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Ephedrine versus norepinephrine infusion for prevention of haemodynamic instability after declamping of the aorta in abdominal aortic aneurysm repair

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ORIGINAL STUDY

Ephedrine Versus Norepinephrine Infusion for Prevention of Hemodynamic Instability After Declamping of the Aorta in Abdominal Aortic Aneurysm Repair

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Abstract

Background: During general anesthesia, hypotension is often experienced and is linked to both postoperative morbidity and death. Anesthesiologists have long had a hurdle while performing abdominal aortic aneurysm (AAA) repair, a high-risk treatment that increases vulnerability to hemodynamic disturbances during open surgery. A common vasopressor that is a combined α -agonist and β -agonist, ephedrine, is used to treat hypotension in general anesthesia. Conversely, norepinephrine has a favorable chronotropic impact on the heart in addition to acting as an agonist for both α -receptor and β -receptor.

Aim: To examine the differences in the effects of intravenous ephedrine hydrochloride and noradrenaline on maintaining arterial pressure during aortic declamping during AAA surgery.

Patients and methods: The current research included 60 patients who were enrolled for surgical repair of AAA who were randomly assigned into two groups, group E (n = 30) that received intraoperative ephedrine infusion, and group N (n = 30) that received intraoperative norepinephrine infusion. The main outcomes of the current study included intraoperative hemodynamic changes, including the prevalence of tachycardia, hypotension, bradycardia, and hypertension, the volume of the infusion needed, the time elapsed till infusion cessation, the need for extra drug bolus, the number of boluses given, and the prevalence of complications (nausea and vomiting).

Results: According to the present investigation, there was no statistically substantial change in heart rate or mean arterial pressure between the two study groups at follow-up. Compared with the NE group, the ephedrine group had a greater incidence of vasopressor demand (40 %) but not to a statistically substantial level (P = 0.165). Also, the number of boluses, volume of infusion, and the time to stop infusion were similar in the two groups.

Conclusion: Ephedrine and norepinephrine controlled hemodynamic changes and alternations during AAA surgery similarly and effectively. NE reduced vasopressor doses, a slight advantage.

Keywords: Aortic aneurysm, Ephedrine, Hypotension, Norepinephrine

1. Introduction

A bdominal aortic aneurysm (AAA) describes a pathologic widening of a segment of the abdominal aorta due to the weakening of the vessel wall, with an estimated prevalence between 2 and 12 % (Budiman et al., 2023). The illness is mostly asymptomatic, but because of the possibility of rupturing, it might be fatal (Wang et al., 2022).

If the aneurysm is developing quickly or is more than 5.5 cm in males or more than 5.0 cm in women, elective surgical surgery may be necessary for asymptomatic individuals. If there is a suspected rupture, emergency surgery is needed (Puttur Rajkumar et al., 2021).

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https://doi.org/10.58775/2735-3990.1405 2735-3990/© 2024 The Authors. Published by Mansoura University Faculty of Medicine. This is an open access article under the CC BY 4.0 license (http://creativecommons.org/licenses/by/4.0/). After aortic clamping causes intraoperative blood flow to stop, acute organ damage is one of the most frequent problems seen after AAA repair. Clamping during surgery might result in mortality or serious consequences, including SIRS and organ malfunction (Behnaz et al., 2020). An almost universal rise in systemic vascular resistance and arterial blood pressure is seen after aortic clamping (Zammert and Gelman, 2016).

Aortic cross-clamp therapy also results in a rise in catecholamine release in addition to angiotensin. The rise in these vasoactive compounds may cause the venules and arterioles to contract, which may help to shift blood flow toward the body's areas closest to the aortic clamp (Khassawneh et al., 2023).

Removing the aortic cross-clamp results in a second physiological insult. Three-quarters less peripheral vascular resistance occurs, which might lead to severe hypotension. Blood sequestration in the lower body, ischemia—reperfusion damage, and the production of anaerobic metabolites may all exacerbate a drop in arterial pressure (Duncan and Pichel, 2019).

It is advised to take a hemostatic break before unclamping. Achieving sufficient volume resuscitation and cardiovascular stability, addressing acid—base and electrolyte imbalances, and returning the temperature to normal should all be priorities during this period (Aranda-Michel et al., 2023). Even after replenishing fluids, vasoconstrictors and positive inotropes could be necessary (Nisi et al.).

During surgery, phenylephrine, a direct α 1agonist, is administered to keep blood pressure stable (Rajanathan et al., 2023). Positive inotropic and chronotropic effects are caused by its sympathomimetic stimulant action on α -adrenergic and β adrenergic receptors; however, its vasoconstrictive impact is diminished by repeated dosing owing to tachyphylaxis (Kee, 2017).

A strong α -adrenergic receptor agonist and modest β -adrenergic receptor agonist norepinephrine is. It could be a better choice to keep mom's blood pressure stable with fewer detrimental effects on her heart rate (Heesen et al., 2015).

To the best of our knowledge, no previous studies had compared the effects of ephedrine versus norepinephrine in controlling the hemodynamic state in cases that underwent AAA repair. For this reason, the current research was conducted to compare the effects of ephedrine hydrochloride and noradrenaline administered intravenously on maintenance of arterial pressure after declamping of the aorta in AAA surgery.

2. Patients and methods

The current prospective randomized research was conducted over a 5-month duration, from January to June 2023, at Mansoura University Cardiothoracic and Vascular Surgery Center. Patient enrollment was started after we gained ethical approval from the Institutional Review Board (IRB) of our medical school (IRB code). The study was designed for patients aged 40 years or more presented to the previous center and diagnosed with AAA requiring surgical repair.

2.1. Publication ethical statement

All patients gave their informed consent for inclusion before they participated in this study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by IRB (MS. R.23.07.2265 at 24/07//2023).

The typical preoperative evaluation was given to each patient and included detailed history taking (focusing on age, sex, and preexisting systemic comorbidities), clinical examination (focusing on BMI, cardiac and chest examination, and assessment of vital signs), and routine laboratory investigations. Additionally, a chest radiograph and abdominal computed tomography were ordered for all cases. The latter was used to objectively estimate the aneurysm size and its extent. The extent was classified according to the Crawford classification (Crawford et al., 1986; Green et al., 2018). The physical status for all patients was classified according to the 'American Society of Anesthesiologist' (Tassemeier et al., 2018). Patients with class III or more were excluded from our study. We also excluded patients with the following criteria: BMI more than or equal to 35 kg/m², previous abdominal aortic surgery, myocardial infraction in the previous 6 months, drug abuse, aneurysms requiring emergent or urgent operations, chronic liver disease (Child classification B and C), chronic kidney disease (serum creatinine >2 mg/dl), and pregnancy.

Sixty patients were found eligible for our previous enrollment criteria. The aim of the research was simply explained for them, and their approval to participate in the study was documented in a signed written consent. Via 'Compute-based randomization,' they were randomly assigned into two groups, group E (n = 30) that got intraoperative ephedrine infusion, and group N (n = 30) that received intraoperative norepinephrine infusion. At the operative theater, the patients were routinely monitored by ECG and pulse oximetry. Additionally, a peripheral intravenous line was secured into a suitable forearm vein using 18-G cannula. Intravenous Ringer solution was commenced (2–4 ml/kg/h), and the blood pressure was invasively monitored through radial artery cannulation. All patients were preoxygenated by 100 % oxygen for 5 min.

General anesthesia was induced by intravenous midazolam (0.1 mg/kg), intravenous fentanyl (5 µg/ kg), and intravenous propofol (2 mg/kg). Additionally, in order to make endotracheal intubation easier, intravenous atracurium (0.5 mg/kg) was given. An appropriate-sized cuffed endotracheal tube was used for the procedure. After intubation, anesthetic maintenance was done with an air-oxygen mixture by isoflurane using minimum alveolar concentration 1-1.5. The volume-controlled mode was used to deliver a tidal volume of 8 ml/kg (according to ideal body weight), and to keep positive end-expiratory pressure around 7-cmH₂O. The respiratory rate and FiO₂ were adjusted to keep end-tidal CO₂ between 35 and 40 mmHg, with a 1 : 2 inspiratory-to-expiratory ratio.

A broad-spectrum antibiotic was commenced at the time of skin incision after performing the sensitivity test. According to group allocation, the infusion of vasoactive medications was started immediately after aortic declamping using either ephedrine (0.05 μ g/kg/min) or norepinephrine (the same dose and rate of infusion). The infusion of these medications aimed to maintain systolic blood pressure (SBP) within 100–120 % of its baseline value. We kept in mind to keep SBP higher than 90 mmHg, and the gradual withdrawal of the infusion was done.

Continuous monitoring of the vital signs was maintained during the procedure. Both heart rate and mean arterial pressure were recorded before clamping, after clamping, and after 15, 30, 60, and 90 min after aortic declamping during the surgical procedure.

Any hypertensive episodes (known as SBP >120 % of baseline value (Ngan Kee et al., 2007)) were managed by cessation of vasoactive infusion. The infusion was restarted if the SBP reduced below the upper target limit (120 % of baseline value). The infusion was permanently stopped if we encountered three episodes of hypertension, and any subsequent hypotensive episodes were managed by intravenous bolus of ephedrine.

Bradycardia was known as heart rate below 50 bpm (Lesser et al., 2003), and it is managed by intravenous glycopyrrolate (0.4 mg) or intravenous ephedrine (5–10 mg). After closure of the skin

incision, reversal of anesthesia was done by intravenous atropine and neostigmine, and the patient was extubated and then transferred to the PACU.

2.2. Outcomes

The main outcomes of the current study included intraoperative hemodynamic changes, including the prevalence of tachycardia, bradycardia, hypotension, and hypertension, the volume of the infusion needed, the time elapsed till infusion cessation, the need for extra drug bolus, the number of boluses given, and the prevalence of complications (nausea and vomiting).

2.2.1. Sample size calculation

Utilizing IBM SPSS Sample Power, version 3.0.1 (IBM Corp., Armonk, New York, USA), the necessary sample size was determined. An extensive analysis of the literature revealed that in the Hassani et al. (2018) research, the mean frequency of hypotension events was 1.25 ± 0.44 in the ephedrine group and one in the norepinephrine group.

The sample size was determined by taking these group differences. With a 95 % level of significance and 80 % power, 52 samples were needed on average (26 in each group). For considering of the dropout, the required sample will be increased to 30 in each group.

2.3. Statistical analysis

SPSS version 26 for Windows (Statistical Package for Social Sciences) was utilized to code, process, and analyze the data (IBM, SPSS Inc., Chicago, Illinois, USA). Numbers (frequency) and percentages representing qualitative data were shown. The Monte–Carlo test, which is a correction to Fisher's exact test, or the χ^2 test was utilized to compare the groups. The Kolmogorov–Smirnov test examined the normality of quantitative data. Nonparametric data were reported as median (range), while parametric data was presented as median±SD.

The Student *t* test for independent samples was utilized to compare two groups with regularly distributed quantitative characteristics; if the data were irregularly distributed, the Mann–Whitney *U* test was utilized. *P* values less than 0.05 are regarded as significant for all tests.

3. Results

Table 1 shows that between the cases in the two research groups, there was no statistically substantial variation in the fundamental preoperative data. The mean age of the cases in the ephedrine group

Table 1.	Demographic	data of	f the study	cases.
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	Ephedrine group (N = 30)	NE group $(N = 30)$	P value
Age (years)	54.43 ± 9.67	56.40 ± 10.76	0.459
Sex [n (%)]			
Male	19 (63.3)	21 (70)	0.584
Female	11 (36.7)	9 (30)	
BMI (kg/m ²)	24.70 ± 2.78	25.15 ± 2.97	0.593
Smoking [<i>n</i> (%)]	9 (37.5)	6 (25)	0.350
Comorbidities [n (%)]			
DM	9 (30)	7 (23.3)	0.559
HTN	6 (20)	7 (23.3)	0.754
CKD	5 (16.7)	4 (13.3)	0.718

CKD, chronic kidney disease; DM, diabetes mellitus; HTN, hypertension.

Table 2. Clinical examination and operative data in the study cases.

	Ephedrine group $(N = 30)$	NE group (<i>N</i> = 30)	P value
Size of aneurysm (cm)	6.38 ± 0.79	6.77 ± 0.82	0.067
Anatomical extent [n (%)]			
Ι	6 (20)	7 (23.3)	
П	11 (36.7)	13 (43.3)	0.847
III	8 (26.7)	7 (23.3)	
IV	5 (16.7)	3 (10)	
Wall condition [n (%)]			
Intact	25 (83.3)	27 (90)	0.448
Ruptured	5 (16.7)	3 (10)	
ASA score $[n (\%)]$			
ASA I	14 (46.7)	16 (53.3)	0.606
ASA II	16 (53.3)	14 (46.7)	
Operative time (min)	254.33 ± 32.40	256 ± 38.98	0.858

ASA, American Society of Anesthesiologist.

was 54.43 ± 9.67 years, while in the NE group, the mean age was 56.40 ± 10.76 . Males represented 63.3 and 70 % in the ephedrine and NE groups, respectively.

Diabetes was the most common associated comorbidity in 30 and 23.3 % ephedrine and NE groups, respectively.

Table 2 shows that there was no statistical substantial variation between the groups as regards the size of the aneurysm, anatomical extent of the aneurysm, and the condition of the wall.

The American Society of Anesthesiologist classification and the operative time were also comparable between the two groups. Table 3 and Fig. 1 show that there was no statistical substantial variation between the two study groups as regards the heart rate during follow-up. After clamping, there was initial drop in the heart rate in both groups.

Table 4 and Fig. 2 show that there was no statistical substantial variation between the two study groups as regards the mean arterial pressure during follow-up.

As shown in Table 5, the prevalence of vasopressor requirement was 40 % in the ephedrine group that was higher as compared with the NE group, but it did not reach a statistically substantial value (P = 0.165).

Table 3. Throughout the investigation, heart rate (beats per minute) of the examined groups was monitored.

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Heart rate (beat/min)	Ephedrine group $(N = 30)$	NE group $(N = 30)$	Р
Before clamping	83.87 ± 8.76	81.17 ± 7.21	0.198
After clamping	79 ± 9.26	76.83 ± 8.11	0.339
MAP at 15 min	85.80 ± 7.58	82.67 ± 8.22	0.130
MAP at 30 min	85.57 ± 11.49	81.30 ± 7.86	0.099
MAP at 1 h	84.77 ± 6.78	82.20 ± 6.41	0.137
MAP at 90 min	83.60 ± 7.25	82.70 ± 7.08	0.629

MAP, mean arterial pressure.



Fig. 1. Throughout the investigation, heart rate (beats per minute) of the examined groups was monitored.

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MAP (mmHg)	Ephedrine group $(N = 30)$	NE group (<i>N</i> = 30)	Р
Before clamping	77.73 ± 8.30	77.17 ± 7.51	0.783
After clamping	76.97 ± 9.60	75.97 ± 7.67	0.657
MAP at 15 min	75.87 ± 8.92	75.53 ± 7.32	0.875
MAP at 30 min	75.30 ± 8.70	74.77 ± 7.38	0.799
MAP at 1 h	74.93 ± 8.02	74.10 ± 6.99	0.670
MAP at 90 min	74.67 ± 7.42	73.67 ± 7.04	0.595

MAP, mean arterial pressure.



Fig. 2. Throughout the investigation, pulse rate (beats per minute) of the examined groups was monitored.

Table 5. Clinical examination and operative data in the study cases.

	Ephedrine group $(N = 30)$	NE group $(N = 30)$	P value
Requirement of boluses $[n(\%)]$			
No	18 (60)	23 (76.7)	0.165
Yes	12 (40)	7 (23.3)	
Number of boluses	2 (1-3)	2 (1-3)	0.808
Volume of infusion (ml)	1500 (1000-2000)	1500 (1000-2000)	0.243
Time to stop infusion (min)	32.40 ± 1.61	31.70 ± 2.18	0.163

	Ephedrine group $(N = 30) [n (\%)]$	NE group $(N = 30) [n (\%)]$	P value
Tachycardia	9 (30)	5 (16.7)	0.222
Bradycardia	3 (10)	2 (6.7)	0.640
Hypotension	7 (23.3)	7 (23.3)	1
Hypertension	1 (3.3)	2 (6.7)	0.554
Nausea and vomiting	9 (30)	7 (23.3)	0.506

Table 6. Complications in the study cases.

Also, the number of boluses, volume of infusion, and the time to stop infusion were comparable between the two groups.

Table 6 shows the associated complications in the two study groups. Tachycardia was reported in 30 % of the cases of ephedrine group that was higher compared with NE group, yet it failed to get to a number that was statistically substantial (P = 0.22). Bradycardia was reported in 10 and 6.7 % in ephedrine and NE groups, respectively. Nausea and vomiting were reported in 30 and 23.3 % in ephedrine and NE groups, respectively. The prevalence of hypotension was 23.3 % in both groups.

4. Discussion

Open aortic surgery is a large procedure that has hazards for the patient, including those connected to major surgery and hemodynamic impairment from the aortic cross-clamping and declamping phases (Nisi et al., 2022).

Applying the cross-clamp causes an abrupt rise in arterial pressure close to the clamp, making collateral circulation the only source of perfusion available to the lower body. This raises the heart's left ventricular wall tension and afterload, increasing the strain and oxygen demand on the heart (Duncan and Pichel, 2022).

In recent years, pertinent data have been developed by research on the issue of blood pressure regulation and intraoperative hypotension avoidance during surgery. In fact, it has been said that controlling blood pressure during surgery is crucial since even momentary hypotension has been linked to difficulties after the procedure (Sessler et al., 2019; Walsh et al., 2013).

The goal of the present research was to investigate how intravenous administration of noradrenaline and ephedrine hydrochloride affected the maintenance of arterial pressure during aortic declamping during AAA surgery.

The instances' operational and fundamental data in the two groups were similar, demonstrating a successful randomization approach.

Regarding the extent of the aortic aneurysms, grade-II extension showed the highest percentage in

the two groups representing 36.7 and 43.3 % in the ephedrine and NE groups, respectively.

Type II is the largest, reaching from the subclavian to the aortoiliac bifurcation, as was previously documented. Type III affects the aortoiliac bifurcation and the distal thoracic aorta. Because type-I and type-II TAAA repairs entail complicated multiorgan systems, they carry the greatest risk of morbidity and death. Only the abdominal aorta under the diaphragm is affected by type-IV TAAAs (Safi et al., 1999).

The study's findings showed that an infusion of norepinephrine and ephedrine was sufficient to control hypotension during the repair of an AAA. With fewer episodes of tachycardia and hypertension, both drugs were successful in maintaining stable blood pressure and heart rate.

Since it is safe, readily accessible, and well-known to most anesthesiologists, ephedrine has been the gold standard vasopressor. It results in peripheral vasoconstriction, which raises blood pressure and increases cardiac output by increasing myocardial contractility and heart rate (Ngan Kee et al., 2015; Elnabtity and Selim, 2018).

Conversely, norepinephrine counteracts the effects of the sympathetic block right away and may be a better option for maintaining blood pressure since it has fewer detrimental effects on heart rate and cardiac output (Kee et al., 2018).

When comparing the two drugs against each other, norepinephrine had slightly earlier onset with less requirement of boluses of vasopressors.

With aortic cross-clamp release, reduced arterial blood pressure and systemic vascular resistance are usually the main hemodynamic abnormalities seen. Multifactorial hypotension is seen following unclamping (Goel et al., 2019).

Central hypovolemia results from shift of blood volume to the lower extremities. Vasoactive and myocardial-depressant metabolites, such as lactate, accumulate in tissues distal to the aortic cross-clamp due to hypoperfusion, and are released when the cross-clamp is removed (Monaco et al., 2022). Reduced aortic cross-clamp duration, volume loading, the infusion of vasoactive drugs, the timely treatment of metabolic anomalies, and the progressive removal of aortic cross-clamp may all help prevent hypotension after aortic cross-clamp release (Lester and Kostibas, 2022).

In the event of a mixed respiratory acidosis, sodium bicarbonate should be administered with caution in order to offset this metabolic acidosis. To guarantee sufficient renal and spinal cord perfusion after crossclamp release, it is often advised to maintain elevated blood pressure than usual (Izumi et al., 2010).

Although the two drugs have not been compared previously during the surgery of aortic aneurysm repair, but the superiority of NE has been proved in other surgical interventions.

For example, a recent Egyptian study by Elagamy and colleagues that 120 pregnant women having elective cesarean section were split into two groups at random: 'group N' for norepinephrine and 'group E' for ephedrine, with 60 women in each group. The findings demonstrated that norepinephrine preserved mother's blood pressure in comparison to ephedrine. Moreover, it was linked to a higher incidence of bradycardia following cesarean birth but fewer instances of hypotension (Elagamy et al., 2021).

In coronary artery disease patients performing knee arthroscopy, a study comparing the safety and effectiveness of bolus administration of NE versus EPH for maintaining of SBP during spinal anesthesia revealed that efficiency was found in 20 (40 %) patients of group EPH and in 40 (80 %) patients of group NE. The outcomes were quite important (Elhadidy et al., 2019).

Another research examined the effectiveness of treating hypotension after spinal anesthesia with intermittent bolus delivery of EPH versus NE. The findings showed that patients in NE group 21 (46.7 %) and EPH group 16 (35.6 %) did not need extra vasopressor boluses, but the distinction was not statistically substantial (Awad, 2019).

Vallejo et al. (2017) revealed that every hemodynamic metric, such as heart rate, blood pressure, cardiac output, and stroke volume, was comparable across the two medications.

The effects of a prophylactic norepinephrine and phenylephrine bolus on spinal hypotension were examined in research by Dong et al. (2017) and Wang et al. (2020). They discovered that although phenylephrine and norepinephrine both work well to prevent spinal hypotension, norepinephrine has less of an adverse impact on heart rate and cardiac output than phenylephrine.

Numerous investigators investigated the use of various dosages and delivery schedules of norepinephrine to avoid hypotension during spinal block. Wang et al. (Wang et al., 2020) looked at the effects of boluses of norepinephrine at various dosages, while Chen et al. (2018) and Hasanin et al. (2019) investigated various norepinephrine infusion dosages. The findings showed that norepinephrine maintains blood pressure without causing any appreciable adverse effects. The average recommended dosage for this research is the beginning dose that we employed, and we modify it based on response.

Based on the current results, the selection of vasopressor during the repair of AAA did not have a certain recommendation of one drug over another. So, further studies are still warranted to confirm the superiority of ephedrine or NE in controlling hemodynamic changes during surgical repair of AAA.

The small included number of cases could reduce the power of the obtained results, but the condition itself is relatively of low prevalence, especially the process of elective repair.

4.1. Conclusion

Based on the current results, both ephedrine and NE were comparable and efficient in controlling the hemodynamic changes and alternations during the surgical repair of AAA. The use of NE showed a slight privilege in the form of decreasing the use of additional vasopressor doses, although it did not reach a significant value that could be mostly due to small included sample size. Of course, further largescale studies are still required for more generalization of the results.

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Conflicts of interest

There are no conflicts of interest.

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