ISRCTN17085700 https://doi.org/10.1186/ISRCTN17085700

Changing doctors' behaviour in the treatment of low blood pressure

Submission date 15/04/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/05/2019	**Overall study status** Completed	
Last Edited 08/01/2024	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Low blood pressure during surgery (intraoperative hypotension) is poorly defined due to the lack of a standardised definition, however, regardless of the definition, the incidence is high. If we look at relative extremes, 56% and 27% of patients experienced a drop in mean blood pressure of greater than 40% from baseline for a duration of 1 and 10 minutes respectively, whilst 50% and 24% experience a systolic blood pressure drop of > 40% at these time scales. This is consistent with other studies examining intraoperative hypotension. In a study of 33,000 patients undergoing major surgery, the authors calculated the time that mean arterial pressure (MAP) was less than various thresholds ranging from 55-75 mmHg. A MAP of less than 55 mmHg was associated with both kidney and cardiac injury and the risk increased with the amount of time spent below this blood pressure. More recent work has added to this evidence looking at the association of kidney injury and intraoperative hypotension in elective surgery. There was a graded relationship between hypotension both in terms of magnitude and duration and the severity of kidney injury. There is now technology that works off a standard arterial line that is able to predict hypotension before it happens (hypotension probability index [HPI]), and the rationale is that by using the HPI and secondary information intraoperative hypotension can be reduced and appropriately treated. However, hypotension can also be avoided simply by requiring the treating clinician to keep the MAP above 65 mmHg, although the treatments may be inappropriate to the cause. Therefore the aim of this study is to find out whether through the use of the HPI and the secondary information clinician behaviour to the treatment of hypotension is altered compared to standard practice.

Who can participate?
Patients due to undergo elective major abdominal, orthopaedic, head and neck or vascular surgery requiring invasive arterial monitoring (decided at the discretion of the treating clinician) under general anaesthesia with positive pressure ventilation, and with an expected duration of greater than 90 minutes, who will have goal-directed fluid therapy performed as part of their standard care.
Clinicians and other allied medical staff will be included in the qualitative study on the basis that they are involved in the care of patients meeting the above criteria and are willing to participate in the interviews and questionnaires.

What does the study involve?
The study involves three groups of 50 patients.
The first group of patients receive standard care for patients undergoing major surgery. They receive goal-directed fluid therapy (GDFT) during surgery and clinicians have access to the all haemodynamic (blood flow) data except for the new advanced parameters.
Clinicians who treat patients in the second group receive a short presentation that outlines the current evidence of the association with intraoperative hypotension and adverse clinical outcomes. The patients receive GDFT during surgery and clinicians have access to the all haemodynamic (blood flow) data except for the new advanced parameters. Clinicians are asked to maintain a MAP of over 65 mmHg.
Clinicians who treat patients in group 3 receive a short presentation that describes HPI and the new advanced parameters and how these may be used clinically. Patients receive GDFT during surgery, and clinicians have access to the all haemodynamic data including the new advanced parameters. Clinicians are asked to keep the MAP over 65 mmHg and to proactively treat an HPI of > 85% using their knowledge of the advanced parameters.

What are the possible benefits and risks of participating?
There are no expected benefits or risks of participating.

Where is the study run from?
York Teaching Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2019 to August 2021

Who is funding the study?
Edwards Lifesciences (USA)

Who is the main contact?
Dr Simon James Davies
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
38608

Study information

Scientific Title
Effects of FloTrac IQ on changing clinician behaviour in the management of intraoperative hypotension

Acronym
HypoIQ

Study objectives
This study will be measuring a range of social-cognitive determinants of behaviour change including attitudes, self-efficacy, social norms, skills, as well as factors relating to the normalisation of technology, in this case the FlotracIQ designed to aid the management of hypotension, into routine practice through qualitative data analysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/11/2018, REC Yorkshire and the Humber – Sheffield (Tel: +44 (0)207 104 8084; Email: nrescommittee.yorkandhumber-sheffield@nhs.net), ref: 18/YH/0185

Study design
Non-randomised; Both; Design type: Treatment, Device, Management of Care, Surgery, Active Monitoring, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Intraoperative hypotension

Interventions
This will be a prospective non-randomised trial with three sequential cohorts of 50 patients. The first cohort will act as the control group representing standard practice at the institution, whilst the subsequent two cohorts will have different interventions applied. Randomisation was not considered appropriate due to the potential for observation bias (Hawthorn effect).

Cohort 1 - Standard institutional care (GDFT) - 50 patients

Study participants will receive standard institutional care for patients undergoing major surgery. All patients will have an arterial line connected to FloTrac IQ transducers and haemodynamic data will be displayed on the EV 1000 platform. Patients will receive goal-directed fluid therapy intraoperatively to maintain a stroke volume variation of less than 12% (15% in laparoscopic surgery with pneumoperitoneum) and clinicians will have access to the all haemodynamic data except for hypotension probability index, Eadyn and dP/dT which are the new advanced parameters.

Management of hypotension will be entirely at the discretion of the attending anaesthetist both in terms of the threshold for treatment and mode of treatment. All fluid management and administration of vasopressor therapy will be at the discretion of the anaesthetist as per the current practice at the host institution.

All interventions relating to the treatment of hypotension will be entered on to the clinical monitor, and at the end of surgery data will be downloaded that will provide measurements of cardiac output, cardiac index, stroke volume variation, stroke volume, stroke volume index, hypotension probability index, pulse rate variability, pulse rate, and systolic, diastolic and mean arterial pressure. Anonymised data will be sent to Edwards Lifesciences for data capture of dP /dT, Eadyn and PPV.

Education intervention 1

All clinicians who will treat patients enrolled into cohort 2 will receive a short presentation via email or at a departmental meeting that outlines the current evidence of the association with intraoperative hypotension and adverse clinical outcomes. All clinicians will be required to sign a statement acknowledging that they have received and understood this education package

Cohort 2 (GDFT and intraoperative MAP >65 mmHg) - 50 patients

All patients will have an arterial line connected to FloTrac IQ transducers and haemodynamic data will be displayed on the EV 1000 platform. Patients will receive goal-directed fluid therapy intraoperatively to maintain a stroke volume variation of less than 12% (15% in laparoscopic surgery with pneumoperitoneum) and clinicians will have access to the all haemodynamic data except for hypotension probability index, Eadyn and dP/dT.

Clinicians will be asked to maintain a MAP >65 mmHg. No specific guidance will be issued on how to achieve this target and it will be left to the clinical discretion of the treating clinician. All fluid management and administration of vasopressor therapy will be at the discretion of the anaesthetist.

All interventions relating to the treatment of hypotension will be entered on to the EV1000 platform, and at the end of surgery data will be downloaded from the EV1000 platform that will provide measurements of cardiac output, cardiac index, stroke volume variation, stroke volume, stroke volume index, hypotension probability index, pulse rate variability, pulse rate, and systolic, diastolic and mean arterial pressure. Anonymised data will be sent to Edwards Lifesciences for data capture of dP/dT, Eadyn and PPV.

Education intervention 2

All clinicians who will treat patients enrolled into cohort 3 will receive a short presentation via email or at a departmental meeting that describes the hypotension probability index, and the two additional parameters of Eadyn and dP/dT and how these may be used clinically. All clinicians will be required to sign a statement acknowledging that they have received and understood this education package.

Cohort 3 (GDFT and HPI)

All patients will have an arterial line connected to FloTrac IQ transducers and haemodynamic data will be displayed on the EV 1000 platform. Patients will receive goal-directed fluid therapy intraoperatively as per the institutions' local policy, and clinicians will have access to the all haemodynamic data including hypotension probability index, Eadyn and dP/dT.

Clinicians will be asked to keep the MAP > 65 mmHg and to proactively treat an HPI of > 85% using their knowledge of the advanced haemodynamic parameters Eadyn and dP/dT. Guidance on potentially suitable intervention will be given (see protocol)

All interventions relating to the treatment of hypotension will be entered on to the EV1000 platform, and at the end of surgery data will be downloaded from the EV1000 platform that will provide measurements of cardiac output, cardiac index, stroke volume variation, stroke volume, stroke volume index, hypotension probability index, pulse rate variability, pulse rate, and systolic, diastolic and mean arterial pressure. Anonymised data will be sent to Edwards Lifesciences for data capture of dP/dT, Eadyn and PPV.

Clinical staff interviews

Structured interview will take place and questionnaires distributed both designed to provide insights into the following research questions and given to clinical staff at the time scale described below.

Research question 1: What are the beliefs amongst *clinical staff of the costs and benefits of controlling hypotension during surgery following initial training?

Interviews with 15-20 clinical staff will be performed across both sites using the Theoretical domains framework (Michie et al., 2005) to structure interviews (Sample interview appendix 3).

Research question 2: What do clinical staff perceive to be the barriers to effective control of hypotension during phase 2 and 3?

Questionnaires based on information from the above interviews (section 7.1) will be developed as well as the Influences on Patient Safety Behaviour Questionnaire (Taylor et al., 2013) distributed to all staff attending training at phase 2 and phase 3 and others who might be involved in caring for patients before, during or after major surgery. Aim to achieve an overall sample of 50+.

Research question 3: How useful and usable is the new technology and can it readily be integrated into routine practice?

Items from Standardised Normalisation Process Theory questionnaire (NOMAD, 2016) and Implementation of medical devices questionnaire (Green et al., 2009) used in testing of usability of new devices to be distributed to all staff as in section 7.2 approximately 2 months post-training and FloTrac IQ implementation. In addition observations of practice during 6-8 surgical procedures at York and Groningen will occur with post-procedure interviews with key staff.

Research question 4: What are the attitudes of other clinicians (outside of the two sites) to the use of FloTrac IQ technology? What is the likelihood of wider adoption?

Workshop with 30+ Yorkshire and Humber clinicians including embedded focus group discussions and brief exit questionnaires.

*Clinical staff refers primarily to anaesthetists, but surgeons, ODPs, recovery staff may also have a role in supporting the monitoring and control of hypotension, so while sampling will attempt to represent at least 40%+ of anaesthetists in each unit, other clinical staff will also be included /represented.

Intervention Type
Other

Primary outcome measure
Social-cognitive determinants of behaviour change including attitudes, self-efficacy, social norms, skills, as well as factors relating to the normalisation of technology into routine practice, assessed through
qualitative data analysis of interviews and questionnaires across the study at different timepoints (end of phase 1, 2 and 3)

Secondary outcome measures
1. Treatment of hypotension in the different cohorts, measured at the end of surgery, analysis after cohort 3
2. Incidence of hypotension (defined as no of episodes with MAP <65 mmHg) in each cohort, measured the end of surgery, analysis after cohort 3
3. Time weighted average spent in hypotension between cohorts, measured at the end of surgery
4. Proportion of interventions deemed suboptimal to treat hypotension, measured at the end of each cohort
5. Effects of interventions (fluid, vasopressors and inotropes) on secondary parameters including SVV, PPV, CI, SVI, Eadyn and dP/dT, measured at the end of surgery, analysis after cohort 3
6. Health psychology analysis, measured at the end of surgery, analysis after cohort 3

Overall study start date
06/03/2019

Completion date
31/08/2021

Eligibility

Key inclusion criteria
1. Patients due to undergo elective major abdominal, orthopaedic, head and neck or vascular surgery requiring invasive arterial monitoring (decided at the discretion of the treating clinician) under general anaesthesia with positive pressure ventilation, and with an expected duration of greater than 90 minutes, who will have goal-directed fluid therapy performed as part of their standard care
2. Clinicians and other allied medical staff will be included in the qualitative study on the basis that they are involved in the care of patients meeting the above criteria and are willing to participate in the structured interviews and questionnaires

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 150; UK Sample Size: 75

Total final enrolment
150

Key exclusion criteria
1. Requirement for an intraoperative mean arterial pressure of greater than 65mmHg as decided by the treating surgeon and/or anaesthetist
2. A preoperative MAP of lower than 65 mmHg documented on 2 separate occasions at preoperative assessment clinic
3. Significant right or left ventricular heart failure
4. Known intracardiac shunt
5. Known severe aortic stenosis (peak velocity greater than 4m per second and/or aortic valve area less than 1 cm2)
6. Cardiac arrhythmias
7. Planned positive pressure ventilation with tidal volume < 7 ml/kg
8. Hepatic surgery
9. Subjects requiring dialysis
10. Subjects who do not have the capacity to consent
11. Subjects aged less than 18 years of age

Date of first enrolment
11/05/2019

Date of final enrolment

31/08/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
York Teaching Hospital NHS Foundation Trust
York Hospital
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/027e4g787

Funder(s)

Funder type
Industry

Funder Name
Edwards Lifesciences

Alternative Name(s)
Edwards, Edwards Lifesciences Corporation, Edwards Lifesciences Corp., Edwards Lifesciences LLC, ELC

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
1. Peer reviewed scientific journals
2. Conference presentation

Intention to publish date
31/08/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V5	18/10/2018	09/05/2019	No	No
HRA research summary			28/06/2023	No	No
Results article		19/12/2023	08/01/2024	Yes	No