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Permanent complications after thyroid surgery and effect of surgeon volume

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Abstract

Introduction: Thyroidectomy is a surgical method for the management of benign and malignant thyroid disease. Thyroidectomy may cause significant complications including hypocalcemia and recurrent laryngeal nerve injury. Permanent complications after thyroid surgery pose significant costs for healthcare system, as patients require lifelong alternative treatments and healthcare facilities.
Objectives: The purpose of this study was to evaluate the incidence and risk factors for permanent complications following thyroidectomy.
Patients and Methods: A total of 204 consecutive patients who underwent thyroid surgery between 2017 and 2018 were included in this prospective study. The patients were followed for 12 months after surgery and clinical and biochemical data were recorded.
Results: The incidence of transient and permanent hypocalcemia was 46.8% and 6.38%, respectively. Transient hoarseness affected 30.3% of patients and 2.1% had recurrent laryngeal nerve paralysis as detected by video laryngoscopy 12 months after surgery. Surgeons volume was significantly related to the presence of permanent hypocalcemia ($P=0.003$). In comparison to high-volume-surgeons, intermediate-volume-surgeons had an odds ratio of 5.25 ($P=0.042$) for permanent complications.
Conclusion: Hypocalcaemia remained the most common long-term complication of thyroid surgery. High volume surgeons had lower complication rates and better outcomes. In this regard, methods for improving surgical performance are worthy of investigation.

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Introduction

Thyroidectomy is a surgical method for the management of benign and malignant thyroid disease (1). Thyroidectomy may cause significant complications including hypocalcemia, recurrent laryngeal nerve injury, Honor's syndrome, hematoma and infection (2). Hypocalcemia is a major complication of thyroidectomy characterized by symptoms ranging from tingling and numbness to seizures and tetany (3). Hypocalcemia increases hospitalization time and the number of outpatient visits and requires concise observations (4). Hypocalcemia is caused by hypoparathyroidism, the result of devascularization and ischemia of the parathyroid glands or their removal or damage during surgical procedures (5). Another major complication of thyroidectomy is recurrent laryngeal nerve injury which causes a paresis or palsy of the vocal cord that may result in postoperative dysphonia with dyspnea (6).

There is controversy about the precise definition of transient and permanent complications after thyroidectomy. Some studies use six months after thyroid surgery as the cut-off time to distinguish between transient and permanent complications (7-9) while others recommend 12 months (10, 11). Permanent complications after thyroid surgery pose significant costs for healthcare system, as patients require lifelong alternative treatments and healthcare facilities. Furthermore, these complications influence an individuals' life in negative manner regarding quality of life and social activity performances (12-14). Thus, it is important to identify potential risk factors that can predict the likelihood of permanent complications.

Objectives

The aim of this study was to examine risk factors related to surgery, diseases, patient characteristics as well as surgeon performance that may be associated with permanent complications after thyroid surgery. Moreover, to the best of our knowledge, there

Key point

Thyroidectomy is a surgical method for the management of benign and malignant thyroid disease. Thyroidectomy may cause significant complications including hypocalcemia, recurrent laryngeal nerve injury, Honor's syndrome, hematoma and infection. Permanent complications after thyroid surgery pose significant costs for healthcare system, as patients require lifelong alternative treatments and healthcare facilities. Our study showed that hypocalcemia remained the most common long-term complication of thyroid surgery among Iranian patients. More experienced surgeons are less likely to have complications following surgery. In this regard, methods for improving surgical performance are worthy of investigation.

is no published data on the rates and risk factors related to long-term complications in Iranians undergoing thyroid surgery.

Patients and Methods

Study design

This cohort study was conducted in Isfahan, a large urban area located in the central of Iran. A total of 204 patients older than 18 years who underwent thyroid surgery at medical educational centers of Al-Zahra and Kashani hospitals in Isfahan between March 2017 and March 2018 were enrolled. Clinical data are collected for all patients by continuous enrollment. The patients were examined before surgery, and the patient's demographic characteristics, medical history, and indication for thyroid surgery were recorded. A general examination and measurements of height and weight were conducted. These patients were excluded if they had a history of hypocalcemia, vocal cord paralysis, Horner's syndrome, trachea injury, esophagus injury or thyroid surgery. All patients were followed three, six, and twelve months after surgery and possible complications, including hoarseness and vocal cord paralysis, hypocalcemia, tracheal injury, Horner's syndrome, and esophageal injuries, were assessed and recorded.

The corrected levels of total calcium for albumin concentration below 8.5 mg/dL were considered as hypocalcemia. Hypocalcemia that continued for more than 12 months and required treatment, supplements of calcium and active vitamin D, was classified as permanent hypoparathyroidism. The term of hoarseness was conducted to describe any change in voice quality. Examination by otolaryngologists was conducted on patients with hoarseness for more than 12 months to assess the vocal cord mobility.

The examination included visual inspection and video laryngoscopy. Nerve palsy that continued for more than 12 months was labeled as permanent recurrent laryngeal nerve palsy.

Independent factors that were assessed including (a) patient demographics: gender, age (<40, 40–60, >60 years old); (b) body mass index (BMI) of patients, BMI was calculated as weight in kg divided by squared height in meters. Underweight, normal weight, overweight and obese were defined as <18.5 kg/m^2, 18.5 –24.9 kg/m^2, 25–29.9 kg/m^2 and ≥ 30 kg/m^2, respectively; (c) past-medical history of disease including diabetes, hypertension, hyperlipidemia, ischemic heart disease, chronic obstructive pulmonary disease and cancer; (d) indication of surgery(multinodular goutier, graves' disease, suspicious fine-needle aspiration for malignancy and medullary thyroid carcinoma); (e) type of surgery (lobectomy, subtotal thyroidectomy, near total thyroidectomy and total thyroidectomy with and without lymph node dissection); (f) length of hospitalization after surgery (≤3 days , >4 days); (g) post-surgery pathological analysis (benign, differentiated thyroid carcinoma and undifferentiated thyroid carcinoma) and (h) volume of surgeon that was classified on the basis of the number of thyroid surgery performed per year by a surgeon as low-volume (lesser than 10 thyroid surgery/year), intermediate volume (10–99 thyroid surgery/year), and high-volume (more than 99 thyroid surgery/year).

Statistical analysis

Obtained data were entered to SPSS version 20 (IBM, USA). *P* value of less than 0.05 was considered as significant level. Descriptive data were presented in mean and percentages. Student's *t* test was conducted for comparison between genders. The Fisher's exact test and chi-square were employed to compare differences between groups. Logistic regressions were employed to identify the independent risk factors for permanent complications.

Results

The current prospective study followed up 204 patients (81.9% females and 18.1% males) who underwent thyroidectomy. Mean (standard deviation) of the age and BMI at baseline were 41.2 (13.4) (years) and 25.30 (3.6) (kg/m^2), respectively. Table 1 presents baseline characteristics by gender.

In the early phase after surgery, 111 (54.4%) patients developed hypocalcaemia (41.4% [n = 46] on the first day, 54.9% [n = 61] on the second day, and 3.6% [n = 4] on the third day) and 68 (33.3%) developed hoarseness. There were no records of esophageal injury, Horner's syndrome, or tracheal injury. At the end of study, 10 patients lost follow-up and six patients (4 females and 2 males) died, while 188 patients completed the follow-up. Around 16 (8.5%) patients developed permanent complications after the surgery. Twelve patients developed permanent hypocalcemia, while four had recurrent laryngeal nerve paralysis and permanent hoarseness in ENT (ear, nose and throat) examinations by laryngoscopy.

Table 2 presents data regarding the association between patients' basic information with transient hoarseness and permanent recurrent laryngeal nerve paralysis incidence after surgery. Based on this table, age, gender, BMI, past medical history of disease, etiology of thyroid surgery, type of thyroid surgery, surgeons' volume,

Table 1. Baseline data of patients that underwent thyroid surgery

Characteristics	Male (n=37)	Female (n=167)	Total (n=204)	*P* value
Age (year)	42.7±14.9	40.8±13.1	41.2±13.4	0.447
BMI (kg/m²)	25.0±2.9	25.4±3.7	25.3±3.6	0.573
Indication of surgery				
MNG	10 (27%)	50 (29.9%)	60 (29.4%)	0.319
Graves' disease	1 (2.7%)	0 (0%)	1 (0.5%)	
Suspicious FNA	22 (59.5%)	96 (57.5%)	118 (57.8%)	
MTC	2 (5.4%)	11 (6.6%)	13 (6.4%)	
Other	2 (5.4%)	10 (6%)	12 (5.9%)	
Type of surgery				
Lobectomy	2 (5.4%)	17 (10.2%)	19 (9.3%)	0.666
STT	1 (2.7%)	5 (3%)	6 (2.9%)	
NTT	4 (10.8%)	24 (14.4%)	28 (13.7%)	
TT	21 (56.8%)	95 (56.9%)	116 (56.9%)	
TT and LND	9 (24.3%)	26 (15.6%)	35 (17.2%)	

Data are shown as mean ± SD or No. (%).

BMI, Body mass index; MNG, multinodular goiter; FNA, Fine needle aspiration; MTC, Medullary thyroid cancer; STT, Subtotal thyroidectomy; NTT, Near total thyroidectomy; TT, Total thyroidectomy; LND, lymph node dissection.

hospitalization length, and pathology of resected thyroid tissue were not statistically associated with hoarseness after surgery ($P>0.05$). However, hypocalcemia, the other complication, was significantly associated with surgeon volume ($P=0.003$). Other variables were not significantly associated with hypocalcemia occurrence following the surgical procedure ($P>0.05$). Table 3 shows detailed data.

Logistic regressions were directed to identify the independent risk factors for permanent complications. This assessment revealed outcome is associated with volume surgeons. High volume surgeons had lower complication rates and better outcomes. In comparison to high volume surgeons, intermediate volume surgeons had an odds ratio of 5.25 ($P=0.042$) for permanent complications (Table 4).

Discussion

The current study evaluated long-term complications of thyroidectomy and related risk factors. We followed the patients for a year after thyroidectomy. Among 188 patients with complete follow-ups, 30.3% (n=57) had transient hoarseness and 2.1% (n=4) had recurrent laryngeal nerve paralysis on video laryngoscopy and were complaining of permanent hoarseness. One out of four patients with recurrent laryngeal nerve paralysis was rehabilitated by local injections. No statistical relationship was found between hoarseness and factors including gender, age, BMI, prior history of diseases, type of surgery, length of hospitalization, and pathology of surgically resected tissue.

The main etiology of post-thyroidectomy hoarseness is recurrent laryngeal nerve injuries (2). Unilateral recurrent laryngeal nerve injury causes dysphonia or hoarseness due to unilateral vocal cord immobility. This complication may be accompanied by dyspnea as well as swallowing disturbances, mainly with liquids, while its bilateral injury can lead to life-threatening dyspnea (15). Other explained causes for voice alteration after thyroidectomy are laryngeal edema, vocal fold bowing, extra-laryngeal strap muscles damage or temporary malfunction of these muscles, which impairs the larynx vertical movement (16). Different incidences for hoarseness have been reported. Temporary or transient recurrent laryngeal nerve paralysis rates ranged from 1.4% to 38.4%, with an average incidence of 9.8% (17). The frequency of permanent recurrent laryngeal nerve paralysis varied from 0% to 18.6% with an average of 2.3% (17). Borel et al observed a 20% rate for hoarseness in their study population in a short-term follow-up, while it declined to 5.7% six months after surgery (8). In addition, they assessed the relation between postoperative hoarseness and some risk factors such as age, gender, BMI, lymph node dissection, cancer, thyroiditis, thyroid weight, and permanent hypoparathyroidism. They found no statistical association (8). Park et al reported another study and identified age and extent of surgery as risk factors for postoperative hoarseness at a 2-week follow-up. Older patients and those who underwent total thyroidectomy had significantly more hoarseness at the 2-week follow-up than younger patients and those who underwent lobectomy, though there was no difference at the 3-, 6-, and 12-month follow-ups (10). In another study, Vicente et al reported the extent of thyroidectomy impacts voice outcomes in the early postoperative period. Hoarseness occurred in 46% and 14% of total thyroidectomy and partial thyroidectomy, respectively. The majority of voice disturbances resolve within 6 months with no difference among all groups (9).

Hypocalcemia is another main complication. In the 188 patients who completed the study, 46.8% (n=88) experienced transient and 6.38% (n=12) had permanent hypocalcemia. A risk assessment of hypocalcemia after thyroid surgery shows only a significant relationship with surgeons' volume. Hypocalcemia is the most common complication following thyroid gland surgeries. It usually occurs due to parathyroid glands manipulation during thyroid surgery including devascularization, removal or

Table 2. Frequency of transient hoarseness and permanent RLN paralysis regarding different variables

Variable	Healthy	Transient hoarseness	Permanent RLN paralysis	*P* value
Gender				
Male	24 (18.9%)	8 (14.0%)	1 (25.0%)	0.49*
Female	103 (81.1%)	49 (86.0%)	3 (75.0%)	
BMI (kg/m^2)				
Low	7 (5.5%)	4 (7.0%)	0 (0.0%)	0.36*
Normal	84 (66.1%)	31 (54.4%)	3 (75.0%)	
Overweight	30 (23.6%)	14 (24.6%)	1 (25.0%)	
Obese	6 (4.7%)	8 (14.0%)	0 (0.0%)	
Age (year)				
<40	75 (59.1%)	36 (63.2%)	1 (25.0%)	0.51*
40-60	41 (32.3%)	16 (28.1%)	3 (75.0%)	
>60	11 (8.7%)	5 (8.8%)	0 (0.0%)	
Past-medical history[a]				
No	86 (67.7%)	38 (66.7%)	2 (50.0%)	0.75*
Yes	41 (32.3%)	19 (33.3%)	2 (50.0%)	
Indication of surgery				
MNG	36 (28.3%)	19 (33.3%)	1 (25.0%)	0.83*
Graves' disease	0 (0.0%)	1 (1.8%)	0 (0.0%)	
Suspicious FNA	74 (58.3%)	32 (56.1%)	3 (75.0%)	
MTC	10 (7.9%)	3 (5.3%)	0 (0.0%)	
Other	7 (5.5%)	2 (3.5%)	0 (0.0%)	
Type of surgery				
Lobectomy	13 (10.2%)	4 (7.0%)	1 (25.0%)	0.78*
TT	70 (55.1%)	33 (57.9%)	3 (75.0%)	
STT	3 (2.4%)	3 (5.3%)	0 (0.0%)	
NTT	18 (14.2%)	9 (15.8%)	0 (0.0%)	
TT and LND	23 (18.1%)	8 (14.0%)	0 (0.0%)	
Volume of surgeon[b]				
Low	14 (11.0%)	6 (10.5%)	1 (25.0%)	0.45*
Intermediate	40 (31.5%)	24 (42.1%)	1 (25.0%)	
High	73 (57.5%)	27 (47.4%)	2 (50.0%)	
Length of hospitalization				
≤3	66 (52.0%)	29 (50.9%)	2 (50.0%)	0.98*
>4	61 (48.0%)	28 (49.1%)	2 (50.0%)	
Pathology				
Benign	57 (45.2%)	32 (56.1%)	2 (50.0%)	0.54*
DTC	68 (54.0%)	25 (43.9%)	2 (50.0%)	
UDTC	1 (0.8%)	0 (0.0%)	0 (0.0%)	

BMI, Body mass index; MNG, Multinodular goiter; FNA, Fine needle aspiration; MTC, Medullary thyroid cancer; TT, Total thyroidectomy; STT, Subtotal thyroidectomy; NTT, Near total thyroidectomy; LND, Lymph node dissection; DTC, Differentiated thyroid carcinoma; UDTC, Undifferentiated thyroid carcinoma. *Fisher's exact test.

[a] Past medical history**:** diabetes, hypertension, hyperlipidemia, ischemic heart disease, chronic obstructive pulmonary disease, smoking and cancer.

[b] Surgeon volume: low volume <10 thyroid surgeries/year; intermediate volume: 10-99 surgeries/year; high volume: >99 thyroid surgeries/year.

injury (5). Almquist et al showed 19.1% for the incidence of hypocalcemia at the start of the study, but it declined to 1.9% after two years of follow-up (5). Moreover, a systematic review reported the median (interquartile range) incidence of transient and permanent hypocalcaemia 27 (19–38) and 1 (0–3) percent, respectively (18).

Any damage to parathyroid glands, such as accidental removal or occlusion of blood vessels, has been presented abundantly as a cause of transient and permanent hypocalcemia (19). The site of inferior thyroid artery

Table 3. Frequency of transient and permanent hypocalcemia regarding different variables

Variable	Healthy	Transient	Permanent	*P* value
Gender				
Male	12 (13.6%)	19 (21.6%)	2 (16.7%)	0.38**
Female	76 (86.4%)	69 (78.4%)	10 (83.3%)	
BMI				
Low	5 (5.7%)	5 (5.7%)	1 (8.3%)	
Normal	50 (56.8%)	61 (69.3%)	7 (58.3%)	0.60*
Overweight	25 (28.4%)	17 (19.3%)	3 (25.0%)	
Obese	8 (9.1%)	5 (5.7%)	1 (8.3%)	
Age (year)				
<40	53 (60.2%)	53 (60.2%)	6 (50.0%)	
40-60	27 (30.7%)	28 (31.8%)	5 (41.7%)	0.94*
>60	8 (9.1%)	7 (8.0%)	1 (8.3%)	
Past medical history[a]				
No	60 (68.2%)	58 (65.9%)	8 (66.7%)	0.95**
Yes	28 (31.8%)	30 (34.1%)	4 (33.3%)	
Indication of surgery				
MNG	23 (26.1%)	29 (33.0%)	4 (33.3%)	
Graves' disease	1 (1.1%)	0 (0.0%)	0 (0.0%)	
Suspicious FNA	51 (58.0%)	50 (56.8%)	8 (66.7%)	0.87*
MTC	7 (8.0%)	6 (6.8%)	0 (0.0%)	
Other	6 (6.8%)	3 (3.4%)	0 (0.0%)	
Type of surgery				
Lobectomy	9 (10.2%)	8 (9.1%)	1 (8.3%)	
TT	46 (52.3%)	53 (60.2%)	7 (58.3%)	
STT	4 (4.5%)	2 (2.3%)	0 (0.0%)	0.87*
NTT	16 (18.2%)	10 (11.4%)	1 (8.3%)	
TT and LND	13 (14.8%)	15 (17.0%)	3 (25.0%)	
Volume of surgeon[b]				
Low	10 (11.4%)	9 (10.2%)	2 (16.7%)	
Intermediate	20 (22.7%)	37 (42.0%)	8 (66.7%)	0.003**
High	58 (65.9%)	42 (47.7%)	2 (16.7%)	
Length of hospitalization				
≤ 3	45 (51.1%)	47 (53.4%)	5 (41.7%)	0.74**
>4	43 (48.9%)	41 (46.6%)	7 (58.3%)	
Pathology				
Benign	43 (48.9%)	43 (49.4%)	5 (41.7%)	
DTC	45 (51.1%)	43 (49.4%)	7 (58.3%)	0.93*
UDTC	0 (0.0%)	1 (1.2%)	0 (0.0%)	

BMI, Body mass index; MNG, Multinodular goiter; FNA, Fine needle aspiration; MTC, Medullary thyroid cancer; TT, Total thyroidectomy; STT, Subtotal thyroidectomy; NTT, Near total thyroidectomy; LND, Lymph node dissection; DTC, Differentiated thyroid carcinoma; UDTC, Undifferentiated thyroid carcinoma.
* Fisher's exact test; ** Chi-square test.
[a] Past medical history**:** diabetes, hypertension, hyperlipidemia, ischemic heart disease, chronic obstructive pulmonary disease, smoking and cancer.
[b] Surgeon volume: low volume <10 thyroid surgeries/year; intermediate volume: 10-99 surgeries/year; high volume: >99 thyroid surgeries/year.

ligation has been reported as a cause of transient hypocalcemia after thyroidectomy in some studies (20) whereas others found no correlation with hypocalcemia (21,22). Chadwick reported that 7.3% of patients had persistent hypocalcaemia, which was associated with concomitant level VI lymph node dissection, re-operative surgery and individual surgeon performance (7). Similarly, other studies indicated that surgeons' experience and surgical technique are important factors in the etiology of transient and permanent hypoparathyroidism and were predictive of better outcomes (23,24).

Table 4. Logistic regression analysis for risk factors for permanent complications

Variable	Permanent complications		OR	95% Confidence Interval		*P* value
	Yes	No		Lower	Upper	
Gender						
Male	3 (20.0%)	34 (18.0%)		References		
Female	12 (80.0%)	155 (82.0%)	1.14	0.30	4.26	0.84
BMI						
Low	1 (6.7%)	10 (5.3%)		References		
Normal	10 (66.7%)	117 (61.9%)	1.17	0.13	10.09	0.88
Overweight	3 (20.0%)	49 (25.9%)	1.63	0.15	17.35	0.68
Obese	1 (6.7%)	13 (6.9%)	1.30	0.07	23.43	0.85
Age (year)						
40<	7 (46.7%)	112 (59.3%)		References		
40-60	7 (46.7%)	56 (29.6%)	0.50	0.16	1.49	0.21
>60	1 (6.7%)	21 (11.1%)	1.31	0.15	11.22	0.80
Past medical history[a]						
No	10 (66.7%)	122 (64.6%)		References		
Yes	5 (33.3%)	67 (35.4%)	1.09	0.36	3.34	0.86
Indication of surgery						
MNG	4 (26.7%)	56 (29.6%)		References		
Graves' disease	0 (0.0%)	1 (0.5%)	-	-	-	
Suspicious FNA	11 (73.3%)	107 (56.6%)	0.69	0.21	2.28	0.54
MTC	0 (0.0%)	13 (6.9%)	-	-	-	
Other	0 (0.0%)	12 (6.3%)	-	-	-	
Type of surgery						
Lobectomy	2 (13.3%)	17 (9.0%)		References		
TT	9 (60.0%)	107 (56.6%)	1.39	0.27	7.03	0.68
STT	0 (0.0%)	6 (3.2%)	-	-	-	-
NTT	1 (6.7%)	27 (14.3%)	3.17	0.26	37.77	0.36
TT and LND	3 (20.0%)	32 (16.9%)	1.25	0.19	8.25	0.81
Volume of surgeon[b]						
High	3 (20.0%)	105 (55.6%)		References		
Intermediate	9 (60.0%)	64 (33.9%)	5.25	1.98	27.89	0.042
Low	3 (20.0%)	20 (10.6%)	1.06	0.26	4.32	0.92
Length of hospitalization						
≤3	7 (46.7%)	92 (48.7%)		References		
>4	8 (53.3%)	97 (51.3%)	0.92	0.32	2.64	0.88
Pathology						
Benign	6 (40.0%)	88 (48.1%)		References		
DTC	9 (60.0%)	92 (50.3%)	0.69	0.23	2.03	0.51
UDTC	0 (0.0%)	3 (1.6%)	-			

BMI, Body mass index; MNG, Multinodular goiter; FNA, Fine needle aspiration; MTC, Medullary thyroid cancer; TT, Total thyroidectomy; STT, Subtotal thyroidectomy; NTT, Near total thyroidectomy; LND, Lymph node dissection; DTC, Differentiated thyroid carcinoma; UDTC, Undifferentiated thyroid carcinoma

[a] Past medical history**:** diabetes, hypertension, hyperlipidemia, ischemic heart disease, chronic obstructive pulmonary disease, smoking and cancer.

[b] Surgeon volume: low volume <10 thyroid surgeries/year; intermediate volume: 10-99 surgeries/year; high volume: >99 thyroid surgeries/year.

Conclusion

The incidence of permanent hypocalcaemia and recurrent laryngeal nerve paralysis after thyroid surgery was 6.38% and 2.1%, respectively. Hypocalcaemia remained the most common long-term complication of thyroid surgery. High volume surgeons had lower complication rates and better outcomes. In this regard, methods for improving surgical performance are worthy of investigation.

Limitations of the study

Any change in voice quality after surgery was considered as hoarseness and examination by otolaryngologists was

undergone on patients with hoarseness for more than 12 months to evaluate recurrent laryngeal nerve. Due to this, we described transient recurrent laryngeal nerve (RLN) palsy as hoarseness.

Authors' contribution

Conceptualization: RS and BAE.
Methodology: RS and BAE.
Investigation: RS, BAE, MA, AA, MK and MN.
Resources: RS, BAE, MA, AA, MK and MN.
Data curation: RS and BAE.
Writing—original draft preparation: RS and BAE.
Writing—review and editing: RS, BAE, Ma, AA, MK and MN.
Supervision: RS.
Project administration: RS, BAE, MA, AA, MK and MN.

Conflicts of interest

The authors declare that they have no competing interests.

Ethical issues

The research followed the tenets of the Declaration of Helsinki. The Ethics Committee of Isfahan University of Medical Sciences approved this study (Ethical code# IR.MUI.REC.1396.3.632). Accordingly, written informed consent was taken from all participants before any intervention. This study was extracted from the postdoctoral thesis of Bahareh Abrishamkar at this university (Thesis # 396632). Besides, ethical issues (including plagiarism, data fabrication and double publication) have been completely observed by the authors.

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