaluating treatment adherence are fundamental. In the indirect method, before using any type of questionnaire, its reliability and validity must have a sufficient score, and it must have the best fit with the disease and population under study. SEMAS and MMAS-8 questionnaires have gained the most credibility in evaluating adherence to treatment in chronic heart diseases. In the present study, a questionnaire was used, and seven areas were used: interest in treatment, willingness to participate in treatment, ability to adapt, combining treatment with anxiety, adherence to treatment, commitment to treatment, and hesitation in implementing treatment. Most of the influencing aspects of adherence are investigated.

Limitations

One of the limitations of the current research can be the level of accuracy in answering the questions about the mental and psychological conditions of the research units when answering the questionnaires. Also, since only just one hospital was selected as the research environment, generalizing the results to other hospitals should be done with caution.

Conclusion

The findings of the present survey showed that gender, age, marital status, place of residence, underlying disease, smoking, use of cardiac drugs, patient conditions, and the number of vessels involved did not affect the score of treatment compliance and its areas. The average adherence to the treatment regimen in the participants was perfect. It is also recommended that the mental state and depression of the patient should be taken into consideration during the evaluation of adherence. Choosing the adherence monitoring method has an undeniable effect on the final results; a tool should be used that examines several dimensions, not only the dimension of drug consumption.

Ethical approval

The Ethics Committee approved in University of Medical Sciences (Ethics number: IR.RHC.REC.1398.038) in 17 August 2019.

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Conflict of Interest

The authors declare that they have no competing interests.

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