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The effects of Trendelenburg Position on Patient Care during Open Radical Prostatectomy: A Randomized Controlled Clinical Trial

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Abstract

Background: Low quality of surgical field is a common problem during open radical prostatectomy (ORP).

Aim: This study was performed aimed to survey the effects of Trendelenburg position on the quality of surgical field, mean arterial blood pressure (MABP), heart rate (HR), regional cerebral oxygen saturation (rSO2) and cognitive function in patients undergoing ORP.

Method: This randomized controlled clinical trial study was done on 60 patients candidates for ORP in Shahid Beheshti Hospital of Hamadan in 2022. Patients were selected by the convenience sampling method and were divided into two intervention and control groups using the random blocking method. In intervention group, patients were placed in a 15° head-down tilt before surgery. The control group was remained in a sleeping position on the back during surgery. The surgical field quality was assessed after surgery. The MABP, HR, and rSO2 were assessed after anesthesia induction, after positioning, and consecutively in 30-minute intervals during the surgery.

Results: The mean age was 60.93±4.24 years. A significant difference was found between the two groups regarding the surgeon's satisfaction with the surgical field quality (P=0.04). There was a significant difference between the two groups regarding surgery time (t=-3.00, P=0.004). No significant differences were found between the two groups in terms of MABP, HR, and rSO2 in either of the measurements (P>0.05).

Implications for Practice: It is recommended to use Trendelenburg position, as a safe position, to improve exposure to the pelvis during surgery.

Keywords: Head-down tilt, Hemodynamics, Intraoperative, Prostatectomy, Surgical field

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Introduction

Radical prostatectomy (RP) is an approved treatment for clinically localized prostate cancer (1, 2). RP is mainly performed as open surgery, typically via a retro pubic approach. The rate of ORP is still considerably high in the world due to the cost, the steep learning curve and difficult technique and availability of the minimal invasive techniques. Some evidences reported that perioperative adverse outcomes such as relative long operative time, blood loss, long hospitalization duration and major complications (pain, physical and cognitive dysfunction, fatigue, psychological distress and time to return to work) can be caused by performing ORP procedure in the supine position (3-5). Conditions that increase intra-abdominal pressure in the supine position decrease venous return and cardiac output (6). Pharmacological and non-pharmacological interventions are suggested to prevent these adverse outcomes (7). Today, the use of non-pharmacological interventions in health care services has been more emphasized that one of them is patient positioning during surgery (8). The goal of positioning is to facilitate the surgeon's technical approach while balancing the risk to the patient. Therefore, the positioning is critical for a safe surgery (6).

Patient safety, one of the most important aspects of the quality of health care services, refers to the prevention of patient's injury during surgery (9). Preventive activities for remaining patient safety due to correct positioning play an important part in operating room nurse cares (10). The supine position has been traditionally used from the first inception of ORP. However, Trendelenburg position has been proposed (11).

The Trendelenburg position fulfills different purposes, like treatment of venous air embolism (12), facilitation of intestinal operation for obese cases (13), and acute treatment of hypotension (14). The angle of the Trendelenburg position does not commonly exceed 30°(15). Trendelenburg position could further increase translocation of blood to the central compartment and is effective in the prevention of acute hypotension (16). Regarding Trendelenburg position outcomes during surgery in patients undergoing robotic-assisted prostatectomy, perioperative stability of hemodynamics is not influenced by the Trendelenburg position (17); Kalmar et al. showed that cerebral perfusion is not compromised with this position (18). Some studies also revealed that Trendelenburg position causes no difference in postoperative cognitive function and does not alter regional cerebral oxygen saturation (rSO2) during a surgical procedure (15, 19). Moreover, Pereira et al. indicated that Trendelenburg position is effective in improving pelvic exposure during surgery (11). However, there is a lack of study on the Trendelenburg position during open radical prostatectomy procedure. Therefore, the present study was performed with aim to evaluate the effects of Trendelenburg position on the surgical field quality, mean atrial blood pressure (MABP), heart rate, rSO2, and cognitive function in patients with ORP indications.

Methods

This two-group randomized clinical trial study was conducted in 2022 on the patients who were candidates for ORP in Shahid Beheshti Hospital of Hamadan, Iran. The sample size was determined according to a previous report by Zorko et al. (20). Considering the mean and standard deviation of blood pressure of patients ($\sigma=4$, $\mu_2-\mu_1=2.5$) and using the formula of comparing two means, with $\alpha=0.05$ and $\beta=0.1$, the minimum sample size required was set as twenty subjects per group.

However, predicting a possible sample loss and to increase the power of the statistical tests, a total of 60 cases were selected using convenience sampling and divided into two intervention and control groups, by block randomization with six blocks, using Random Allocation Software Version 1 (21). A random allocation sequence was generated by a person who was not involved in this study. Allocation into the groups was concealed using sequentially numbered, uniform, opaque, and sealed envelopes, which were numbered from one onwards. Envelope No. 1 was given to the first participant; this process continued until all participants were recruited. No participant was excluded from the study during the follow-up in either of the groups. Therefore, the final analysis was carried out on 60 patients (Figure 1). The inclusion criteria were: willingness to participate in the study, indications for prostatectomy based on the instructions of the European Association of Urology (EAU) regarding prostate cancer. American Society of Anesthesiologists (ASA) grade I or II, no history of ischemic injuries or cerebrovascular hemorrhage, and no history of degenerative neurological diseases (Parkinson's and Alzheimer's disease) or intracranial pathologies.

Patients in the intervention group were placed in a 15° head-down tilt after general anesthesia induction, while cases of the control group remained in supine position during surgery. Premedication was done with midazolam (0.05 mg/kg), metoclopramide (0.1 mg/kg), and fentanyl (2 μg/kg). Propofol (150-200 μg) and atracurium (0.5 mg/kg) were used to induce general anesthesia. Anesthesia was maintained with N2O (60%) and isoflurane.

The demographic and clinical data questionnaire was developed with nine items including age, height, weight, history of diabetes, history of hypertension (HTN), ASA class, Hemoglobin, Hematocrit rates and total intra-operative blood loss. The Mini-Mental Status Examination (MMSE) was applied to assess the cognitive function score. The test is 30-point questionnaire that is used extensively in clinical and research settings (12). According to a study by Foroughan et al., this tool is both valid and reliable (r=0.84) for measuring cognitive function (22). Additionally, the surgical field quality was assessed using a researcher-made criteria depending on the surgeon's satisfaction with pelvic vision during the surgery on a three-point Likert scale, ranging from “high” (a surgical field maintaining adequate vision throughout the surgery) (2) to “low” (an invisible surgical field) (0). This test is designed based on the study of Mohseni et al (23). To survey the face validity, the level of difficulty and clarity of the items were examined by 10 surgeons and assistant surgeons. The appropriateness of the items of this test was confirmed by 10 surgeons and assistant surgeons by using the content validity index (CVI). At this stage, the CVI of each item (at least 0.9) was reported excellent. The intra-rater method was used to survey the reliability of the test, and it was completed by two surgeons for an open radical prostatectomy surgery. The reliability of the test was confirmed with a kappa coefficient of 0.84. Monitoring of the MABP and heart rate (HR) was done using a non-invasive blood pressure (NIBP) monitoring device and pulse oximetry, respectively. The bilateral cerebral

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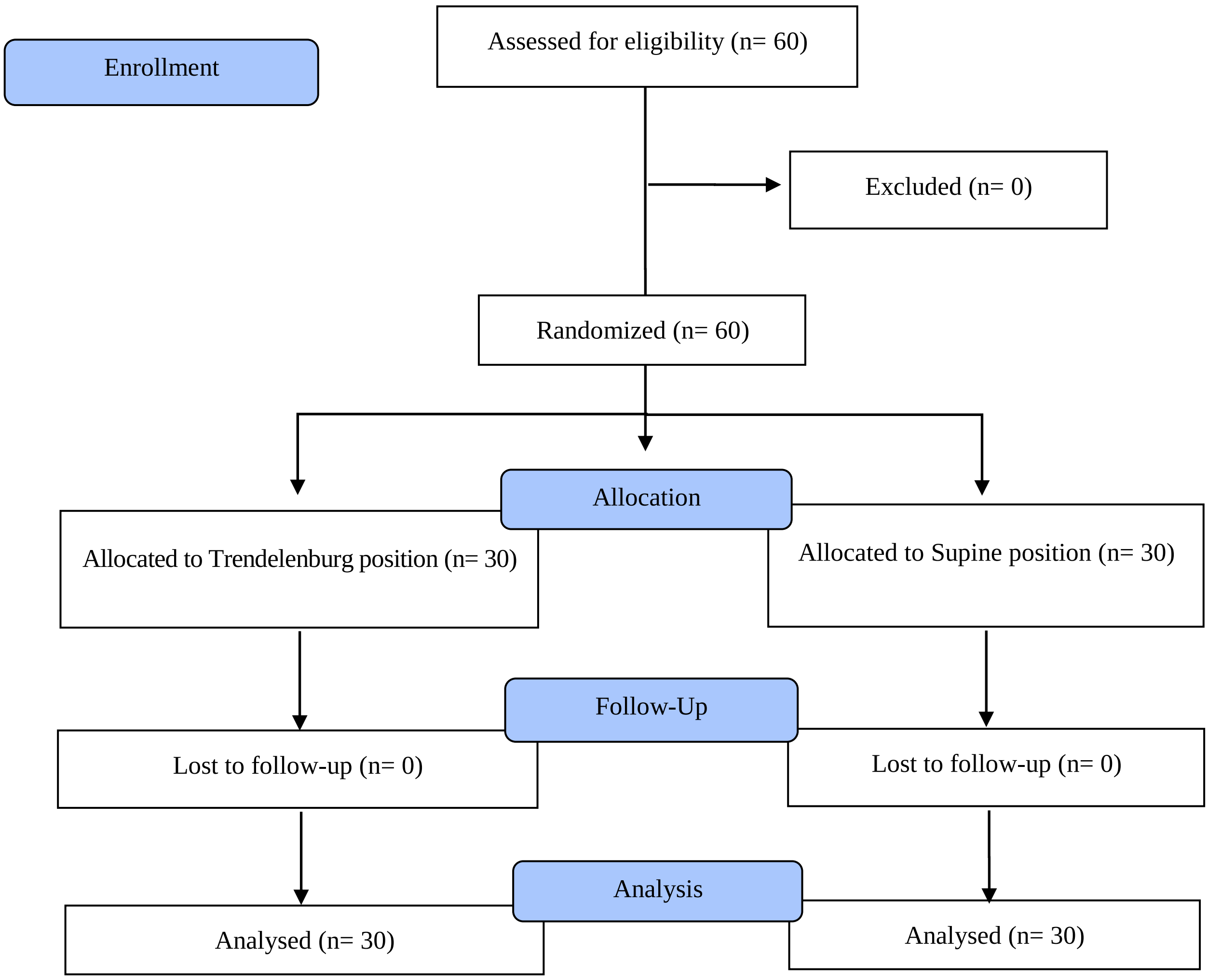

Figure 1. Consort flowchart diagram

oximetry sensors were located on the patient's forehead, and monitoring of rSO2 was continuously done by near-infrared spectroscopy (NIRS) and the INVOS Analytics Tool. A researcher-made checklist was used to document the patients' complications. First, MMSE was performed six hours before the surgery. Then, the demographic and clinical data questionnaire was completed for each patient. The hemodynamics (MABP and HR) and rSO2 were calculated and recorded before and after anesthesia induction, after positioning, and consecutively in 30-minute intervals during the surgery. The surgical field quality was assessed by a surgeon after the operation. All patients underwent MMSE within six hours after the surgery.

After collecting and coding the data, it was entered into the computer. After ensuring the accuracy of data entry, SPSS software (version 22) was utilized for statistical analysis. Descriptive statistics (mean, standard deviation, frequency, and percentage) and analytical tests, including the Fisher's exact test, Chi-square test, independent t-test, paired tests, and repeated measures analysis of variance (RMANOVA) were used. A 95% confidence interval (α=5%) was considered for the performed tests. P<0.05 was considered statistically significant.

Results

A total of 60 patients were enrolled in the research. No individual was excluded from the study because of eligibility or during follow-up. Thus, the final analysis was carried out for all participants (Figure 1). The patients' mean age was 60.93±4.24 years, and mean body mass index (BMI) was 24.76±3.58 kg/m^2. The two groups were not significantly different considering age, history of diabetes, history of HTN, ASA class, weight, height, Hemoglobin, Hematocrit rates and total intra-operative blood loss (P>0.05) (Table 1).

Table 1. Participants' demographic and clinical characteristics in the intervention and control groups

Variable		Groups		Statistic test results
		Intervention n (%)	Control n (%)	
History of Diabetes	Yes	17 (56.7)	18 (60.0)	χ2 = 0.06, P = 0.793 [a]
	No	13 (43.3)	12 (40.0)	
History of HTN	Yes	14 (46.7)	15 (50.0)	χ2 = 0.06, P = 0.796 [a]
	No	16 (53.3)	15 (50.0)	
ASA class	I	7 (23.3)	5 (16.7)	χ2 = 0.41, P = 0.519 [a]
	II	23 (76.7)	25 (83.3)	
Age (Mean±SD)		61.16 ± 4.22	60.70 ± 4.32	t = 0.42, P = 0.674 [b]
Height (Mean±SD)		158.53 ± 5.33	161.20 ± 8.38	t = -1.47, P = 0.147 [b]
Weight (Mean±SD)		61.13 ± 5.71	64.86 ± 9.23	t = -1.88, P = 0.065 [b]
Hemoglobin (Mean±SD)		12.63 ± 1.06	12.71 ± 1.11	t = -0.29, P = 0.768 [b]
Hematocrit (Mean±SD)		39.23 ± 3.62	39.60 ± 3.29	t = -0.41, P = 0.683 [b]
Intra-operative blood loss (Mean±SD)		39.23 ± 3.62	39.60 ± 3.29	t = -1.75, P = 0.085 [b]
Duration of operation (Mean±SD)		176.0 ± 18.26	189.16 ± 15.59	t = -3.00, P = 0.004 [b]

[a] Chi-square test; [b] Independent t-test

According to Fisher's exact test, a significant difference was found between the two groups in terms of surgeon's satisfaction with the surgical field quality (P=0.04) (Table 2). Also, the result of independent t-test indicated significant difference between the two groups regarding surgery time

Table 2. Level of surgeon's satisfaction about a proper vision in surgery field and the mean scores of cognitive function before and after surgery between intervention and control groups

Variable		Groups		Statistic test results
		Intervention n (%)	Control n (%)	
Level of surgeon's satisfaction	Low	0 (0.0%)	4 (13.3%)	Fisher exact, P = 0.047 [a]
	Moderate	10 (33.3%)	14 (46.7%)	
	High	20 (66.7%)	12 (40.0%)	
Mean scores of cognitive function	6 h prior to surgery	1.11±24.26	1.30±24.40	t = -0.42, P = -0.42 [b]
	6 h after surgery	0.80±23.90	0.85±23.23	t = 3.1, P = 3.10 [b]

[a] Fisher exact; [b] Independent t-test

Table 3. Comparison of mean arterial blood pressure and heart rate between intervention and control groups in phases of the study

Variables	Phase	Intervention (Mean±SD)	Control (Mean±SD)	P-value (intragroup)
Mean arterial blood pressure	Before induction	90.40 ± 8.62	92.11 ± 5.56	0.365 [a]
	After induction	76.52 ± 7.81	75.07 ± 6.41	0.437 [a]
	After positioning	83.27 ± 8.48	80.22 ± 8.16	0.160 [a]
	30 min after positioning	80.45 ± 8.26	77.34 ± 4.44	0.075 [a]
	60 min after positioning	81.44 ± 6.66	78.27 ± 5.66	0.052 [a]
	90 min after positioning	82.66 ± 6.99	81.55 ± 6.01	0.512 [a]
	120 min after positioning	82.83 ± 7.73	81.38 ± 6.63	0.441 [a]
	P-value (intergroup)	<0.001 [b]	<0.001 [b]	
Heart rate	Before induction	71.06 ± 7.75	71.20 ± 6.22	0.942 [a]
	After induction	64.10 ± 9.82	61.00 ± 5.15	0.131 [a]
	After positioning	66.43 ± 7.22	64.33 ± 5.20	0.202 [a]
	30 min after positioning	65.96 ± 6.08	63.56 ± 4.46	0.087 [a]
	60 min after positioning	64.86 ± 5.44	63.06 ± 3.78	0.143 [a]
	90 min after positioning	65.20 ± 4.84	63.60 ± 3.67	0.155 [a]
	120 min after positioning	69.0 ± 6.17	70.83 ± 7.05	0.288 [a]
	P-value (intergroup)	<0.001 [b]	<0.001 [b]	

[a] Independent t- test; [b] RMANOVA

(t=-3.00, P=0.004) (Table 1).

The result of independent t-test indicated no significant difference regarding MABP between the two groups before the anesthesia induction (t=-0.91, P=0.365). The results of this test showed no significant differences between the two groups in either of the measurements (P>0.05) (Table 3). The RMANOVA test revealed a significant reduction in MABP during the study in both intervention and control groups (sphericity assumed, F=37.15, P<0.001).

The two groups were not significantly different regarding HR before anesthesia induction (t=-0.07, P=0.942). The independent t-test showed no significant difference regarding HR between the intervention and control groups in either of the measurements (P>0.05) (Table 3). The results of RMANOVA revealed a significant decline in HR both in the intervention and control groups during the study (sphericity assumed, F=20.20, P<0.001).

Moreover, the independent t-test results indicated no significant difference between the two groups in the left (t=1.36, P=0.178) and right (t=1.20, P=0.232) sides mean rSO2 before anesthesia induction. The results of this test showed no significant difference between the two groups in either of the measurements (P>0.05) (Table 4). The mean values of rSO2 in the intervention group reduced by

Table 4. Comparison of Mean rSO_2 (%)between intervention and control groups in phases of the study

Cerebral Hemisphere	Phase	Intervention (Mean±SD)	Control (Mean±SD)	P-value (intragroup)
Right	Before induction	74.26±3.16	73.13±4.04	0.232 [a]
	After induction	75.06±3.08	73.80±3.77	0.160 [a]
	After positioning	73.80±2.89	73.60±3.80	0.819 [a]
	30 min after positioning	74.16±3.20	73.63±3.73	0.555 [a]
	60 min after positioning	74.13±2.86	73.60±3.57	0.526 [a]
	90 min after positioning	74.40±2.97	73.66±3.52	0.388 [a]
	120 min after positioning	74.60±2.93	73.70±3.32	0.271 [a]
	P-value (intergroup)	<0.001 [b]	0.207 [b]	
Left	Before induction	74.43±2.92	73.20±4.00	0.178 [a]
	After induction	75.06±3.12	73.90±3.67	0.190 [a]
	After positioning	73.54±3.12	73.60±3.80	0.941 [a]
	30 min after positioning	74.23±3.11	73.53±3.72	0.433 [a]
	60 min after positioning	74.26±2.83	73.80±3.51	0.574 [a]
	90 min after positioning	74.56±2.84	73.66±3.47	0.277 [a]
	120 min after positioning	74.60±2.79	73.70±3.20	0.252 [a]
	P-value (intergroup)	0.024 [b]	0.923 [b]	

[a] Independent t- test; [b] RMANOVA

1.7% and 2.0% in the left and right sides after positioning compared to the post-anesthesia phase.
According to the independent t-test results, no significant difference was detected between the two groups in the cognitive function score at six hours before the surgery (t=-0.42, P=0.671). However, a significant difference was found between the two groups regarding the cognitive function score at six hours after the surgery (t=3.1, P=0.003). Therefore, the control group experienced more significant reduction in cognitive function (Table 2). On the other hand, the paired t-test results revealed no significant difference in the cognitive function score in the intervention group after the surgery compared to the preoperative period (t=1.61, P=0.118). There were no complications related to the position of surgery (e.g., neurological complications due to traction) in any of the groups during the study.

Discussion

This research aimed to survey the effects of Trendelenburg position on the surgical field quality, MABP, HR, regional cerebral oxygen saturation (rSO2) and cognitive function in patients undergoing ORP. The findings indicated the significant effect of Trendelenburg position on surgeon's satisfaction with the surgical field quality. Additionally, the results of the present study showed that Trendelenburg position caused no significant difference in the brain function after the surgery and did not change MABP or HR during ORP. Besides, the level of surgeon's satisfaction with the quality of surgical field was higher in the intervention group than the control group. This finding is congruent with another report, which showed that Trendelenburg position could improve exposure to the pelvis (11). The adequate quality of the surgical field in the intervention group can be explained by a better surgical field exposure during surgery.
According to the results of the present study, MAPB and HR did not differ significantly between the intervention and control groups. These hemodynamic responses are consistent with the results of previous studies (17, 24). In this regard, Laskov et al. indicated that Trendelenburg position could provide perioperative hemodynamic stability in patients undergoing minimally invasive hysterectomy (17). Moreover, Lestar et al. revealed that Trendelenburg position is an effective and safe position which can provide stable hemodynamics in cases subjected to robot-assisted radical laparoscopic prostatectomy (24). These consistent findings can be explained by the preventive effect of the Trendelenburg position on hypotension by increasing the venous return to the heart (25-27).
The results of the present study showed that in after positioning phase, the mean rSO2 decreased compared to the level measured after anesthesia induction in the intervention group. Also, Closhen et al. indicated a clinically irrelevant decline in cerebral oxygen saturation (< 5%) during robotic-assisted prostatic surgery in Trendelenburg position and suggested that this position could be acceptable for cerebral oxygenation (19). This decline in cerebral oxygen saturation can be explained by the impact of Trendelenburg position on intracranial pressure (ICP) by decreasing venous drainage from the cranium (28-31).
The findings of the current research showed that Trendelenburg position is a safe position with no significant negative effects on the cognitive function. This finding is in consistent with the results of another study reporting no significant adverse effects of cognitive function through intraoperative positioning (15); this could be a result of hemodynamic stability (MABP and HR) and maintenance of brain perfusion during surgery (18, 32).
One of the strengths of the present study was extensive review of the literature to investigate the influence of Trendelenburg position on surgical field in patients undergoing ORP. One of the limitations of this study was the small number of patients who were candidates for ORP. Moreover, blinding was not possible for the surgeons. So, study with large sample size was recommended to confirm the result.

Implications for practice

The main finding of the present study was that a 15-degree Trendelenburg position could be safe and effective in improving exposure to the pelvis during surgery and maintain stable hemodynamics (MABP and HR) in patients undergoing ORP. Further trials are recommended to survey the effect of Trendelenburg position on surgical field in other open surgeries for example hysterectomy.

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No. 140103171738) and was approved by the Institutional Review Board and the Research Ethics Committee of Hamadan University of Medical Sciences, Hamadan, Iran (IR.UMSHA.REC.1401.033). Also, this study was registered in the Iranian Registry of Clinical Trials (IRCT20220410054482N1). The authors would like to express their gratitude to the Deputy of Research of Hamadan University of Medical Sciences, Hamadan, Iran, and grateful assistance of all the patients who were recruited in this trial.

Conflicts of interest

The authors declared no conflict of interest.

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