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Individualized Perioperative Blood Pressure Management in Patients Undergoing Major Abdominal Surgery
The IMPROVE-multi Randomized Clinical Trial

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IMPORTANCE Intraoperative hypotension is associated with organ injury. However, it remains unknown if targeted blood pressure management during surgery can improve clinical outcomes.

OBJECTIVE To evaluate whether individualized vs routine perioperative blood pressure management during major abdominal surgery improves clinical outcomes in patients considered at high risk of postoperative complications.

DESIGN, SETTING, AND PARTICIPANTS This randomized single-blind clinical trial enrolled patients 45 years or older undergoing elective major abdominal surgery with general anesthesia expected to last 90 minutes or longer who had at least 1 additional high-risk criterion between February 26, 2023, and April 25, 2024, at 15 German university hospitals. The date of last follow-up was July 25, 2024.

INTERVENTION Patients were randomized in a 1:1 ratio to individualized perioperative blood pressure management (with mean arterial pressure [MAP] targets based on preoperative mean nighttime MAP assessed using automated blood pressure monitoring) or routine blood pressure management with a MAP target of 65 mm Hg or higher.

MAIN OUTCOMES AND MEASURES The primary outcome was the incidence of a composite outcome of acute kidney injury, acute myocardial injury, nonfatal cardiac arrest, or death within the first 7 postoperative days. There were 22 secondary outcomes, including infectious complications within the first 7 postoperative days and a composite outcome of need for kidney replacement therapy, myocardial infarction, nonfatal cardiac arrest, or death within 90 days after surgery.

RESULTS Of the 1272 patients enrolled, 1142 were randomized (571 patients to each group), and 1134 were included in the primary analysis (median age, 66 years [IQR, 59-73 years]; 34.1% female). The primary outcome occurred in 190 of 567 patients (33.5%) assigned to individualized blood pressure management and 173 of 567 patients (30.5%) assigned to routine blood pressure management (relative risk, 1.10 [95% CI, 0.93-1.30]; $P = .31$). None of the 22 secondary outcomes were significantly different, including infectious complications within the first 7 postoperative days (90/567 [15.9%] vs 97/567 [17.1%]; $P = .63$) and a composite outcome of need for kidney replacement therapy, myocardial infarction, nonfatal cardiac arrest, or death within 90 days after surgery (32/566 [5.7%] vs 20/567 [3.5%]; $P = .12$).

CONCLUSIONS AND RELEVANCE Among patients at high risk of postoperative complications undergoing major abdominal surgery, individualized perioperative blood pressure management with MAP targets based on preoperative mean nighttime MAP did not decrease the composite outcome of acute kidney injury, acute myocardial injury, nonfatal cardiac arrest, or death within the first 7 postoperative days compared with routine blood pressure management with a MAP target of 65 mm Hg or higher.

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Group Information: A list of participating centers and investigators of the IMPROVE-multi trial is provided in Supplement 5.

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Intraoperative hypotension is common among patients undergoing noncardiac surgery and is associated with organ injury and death.[1-6] The risk of organ injury increases when intraoperative mean arterial pressure (MAP) is less than 60 to 65 mm Hg.[1] The association between intraoperative hypotension and organ injury is a function of hypotension severity and duration.[7] A systematic review that included 42 studies reported that an intraoperative MAP less than 65 mm Hg sustained for 10 minutes or longer was associated with a relative increase in the risk of acute kidney injury by 60%, of myocardial injury by 30%, and of mortality by 4%.[5] Therefore, guidelines and consensus statements recommend keeping MAP above 60 to 65 mm Hg during noncardiac surgery.[7-10]

However, it remains uncertain if the relationship between intraoperative hypotension and organ injury is causal and if targeted blood pressure management can improve outcomes in surgical patients. Preoperative blood pressures vary considerably among surgical patients,[11,12] and about one-half of the patients presenting for elective major noncardiac surgery have chronic arterial hypertension.[13-15] It is unknown if surgical patients with high preoperative blood pressure require higher intraoperative blood pressure to maintain adequate organ perfusion and avoid organ injury. Therefore, this multicenter trial was conducted to test the hypothesis that keeping perioperative MAP at least at the individual preoperative mean nighttime MAP reduces the incidence of a composite outcome of acute kidney injury, acute myocardial injury, nonfatal cardiac arrest, or death within the first 7 postoperative days in high-risk patients undergoing major abdominal surgery compared with routine blood pressure management with a MAP target of 65 mm Hg or higher.

Key Points

Question Does individualized perioperative blood pressure management based on preoperative nighttime mean arterial pressure (MAP) improve outcomes in patients undergoing abdominal surgery who are considered at high risk of postoperative complications?

Findings In this randomized clinical trial that included 1272 participants, the incidence of a composite primary outcome (acute kidney injury, acute myocardial injury, nonfatal cardiac arrest, or death within the first 7 postoperative days) was not significantly different between patients assigned to individualized MAP targets and patients assigned to routine blood pressure management with a MAP target of 65 mm Hg or higher.

Meaning This trial does not support individualizing blood pressure targets based on preoperative nighttime MAP in high-risk patients undergoing abdominal surgery.

Methods

Trial Design and Oversight

The IMPROVE-multi trial was a multicenter randomized single-blind clinical superiority trial conducted at 15 German university medical centers. The trial protocol, including details of trial monitoring, has been published[16] and is available in Supplement 1 and Supplement 2; the statistical analysis plan is available in Supplement 3. Ethical approval was obtained from the ethics committee Hamburg (Ethikkommission der Ärztekammer Hamburg, Hamburg, Germany [registration No. 2022-100879-BO-ff]) acting as the primary ethics committee for this trial. Secondary ethics committee approvals were obtained at each site. An independent data and safety monitoring board oversaw the trial and reviewed the results of the interim analysis. All patients provided written informed consent. This trial adheres to the CONSORT (Consolidated Standards of Reporting Trials) statement.[17,18]

Patient Population

We enrolled consenting patients 45 years or older scheduled for elective major abdominal surgery with general anesthesia expected to last 90 minutes or longer who had at least 1 additional high-risk criterion (**Table 1**; eMethods in Supplement 4). We excluded patients undergoing nephrectomy or kidney transplant; those with prior kidney, liver, heart, or lung transplant; patients with sepsis or treated with kidney replacement therapy; pregnant women; and patients in whom preoperative automated blood pressure monitoring was not possible. A complete list of inclusion and exclusion criteria is provided in the eMethods in Supplement 4.

Preoperative Automated Blood Pressure Monitoring

In all enrolled patients, preoperative blood pressure was measured at 30-minute intervals for 1 night using an automated blood pressure monitoring device (boso TM-2450; Bosch + Sohn). Preoperative automated blood pressure monitoring could be performed in the hospital or at home, with no specific requirements for its timing. After excluding artifacts, we calculated the preoperative mean nighttime MAP for each patient based on nighttime MAP values measured between midnight and 6:00 AM.[19,20]

Randomization and Treatment

Patients were randomized in a 1:1 ratio, using central block-wise randomization with variable block sizes (blocks of 2 and 4), to individualized blood pressure management or routine blood pressure management. Randomization was stratified by center and was performed centrally using an online data-management system before induction of general anesthesia.

For patients assigned to individualized blood pressure management, anesthesiologists were instructed to keep MAP at least at the individual preoperative mean nighttime MAP from the start of induction of general anesthesia until 2 hours after the end of surgery. For patients with a preoperative mean nighttime MAP lower than 65 mm Hg, the perioperative MAP target was defined as 65 mm Hg or higher (as recommended by current guidelines[10]). For patients with a preoperative mean nighttime MAP higher than 110 mm Hg, the perioperative MAP target was defined as 110 mm Hg or higher. The limit of 110 mm Hg was chosen based on clinical considerations because maintaining MAP higher than 110 mm Hg during surgery with general anesthesia typically

Table 1. Baseline Patient Characteristics

Characteristic	Individualized blood pressure management (n = 567)	Routine blood pressure management (n = 567)
Age, median (IQR), y	67 (59-73)	66 (59-73)
Height, median (IQR), cm	174 (168-180)	174 (167-180)
Weight, median (IQR), kg	80 (70-91)	79 (68-92)
BMI, median (IQR)[a]	26.2 (23.1-29.7)	25.9 (23.1-29.3)
Sex, No. (%)		
Female	186 (32.8)	201 (35.4)
Male	381 (67.2)	366 (64.6)
ASA physical status, No. (%)[b]		
I (Healthy)	12 (2.1)	9 (1.6)
II (Mild systemic disease)	235 (41.4)	235 (41.4)
III (Severe systemic disease)	316 (55.7)	316 (55.7)
IV (Life-threatening severe systemic disease)	4 (0.7)	7 (1.2)
High-risk criteria, No. (%)		
Expected anesthesia duration ≥180 min	448 (79.0)	456 (80.4)
Immunodeficiency due to a disease or therapy	423 (74.6)	409 (72.1)
Kidney impairment	396 (69.8)	377 (66.5)
Age ≥65 y	339 (59.8)	318 (56.1)
BMI ≥30[a]	133 (23.5)	123 (21.7)
Current smoking or 15 pack-year history of smoking	133 (23.5)	142 (25.0)
Diabetes requiring medication	105 (18.5)	86 (15.2)
Coronary artery disease	71 (12.5)	67 (11.8)
Exercise tolerance <4 metabolic equivalents	39 (6.9)	38 (6.7)
Chronic obstructive pulmonary disease or pulmonary fibrosis	31 (5.5)	29 (5.1)
History of stroke	27 (4.8)	27 (4.8)
Chronic heart failure	21 (3.7)	17 (3.0)
BNP >80 ng/L or NT-proBNP >200 ng/L within the last 6 mo	17 (3.0)	15 (2.6)
Valvular heart disease	21 (3.7)	10 (1.8)
Peripheral arterial occlusive disease	8 (1.4)	16 (2.8)
Liver cirrhosis	7 (1.2)	16 (2.8)
Other comorbidities and coexisting conditions, No. (%)		
Solid organ cancer	430 (75.8)	427 (75.3)
Chronic arterial hypertension	307 (54.1)	265 (46.7)
Statin therapy	168 (29.6)	155 (27.3)
Aspirin therapy	95 (16.8)	102 (18.0)
Oral anticoagulation therapy	91 (16.0)	71 (12.5)
Atrial fibrillation	60 (10.6)	35 (6.2)
eGFR <60 mL/min/(1.73 m^2)[c]	58 (10.2)	52 (9.2)
Aortic aneurysm	10 (1.8)	7 (1.2)
Hematologic malignancies	6 (1.1)	6 (1.1)
Antihypertensive medication, No. (%)		
Any	327 (57.7)	296 (52.2)
β-Blocker	172 (30.3)	138 (24.3)
Angiotensin receptor blocker	131 (23.1)	112 (19.8)
Calcium channel blocker	126 (22.2)	89 (15.7)
Angiotensin-converting enzyme inhibitor	117 (20.6)	101 (17.8)
Diuretic	111 (19.6)	87 (15.3)
Aldosterone antagonist	27 (4.8)	18 (3.2)
Preoperative automated blood pressure monitoring		
At home, No. (%)	32 (5.6)	27 (4.8)
In hospital, No. (%)	535 (94.4)	540 (95.2)
Time from start of preoperative automated blood pressure monitoring to start of anesthetic induction, median (IQR), d	1 (1-1)	1 (1-1)
Nighttime MAP measurements, median (IQR), No.	12 (11-12)	12 (11-12)
Mean nighttime MAP, median (IQR), mm Hg	84 (77-92)	82 (76-89)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; BNP, brain natriuretic peptide; eGFR, estimated glomerular filtration rate; MAP, mean arterial pressure; NT-proBNP, N-terminal prohormone of brain natriuretic peptide.

[a] Calculated as weight in kilograms divided by square of height in meters.

[b] ASA physical status classification: ASA I, healthy patient; ASA II, patient with mild systemic disease; ASA III, patient with severe systemic disease; ASA IV, patient with severe systemic disease that poses a constant threat to life.

[c] eGFR was calculated for all patients using the Chronic Kidney Disease Epidemiology Collaboration Equation 2021 (CKD-EPI 2021) equation. Data were missing for 1 patient assigned to individualized blood pressure management.

requires high doses of vasopressors or fluids, which may increase the risk of complications.[4,21] The individualized MAP target thus could range from 65 mm Hg or higher to 110 mm Hg or higher. For patients assigned to routine blood pressure management, the target MAP was 65 mm Hg or higher.[10,22,23] In both groups, interventions used to manage blood pressure were determined by treating anesthesiologists and there was no specific hemodynamic management protocol.

Perioperative Blood Pressure Monitoring

Patients had intra-arterial or oscillometric blood pressure monitoring per institutional routine during the perioperative period. We quantified perioperative blood pressure using "area under a MAP threshold" and "time-weighted average MAP less than threshold" (eFigure 1 in Supplement 4). The area under a MAP threshold quantifies blood pressure by integrating both the severity and duration of exposure to MAP values less than given thresholds. The time-weighted average MAP less than threshold is calculated by dividing the area by the total measurement duration, allowing for standardized comparisons between patients with different measurement durations.

Outcomes

The primary outcome was the incidence of a composite outcome of acute kidney injury (defined as a ≥50% increase in serum creatinine concentration from baseline or need for kidney replacement therapy) within the first 7 postoperative days,

acute myocardial injury (defined as an increase in high-sensitivity troponin concentration according to the definition of myocardial injury and infarction associated with noncardiac procedures set forth in the Fourth Universal Definition of Myocardial Infarction [2018][24] or a myocardial infarction) within the first 7 postoperative days, nonfatal cardiac arrest within the first 7 postoperative days, or death within the first 7 postoperative days.

There were 22 secondary outcomes, which included the incidence of the individual components of the primary outcome within the first 3 and 7 postoperative days; the incidence of a composite outcome of infectious complications within the first 7 postoperative days; the incidence of a composite outcome of need for kidney replacement therapy, myocardial infarction, nonfatal cardiac arrest, or death within 30 and 90 days after surgery; the incidence of individual components of this composite outcome within 30 and 90 days after surgery; the incidence of unplanned hospital readmission within 30 days after surgery; and time to hospital discharge within 90 days after surgery. A complete list of outcome definitions is provided in the eMethods in Supplement 4.

Statistical Analysis

For the sample size, we assumed an incidence of the composite primary outcome of 25% in patients assigned to routine blood pressure management (adapted from our own data and literature[25-27]) and 17% in patients assigned to individualized blood pressure management. The assumed absolute risk reduction of 8% was a conservative estimate based on a previous trial investigating the effect of individualized blood pressure management on postoperative organ failure.[28] We estimated that a total sample size of 1144 patients would provide 90% power to detect an absolute 8% difference between the groups at a global significance level of .05 using a 2-sided test of proportions with continuity correction, including an interim analysis (unblinded to an independent statistician and the members of the data and safety monitoring board) at 50% recruitment. The O'Brien-Fleming α-spending function was used to establish a boundary for early stopping of the trial after the interim analysis, while controlling the overall type I error rate for both the interim and final analysis. Allowing for a 10% dropout rate, we planned to include 1272 patients.

Primary and secondary outcomes were analyzed in the primary analysis by including all patients who consented, were randomized, and underwent surgery and analyzing patients according to the groups to which they were randomized. The primary outcome analysis was conducted using a 2-sided test of proportions with continuity correction. As a sensitivity analysis, the primary outcome was analyzed using a mixed-effects logistic regression model including a fixed effect for the randomized treatment group and a random intercept for center. The primary outcome analysis was repeated in the per-protocol population, excluding patients assigned to individualized blood pressure management who had major protocol deviations.

Secondary outcomes were analyzed using a 2-sided test of proportions with continuity correction. Treatment effects are reported as relative risks (RRs) with 95% CIs. We performed prespecified subgroup analyses of patients with various degrees of arterial hypertension according to preoperative automated blood pressure monitoring.[29]

All analyses were conducted as complete case analyses, and no imputation was performed for missing data. All analyses were performed using R version 4.4.3 (R Foundation for Statistical Computing) and are completely described in the eMethods and eResults in Supplement 4.

Results

Trial Participants

Between February 26, 2023, and April 25, 2024, a total of 7621 patients were screened, 1272 were enrolled, and 1142 were randomized—571 to individualized and 571 to routine blood pressure management (**Figure 1**). Of the 130 enrolled patients who were not randomized, 105 (80.8%) were excluded for having 3 or fewer nonartifactual blood pressure measurements during the nighttime or for technical problems with preoperative automated blood pressure monitoring. Eight patients were excluded after randomization due to cancellation of surgery or withdrawal of consent. We thus included 1134 patients in the modified intention-to-treat analysis, 567 assigned to individualized and 567 to routine blood pressure management. Data for the primary outcome were available for all 1134 patients. The randomized groups were comparable for baseline demographics and clinical characteristics (Table 1).

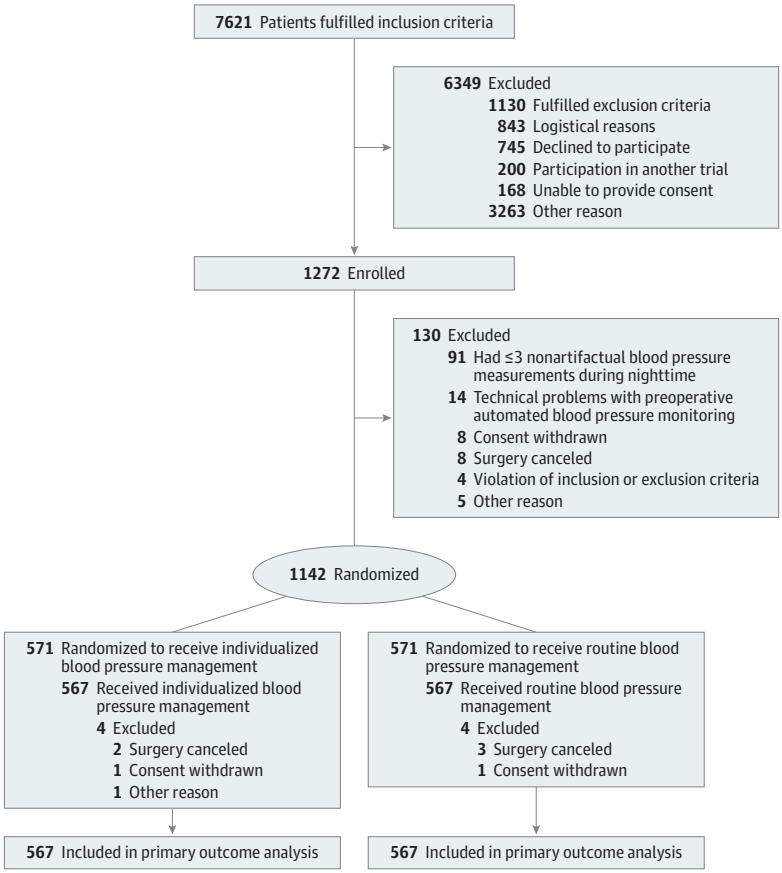
Preoperative Automated Blood Pressure Monitoring

Preoperative automated blood pressure monitoring was performed in the hospital—usually the night before surgery—for 535 patients (94.4%) assigned to individualized blood pressure management and 540 patients (95.2%) assigned to routine blood pressure management (Table 1). The remaining patients had preoperative automated blood pressure monitoring at home. A median of 12 (IQR, 11-12) nighttime blood pressure measurements per patient was available to calculate the preoperative mean nighttime MAP (Table 1). The median preoperative mean nighttime MAP was 84 mm Hg (IQR, 77-92 mm Hg; range, 56-133 mm Hg) in patients assigned to individualized blood pressure management and 82 mm Hg (IQR, 76-89 mm Hg; range, 59-131 mm Hg) in patients assigned to routine blood pressure management (eFigure 2 in Supplement 4). Twenty patients (3.5%) assigned to individualized blood pressure management and 8 patients (1.4%) assigned to routine blood pressure management had a preoperative mean nighttime MAP lower than 65 mm Hg.

Perioperative Blood Pressure Management

Perioperative blood pressure was measured using an arterial catheter in 74.3% of patients assigned to individualized blood pressure management and 74.6% of patients assigned to routine blood pressure management. Among patients assigned to individualized blood pressure management, the median proportion of time that perioperative MAP was at least at the preoperative mean nighttime MAP was 79% (IQR, 62%-91%) (**Table 2**). Compared with patients assigned to routine blood

Figure 1. Enrollment and Randomization in a Trial of Individualized Perioperative Blood Pressure Management in Patients Undergoing Major Abdominal Surgery



pressure management, patients assigned to individualized blood pressure management had higher median MAP throughout the intervention period and smaller areas under MAP thresholds (**Figure 2**, Table 2; eTable 1 and eFigure 3 in Supplement 4). The median total volume of fluids administered during the intervention period was similar between the 2 groups, but patients assigned to individualized blood pressure management were given more norepinephrine (Table 2; eTable 1 in Supplement 4).

Primary Outcome

The composite primary outcome occurred in 190 patients (33.5%) assigned to individualized blood pressure management and in 173 patients (30.5%) assigned to routine blood pressure management (RR, 1.10 [95% CI, 0.93-1.30]; P = .31) (**Table 3**; eFigures 4-6 and eTable 2 in Supplement 4). After accounting for center effects in a mixed-effects logistic regression model, the adjusted odds ratio was 1.16 (95% CI, 0.90-1.49; P = .26; intraclass correlation coefficient, 0.056).

For 8 patients assigned to individualized blood pressure management, clinicians did not adhere to the protocol: for 7 patients, preoperative mean nighttime MAP was calculated incorrectly; for 1 patient, the treating anesthesiologist stopped the trial intervention. The per-protocol population therefore included 1126 patients—559 (49.6%) assigned to individualized blood pressure management and 567 (50.4%) assigned to routine blood pressure management. In the per-protocol analysis, the composite primary outcome occurred in 187 patients (33.5%) assigned to individualized blood pressure management and in 173 patients (30.5%) assigned to routine blood pressure management (RR, 1.10 [95% CI, 0.92-1.30]; P = .32).

A total of 292 patients (51.5%) assigned to individualized blood pressure management and 278 patients (49.0%) assigned to routine blood pressure management had arterial hypertension according to preoperative automated blood pressure monitoring. Individualized blood pressure management did not reduce the odds for the primary composite outcome in any of the prespecified subgroups of patients with different degrees of preoperative arterial hypertension (eTable 3 in Supplement 4).

Secondary Outcomes

Secondary outcomes are shown in Table 3 and in eTable 4 and eFigure 7 in Supplement 4. There were no significant differences in any of the 22 secondary outcomes, including the incidence of individual components of the composite primary outcome within the first 3 or 7 postoperative days and the incidence of a composite outcome of infectious complications within the first 7 postoperative days. Within 30 days after

Table 2. Clinical Characteristics[a]

Variable	Individualized blood pressure management (n = 567)	Routine blood pressure management (n = 567)
Type of surgery, No. (%)		
General	259 (45.7)	270 (47.6)
Urologic	232 (40.9)	210 (37.0)
Gynecologic	51 (9.0)	64 (11.3)
Liver	25 (4.4)	20 (3.5)
Vascular	0	3 (0.5)
Time from randomization to start of anesthetic induction, median (IQR), min	79 (52-142)	79 (51-178)
Duration of surgery, median (IQR), min	207 (155-274)	211 (156-290)
Postoperative admission to intensive care unit, No. (%)	268 (47.3)	283 (49.9)
Anesthetic technique, No. (%)		
Balanced anesthesia	374 (66.0)	362 (63.8)
Total intravenous anesthesia	193 (34.0)	205 (36.2)
Epidural block	252 (44.4)	248 (43.7)
Intra-arterial blood pressure monitoring (arterial catheter)	421 (74.3)	423 (74.6)
Fluids		
Crystalloids, median (IQR), mL	3000 (2000-4164)	3000 (2000-4000)
Use of colloids, No. (%)	111 (19.6)	97 (17.1)
Colloids, median (IQR), mL[b]	750 (500-1000)	500 (500-1000)
Blood products		
Use of packed red blood cells, No. (%)	51 (9.0)	55 (9.7)
Packed red blood cells, median (IQR), units[b]	2 (2-4)	2 (1-5)
Use of fresh frozen plasma, No. (%)	24 (4.2)	26 (4.6)
Fresh frozen plasma, median (IQR), units[b]	5 (3-6)	5 (3-6)
Vasopressors		
Use of norepinephrine, No. (%)	536 (94.5)	495 (87.3)
Norepinephrine, median (IQR), mg[b]	1.53 (0.62-3.83)	1.25 (0.41-3.19)
Perioperative blood pressures, median (IQR)[c]		
Area under a MAP of 65 mm Hg, mm Hg × min	6 (0-54)	48 (7-151)
Proportion of time with MAP ≥preoperative mean nighttime MAP, %	79 (62-91)	57 (28-81)

Abbreviation: MAP, mean arterial pressure.

[a] All data in table for administered medications—including fluids, blood products, and vasopressors—and for blood pressure data refer exclusively to the intervention period, defined as the time from the start of induction of general anesthesia until 2 hours after the end of surgery.

[b] Data were calculated only for patients who received the respective drug.

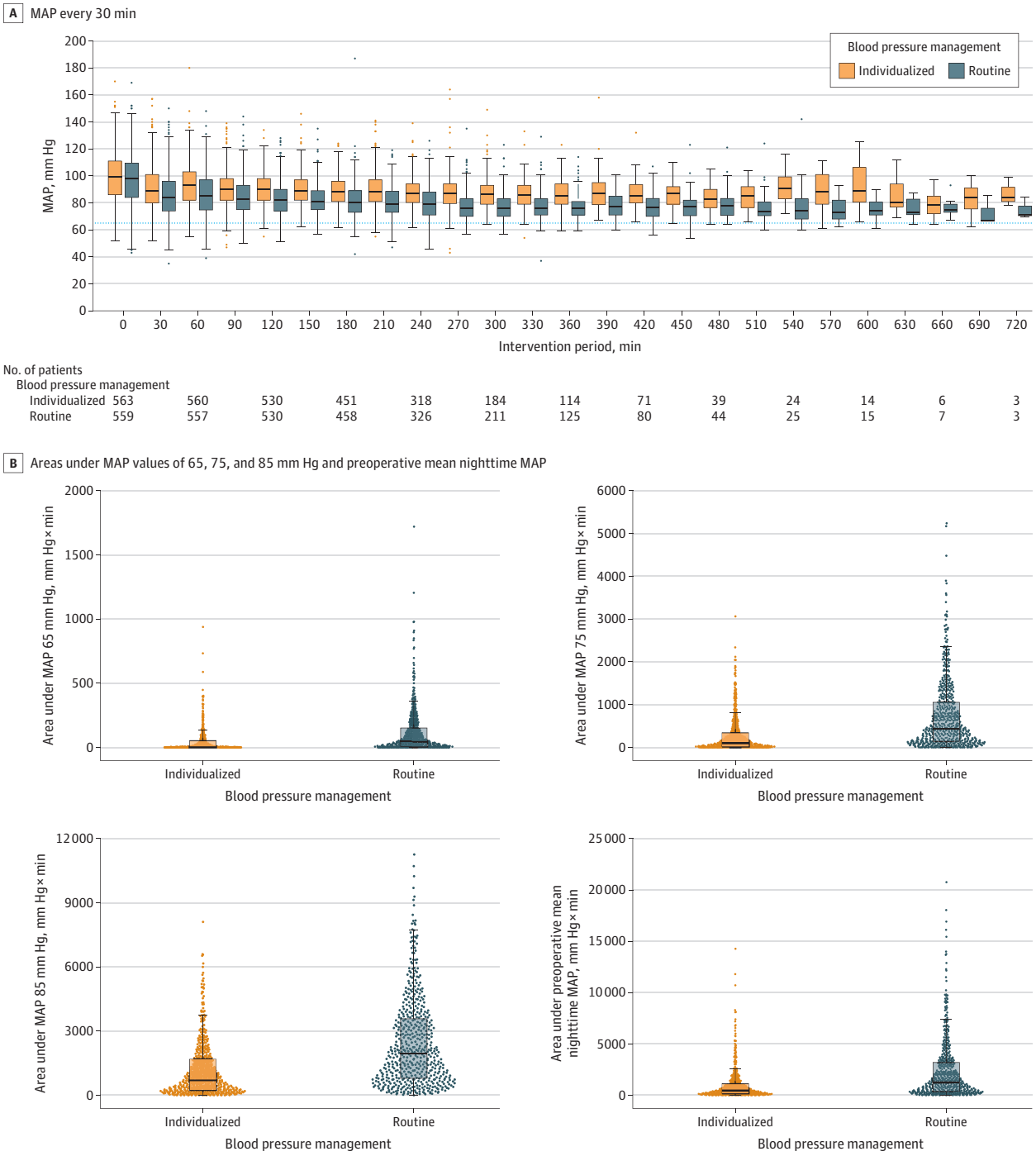
[c] An illustration of the measures "area under MAP threshold" and "time-weighted average MAP less than threshold" is provided in eFigure 1 in Supplement 4.

surgery, 53 patients (9.4%) assigned to individualized blood pressure management and 52 patients (9.3%) assigned to routine blood pressure management were readmitted to the hospital (RR, 1.02 [95% CI, 0.71-1.47]; $P > .99$).

Discussion

The findings that individualized perioperative blood pressure management with MAP targets based on preoperative mean nighttime MAP, compared with a MAP target of 65 mm Hg or higher, did not reduce the incidence of a composite outcome of acute kidney injury, acute myocardial injury, nonfatal cardiac arrest, or death within the first 7 postoperative days contrast with the results of the 292-patient INPRESS trial.[28] That trial reported that individualization of blood pressure management by keeping perioperative systolic arterial pressure within 10% of a single preoperative measurement reduced the incidence of a composite outcome of systemic inflammatory response syndrome and organ dysfunction in patients undergoing noncardiac surgery (38% vs 52%; RR, 0.73 [95% CI, 0.56-0.94]; $P = .02$). Two other randomized trials compared fixed (rather than individualized) higher vs lower MAP targets.[30,31] A single-center trial with 458 patients reported that compared with a MAP goal of 60 mm Hg or higher, a target MAP of 75 mm Hg or higher did not reduce the incidence of a composite outcome of acute myocardial injury, acute kidney injury, or major adverse cardiovascular events.[30] Similarly, in the POISE-3 trial, which included 7490 patients, a complex perioperative hypotension-avoidance strategy including keeping intraoperative MAP at 80 mm Hg or higher during noncardiac surgery—compared with a hypertension-avoidance strategy including keeping intraoperative MAP at 60 mm Hg or higher—did not reduce the incidence of a composite outcome of vascular death, myocardial injury after noncardiac surgery, stroke, and cardiac arrest.[31] The findings of the current trial extend these 2 previous trials by using individualized rather than fixed blood pressure targets. Notably, two-thirds of the patients in the current trial assigned to individualized blood pressure management had MAP targets of 80 mm Hg or higher, meaning that targets in the trial were generally higher than in previous trials. Nonetheless, our results show that targeting higher MAP

Figure 2. Perioperative Blood Pressures



A, Mean arterial pressures (MAP) every 30 minutes during the intervention period (censored after 720 minutes) in patients assigned to individualized and routine blood pressure management. B, Boxplots with overlaying 1-dimensional scatter plots illustrating areas under MAP values of 65, 75, and 85 mm Hg and under the preoperative mean nighttime MAP throughout the complete intervention period. Boxes represent the 25th and 75th quantiles; horizontal bold lines inside boxes, medians. Whiskers indicate the lowest and highest value no further than 1.5 times the IQR; dots, values greater or less than 1.5 times the IQR. Areas under MAP thresholds quantify both how long and to what extent MAP was below a respective threshold (eFigure 1 in Supplement 4). Data were missing for 12 patients (4 patients assigned to individualized blood pressure management and 8 patients assigned to routine blood pressure management).

values, rather than the conventional target of 65 mm Hg or higher, did not prevent organ injury or improve outcomes.

This trial considered individually defining perioperative blood pressure targets based on each patient's preoperative

Table 3. Primary and Secondary Outcomes

Outcome	No./total (%)		Absolute difference (95% CI), %	Relative risk (95% CI)	*P* value
	Individualized blood pressure management	Routine blood pressure management			
Primary outcome					
Composite outcome of acute kidney injury, acute myocardial injury, nonfatal cardiac arrest, or death within 7 d after surgery	190/567 (33.5)	173/567 (30.5)	3.00 (−2.61 to 8.60)	1.10 (0.93 to 1.30)	.31
Secondary outcomes[a]					
Acute kidney injury within 7 d after surgery	72/566 (12.7)	58/567 (10.2)	2.49 (−1.39 to 6.38)	1.24 (0.90 to 1.72)	.22
Acute myocardial injury within 7 d after surgery	153/558 (27.4)	138/561 (24.6)	2.82 (−2.50 to 8.14)	1.11 (0.91 to 1.36)	.31
Nonfatal cardiac arrest within 7 d after surgery	2/567 (0.4)	0/567 (0.0)	0.35 (−0.31 to 1.02)	Not defined	.48
Death within 7 d after surgery	0/567 (0)	4/567 (0.7)	−0.71 (−1.57 to 0.16)	0.00 (0.00 to 2.36)	.13
Composite outcome of acute kidney injury, acute myocardial injury, nonfatal cardiac arrest, or death within 3 d after surgery	166/567 (29.3)	154/567 (27.2)	2.12 (−3.30 to 7.53)	1.08 (0.90 to 1.30)	.47
Acute kidney injury	56/566 (9.9)	49/567 (8.6)	1.25 (−2.30 to 4.80)	1.14 (0.79 to 1.65)	.53
Acute myocardial injury	134/558 (24.0)	120/561 (21.4)	2.62 (−2.46 to 7.71)	1.12 (0.90 to 1.39)	.33
Nonfatal cardiac arrest	2/567 (0.4)	0/567 (0)	0.35 (−0.31 to 1.02)	Not defined	.48
Death	0/567 (0)	4/567 (0.7)	−0.71 (−1.57 to 0.16)	0.00 (0.00 to 2.36)	.13
Composite outcome of infectious complications within 7 d after surgery	90 (15.9)	97 (17.1)	−1.23 (−5.73 to 3.26)	0.93 (0.71 to 1.21)	.63
Composite outcome of need for kidney replacement therapy, myocardial infarction, nonfatal cardiac arrest, or death within 30 d after surgery	21/566 (3.7)	13/567 (2.3)	1.42 (−0.74 to 3.58)	1.62 (0.82 to 3.20)	.22
Need for kidney replacement therapy	5/566 (0.9)	3/567 (0.5)	0.35 (−0.80 to 1.51)	1.67 (0.40 to 6.95)	.72
Myocardial infarction	9/566 (1.6)	2/567 (0.4)	1.24 (−0.08 to 2.55)	4.51 (0.98 to 20.77)	.07
Nonfatal cardiac arrest	4/566 (0.7)	2/567 (0.4)	0.35 (−0.67 to 1.38)	2.00 (0.37 to 10.89)	.68
Death	5/567 (0.9)	10/567 (1.8)	−0.88 (−2.39 to 0.62)	0.50 (0.17 to 1.45)	.30
Composite outcome of need for kidney replacement therapy, myocardial infarction, nonfatal cardiac arrest, or death within 90 d after surgery	32/566 (5.7)	20/567 (3.5)	2.13 (−0.48 to 4.74)	1.60 (0.93 to 2.77)	.12
Need for kidney replacement therapy	7/566 (1.2)	4/567 (0.7)	0.53 (−0.79 to 1.85)	1.75 (0.52 to 5.96)	.54
Myocardial infarction	10/566 (1.8)	3/567 (0.5)	1.24 (−0.18 to 2.65)	3.34 (0.92 to 12.07)	.09
Nonfatal cardiac arrest	4/566 (0.7)	3/567 (0.5)	0.18 (−0.91 to 1.27)	1.34 (0.30 to 5.94)	>.99
Death	16/567 (2.8)	16/567 (2.8)	0 (−1.93 to 1.93)	1.00 (0.51 to 1.98)	>.99
Incidence of unplanned hospital readmission within 30 d after surgery	53/562 (9.4)	52/562 (9.3)	0.18 (−3.40 to 3.76)	1.02 (0.71 to 1.47)	>.99

[a] The secondary outcomes incidence of individual components of the composite outcome of infectious complications within the first 7 postoperative days and time to hospital discharge within 90 days after surgery are shown in eTable 4 and eFigure 7, respectively, in Supplement 4.

normal blood pressure. However, the most effective means of determining preoperative normal blood pressure in surgical patients remains unclear—and is affected by circadian variations in blood pressure. In the current trial, individualized blood pressure management was based on preoperative mean nighttime MAP assessed using automated blood pressure measurements obtained between midnight and 6:00 AM. In contrast, single blood pressure measurements in the hospital[32] or immediately before anesthetic induction[11,33] poorly represent normal preoperative blood pressures, and ambulatory automated blood pressure monitoring is considered the best method for assessing a patient's normal blood pressure.[34-36] This trial targeted individual preoperative mean nighttime MAP, which is usually lower than daytime MAP (except for individuals who are "reverse dippers," in whom nighttime blood pressure is higher than daytime blood pressure).[11] The trial assumed that nighttime MAP (measured during physiological sleep) may be a surrogate for the individual lower MAP intervention threshold during surgery with general anesthesia because people tolerate their lowest nighttime blood pressures. However, use of the lowest nighttime value as perioperative target may have carried the risk of including artifactual outlier measurements, so preoperative mean nighttime MAP was selected as the perioperative target for individualized blood pressure management.

Profound and prolonged hypotension was rare even in patients assigned to routine blood pressure management, as indicated by the low median area under a MAP of 65 mm Hg. The care of patients assigned to routine blood pressure management was therefore managed according to current guidelines.[7-10] As a consequence, the trial cannot identify thresholds at which hypotension becomes harmful. However, many observational analyses report that profound and prolonged intraoperative hypotension is associated with

organ injury in at-risk patients,[1-6] and guidelines recommend targeting intraoperative MAP above 60 to 65 mm Hg during noncardiac surgery.[7-10]

Hypotension can result from vasodilation, hypovolemia, myocardial depression, and bradycardia,[3,7] and treatment of hypotension depends on the individual clinical context.[7] Because anesthesiologists have expertise in identifying and treating hypotension, blood pressure management was left to their discretion. The median volume of fluids administered did not differ substantially between the 2 groups. However, patients assigned to individualized blood pressure management received more vasopressors.

The trial included high-risk patients who were at least 45 years old, of whom about one-half had a history of chronic arterial hypertension and were therefore potentially at increased risk from adverse effects of hypotension. However, subgroup analyses of patients with arterial hypertension analyzed based on preoperative blood pressure levels did not indicate any benefit from individualized blood pressure management. Subgroup analyses were limited to those prespecified in the statistical analysis plan. However, additional subgroup analyses—for example, by age or comorbidities, such as chronic kidney disease or atherosclerotic cardiovascular disease—warrant further investigation in future studies specifically designed to explore them.

Limitations

This trial has several limitations. First, the approach of individualizing MAP targets using preoperative mean nighttime MAP was based on pathophysiological rationale, but there is no evidence that nighttime MAP during normal sleep reflects the optimal MAP during surgery with general anesthesia. Second, about 95% of the patients had preoperative blood pressure monitoring in the hospital, although ambulatory measurements would presumably have better reflected individual preoperative baseline blood pressure. However, implementing ambulatory automated blood pressure monitoring in routine clinical practice would be complex and costly.

Third, anesthesiologists were not blinded to treatment allocation. However, all components of the primary outcome were objectively measurable and were independently monitored. Although data were systematically collected on intraoperative management, the possibility that knowledge of group allocation influenced how clinicians managed the care of patients beyond what was documented in the trial cannot be ruled out. Fourth, approximately 25% of patients in each group had oscillometric blood pressure measurements during surgery, which may be less accurate than intra-arterial blood pressure monitoring with an arterial catheter.

Fifth, the trial did not include advanced hemodynamic monitoring (such as cardiac output monitoring) to assess the underlying causes of hypotension or a specific hemodynamic management protocol. Sixth, among the components of the primary outcome, nonfatal cardiac arrest and death were very rare, so conclusions cannot be drawn about the effect of individualized blood pressure management on these outcomes. Seventh, data on the continuation or discontinuation of antihypertensive medications were not collected and therefore whether their preoperative management influenced the intervention or outcomes cannot be assessed. In current clinical practice, when antihypertensive medications—such as angiotensin-converting enzyme inhibitors or angiotensin receptor blockers—are withheld, they are typically discontinued on the morning of surgery.

Conclusions

Among patients at high risk of postoperative complications undergoing major abdominal surgery, individualized perioperative blood pressure management with MAP targets based on preoperative mean nighttime MAP did not decrease the composite outcome of acute kidney injury, acute myocardial injury, nonfatal cardiac arrest, or death within the first 7 postoperative days compared with routine blood pressure management with a MAP target of 65 mm Hg or higher.

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