

Quality of Life and Utility Values in Iranian Colorectal Cancer Patients: Using Generic and Specific Instruments

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Abstract

Background: Health-related quality of life (HRQoL) is a key indicator in evaluating healthcare outcomes. Given the rising prevalence and high treatment costs of colorectal cancer (CRC) in Iran, assessing patients' HRQoL is crucial for guiding health policy and effective resource planning. Accordingly, this study aimed to evaluate the QoL of CRC patients in Iran.

Methods: The population of this study included 60 CRC patients (30 cases in the stable state and 30 cases in the progressive state of the disease), who had been referred to hospitals affiliated with Shahid Beheshti University of Medical Sciences in 2019-2020. The patients' QoL was estimated using EQ-5D-VAS, QLQ-CR29, and QLQ-C30 questionnaires.

Results: The mean VAS score was 0.62 ± 0.07 , and the patients' mean QLQ-CR29 and QLQ-C30 scores were 38.80 ± 9.70 and 48.90 ± 12.10 , respectively. Moreover, the utility value of EQ-5D for the EQ-5D health states in the stable and progressive groups was 0.87 ± 0.11 (VAS: 0.82 ± 0.15) and 0.36 ± 0.30 (VAS: 0.44 ± 0.28). The results confirmed a significant difference ($P < 0.001$) between the two groups. Additionally, having an ostomy, rectal cancer, higher stages of cancer, and metastasis was significantly ($P < 0.05$) associated with a decreased QoL.

Conclusions: Overall, the QoL of CRC patients in Iran was comparable to that of the general population in stable stages but significantly decreased with disease progression. Consistent findings across EQ-5D, QLQ-C30, and QLQ-CR29 highlight reduced utility in advanced and metastatic cases. Compared with global studies, Iranian patients demonstrated similar or slightly lower QoL, indicating the need for local data in health economic evaluations.

Keywords: Cancer; Colorectal; Quality of Life; Utility; EQ-5D; VAS; QLQ-CR29; QLQ-C30

1. Background

Assessing the health-related quality of life (HRQoL) has become an essential issue in research. In addition, it is considered a critical indicator for assessing the outcome of treatment and care interventions. This value is frequently used to evaluate health technologies, including medicine, to explore their cost-effectiveness.

Furthermore, cost-utility analysis is one of the most popular economic evaluation methods for healthcare interventions. In this respect, studies need data on quality-adjusted life-years as a primary outcome. Quality-adjusted life-years is a measure that combines the quality and quantity of life and varies in healthcare contexts (1).

Nowadays, the evaluation of the QoL is considered to compare the efficacy and relative value of various treatments in investigations related to health policy-making, evaluation of health services, and upgrading of the relationship between medical staff and patients (2). The QoL in the healthcare domain implies the HRQoL measure, which frequently addresses the health dimensions expressed by the World Health Organization (3). HRQoL is the outcome of all health interventions; its reduction leads to an increased burden of diseases.

Therefore, patients' QoL is not only crucial for patients and healthcare providers but also for payers and policymakers.

Cancer is regarded as the third major cause of mortality in Iran after cardiovascular disease and accidents (4). Exploring the incidence and prevalence of cancers in Iran during recent years has reflected an increase in colorectal cancer (CRC), so the prevalence of this cancer has had an upward trend (i.e., from the ninth to the fifth place) in this country. Moreover, it is among the most common gastrointestinal cancers in Iran (5).

However, there are no accurate data on utility and HRQoL scores in Iranian colorectal patients. A few studies have been conducted on the QoL of CRC patients using specially designed questionnaires, such as the five-level EuroQol five-dimensional questionnaire (EQ-5D), the QoL questionnaire (QLQ-CR29), and the cancer-specific QoL questionnaire (QLQ-C30) worldwide; nonetheless, to the best of our knowledge, no such study has so far been performed in Iran. Determining the utility of patients' lives is vital for decision-makers at the micro and macro levels of the health system.

Hence, the present study intends to assess the QoL of



patients with CRC in Iran due to its high prevalence in Iran and its high therapeutic expenditures.

Several tools are used for evaluating the QoL in general and colorectal patients in particular. The European Organization for Research and Treatment of Cancer (EORTC) has developed the QLQ-C30 to assess the QoL of cancer patients. This questionnaire includes 30 questions and five multi-item scales (physical, role, social, emotional, and cognitive function). Typically, cancer patients have symptoms (e.g., anorexia, insomnia, constipation, diarrhea, and nausea/vomiting) that affect the QoL but are not considered in general questionnaires. These scales are included in this inventory, and the scores range from 0 to 100; a higher score for scales reflects a better QoL (6).

The QLQ-CR29 questionnaire (CRC module) is a cancer site-specific supplemental module designed by the EORTC working group to evaluate the QoL in CRC patients. This instrument investigates items and symptoms (e.g., gastrointestinal and urinary pain) and functional status (e.g., sexual interest and body image) associated with CRC. Responses are in the form of a four-point Likert-type scale ranging from 0 to 4. In addition, the final score of the questionnaire is converted from 0 (worst symptomatic status) to 100 (ideal health status) for the functional index and 0 (no symptoms) to 100 (higher levels of symptoms) for symptomatic indices (7).

In addition to the above-mentioned specific questionnaires, many tools are available for assessing the QoL; among them, EQ-5D is the most common instrument, which is extensively exploited to measure HRQoL for economic evaluation (8); however, some of them can produce a utility measure between 0 and 1, which is applicable in cost-effectiveness and cost-utility studies.

Numerous countries have established a set of values (preference weights) for their population and applied it for estimating utility based on QoL questionnaires (9).

The EQ-5D visual analog scale (VAS) questionnaire encompasses two components: a health state description followed by a visual evaluation. In the health state description section, the respondent classifies his or her prevailing state of health by selecting one of three different levels of problem severity within each of the five health domains. The levels are none, moderate, and severe/extreme (coded one through three, respectively). Moreover, the domains include mobility, capacity for self-care, the conduct of usual activities, pain/discomfort, and anxiety/depression.

In the visual evaluation section, the respondent then explores his/her health status using a VAS, which is a vertical, calibrated line bounded at 0 (worst imaginable health state) and 100 (best imaginable health state) (10). When the health status is extracted from the first part of the questionnaire, the numbers can be converted to a preferred weight based on each country's set of preferential values, called utility, which can be compared with the VAS results to ensure validity.

QoL measurements should be calculated for each disease to understand the therapeutic outcomes accurately, and each country should compute this index for its patients. Therefore, this study seeks to investigate the QoL of patients with CRC, which is one of the diseases that has a high treatment cost.

2. Materials and Methods

This descriptive and analytical cross-sectional study was designed to assess the QoL of CRC patients admitted to the hospitals of Shahid Beheshti University of Medical Sciences (SBMU) in Iran between May and September 2020. The EQ-5D-VAS, QLQ-CR30, and QLQ-C29 standard questionnaires were used for data collection (6,8,11). The EQ-5D-VAS is a tool for measuring the QoL related to general health. In addition, the QLQ-CR30 assesses the QoL of cancer patients, and the QLQ-C29 is specifically designed for patients with CRC. The researcher completed these questionnaires during the study.

The patients were asked for their demographic information, including age, gender, educational level, marital and insurance status, and the number of family members. After reviewing the literature and extracting the main factors affecting the QoL in cancer patients, particularly CRC, the factors were screened through an expert panel. Additionally, demographic questions were selected for addition to the questionnaire. Furthermore, the patients were questioned about health literacy, including the need for assistance in reading medical instructions, pamphlets, and other written materials from the doctor or pharmacy and difficulty in recognizing and understanding medical conditions and personal health status. Other questions were related to requiring assistance from another person in understanding information provided at hospitals, clinics, pharmacies, insurance organizations, and other healthcare institutions and ensuring the accuracy of responses when filling out medical and treatment forms or answering related questions. Therefore, the questionnaire included demographic questions, health literacy, EQ-5D-VAS, QLQ-CR29, and QLQ-C30. All colorectal patients referred to the SBMU cancer centers (cancer research center, crc@sbmu.ac.ir) were included if they were willing to participate in the study. Due to the small number of patients in the progressive stage, their general dissatisfaction with participation, and poor physical and mental conditions, 60 patients with CRC were finally enrolled in this study, including 30 in a stable state and 30 in the progressive state. The inclusion criteria for participation in the study were having confirmed pathological data that demonstrated CRC, being able to speak, and giving informed consent. The study was conducted after receiving approval from the Research Ethics Committee of Shahid Beheshti University of Medical Sciences (IR-SBMU.PHARMACY.REC.1398.218). Patients' consent for willingness to respond was obtained, and they were assured of data confidentiality and withdrawal from the study at any time of the process without concern. To

this end, 60 patients with CRC (30 in the stable state and 30 in the progressive state of the disease) made up the subjects of the study. After the sample population filled the questionnaires, the data were analyzed using SPSS 20 and STATA software (version 22).

3. Results

Due to the missing values, three questionnaires were removed from the analysis of 60 patients participating in the study. The mean age of the patients was 58.3 ± 10.1 years. In addition, the minimum and maximum ages of the individuals were 29 years and 76 years, and 97% were married.

Sixteen patients (26.7%) had rectal cancer, and the remaining ones had colon involvement in a cancer subtype. Furthermore, 75% of the patients were in stages II and III of the disease, and the remaining were in stages I and IV. Additionally, 29 patients (48.3%) had distant metastases in the abdominal area.

A combination of surgery and chemotherapy (68.3%) was the most conventional approach for managing patients. Merely five patients (8.3%) were treated with surgery, and others (23.2%) had received chemotherapy with or without radiotherapy. Moreover, the stoma was observed in 22 patients (36.7%).

Table 1 presents the scores in different domains of the QLQ-CR29 questionnaire. The QoL score was 38.8 ± 9.7 .

Table 1. Quality of Life Scores According to the QLQ-CR29 Questionnaire

Health-Related QoL Domains	Mean	SD
Urinary frequency	36.7	19.1
Blood and mucus in stool	28.3	7.9
Stool frequency	32.9	14.5
Body image	53.6	17.3
Urinary incontinence	30	13.6
Dysuria	30.8	14.1
Abdominal pain	48.3	22.5
Buttock pain	39.6	19.1
Bloated feeling	50.4	22.3
Dry mouth	30	12.9
Hair loss	26.7	6.2
Trouble with taste	47.1	21.6
Anxiety	48.8	20.8
Weight	32.9	18.1
Flatulence	35.8	14.8
Fecal incontinence	37.5	18.1
Sore skin	45	21.9
Embarrassed by bowel movement	34.4	16
Stoma care problems	31.3	14.2
Sexual dysfunction men	39.4	11.8
Sexual dysfunction women	39.4	11.7
Average	38.8	9.7

Note. QLQ-CR29: Colorectal Cancer-Specific Quality of Life Questionnaire; SD: Standard deviation; QoL: Quality of life.

out of 100. Patients reported low to moderate symptoms in different domains. Thus, the weight, hair loss, and urinary incontinence had the lowest intensity, and the body image and anxiety had the worst conditions.

The QLQ-C30 questionnaire evaluated the QoL in terms of patient performance (involving physical, role, social, emotional, and cognitive functioning), physical symptoms (e.g., fatigue and financial difficulties), and the overall QoL.

In the QLQ-CR30 questionnaire, although the mean score of the overall health-related QoL was about 59.6 ± 23.1 , which is a moderate-to-high level, the mean score of the questionnaire was 48.9 ± 12.1 (Table 2). Overall, individuals acquired intermediate to high scores in the domains of functional dimension, so that cognitive functioning and role functioning had higher scores. However, in the physical functioning dimension, patients had low-to-moderate severity of symptoms, and fatigue and the financial burden showed the worst outcomes.

Then, the status of patients in the five domains of the EQ-5D-VAS questionnaire (including mobility, capability for self-care, conducting usual activities, pain/affliction, and anxiety/depression) is as follows (an end to a VAS scale):

Forty individuals (66.7%) had no gait disorders, and the remaining ones had varying levels of difficulty in walking. Likewise, 41 people (68.3%) had no problem conducting usual activities (e.g., bathing and dressing), and patients could not perform personal tasks in 10% of cases. Further, 41 patients (68.4%) expressed that they feel some degree of pain during the day. Nearly 38% of individuals had low to high degrees of dysfunction in performing daily

Table 2. Quality of Life Scores Based on the QLQ-C30 Questionnaire

Health-Related QoL Domains/Single Items	Mean	SD
Functions		
Physical function	46.6	21.1
Role function	39.3	18.8
Emotional function	37.7	16.9
Cognitive function	55.3	20.4
Social function	62.7	20.6
Symptoms		
Fatigue	50.5	22.3
Nausea/vomiting	38.9	22.1
Pain	52.9	25.2
Dyspnea	30.8	14.1
Insomnia	46.6	22.7
Anorexia	40.4	23.1
Constipation	39.6	22.6
Diarrhea	42.1	23.2
Financial problems	54.2	23.5
Overall health-related quality of life	59.6	23.1
Average	48.9	12.1

Note. QLQ-C30 Questionnaire: Core Quality of Life Questionnaire.

tasks (e.g., work and study). In addition, 39 patients (65%) had a feeling of varying degrees of anxiety or depression (Table 3).

In the VAS section of the EQ-5D-VAS questionnaire, the patients were requested to depict their feelings of health with values between 0 (worst imaginable feeling) and 100 (best imaginable feeling). The mean utility was 0.82 and 0.44 in the stable and progressive groups, respectively (Table 4). Moreover, the average utility was 0.62 ± 0.07 for all patients in the VAS. The results of the EQ-5D questionnaire that mapped on population-based preference weights for the EQ-5D health states (A1) were in line with the data obtained from the VAS (Table 4).

In assessing the dimensions of the QLQ-C30 questionnaire, rectal involvement, higher cancer stage, metastasis, and availability of an ostomy bag had a direct and significant correlation with the weaker performance of individuals in physical, role, social, emotional, and cognitive functioning, so that the role of metastasis and availability of an ostomy bag had a stronger correlation.

Table 5 compares the EQ-5D and VAS utility scores based on the demographic information of the patients. Based on the analysis, unemployed patients were worse off than employees, retirees, or homemakers. Having an income level higher than 3-4 million tomans significantly improved both of the above utility points.

The patients with colon involvement had a significantly better condition. The higher stage of the disease merely caused a significant decrease in VAS while not affecting

the utility rate of EQ-5D. Having metastasis and stoma bags could noticeably intensify both of the above-listed variables. It should be noted that the treatment method, insurance status, age, and gender did not influence the utility rate.

All patients received 5-fluorouracil, and 59 patients received leucovorin; thus, comparing the two groups of users and non-users was impossible. There was no significant correlation between pharmaceutical literacy and health literacy with the utility rate. The use of irinotecan resulted in a significant reduction in the utility rate. Conversely, the consumption of bevacizumab caused a remarkable improvement in the VAS utility rate.

Ultimately, the correlation results (Table 5) varied between the EQ-5D and VAS, and the VAS values were more sensitive to demographic and situational characteristics.

4. Discussion

CRC is one of the most prevalent types of cancer in communities. Unfortunately, the condition of this disease damages the QoL of patients. This study assessed patients' QoL and factors that affected service quality and were crucial for economic evaluation-related interventions (12,13). Although several studies have evaluated the QoL of CRC patients with various questionnaires (e.g., 12-item Short Form Health Survey, 36-item Short Form Survey, Functional Assessment of Cancer Therapy, and Rowsource Structured Query Language), rare data are available on new and specific questionnaires, including

Table 3. EQ-5D and VAS Descriptive Frequency Analysis

		Stable		Progressive		<i>P</i> value
		N	%	N	%	
Mobility	No problem	30	100	10	33.4	0.0001
	Moderate problem	0	0	14	46.7	
	Severe problem	0	0	6	20	
Self-care	No problem	30	100	11	36.7	0.0001
	Moderate problem	0	0	13	43.4	
	Severe problem	0	0	6	20	
Usual activities	No problem	29	96.7	8	26.7	0.0001
	Moderate problem	1	3.3	16	53.3	
	Severe problem	0	0	6	20	
Pain/discomfort	No problem	19	63.3	0	0	0.0001
	Moderate problem	11	33.7	14	46.7	
	Severe problem	0	0	16	53.3	
Anxiety/depression	No problem	18	60	3	10	0.0001
	Moderate problem	10	33.3	11	33.7	
	Severe problem	2	6.7	16	53.3	

Note. EQ-5D: Five-Level EuroQol Five-Dimensional Questionnaire; VAS: Visual analog scale.

Table 4. The Utility Values of Stable and Progressive Iranian Colorectal Cancer Patients Based on the Two Approaches of VAS and Mapped EQ5D

VAS utility in progressive patients	EQ-5D utility in progressive patients	VAS utility in stable patients	EQ-5D utility in stable patients
0.44 ± 0.28	0.36 ± 0.30	0.82 ± 0.15	0.87 ± 0.11

Note. EQ-5D: Five-Level EuroQol Five-Dimensional Questionnaire; VAS: Visual analog scale.

Table 5. Significant Relations Between Utility Scores and Patients' Demographic Characteristics

Variable	EQ-5D utility			P value	VAS utility			P value
	Mean	SD			Mean	SD		
Employment status	Employee	0.50	0.20	0.20	0.60	0.20		0.01*
	Unemployed	0.70	0.10		0.60	0.10		
	Retired	0.50	0.20		0.30	0.20		
Medications	Irinotecan	0.70	0.20	0.03*	0.50	0.10	0.02*	
		0.50	0.20		0.70	0.20		
	Bevacizumab	0.60	0.20		0.40	0.20		
		0.50	0.20		0.60	0.20		
Type of disease	Rectum	0.70	0.20	0.01*	0.70	0.10	0.09	
	Colon	0.50	0.20		0.70	0.20		
Disease stage	1	0.50	0.20	0.09	0.70	0.10	0.001*	
	2	0.50	0.20		0.70	0.20		
	2	0.60	0.20		0.50	0.20		
	4	0.50	0.10		0.50	0.10		
Metastasis	Yes	0.60	0.20	0.000*	0.40	0.15	0.000*	
	No	0.40	0.08		0.80	0.10		
Ostomy bag	Yes	0.60	0.20	0.01*	0.50	0.20	0.02*	
	No	0.40	0.10		0.60	0.20		

Note. * Means significant at 0.05. Note. EQ-5D: Five-Level EuroQol Five-Dimensional Questionnaire; VAS: Visual analog scale; SD: Standard deviation.

QLQ-CR29 and EQ-5D (14). The results indicated that the two questionnaires had similar or higher accuracy in assessing the QoL of CRC patients and evaluating the interventional aspects (15,16). Furthermore, the QoL is context-related, so having local data on patients' utilities may improve the accuracy of economic evaluations.

Therefore, this study evaluated the QoL of Iranian patients with CRC using QLQ-CR29, QLQ-C30, and EQ-5D-VAS questionnaires and Iran's health system. Moreover, this study assessed the utility level of patients' QoL in two groups of patients with stable and recurrent cancer.

The patients' utility rates were extracted from the VAS questionnaire mapped on population-based preference weights for the EQ-5D health states (17,18). The colorectal patients' utility in Iran was 0.62 in the VAS method, which was 0.82 ± 0.15 and 0.44 ± 0.28 for stable and progressive states, respectively. The utility values extracted from the EQ-5D questionnaire mapped on the Iranian data set for preference weights were also 0.87 ± 0.11 and 0.36 ± 0.30 for stable and progressive states of Iranian colorectal patients. Over 40% of patients in the EQ-5D questionnaire had difficulty in mobility and capacity for self-care. In addition, 81% of cases experienced pain, and 79% experienced some degree of anxiety and depression. The utility rate of QoL in the EQ-5D questionnaire in the stable patients' group was almost the same as that of the general population, but was significantly better than that of the QoL in the progressive patients' group. The results of all three questionnaires in this study similarly confirmed these findings. The score of EQ-5D in the study performed by Huang et al on 300 Chinese CRC patients, who had

recently been detected, was 0.62 (19), which is close to our results. In another research conducted in Vietnam on 197 patients, the utility value of EQ-5D was 0.56, which is close but lower than our results. In a Brazilian study examining 46 patients undergoing chemotherapy, the values of EQ-5D ranged between 0.67 and 0.85 (20), which conforms to the results of our study.

Another survey in Japan evaluating 30 patients with CRC reported that the mean EQ-5D of patients was 0.87 (21), demonstrating that their patients had better conditions than ours; however, the ratio of stable and progressive patients in this study is not apparent.

In an investigation in Finland, 508 colorectal patients were assessed using the EQ-5D questionnaire and then compared with the general population. Except for those who underwent palliative and supportive treatment, the researchers found that the QoL of these individuals was similar to that of the general population (22), which corroborates the results of this study in general. The overall score of EQ-5D in their study was 0.81 ± 0.2 , displaying that the patients enjoyed better conditions compared to the patients in this study. In the study conducted by Yousefi et al in Iran, the amount of EQ-5D in CRC patients was 0.72, which was a better score compared to the scores obtained by our patients. However, patients at higher stages of cancer had significantly weaker conditions (23), which matches our findings.

Although the previously mentioned studies discussed the QoL of CRC patients, they did not explain the exact values for patients in stable and progressive stages, which is crucial information for cost-effectiveness modeling.

Based on the EQ-5D questionnaire, the QoL of our patients was similar to that of patients investigated in studies performed in China, Vietnam, and Brazil, and they had weaker performance than patients evaluated in European countries and Japan.

Based on the findings of the study conducted by Montazeri et al, people with a stoma had more urinary problems, bleeding, urinary incontinence, abdominal pain, flatulence, skin ulcers, and dyspareunia, and cancer treatment had no considerable impact on improving their scores (24).

In the Spanish study performed by Arraras et al, the score of the QLQ-CR29 questionnaire had a range of items of 64.4–87.3, and the majority of patients had few symptoms (25), which is in line with the results of this survey. In the investigation conducted by van der Hout et al, patients with rectal involvement had worse performance, weaker body image, and more anxiety and weight loss on the EQ-5D questionnaire. Additionally, people experiencing rectal cancer had weaker performance and more symptoms by receiving neoadjuvant chemotherapy (26).

In the research performed by Allal et al in the Netherlands, the mean score of the QLQ-C30 for patients' functional domain was 67–86 (27). In another questionnaire of the survey conducted by Montazeri et al, the distribution of QLQ-C30 scores in functional dimensions had the values of 84.1–67.4 (24). Based on the results of Akhondi-Meybodi et al, the mean QoL score of the QLQ-C30 questionnaire for colon and rectal cancer was 77.3 and 76.5, respectively (28), which is in conformity with the results of the current study concerning the upper and lower quartiles.

In another study in the United Kingdom, advanced disease, availability of an ostomy bag, and rectal involvement were the leading causes of these people's decreased QoL scores. Although ostomy declined digestive problems, patients in problematic cases reported moderate or higher severity compared to patients without ostomy (29). Similar to the present study, patients with a recurrence of the disease had a poorer QoL in a study performed in Japan (21). Unlike the present results, male gender and underlying disease in a study conducted by Arraras et al were correlated with lower performance scores and more symptoms on the QLQ-CR29 questionnaire (25).

5. Limitations of the Study

This study had some limitations. First, the coronavirus disease 2019 pandemic impacted data collection, particularly in accessing patients. The restrictions on in-person interactions and the limitations on recruitment during the pandemic resulted in a smaller and potentially less diverse sample, which may have affected the external validity and generalizability of the findings. Additionally, selection bias may have influenced the results, as the sample may not fully represent the broader population. Finally, the non-random selection process could have skewed the relationships between variables,

further limiting the generalizability of the conclusions. Accordingly, these factors should be taken into account when interpreting the study's results.

6. Conclusion

In comparing stable and progressive patients in this study, the progressive group had a substantially weaker status in the EQ-5D and QLQ-C30 questionnaires. However, there was no significant difference between the two groups regarding the results of the QLQ-CR29 questionnaire, representing that most patients had more disease-specific functional problems than the severity of physical symptoms (e.g., bloating, nausea, and vomiting). Accordingly, rectal involvement, higher stage of the disease, metastasis, and the availability of an ostomy bag were significantly more common among patients in the progressive group, which, similar to the outcomes of other investigations, could have a remarkable negative influence on the QoL of patients who have progressive cancer.

Eventually, the results of this study demonstrated that the scores of QoL in QLQ-CR29, EQ-5D, and QLQ-C30 questionnaires could be overall in Iran compared with those in other studies performed in Vietnam, China, and Brazil, which had a somewhat weaker condition relative to European countries and Japan. Although the utility rates of EQ-5D and EQ-5D-VAS in stable colorectal patients were the same as those of the general population in Iran, having progressive disease led to a substantial reduction in this regard.

Authors' Contribution

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Competing Interests

The authors declare no conflict of interests associated with this publication.

Data Availability Statement

The data that support the findings of this study are available upon reasonable request from the corresponding author.

Ethical Approval

This study was conducted based on the permission received from the Research Ethics Committee of Shahid

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