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"Oral Health-related Quality of Life and Periodontal Status in Chronic Kidney Disease Patients: A Cross Sectional Study"

Adel Tabesh

Isfahan University of Medical Sciences

Reyhane Narimany (rarimany.rh@gmail.com)

Isfahan University of Medical Sciences

Maryam Abtahi

Isfahan University of Medical Sciences

Omid Fakheran

Isfahan University of Medical Sciences

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Title page

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Authors:

- Adel Tabesh DMD. Dental Research Centre, Department of Oral Medicine, Dental research Institute, Isfahan University of Medical Sciences, Isfahan, Iran. Tel: 0098 913 215 0743
 Fax: none Email: <u>adeltabesh@gmail.com</u>
- 2. Reyhane Narimany. Student Research Committee, School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran

Tel: 0098 913 5739165 Fax: none Email: narimany.rh@gmail.com

- Maryam Abtahi. Student Research Committee, School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran Tel: 0098 913 316 4339 Fax: none Email: maryam.abtahi96@yahoo.com
- Omid Fakheran DMD. Department of oral public health, Dental Implants Research Center, Dental Research Institute, School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran Tel: 0098 913 113 2008 Fax: none Email: omid.fakheran@gmail.com

Corresponding author: Reyhane Narimany. Student Research Committee, School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran

Tel: 0098 913 5739165

Fax: none

Email: <u>narimany.rh@gmail.com</u>

Oral health-related quality of life and periodontal status in chronic kidney disease patients: a cross sectional study

Abstract

Background: Oral health-related quality of life includes the effect of factors such as oral health and oral function on people's lifestyles. Chronic kidney disease is caused by the deterioration of kidney structures, decreasing their function. CKD causes some oral problems, and these problems could affect people's quality of life. This study was conducted to determine OHRQoL and periodontal health status in CKD patients.

Methods: One hundred and four CKD patients participated in the study. Their OHRQoL was assessed by Oral Health Impact Profile-14 (OHIP-14), and their periodontal status was assessed by the community periodontal index of treatment needs (CPITN). The stage of the disease was measured by BUN and creatinine. We used t-test, ANOVA, and Pearson's and Spearman's correlation tests for statistical analyses.

Results: The most frequent CKD stage was 5. The average total score of OHIP-14 in these patients was 14.82 (\pm 4.86). The most frequent CPITN score was 2 (calculus). CPITN had a direct relationship with the total score of OHRQOL (P=0.004) and its physical domains (P<0.05).

Conclusion: There was a significant relationship between periodontal status and OHRQoL in CKD patients. The quality of life in this group of patients might be improved by providing their periodontal treatment needs.

Keywords: Quality of life, Oral health, Periodontal index, Chronic kidney disease, crosssectional study.

Introduction

Chronic kidney disease (CKD) is a progressive and irreversible situation, followed by renal structural demolition and functional decrease in three months or more, leading to the need for hemodialysis or kidney transplantation (1–3). The prevalence of CKD is increasing in developing countries. For example, death caused by CKD in Iran has been doubled from 1990 to 2010 (4). A meta-analysis in 2018 showed a higher prevalence of CKD in Iran than the global status (5). However, due to new treatments, the mortality rate in CKD has decreased, and there are more CKD patients with age-related oral morbidities (6).

CKD is categorized into five stages according to the glomerular filtration rate (GFR), ranging from >90% to <15% of kidney function. In the first stage, GFR is normal or increases slightly (>90%). Kidney damage is also probable. The patient does not have any symptoms, and the functional decrease is 10-20%. In stage two, GFR decreases slightly (60-89%). The third stage is defined by a moderate decrease in GFR (30-59%), and kidney function is halved. In stage four, severe GFR decrease happens (15-29%). At last, in stage five, kidney insufficiency occurs, and functional decrease is >75%, caused by damage of more than two million nephrons (GFR<15%) (7).

Patients with CKD usually experience impaired oral health, and periodontitis is one of the common problems in these patients (3,8). Iwasaki showed that periodontal disease indices were worse and higher in CKD patients than in the control group, and creatinine serum levels correlated with the severity of periodontal disease (9). Other oral and dental problems caused by CKD are decreased bone density, jawbone pain, metal taste, urea

odor in the mouth, xerostomia, gingivitis, petechiae and ecchymosis, enamel hypoplasia, and temporomandibular joint problems (2,6,10–13).

Oral health-related quality of life (OHRQoL) is how oral health status impacts one's daily activities (13). Improving OHRQoL is considered the final achievement of various oral treatments (14). OHRQoL is measured via patient-centered approaches, consisting of questionnaires developed to assess the impact of oral health status or therapies on several aspects of life (15). These domains include functional, emotional, social, and psychological effects of oral health on the quality of life (16). Oral Health Impact Profile-14 (OHIP-14) is one of the questionnaires widely used to measure OHRQoL in systemic disease patients since it has exhibited acceptable discriminant ability and effectiveness regarding oral problems in these patients (11,17).

As CKD patients might suffer from several oral complications, OHRQoL might be impaired among them. A systematic review by Schmalz et al. concluded that OHRQoL is reduced in severe renal disease patients and mentioned the potential effect of oral health parameters of this phenomenon (18). However, Rodakowska et al. reported that subjective OHRQoL means might not reflect all the oral health problems in CKD, and the relationship between these variables and OHRQoL has yet to be established (14). Moreover, geographical variables might determine factors associated with OHrQoL in CKD patients, too (13). Therefore, the present study aimed to evaluate OHRQoL and its relation to periodontal status in different stages of CKD in Isfahan, Iran.

Materials and Methods

Participants

The present cross-sectional study was carried out from May 2019 to February 2020. Patients with a confirmed diagnosis of CKD, who were referred to the Nephrology Center of Al-Zahra Hospital, Isfahan University of Medical Sciences, Isfahan, Iran, were invited to participate in this study. Age>18 years, literacy, and willingness to be examined intraorally were the inclusion criteria. Patients suffering from hereditary syndromes or taking gingival enlargement-inducing drugs were excluded from the study.

Periodontal assessment

Periodontal status was examined with a dental mirror and a WHO probe under the light of the examiner's headlamp. CPITN index was used for periodontal assessment. In this index, each number is related to a specific periodontal status: 0 = healthy periodontal parameters, 1 = bleeding on probing, 2 = presence of calculus, 3 = 4-5 mm of pocket depth, and $4 = \ge 6$ mm of pocket depth. The whole dentition was divided into six sextants, with at least two functional teeth in each. Every single tooth was probed peripherally in six areas. The worst periodontal status of each sextant was considered representative for that sextant, and the worst sextant was considered representative for that patient's CPITN (19,20). A single examiner carried out the periodontal examination process in all the patients. Edentulous patients were excluded from this part of the investigation.

OHRQoL measurement

We used the Persian version of Oral Health Impact Profile-14 (OHIP-14) for evaluating OHRQoL. The validity, reliability, and accuracy of this questionnaire have been confirmed (21). OHIP-14 consists of 14 questions in 7 domains, and each domain consists of 2

consecutive questions. Each question is answered via Likert's 5-scale choices of frequency, ranging from 0 (never) to 4 (very often). To obtain the total score of every questionnaire, the scores of all the questions were summed up, adding up to a value between 0 and 56 (20). The score for each domain of the questionnaire was calculated as well.

Blood chemistry

Serum BUN and creatinine levels were collected from the patient's electronic medical records. Each patient's CKD was staged by determining the amount of GFR using the following formula:

GFR (mL/min/1.73 m²) = $186^{(\text{creatinine}/88.4)}^{(-1.154)} * (age)^{(-0.203)} * (0.742 \text{ if female}) * (1.21 \text{ if male}).$

First stage: GFR>90; second stage: 90<GFR<60; third stage: 59<GFR<30; fourth stage: 29<GFR<15; and fifth stage: GFR<15 (22,23).

Statistical analysis

SPSS 22 was used to analyze data. T-test, ANOVA, and Pearson's and Spearman's correlation tests were utilized. P<0.05 was considered statistically significant.

Results

One hundred four patients participated, with an age range and mean of 18-83 and 52.1 (±18.1) years, respectively. Table 1 shows the CPITN scores in both genders, and Table 2 shows the frequency distribution of CKD stages.

Gender	Frequen cy	CPITN index						
		Health y (0)	BOP (1)	Calcul us (2)	Shallow pocket (3)	Deep pocket (4)	Complete denture	
Female	39.4%	0%	24.4%	31.7%	12.2%	2.4%	29.3%	
Male	60.6%	3.2%	14.3%	25.4%	22.2%	6.3%	28.6%	

Table 1. CPITN and OHIP-14 scores in both genders

CPITN: Community Periodontal Index of Treatment Need

OHIP: Oral Health Impact Profile

Table 2. Frequency distributions of CKD stages

Stage of CKD	Prevalence	Percentage
GFR >90	12	11/5
60 <gfr<90< td=""><td>20</td><td>19/2</td></gfr<90<>	20	19/2
30 <gfr<59< td=""><td>15</td><td>14/4</td></gfr<59<>	15	14/4
15 <gfr<29< td=""><td>12</td><td>11/5</td></gfr<29<>	12	11/5
GFR<15	38	36/5
Unclear	7	6/7
Total	104	100

The total mean score of OHIP-14 was 14.82 (\pm 4.86). Figure 1 shows the frequency distributions of CPITN scores. Spearman's correlation coefficient showed that CPITN was significantly correlated with OHIP-14 total score (P=0.004), functional limitations (P=0.002), physical pain (P=0.002), physical disability (P=0.001), and handicap (P=0.01) domains (Table 3). Moreover, significant and direct correlations were detected between CKD stage/OHIP-14 score (P=0.03, R=0.222) and CKD stage/CPITN score (P=0.007, R=0.271) by Spearman's correlation test.

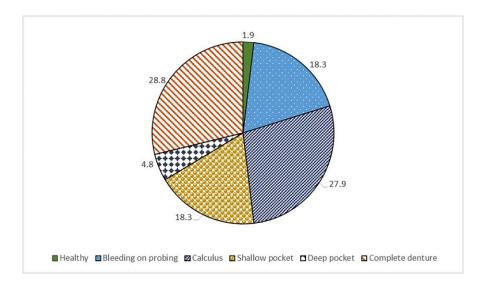


Figure 1. Frequency distributions of CKD stages.

Tables 3. OHIP-14 mean domain scores and their correlation to CPITN (Spearman)

		Versus CPITN		
OHIP-14 domains	Mean (±SD)	Spearman's r	P-value	
Functional limitation	2.59 (±1.13)	0.327	0.001	
Physical disability	2.41 (±1.22)	0.330	0.001	
Physical pain	2.30 (±1.03)	0.297	0.002	
Psychological discomfort	2.55 (±1.10)	0.067	0.50	
Psychological disability	1.72 (±1.19)	0.129	0.19	
Social disability	1.87 (±1.14)	0.178	0.07	
Handicap	1.36 (±0.69)	0.242	0.01	
Total	14.82 (±5.68)	0.278	0.004	

OHIP: Oral Health Impact Profile, CPITN: Community Periodontal Index of Treatment Need, SD: Standard Deviation

Discussion

Periodontal disease is one of the main problems in patients suffering from CKD (19). Furthermore, it is becoming increasingly clear that periodontal disease can significantly impact OHRQoL in the general population (2). Based on the previous reports, the items with the greatest prevalence differences between periodontitis patients and healthy people are mainly related to psychological concerns, halitosis, pain, and aesthetics (2,11,14). However, the association between periodontitis and OHRQoL in patients suffering from CKD in Iran has not previously been explored. Thus, the present study adds new information to the literature.

The present study aimed to measure OHRQoL and periodontal disease in different stages of CKD and verify the possible correlation between these variables. According to the results, stages of CKD correlated with the severity of periodontal disease. In this regard, several other studies have revealed the correlation between periodontal status and CKD (2,10,24–26). In addition, increased levels of inflammatory cytokines in CKD patients might exacerbate periodontitis (2).

The present study also found a significant association between CKD stages and OHIP-14 total score, indicating that the occurrence and severity of CKD affect the OHRQoL in this population. This finding is consistent with previous studies (2,24,26–29), confirming the accordance between objective and subjective measures of disease evaluation in these patients.

It should be noted that the correlation between OHIP-14 and CPITN scores was statistically significant. The same results have been reported by Pakpour et al., Oliveira et al., and Silva et al. (2,27,30). CKD patients lose more teeth due to a high prevalence of periodontitis among them (27). Besides, as the number of missing teeth is associated with speech problems, it can impair OHRQoL in CKD patients (29,31). Of note, more than a quarter of the study sample were edentulous, probably as a consequence of extremely poor past oral and periodontal health status.

On the contrary, some investigations found no significant (25,32–34) or even opposite correlation between periodontal disease status and OHRQoL (35). Conflicting results in different communities could be due to their priorities and various perception of OHrQoL. Various factors affect OHRQoL in the general population, and the situation is even more complicated in chronic systemically compromised patients (16). Developing disease-specific questionnaires to assess OHRQoL in related populations probably ends up with more reliable conclusions in this regard.

Physical aspects of OHIP-14, i.e., functional limitation, physical pain, physical disability, and handicap, were correlated with the CPITN score. On the other hand, psychosocial factors in the OHIP-14 questionnaire, concerning dissatisfaction with diet, deprivation of peace, and being embarrassed by teeth, were not correlated with the CPITN score. In fact, although patients with poor periodontal status reported its relation to physical domains of their life quality, they seemed to be satisfied with their social life and mental state. Fortunately, the high potential of eastern families in cultural and psychological support can explain the lack of significant correlation between periodontal status and psychosocial OHRQoL.

In the present study, 36.5% of patients had severe CKD (stage 5). The high burden of CKD and lack of sufficient financial and social insurance services might have a huge impact on a patient's psychosocial life quality; however, such matters cannot be discussed here in detail. Under such circumstances, patients might ignore their oral health and under-report the true impact of the oral condition on their mental health since it might have already been ruined by more severe medical issues.

This investigation was carried out within the limitations of a cross-sectional study. The absence of temporal relation between variables results in an inability to clarify cause-and-effect analyses in such studies, leading to the controversial understanding of the conclusion. Of course, future studies with novel designs regarding oral health and its related quality of life in CKD will further elucidate the correlation between objective and subjective means of disease evaluation in these patients.

conclusion

In conclusion, there were significant relationships between CPITN and OHIP-14 total and functional limitation, physical pain, physical disability, and handicap domain scores in CKD patients. Thus, paying attention to periodontal treatment needs might improve oral health-related quality of life in these patients.

Availability of data and materials:

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Abbreviations:

CKD: chronic kidney disease OHrQOL: oral health related quality of life GFR: glomerular filtration rate CPITN: community periodontal index of treatment need OHIP-14: Ontario Health Insurance Plan-14

BUN: bllod urea nitogen

References

- Andrade MRTC, Antunes LAA, Soares RM de A, Leão ATT, Maia LC, Primo LG. Lower dental caries prevalence associated to chronic kidney disease: a systematic review. Pediatr Nephrol. 2014;29(5):771–8.
- Silva TMC, Alves LAC, Garrido D, Watanabe A, Mendes FM, Ciamponi AL. Health and oral health-related quality of life of children and adolescents with chronic kidney disease: a cross-sectional study. Qual Life Res. 2019;28(9):2481– 9.
- Jamieson L, Skilton M, Maple-Brown L, Kapellas K, Askie L, Hughes J, et al. Periodontal disease and chronic kidney disease among Aboriginal adults; an RCT. BMC Nephrol. 2015;16(1):181.
- Sepanlou SG, Barahimi H, Najafi I, Kamangar F, Poustchi H, Shakeri R, et al. Prevalence and determinants of chronic kidney disease in northeast of Iran: Results of the Golestan cohort study. Reboldi G, editor. PLoS One. 2017;12(5):e0176540.
- Bouya S, Balouchi A, Rafiemanesh H, Hesaraki M. Prevalence of Chronic Kidney Disease in Iranian General Population: A Meta-Analysis and Systematic Review. Ther Apher Dial [Internet]. 2018;22(6):594–9.
- Esmaeeli A, Esmaeeli M, Ebrahimi M, Nasehi A. Association between oral findings and laboratory tests in children and adolescents undergoing dialysis: A

cross-sectional study. Vol. 10, Journal of Clinical and Experimental Dentistry. 2018. p. e462–8.

- Levey AS, Coresh J. Chronic kidney disease. Lancet [Internet].
 2012;379(9811):165–80.
- Kim YJ, Moura LM de, Caldas CP, Perozini C, Ruivo GF, Pallos D. Evaluation of periodontal condition and risk in patients with chronic kidney disease on hemodialysis. Einstein (São Paulo) 2017;15(2):173–7.
- Iwasaki M, Borgnakke WS, Awano S, Yoshida A, Hamasaki T, Teratani G, et al. Periodontitis and health-related quality of life in hemodialysis patients. Clin Exp Dent Res 2017;3(1):13–8.
- Pakpour AH, Kumar S, Fridlund B, Zimmer S. A case-control study on oral healthrelated quality of life in kidney disease patients undergoing haemodialysis. Clin Oral Investig 2015;19(6):1235-43.
- Pontes FSC, Lopes MA, de Souza LL, dos Santos da Mata Rezende D, Santos-Silva AR, Jorge J, et al. Oral and maxillofacial manifestations of chronic kidney disease–mineral and bone disorder: a multicenter retrospective study. Oral Surg Oral Med Oral Pathol Oral Radiol 2018;125(1):31–43.
- Zhang J, Jiang H, Sun M, Chen J. Association between periodontal disease and mortality in people with CKD: a meta-analysis of cohort studies. BMC Nephrol 2017;18(1):269.
- Lira e Silva JA, Bernardino Í de M, da Silva JRC, Lima TLM de A, Soares R de SC, D'Ávila S. Quality of life related to oral health of patients undergoing hemodialysis and associated factors. Spec Care Dent. 2017;37(5):236–45.

- Rodakowska E, Wilczyńska-Borawska M, Fryc J, Baginska J, Naumnik B. Oral health-related quality of life in patients undergoing chronic hemodialysis. Patient Prefer Adherence. 2018;Volume 12:955–61.
- 15. Hebling E, Pereira AC. Oral health-related quality of life: a critical appraisalof assessment tools used in elderly people. Gerodontology. 2007;24(3):151–61.
- Sischo L, Broder HL. Oral Health-related Quality of Life. J Dent Res 2011;90(11):1264–70.
- 17. Nikbin A, Bayani M, Jenabian N, Khafri S, Motallebnejad M. Oral health-related quality of life in diabetic patients: comparison of the Persian version of Geriatric Oral Health Assessment Index and Oral Health Impact Profile: A descriptiveanalytic study. J Diabetes Metab Disord. 2014;13(1):32.
- Schmalz G, Patschan S, Patschan D, Ziebolz D. Oral health-related quality of life in adult patients with end-stage kidney diseases undergoing renal replacement therapy – a systematic review. BMC Nephrol 2020;21(1):154.
- Ausavarungnirun R, Wisetsin S, Rongkiettechakorn N, Chaichalermsak S, Udompol U, Rattanasompattikul M. Association of dental and periodontal disease with chronic kidney disease in patients of a single, tertiary care centre in Thailand. BMJ Open 2016;6(7):e011836.
- 20. Pakpour AH, Kumar S, Scheerman JFM, Lin C-Y, Fridlund B, Jansson H. Oral health-related quality of life in Iranian patients with spinal cord injury: A case–control study. Injury 2016;47(6):1345–52.
- 21. Ravaghi V, Farrahi-Avval N, Locker D, Underwood M. Validation of the Persian short version of the Oral Health Impact Profile (OHIP-14). Oral Health Prev Dent

2010;8(3):229–35.

- 22. Dinsa H, Nedi T, Berha AB. Concordance between modification of diet in renal disease, chronic kidney disease epidemiology collaboration and Cockcroft-Gault equations in patients with chronic kidney disease at St. Paul's hospital millennium medical college, Addis Ababa, Ethiopia. BMC Nephrol 2017;18(1):368.
- Ali A, Asif N, Rais Z. Estimation of GFR by MDRD Formula and Its Correlation to Cockcroft-Gault Equation in Five Stages of Chronic Kidney Disease. Open J Nephrol 2013;03(01):37–40.
- 24. Oduncuoğlu BF, Alaaddinoğlu EE, Çolak T, Akdur A, Haberal M. Effects of Renal Transplantation and Hemodialysis on Patient's General Health Perception and Oral Health–Related Quality of Life: A Single-Center Cross-Sectional Study. Transplant Proc 2020;52(3):785–92.
- Schmalz G, Kollmar O, Vasko R, Müller G, Haak R, Ziebolz D. Oral health-related quality of life in patients on chronic haemodialysis and after kidney transplantation. Oral Dis 2016;22(7):665–72.
- 26. Camacho-Alonso F, Cánovas-García C, Martínez-Ortiz C, De la Mano-Espinosa T, Ortuño-Celdrán T, Marcello-Godino JI, et al. Oral status, quality of life, and anxiety and depression in hemodialysis patients and the effect of the duration of treatment by dialysis on these variables. Odontology 2018;106(2):194–201.
- Pakpour AH, Kumar S, Fridlund B, Zimmer S. A case-control study on oral healthrelated quality of life in kidney disease patients undergoing haemodialysis. Clin Oral Investig [Internet]. 2015;19(6):1235–43.
- 28. Lopez-Pintor R, Lopez-Pintor L, Casanas E, De-Arriba L, Hernandez G. Risk

factors associated with xerostomia in haemodialysis patients. Med Oral Patol Oral y Cir Bucal 2017;22(2):e185-e192.

- Kahar P, Chapman C, Gupta J. Assessment of the Effect of Oral Health on Quality of Life and Oral-Health Indicators among ESRD Patients in Southwest Florida: A Pilot Study. Int J Dent 2019;2019:1–9.
- Oliveira LM, Sari D, Schöffer C, Santi SS, Antoniazzi RP, Zanatta FB.
 Periodontitis is associated with oral health-related quality of life in individuals with end-stage renal disease. J Clin Periodontol 2020;47(3):319–29.
- Ruospo M, Palmer SC, Craig JC, Gentile G, Johnson DW, Ford PJ, et al.
 Prevalence and severity of oral disease in adults with chronic kidney disease: a systematic review of observational studies. Nephrol Dial Transplant 2014;29(2):364–75.
- 32. Schmalz G, Dietl M, Vasko R, Muller G, Rothermund L, Keller F, et al. Dialysis vintage time has the strongest correlation to psychosocial pattern of oral healthrelated quality of life – a multicentre cross-sectional study. Med Oral Patol Oral y Cir Bucal 2018;23(6):e698-e706.
- Ruokonen H, Nylund K, Meurman JH, Heikkinen AM, Furuholm J, Sorsa T, et al. Oral symptoms and oral health-related quality of life in patients with chronic kidney disease from predialysis to posttransplantation. Clin Oral Investig, 2019;23(5):2207–13.
- Guzeldemir E, Toygar HU, Tasdelen B, Torun D. Oral Health–Related Quality of Life and Periodontal Health Status in Patients Undergoing Hemodialysis. J Am Dent Assoc 2009;140(10):1283–93.

35. Hajian-Tilaki A, Oliae F, Jenabian N, Hajian-Tilaki K, Motallebnejad M. Oral health-related quality of life and periodontal and dental health status in Iranian hemodialysis patients. J Contemp Dent Pract. 2014;15(4):482-90.

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Author information

Affiliations

Dental Research Centre, Department of Oral Medicine, Dental research Institute,

Isfahan University of Medical Sciences, Isfahan, Iran.

Adel Tabesh

Student Research Committee, School of Dentistry, Isfahan University of Medical

Sciences, Isfahan, Iran

Reyhane Narimany & Maryam Abtahi

Department of oral public health, Dental Implants Research Center, Dental Research Institute, School of Dentistry, Isfahan University of Medical Sciences,

Isfahan, Iran

Omid Fakheran

Contributions

AT designed and supervised the study, defined the analytic plan, and revised the manuscript. RN and MA conducted the study. RN wrote the article draft. OF revised the manuscript and contributed to the analytic plan. All authors read and approved the final manuscript.

Corresponding author

Correspondence to Reyhane Narimany.

Ethics declarations

Ethics approval

This study followed the Declaration of Helsinki on medical protocol and ethics. The regional Ethics Review Board of Isfahan University of Medical Sciences approved the study protocol. The ethical code is IR.MUI.RESEARCH.REC.1400.130.

Consent to participate

Informed written consent was taken from the participants, and a lack of willingness to participate did not affect the planned treatment of each patient.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.