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# Effect of Early Mobilization on Hemodynamic Parameters of Patients Undergoing Sleeve Gastrectomy; A Randomized Clinical Trial

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## ABSTRACT

**Aims** Today, due to the failure of non-surgical methods in the treatment of obesity, surgical procedures such as sleeve gastrocetomy are used. Similar to other invasive interventions, sleeve gastrectomy causes an imbalance in hemodynamic parameters. The aim of this study was to determine the effect of early mobilization on hemodynamic parameters in patients undergoing sleeve gastrectomy.

**Materials and Methods** The present study is a clinical trial that was conducted in Shiraz in 2016. 88 patients were selected by convenience sampling method and divided into intervention and control groups, using randomized block design. Hemodynamic parameters including systolic and diastolic blood pressure and arterial oxygen saturation were recorded at the time of entering the ward, 6, 12, and 24 hours after departure. T-test, Mann-Whitney, Chi-square, repeated measures ANOVA, Kruskal-Wallis, Friedman test, and SPSS 21 software were used.

**Findings** The changes in systolic and diastolic blood pressure in the intervention group at each time interval after intervention were significantly different from that of the control group ($p>0.05$). Also, changes in arterial oxygen saturation in the intervention group except for the early mobilization, at other times compared to their starting point, were significantly different in comparison to the control group ($p>0.05$).

**Conclusion** The effect of early mobilization is greater compared to the conventional procedure of mobilization for the patients after sleeve gastrectomy surgery in the systolic and diastolic blood pressure and arterial oxygen saturation.

**Keywords** Early Mobilization; Motion; Hemodynamic Parameters; Sleeve Gastrectomy

## CITATION LINKS

[1] Excess skin after bariatric surgery - patients' perspective and objective measurements ... [2] National, regional, and global trends in adult overweight and ... [3] Global status report on noncommunicable diseases ... [4] Bariatric surgery: A systematic review and network meta-analysis ... [5] A prospective study of weight change and health-related quality ... [6] Screening and interventions for obesity in adults: Summary of the evidence for the US preventive services ... [7] Postbariatric surgery deaths, which fall under the jurisdiction of the coroner ... [8] Hospital complication rates with bariatric surgery ... [9] The second international consensus summit for sleeve gastrectomy, March ... [10] Weight loss, appetite suppression, and changes in fasting and postprandial ghrelin and peptide-YY levels after Roux-en-Y gastric bypass and sleeve gastrectomy: A prospective, double ... [11] Effects of positioning on patients back pain and comfort after coronary ... [12] Introduction to progressive ... [13] Clinical practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient - 2013 update: Cosponsored by American Association of Clinical Endocrinologists, the obesity society, and American Society for Metabolic ...[14] The quantity of early upright mobilisation performed following upper abdominal surgery is low: An ... [15] Comparison of early mobilization and diet rehabilitation program with conventional care after laparoscopic colon surgery: A prospective randomized ... [16] Efficacy and safety of postoperative early mobilization for chronic subdural hematoma ... [17] Physiological responses to the early mobilisation of the intubated, ventilated abdominal ... [18] The effect of early activity on patients outcome after open ... [19] Respiratory and hemodynamic responses to mobilization of critically ... [20] The effect of early mobilization on hemodynamic parameters in patients undergoing coronary ... [21] The effect of early mobility on respiratory indices of patients after ... [22] Effects of early mobilization combined with conventional physiotherapy treatment after 4 hrs of lobectomy on ...

## Introduction

Obesity is growing worldwide and today has become a dilemma for human life [1]. The highest rates of obesity are reported in the North America (31.1%), Australia (25.3%) and Western Europe (20.0%) [2]. According to the World Health Organization (WHO), 50% of the adult Iranian populations are obese and suffering from obesity [3]. About 2.5 million obesity-related deaths occur every year based on the available statistics worldwide [4]. In addition to the limitations in life, obesity causes some disorders, most notably cardiovascular, pulmonary, and metabolic disorders. Other complications of obesity in these patients include gastrointestinal, muscular, kidney, cancers, neurological complications, as well as gynaecologic complications. Losing weight in these patients can improve social performance and quality of life [5]. Different types of different treatments for obesity include medication, diet, behavior modification, exercise and surgery [6]. According to studies, non-surgical treatments have not been able to effectively and continuously reduce the weight of these patients. Due to the unsuccessful non-surgical methods for weight loss, surgical procedures are increasing, so it is important to choose the right type of treatment and reduce postoperative complications [7]. In the past two decades, bariatric surgeries have been the second most common abdominal surgeries [8].

In the sleeve gastrectomy surgery, by removing the large stomach flexure, the volume of the stomach is changed to 150-100 cc, and the rest is formed as a tube. In addition, serum ghrelin levels (appetite regulator) are reduced due to the removal of its producing cells [9, 10]. Bariatric surgeries in the world are rising due to the long-term effects of weight loss. In addition, they have been shown to be effective in treating obesity disorders. Sleeve gastrectomy has been used as the most commonly used surgery for obesity, since 2014 [1].

Despite the effectiveness of laparoscopic sleeve gastrectomy in weight loss in obese patients, it has its own complications, if not controlled and treated, lead to an increase in the cost of treatment in addition to increasing the hospital stay [9]. Complications of this surgery are divided into long-term and short-term categories. One of the short-term complications is the imbalance in hemodynamic parameters, including hypoventilation and decreased arterial oxygen saturation (SPO2) and an imbalance in blood pressure [7, 10].

Resting in the bed until the patient has sustained vital signs and consciousness is one of the healthcare methods usually performed post-operation, while the absolute and long rest is not based on scientific background and is mostly based on experience and taste [11]. Immobilization and prolonged rest in the bed increase the risk of many complications in the respiratory, cardiovascular, musculoskeletal, and skeletal systems and skin. Complications such as hypoventilation and respiratory problems, muscle aches and acute low back pain, the risk of blood clot formation and embolism, etc., are the result of immobility and rest in the bed [12]. Accordingly, patients undergoing long surgeries or those with high body masses undergoing sleeve gastrectomy are encouraged for early mobilization after surgery [13].

According to various relevant studies, following abdominal surgery, patients are encouraged to for early mobilization to reduce surgical complications on hemodynamic parameters [14]. Studying the effect of early mobilization in patients undergoing laparoscopic surgery showed that the patient's return to daily activities of life was reduced [15]. In a study by Kurabe *et al.*, a group of patients with early mobilization had less coronary arrhythmia, pneumonia, ileus, constipation, urinary tract infections, stroke, and seizure compared with the control group [16]. The findings of the study by Zafiropoulos *et al.* showed that mobilization of patients has significantly improved the balance of respiratory and hemodynamic parameters [17]. Encouraging patients for early mobilization is one of the healthcare services by nurses to move into core activities is one of the main components of care that can improve gas metabolism, alveolar ventilation, increased cardiac output and cardiac contractility, return of venous blood and strengthen the heart muscle and ultimately reduce hospital stay [18].

The aim of this study was to determine the effect of early mobilization on hemodynamic parameters in patients undergoing sleeve gastrectomy.

## Materials & Methods

The present controlled clinical trial study was conducted in Shiraz in 2016. At the beginning of the study in data collection (from end of the June to the end of September of 2016), the number of samples needed for each group considering the possible falling was calculated 44 subjects for each group regarding the alpha of 0.01 (99% confidence level) and beta of 20% (80% test power). Then, referring to Ghadir Mother and Child Hospital in Shiraz affiliated to Shiraz University of Medical Sciences, among patients undergoing sleeve gastrectomy who had the inclusion criteria, including willingness in participating in the study, the written informed consent, the age range of 18-55 years, having a BMI of 30 or above, no history of respiratory disorder, no history of mental disorders, no use of cigarettes and narcotics, 88 subjects were selected by available sampling method. Using random block assignment, they were divided into intervention and control groups (each group=44 subjects). Exclusion criteria

included no musculoskeletal pain due to surgical procedures and postoperative gastric leak after gastric bypass, which were not observed in any of the research samples. The samples were collected and their demographic and field characteristics including age, sex, BMI and their hemodynamic parameters, including systolic blood pressure, diastolic blood pressure and arterial oxygen saturation were measured and recorded by the SAADAT Vital Signs Monitoring Device (Pooyandegan; Iran). It is carefully made through relevant processes in the Ministry of Health and Medical Education, the Organization for Standardization and Quality Control and the International Organization for Standardization (ISO), and is being used in health centers.

The control group was treated as the patients undergoing surgery. Accordingly, after transferring to the ward, they were mobilized once for an average of 6 h on the first day depending on the mental conditions and desire and they were encouraged for mobilization three times a day on the second day. The early mobilization group 4 h after transferring to the ward, their level of consciousness was first measured and then they sat at the edge of the bed for a long time. At this stage, patients still sat at the edge of the bed for 5 min, if their level of consciousness did not change.

At this stage, the level of consciousness and mental state of the patient was reexamined and after approving by the researcher and the research team, the patients were walking for 15 m around the bed then returned to the bed. Two h after the first mobilization, the patients sat at the bed edge for 5 min followed by 5 min of sitting in the chair and if confirmed by the researcher and the research team and also patient's tolerance, they walked in the ward for 5 min. while walking, the patient was cared to prevent a patient from falling. It was repeated from 6 am to 12 pm every four hours.

In this study, in addition to measuring hemodynamic parameters of all subjects after transferring to the ward, including systolic and diastolic blood pressure and arterial oxygen saturation, their values in the first mobilization, and also 6, 12, and 24 h after mobilization were also recorded.

The present study, all ethical considerations were observed, including obtaining the written informed consent from the subjects, making them assured of withdrawal from the study at any time, confidentiality of data and no deprivation of samples from standard treatment and care.

In order to study the consistency of the qualitative variables in the intervention and control groups at the beginning of the study, Chi-square test was used and also Independent T test or Mann-Whitney test were used to examine the homogeneity of quantitative variables based on data are normalized or not normalized. It is worth noting that systolic blood pressure had normal distribution, diastolic blood pressure was normalized using a Log base 10 and while reporting the results of the main values of diastolic blood pressure in the descriptive findings, the normalized values were used in inferential statistics tests. But despite using all of normalization techniques, arterial oxygen saturation did not have normal distribution. Accordingly, variance analysis with repeated measure was used for intra-group and intergroup comparison of systolic and diastolic blood pressure, considering all the assumptions. Also, due to the lack of normal distribution of arterial oxygen saturation, the Kruskal-Wallis test was used for its intergroup comparison and also Friedman test was employed for its intra-group comparison based on the groups. Data were analyzed by SPSS 21 software blind to the codes assigned to the intervention and control group.

## Findings

The mean age of participants was 35.0 ± 7.9 years and the mean BMI was 45.5±5.2 $g/m^2$, who underwent sleeve gastrectomy for an average of 157.8 ± 29.6 min in the hospital. They were kept at the recovery room for 90.3±35.2 min. After the surgery, the intervention group was mobilized from bed after the average of 248.1±20.6 min and the control group after 361±78 min following transferring to the ward.

At the baseline, there was no significant difference between the subjects in the intervention and control groups in the demographic variables, such as sex, marital status, education level and occupation (Table 1).

The subject in both groups were homogenized in terms of demographic variables, such as age, BMI, duration of surgery and duration of stay in the recovery room and dependent variable, including arterial oxygen saturation (Table 2), however the groups at the baseline were not homogenized for dependent variables, including the systolic and diastolic blood pressure ($p<0.05$). Accordingly, in order to eliminate the non-homogeneity of the predicate variables at the baseline, the values were reported as covariance and the results of the intergroup comparison were reported using ANOVA with repeated measures (Table 2).

Based on intergroup comparison, there was a significant difference between two groups in reduced systolic blood pressure ($p<0.05$; Table 3). However, its decrease was more considerable in the intervention group than the control group (Figure 1).

In addition, intra-group comparison showed that although diastolic blood pressure decreased significantly in the intervention group ($p <0.05$), but in the control group, there was no significant difference between the levels of diastolic blood

pressure in different times (p>0.05; Figure 2).

Intergroup comparison showed that there was a significant difference in the intervention group in arterial oxygen saturation at all measuring times, including the 6, 12 and 24 h after the first mobilization, except for the first mobilization compared with the control group (p <0.05).

According to the intra-group comparison, arterial oxygen saturation in both intervention and control groups was significantly increased (p<0.05), however, it was more considerable in the intervention group than the control group (Figure. 3).

**Table 1)** Chi-square test results and comparing the qualitative demographic variables of the patients undergoing sleeve gastrectomy surgery in the study groups at the baseline (44 subjects in each group; the numbers in parentheses are percentages)

| Qualitative variable | Intervention group | Control group | Total | $\chi^2$ | Two-tail P value |
|---|---|---|---|---|---|
| **Gender** | | | | | |
| Male | (36.4) 16 | 11 (25.0) | 27 (30.7) | 1.34 | 0.25 |
| Female | (63.6) 28 | (75.0) 33 | (69.3) 61 | | |
| **Marital status** | | | | | |
| Single | 19 (43.2) | 15 (34.1) | 34 (38.6) | 0.77 | 0.38 |
| Married | 25 (56. 8) | 29 (65.9) | 54 (61.4) | | |
| **Education** | | | | | |
| Below diploma | 3 (6.8) | 5 (11.4) | 8 (9.1) | 1.78 | 0.41 |
| Diploma | 11 (25.0) | 15 (34.1) | 26 (29.5) | | |
| Higher than diploma | 30 (68.2) | 24 (54.5) | 54 (61.4) | | |
| **Occupation** | | | | | |
| Unemployed | 9 (20.5) | 3 (6.8) | 12 (13.6) | 6.53 | 0.16 |
| Non-governmental | 7 (15.9) | 5 (11.4) | 12 (13.6) | | |
| Employee | 6 (13.6) | 14 (31.8) | 20 (22.8) | | |
| Housewife | 18 (40.9) | 18 (40.9) | 36 (40.9) | | |
| Student | 4 (9.1) | 4 (9.1) | 8 (9.1) | | |

**Table 2)** Comparison of the mean and mean rank of demographic and quantitative variables of patients undergoing sleeve gastrectomy surgery in the studied groups at the baseline

| Quantitative variable | Mean | Mean Rank | Statistic | Two-tail P value |
|---|---|---|---|---|
| **Demographic characteristics** | | | | |
| **Age, year** | | | | |
| Intervention group | 33.7±6.7 | - | 1.56 | 0.12* |
| Control group | 36.3±8.9 | | | |
| **BMI (kg/m²)** | | | | |
| Intervention group | 45.6±4.3 | - | -0.31 | 0.76* |
| Control group | 45.3±5.9 | | | |
| **Duration of surgery (min)** | | | | |
| Intervention group | 155.8±29.3 | 44.07 | -10.16 | 0.87** |
| Control group | 159.9±30.0 | 44.93 | | |
| **Duration of stay in the recovery room (min)** | | | | |
| Intervention group | 87.8±34.3 | 42.19 | -0.86 | 0.39** |
| Control group | 92.7±36.2 | 46.81 | | |
| **The dependent variables** | | | | |
| **Systolic blood pressure (mm Hg)** | | | | |
| Intervention group | 155.9±7.4 | - | -5.7 | 0.0001* |
| Control group | 144.2±11.4 | | | |
| **Diastolic blood pressure (mmHg)** | | | | |
| Intervention group | 96.3±7.1 | - | -5.4 | 0.0001* |
| Control group | 11.9±84.9± | | | |
| **Arterial oxygen saturation, %** | | | | |
| Intervention group | 87.6±2.8 | 46.18 | -0.63 | 0.53** |
| Control group | 88.2±1.8 | 42.82 | | |

*Independent t-test; ** Mann-Whitney test

**Table 3)** Intergroup and intragroup comparison of the homodynamic parameters of the patients undergoing sleeve gastrectomy surgery in the studied groups based on the time

| Variable | Immediately after mobilization from bed | 6 h after mobilization | 12 h after mobilization | 24 h after mobilization | Intragroup comparison | |
|---|---|---|---|---|---|---|
| | | | | | P value | F |
| **Systolic blood pressure (mmHg)** | | | | | | |
| Intervention group | 143.2±10.0 | 129.4±5.6 | 122.0±6.0 | 116.3±5.8 | 0.0001* | 335.8 |
| Control group | 136.5±12.2 | 133.9±9.8 | 131.6±11.7 | 130.4±10.3 | 0.0001* | 31.3 |
| Intergroup Comparison* | | | | | | - |
| P value | 0.0001 | | | | | |
| F | 18.14 | | | | | |
| **Diastolic blood pressure (mm Hg)** | | | | | | |
| Intervention group | 90.7±6.3 | 83.0±7.6 | 75.1±6.0 | 75.9±5.4 | 0.0001* | 118.6 |
| Control group | 80.6±11.5 | 80.4±8.6 | 81.0±11.2 | 80.5±7.9 | 0.12* | 1.9 |
| Intergroup Comparison* | | | | | | - |
| P value | 0.0001 | | | | | |
| F | Feb-36 | | | | | |
| **Arterial oxygen saturation, %** | | | | | **P value** | **$\chi^2$** |
| Intervention group | 90.5±2 | 92.6±1.5 | 94.2±1.4 | 95.5±1.5 | 0.0001*** | $\chi^2$=167.9 |
| Control group | 1.8±90.1 | 91.3±1.4 | 91.9±1.8 | 91.9±1.8 | 0.0001*** | $\chi^2$=84.2 |
| Intergroup Comparison** | | | | | | - |
| P value | 0.18 | 0.0001 | 0.0001 | 0.0001 | | |
| $\chi^2$ | 1-Aug | 13-Jun | 31-May | Jun-47 | | |

* ANOVA with repeated measures; ** Kruskal-Wallis test

***Friedman test

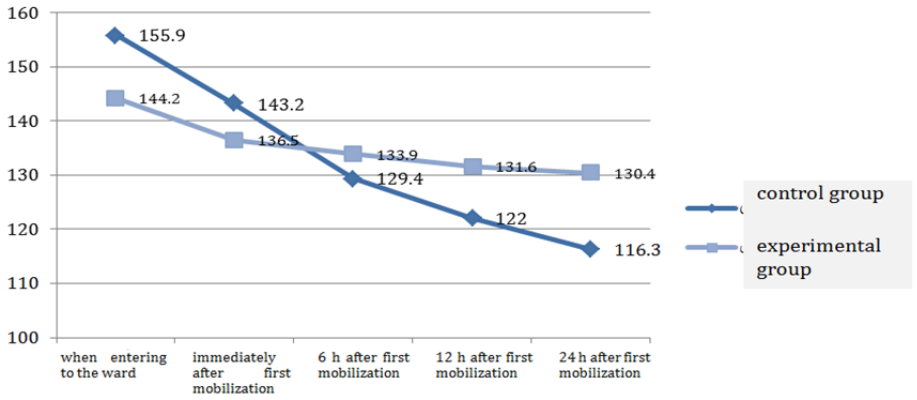


**Figure 1)** Mean systolic blood pressure changes in patients according to the time

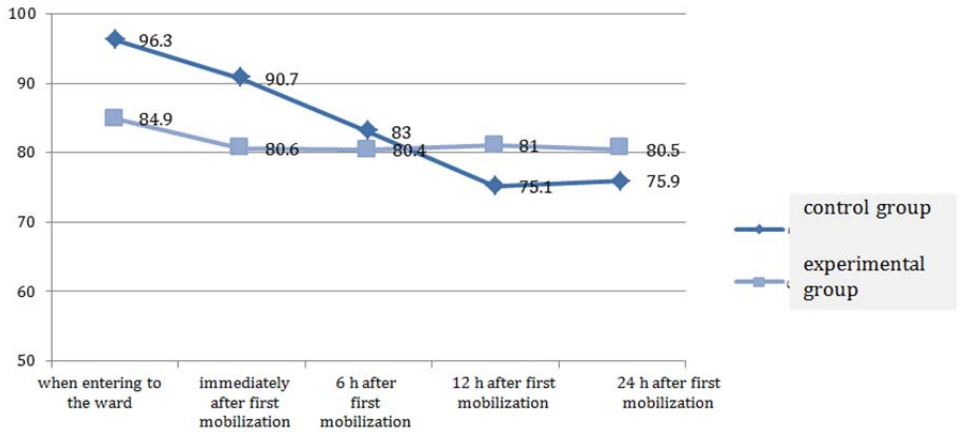


**Figure 2)** Diastolic blood pressure changes in patients based on the time

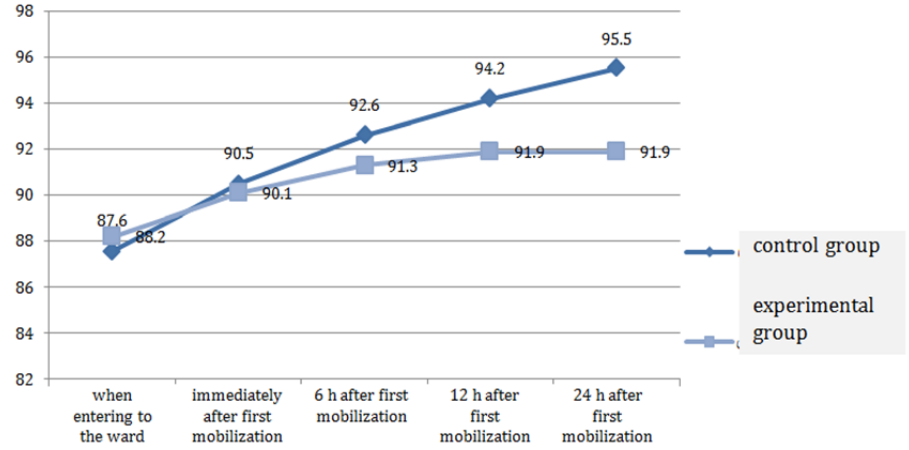


**Figure 3)** Average changes in arterial oxygen saturation in patients based on the time

## Discussion

The aim of this study was to determine the effect of early mobilization on hemodynamic parameters in patients undergoing sleeve gastrectomy.

Considering the obtained findings in significant statistical changes in systolic blood pressure, diastolic blood pressure, arterial oxygen saturation, the findings of this study were compared with the results of other similar studies as follows:

For systolic and diastolic blood pressure, according to a comparison between the present study and Genc *et al.* study, it was observed that although in the Genc *et al.* study, early mobilization caused a slight increase in systolic and diastolic blood pressure, however, this increase can not be considered as a negative hemodynamic factor due to early mobilization, since clinically this increase can be neglected and can not lead to acute changes in patients' clinical condition. Their study also generally suggests that early mobilization improves hemodynamic parameters, which is consistent with the present study [19], but the results of the study by Najaflu *et al.* and Ahmed *et al.*, are not consistent with this study, as early mobilization in the experimental group has led to an increase in systolic and diastolic blood pressure, which does not support the findings of this study [18, 20]. It can be due to the fact that early mobilization is associated with increased activity and since these patients underwent coronary artery bypass surgery has led to an increase in blood pressure. However, the patients in this study did not have cardiovascular problems and their hypertension was due to their surgery as laparoscopic type.

Comparison of the results of this study with other studies regarding arterial oxygen saturation showed that in the present study, arterial oxygen saturation in intervention groups was increased faster than control group and reached a balance, which is consistent with the results of Azarfarin study on the effect of early mobilization on respiratory parameters following open heart surgery. It was observed that arterial oxygen saturation in the experimental group was significantly increased compared with the control group [21]. The results of Genc *et al.* study are consistent with the results of this study, as mobilization of the obese patients in the intensive care units is associated with an increase in arterial oxygen saturation [19]. Unlike the above studies, which were consistent with the results of this study, Qasim *et al.* results are not in line with our results, since after early mobilization as a research intervention, no changes in arterial oxygen saturation in the studied groups were observed [22]. It can be concluded that in their study, the decrease in arterial oxygen saturation is due to the type of surgery (lobectomy), but the dependent variable of this study has changed due to the surgical procedure. According to the findings of the present study, it is suggested that nurses as an active participant in the health-care team working in various centers in the community with an important role in health promotion and prevention, using the results of this study, can recommend patients for early mobilization in patients undergoing sleeve gastrectomy surgery hospitalized in the wards.

Using medications or special interventions probably received by patients within 24 h after the intervention affecting hemodynamic parameters can be considered as the uncontrollable limitations of this study.

Considering the effect of early mobilization on hemodynamic parameters in patients undergoing sleeve gastrectomy surgery, it is suggested to study the effect of early mobilization in other operations affecting hemodynamic parameters.

## Conclusion

The effect of early mobilization is greater compared to the conventional procedure of mobilization for the patients after sleeve gastrectomy surgery in the systolic and diastolic blood pressure and arterial

oxygen saturation

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**Ethical permissions**

The present study was approved by the Research Ethics Committee (Ethics code: IR.YUMS.REC.1395.30) in the Iranian Registry of Clinical Trials (Code: IRCT2016051527904N1).

**Conflicts of interests**

None declared.

**Authors' contribution**

Mohammad Reza Koohpeyma (First author), writing the introduction/main researcher (25%); Seyyed Javad Sadat (Second author);Main researcher/writing the discussion (25%); Ardeshir Afrasiabifar (third author); Methodologist (25%); Mohammad Zoladl (fourth author), statistical analyst/writing the discussion (25%)

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