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The Effect of Induction of Anesthesia in the Leg-Elevation Position and Head-Down Position Versus Supine Position on the Incidence of Post-Induction Hypotension in Non-Cardiac Surgery: A Randomized Controlled Trial

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Abstract

Background: Induction of general anesthesia is associated with hypotension in nearly 50% of surgical patients. Intraoperative hypotension leads to ischemia of vital organs and increases the risk of preoperative mortality; therefore, meticulous hemodynamic management to avoid pre-incision hypotension is essential to avoid serious outcomes.

Various methods are used for the prevention of post-induction hypotension such as preoperative fluid loading and vasopressors. The use of positioning protocols to augment venous return would provide a non-pharmacological option for maintaining the hemodynamic profile without the need for excessive fluids and vasopressors.

Aim of Study: In this study, we aimed to evaluate the efficacy of leg-elevation position and head-down position compared to supine position during induction of anaesthesia in reducing post-induction hypotension.

Patients and Methods: This study included adult patients scheduled for elective noncardiac surgery under general anaesthesia. Before induction of anesthesia, patients were randomly allocated into three groups who started induction of anesthesia in either supine position, leg-elevation position, or head-down position. Blood pressure and heart rate were recorded at 1-minute intervals after induction of anesthesia till 15-minutes after intubation. Our primary outcome was the incidence of post-induction hypotension (defined as systolic blood pressure <80% of the baseline reading). Other outcomes included systolic blood pressure, heart rate, and norepinephrine consumption.

Results: One-hundred and twenty-one patients were available for the final analysis. The incidence of post-induction hypotension was lower in each of leg-elevation group (18/41 [44%] patients) and head-down group (16/40 [40%] patients) compared to the control group (32/40 [80%] patients) (*p*-values <0.001 and <0.001) without significant difference between the two former groups (*p*-value=0.823). Furthermore, the norepinephrine consumption and the duration of hypotension were lower in the leg-elevation group and the head-down group in comparison to the control group.

Conclusion: Compared to the supine position, induction of general anesthesia in either leg-elevation position or head-down position reduced the incidence of post-induction hypotension and the need for vasopressor administration in adult patients undergoing elective non-cardiac surgery.

Key Words: *Head-down – Leg-elevation – Supine – Postinduction – Hypotension – Noncardiac surgery.*

Introduction

INDUCTION of general anesthesia is associated with hypotension in nearly 50% of surgical patients **[1,2]**. Intraoperative hypotension leads to ischemia of vital organs and increases the risk of preoperative mortality **[3-5]**. The risk of preoperative morbidity and mortality increases with the magnitude and duration of blood pressure reduction **[5]**; however, it had been reported that the risk of postoperative myocardial injury and kidney injury is present even with short periods of hypotension **[6]**. The critical period between induction of anesthesia and the surgical skin incision is considered the most critical period with the highest risk of severe hypotension **[7]**; therefore, meticulous hemodynamic management to avoid pre-incision hypotension is essential to avoid serious outcomes **[7,8]**.

Many factors contribute to post-induction hypotension such as reduced sympathetic tone and venous return due to the vasodilator effect of induction agents positive pressure ventilation, hypovolemia, and lack of surgical stimulation. Various methods are used for the prevention of post-induction hypotension such as preoperative fluid loading and vasopressors. Hypovolemia is one of the risk factors for

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hypotension during induction of anesthesia [9,10]; therefore, augmentation of the venous return would improve cardiac output and avoid serious hypotension. The use of positioning protocols to augment venous return would provide a non-pharmacological option for maintaining the hemodynamic profile without the need for excessive fluids and vasopressors. The possible hemodynamic benefits of providing leg-elevation position or head-down position during induction of general anaesthesia were not investigated during induction of anesthesia in non-cardiac surgery.

We aimed to evaluate the effect of leg-elevation position and head-down position in relation to the supine position during induction of general anesthesia on the incidence of post-induction hypotension.

Material and Methods

A randomized controlled study was conducted in Kasr Al-Ainy Hospital, Cairo University. Enrolment into the study started after Research Ethics Committee approval (N-116-2018) and clinical trial registration (NCT03996213) from July to November 2019. Written informed consent was obtained from all participants before the enrolment.

Inclusion criteria:

- Adult patients (above 18 years).
- ASA I-II, scheduled for elective noncardiac surgery under general anesthesia.

Exclusion criteria:

- Patients with cardiac morbidities (impaired contractility with ejection fraction <50%, heart block, arrhythmias, tight valvular lesions).
- Patients at increased risk of aspiration (Emergency procedures with inadequate fasting time, body mass index ≥40kg.m^{-2}, gastroesophageal reflux disease, gastrointestinal obstruction).
- Pregnant patients were also excluded from the study.

A computer-generated random sequence was used to achieve 1:1:1 random allocation into the three study groups. The random sequence was generated by a statistician. One-hundred and twenty-three opaque envelopes containing details of the patient's assigned position during the induction of the anesthesia were prepared by a research assistant who was not included in the study.

Upon arrival to the operating room, routine monitors (electrocardiogram, pulse oximetry, and non-invasive blood pressure monitor) were applied. Routine pre-medications (ranitidine 50mg and midazolam 3-5mg) were administrated after securing intravenous access. Baseline systolic blood pressure (SBP) was obtained in the supine position as an average of three readings before induction of general anesthesia.

Before induction of anesthesia, the attending anesthetist was responsible for opening the envelope and putting the patient into the assigned position according to the group randomization:

- Supine group (n= 41): Received general anesthesia in the regular supine position.
- Head-down group (n=41): Received general anaesthesia in the head-down position. The head-down position was achieved by 30-degree tilting of the whole operating Table (1) minute before induction of anesthesia.
- Leg-elevation group (n=41): Received general anaesthesia in the leg-elevation position.

The leg-elevation position was achieved by raising the patient's legs by 30cm using two standard pillows positioned under the heels while keeping the operating table in the neutral position [11].

Patients were positioned 1-minute before induction of anesthesia and were maintained in the assigned position for 15-minutes or till skin incision.

Induction of anaesthesia was achieved using fentanyl (2mcg.kg^{-1}), propofol (2mg.kg^{-1}), and atracurium (0.5mg.kg^{-1}). An endotracheal tube was inserted after 3 minutes of mask ventilation. Anaesthesia was maintained by isoflurane (1-1.5%) and atracurium 10mg increments every 20 minutes. Ringer lactate solution was infused at a rate of 2mL.kg^{-1}.hour^{-1}.

Any episode of hypotension (defined as SBP <80% of the baseline reading) was managed by 10 mcg norepinephrine. If the hypotensive episode persisted for 2 minutes, another bolus of norepinephrine was administered.

Our primary outcome was the incidence of post-induction hypotension (defined as SBP <80% of the baseline reading during the period from induction of anesthesia until skin incision).

Other outcomes included the incidence of severe post-induction hypotension (defined SBP <60% of the baseline reading during the period from induction of anesthesia until skin incision), the incidence of bradycardia (defined as heat rate <55bpm), SBP (recorded as a baseline, then at 1-minute intervals starting from the baseline preoperative reading until 15-minutes post-induction), heart rate (recorded as a baseline, then at 1-minute intervals starting from the baseline preoperative reading until 15-minutes post-induction), total norepinephrine consumption, and preoperative shock index (calculated as the baseline SBP/baseline heart rate.

Sample size:

In a pilot study on 7 patients, the incidence of post-induction hypotension during the supine position was 70% (unpublished data). At an alpha error of 0.05, we calculated that 98 patients would give

80% power to detect a 30% absolute reduction in the incidence of hypotension in the treatment group. However, to allow the comparisons between the control group and each treatment group, an adjusted P (Bonferroni correction) of 0.025 was set for the primary outcome and the required sample size increased to 116 patients (39 patients per group). The number of prepared envelopes was 123 (41 envelopes per group) to compensate for possible drop-outs. The sample size was calculated using Med Calc Software version 14 (Med Calc Software bvba, Ostend, Belgium).

Statistical analysis:

Statistical package for social science (SPSS) software, version 21 for Microsoft Windows (Armonk, NY: IBM Corp) was used for data analysis. Categorical data were presented as frequency (%) and were analysed using the chi-squared test or fisher's exact test as deemed appropriate. Continuous data were checked for normality using the Shapiro-Wilk test and were presented as mean ± standard deviation or median (quartiles) as appropriate. Continuous data were analysed using one-way analysis of variance (ANOVA) with the post hoc Tukey modification (for normally distributed data) and using the Kruskal-Wallis test on ranks (for skewed data). The two-way ANOVA test was used for the analysis of repeated measures to evaluate position (between-groups factor) and time (repeated measures). Post-hoc pairwise comparison was performed using the Bonferroni test. A *p*-value less than 0.05 was considered statistically significant.

Results

We screened 130 patients for eligibility. Seven patients were excluded for not meeting the study's inclusion criteria. One-hundred and twenty-three patients were randomized to one of the three study groups and 121 of the patients were available for the final analysis. (Fig. 1).

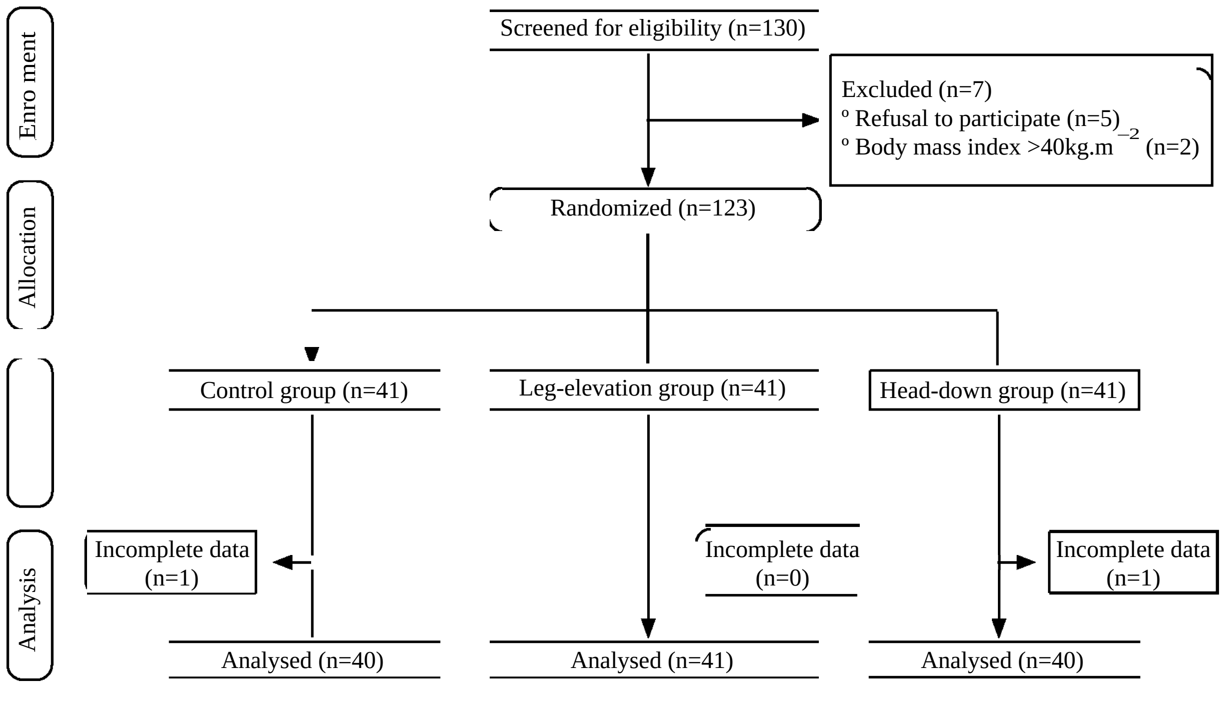

Fig. (1): Patients' enrolment flow chart.

Demographic data and baseline hemodynamics were comparable between the three groups. (Table 1).

The incidence of post-induction hypotension was lower in each leg-elevation group (18/41 [44%]) and head-down group (16/40 [40%]) compared to the control group (32/40 [80%]) ± (*p*-values: 0.001 and 0.001). Furthermore, norepinephrine consumption was lower in both the leg-elevation group and head-down group in comparison to the control group, *p*-values <0.001 and <0.001. The incidence of hypotension and norepinephrine consumption were comparable between the leg-elevation group and head-down group, *p*-values: 0.823 and 0.756, respectively. The duration of hypotension was shorter in the leg-elevation group and head-down group compared to the supine group, *p*-values: 0.012 and 0.008, respectively. The incidence of severe hypotension was comparable among the three study groups. The incidence of bradycardia was lower in the leg-elevation group in relation to the control group, *p*-value=0.035. (Table 2).

Table (1): Demographic data and baseline hemodynamic characteristics. Data presented as mean ± standard deviation, median (quartiles), and frequency (%).

	Control group (n=40)	Leg elevation group (n=41)	Head-down group (n=40)	*p*-value
Age (years)	34±8.8	30±9	34±8.8	0.112
Weight (kg)	77 (64, 86)	77 (61, 85)	75 (70, 88)	0.624
Body mass index (kg.m^{-2})	27±4.4	27±4.9	28±4	0.671
Male sex	18 (45%)	21 (51%)	19 (48%)	0.853
Baseline SBP (mmHg)	123±14	121±10	123±11	0.700
Baseline heart rate (bpm)	92±16	87±16	89±10	0.282

SBP: Systolic blood pressure.

Table (2): Intraoperative outcomes. Data presented as median (quartiles) and frequency (%).

	Control group (n=40)	Leg elevation group (n=41)	Head-down group (n=40)	*p*-value
Incidence of hypotension	32 (80%)	18 (44%)*	16 (40%)*	<0.001
Incidence of severe hypotension	3 (8%)	2 (5%)	1 (3%)	0.588
Incidence of bradycardia	13 (33%)	5 (12%)*	6 (15%)	0.047
NE consumption (mcg)	25 (10, 40)	0 (0, 20)*	0 (0,10)*	<0.001

*Denotes significance in relation to the control group. NE: Norepinephrine.

SBP readings were comparable among the 3 study groups except for the first 2 minutes post-induction as well as 4-,6- and 7-minutes post-intubation where the blood pressure readings were lower in the control group in comparison to the head-down group. SBP 1-minute post-intubation increased in relation to the baseline reading in both leg-elevation group and head-down group. SBP readings were maintained for 1-minutes post-intubation in the control group, 2- and 3-minutes post-intubation in the leg-elevation group, and 1-minute post-induction as well as 2-,3- and 4-minutes post-intubation in the head-down group. The rest of the SBP readings were lower than that of the baseline reading. (Fig. 2).

All the heart rate readings were comparable between the 3 groups. In the control group, all heart rate readings decreased in relation to the baseline except at 1- and 2-minutes post-intubation; whilst, the heart rate was generally maintained in the leg-elevation group and the head-down group. (Fig. 3).

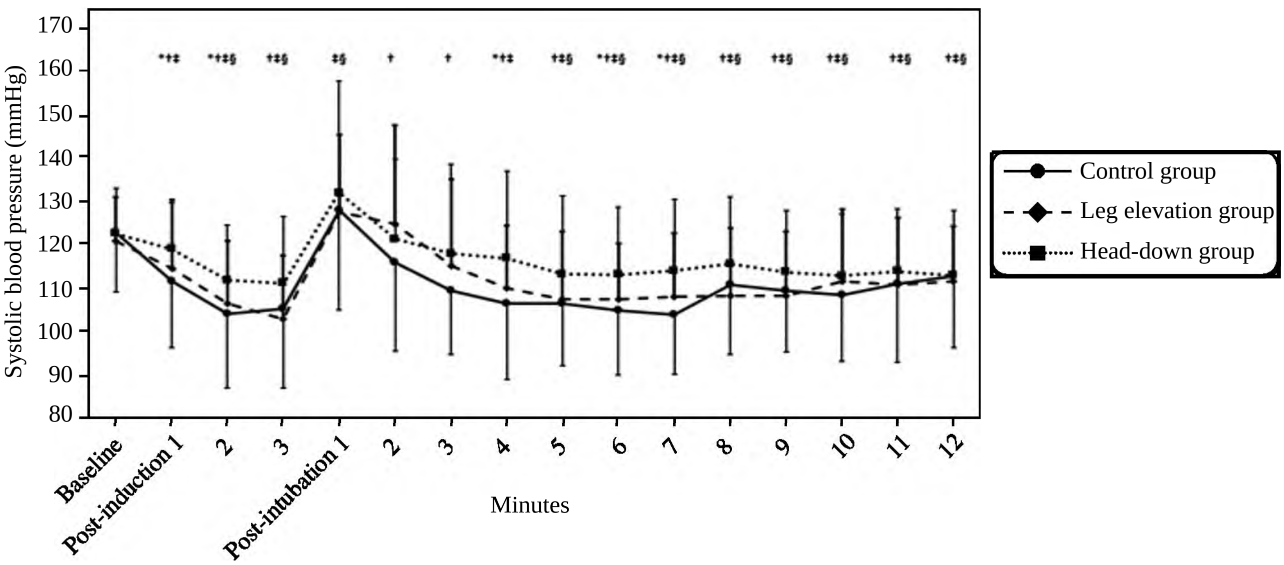

Fig. (2): Systolic blood pressure. Markers are means and error bars are standard deviation. * Denotes significance between the control group and head-down group, †Denotes significance in relation to baseline reading in the control group, ‡ Denotes significance in relation to baseline reading in the leg-elevation group, § Denotes significance in relation to baseline reading in the head-down group.

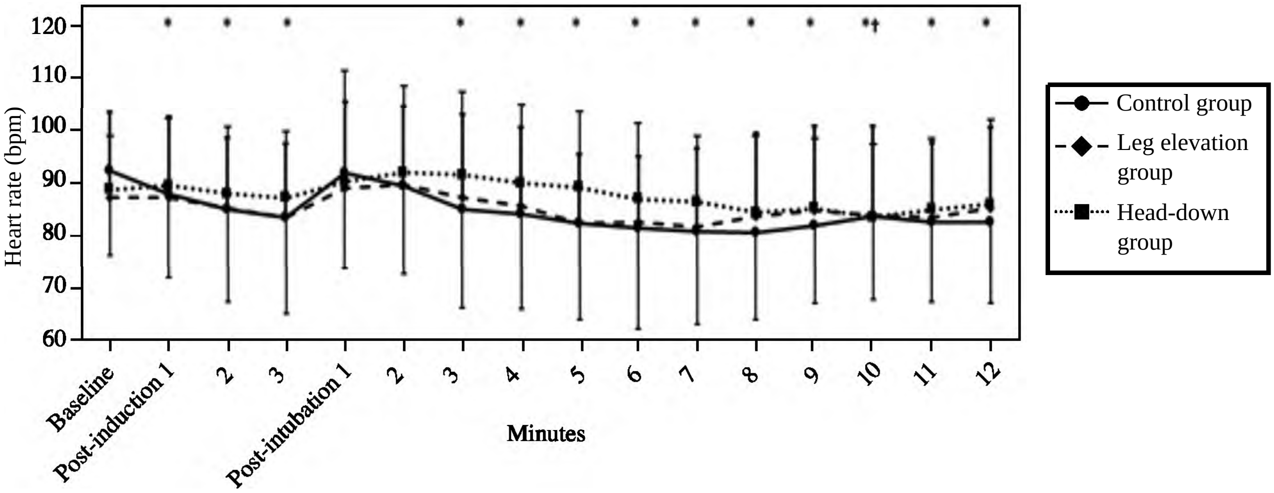

Fig. (3): Heart rate. Markers are means and error bars are standard deviation. *Denotes significance in relation to baseline reading in the control group, †Denotes significance in relation to baseline reading in the head-down group.

Discussion

We reported that the use of either leg-elevation position or head-down position reduced the incidence of post-induction hypotension, and subsequently reduced the frequency of norepinephrine administration compared to supine position.

Post-induction hypotension is caused by the vasodilatory effect of anaesthetic drugs resulting in pooling of blood in the peripheral circulation in the absence of surgical stimulation. Other factors that contribute to post-induction hypotension include positive pressure ventilation and hypovolemia. Both study positions, namely leg-elevation position and head-down position, exerts rapid shift in the intravascular volume from the lower limbs to the central circulation; This rapid fluid shift increases venous return and consequently increases cardiac output [12,13]. Leg-elevation induces an intrinsic transfusion of blood from the lower limbs to the central fluid compartment [11]. Using radiolabelled erythrocytes, the volume of blood mobilized from the calves during leg-elevation was reported to be 150-300mL [14,15]. Although this auto-transfused volume is not large [16], it was effective in maintaining patient hemodynamics because (1) It was transfused over a short period; (2) This volume was blood and not ordinary fluids. The hemodynamic effects of leg-elevation and head-down positions were previously investigated in cardiac surgery; however, the benefit of the two positions showed relatively conflicting results. Leg-elevation is one of the first-aid manoeuvres for the management of acute circulatory failure [13]. Leg-elevation effectively prevented hypotension after induction of anaesthesia for cardiac surgery, [17] and after spinal anaesthesia [11]. The head-down position was previously reported as a useful measure for the management of hypovolemia in various patient groups [18]. The head-down position was reported to be effective in the management of post-induction hypotension during cardiac surgery [19]. On the other hand, some reports showed that neither the leg-elevation position [20] nor the head-down position [21] improved the hemodynamic profile in cardiac surgery patients. No studies to the best of our knowledge had evaluated the hemodynamic effects of the two study positions in non-cardiac surgery. Induction of anaesthesia in non-cardiac surgery is commonly associated with hypotension which is associated with several unfavourable outcomes [7,22]. Furthermore, the response of patients undergoing non-cardiac surgery to the study positions might differ from patients undergoing cardiac surgery due to different chronic medications and different induction protocols.

Although the rate of hypotension was lower in the leg-elevation position and the head-down position, the majority of individual SBP readings were comparable between the three study groups; this is because hypotensive episodes were instantly managed using norepinephrine boluses. The more frequent use of norepinephrine boluses in the supine group is, probably, responsible for the higher incidence of bradycardia in this group compared to the leg elevation group.

We included two positions, leg-elevation, and head-down, and compared both positions to supine positions. Including the two positions aimed to provide more alternatives to the anesthesiologist, if both proved effective because each position is more suitable for a specific population. According to our results both leg-elevation position and head-down position produced a comparable reduction in the incidence of post-induction hypotension and norepinephrine consumption in relation to the control group. Leg-elevation is a relatively simpler and more tolerable manoeuvre than head-down. Furthermore, the head-down position might be also unsuitable with increased intracranial tension. On the other hand, the head-down position might be more appropriate in patients with spine and/or lower extremities fracture. Hence, the choice between the two positions would depend on the patient's condition.

Intraoperative hypotension, even for a short period, increases the risk of postoperative morbidity and mortality *[3,6,7,23]*. Thus, avoiding intraoperative hypotension, especially during the pre-incision period, has been strongly suggested to improve patient outcomes *[4,8,24]*. Post-induction hypotension represents a substantial portion of intraoperative hypotensive episodes *[23]*. Using either position would provide simple and effective manoeuvres for avoiding hypotension during this critical period and would spare the complications of unnecessary fluid and vasopressor administration. Our findings might be of additional benefit in vulnerable patients such as elderly patients, septic patients, and bleeding patients if confirmed in future studies.

Limitations:

Our study had many strengths such as the randomized, controlled design and using a major clinical primary outcome. There are some limitations; blood pressure measurements were obtained non-invasively; this was because some of our patients were scheduled for non-major surgery in which invasive monitoring is not routinely used. Future studies could investigate the effect of the two study positions in a specific high-risk population such as elderly patients and hemodynamically unstable patients (e.g., septic shock patients).

Conclusion:

In conclusion, compared to the supine position, induction of general anesthesia in either leg-elevation position or head-down position reduced the incidence of post-induction hypotension and the need for vasopressor administration in adult patients undergoing non-cardiac elective procedures. We recommend the routine use of either of the two study positions during induction of anaesthesia.

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تاثير خفض رأس المريض لأسفل مقابل رفع الساق مع ابتدأ التخدير الكلى على حسب نسبة حدوث أنخفاض ضغط الدم بعد البدء بالتخدير الكلى : تجربة مراقبة عشوائية

يرتبط بدء التخدير الكلى بحدوث انخفاض فى ضغط الدم فى ٥٠٪ من المرضى. وقد يؤدى هذا الانخفاض الى نقص وصول الدم إلى الأعضاء الحيوية ويزيد من احتمالية حدوث الوفاة اثناء أو بعد إجراء العملية الجراحية .

ولذلك تم استخدام عدة وسائل لمنع انخفاض ضغط الدم مثل اعطاء المحاليل قبل البدء بالتخدير او اعطاء العقارات القابضة للأوعية الدموية. ومن الممكن استخدام رفع الساق لزيادة الدم العائد للقلب او خفض رأس المريض بدلا من استخدام المحاليل او العقار القابض للاوعية الدموية.

وتهدف هذة الدراسة الى تقييم تاثير خفض رأس المريض لأسفل مقابل رفع الساق مع بدء التخدير الكلى مقابل وضعية الاستلقاء على احتمالية حدوث انخفاض ضغط الدم .

وفى هذة الدراسة تم تقسيم ١٢١ مريض يقومون باجراء عمليات جراحية غير قلبية الى ثلاث مجموعات الولى تم رفع ساق المريض والثانية تم خفض رأس المريض والثالثة وضع المريض فى وضع الاستلقاء وتم تسجيل قياس ضغط الدم وسرعة نبضات القلب كل دقيقة لمدة ١٥ دقيقة وقد كان النتائج الاوليه هى احتمالية حدوث انخفاض ضغط الدم بعد بدء التخدير الكلى. وأوضحت النتائج ان انخفاض ضغط الدم حدث بنسبة ٤٤٪ فى مجموعة مرضى رفع الساق و٤٠٪ فى مجموعة مرضى خفض الرأس و ٨٠٪ فى مجموعة مرضى الاستلقاء. وقلت نسبة استخدام عقار النورابينيفرين فى المجموعتين الاولى والثانية عن المجموعة الثالثة.

الخلاصة: ان رفع ساق المريض او خفض الرأس ادى الى نقص فى نسبة حدوث انخفاض فى ضغط الدم و نقص فى استخدام عقار النورابينفرين مع بدء التخدير الكلى لمرضى العمليات الجراحية الغير قلبية.