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Pilot multicentre randomised trial of the impact of preoperative focused cardiac ultrasound on mortality and morbidity in patients having surgery for femoral neck fractures (ECHONOF II Pilot)

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Summary

Hip fracture surgery is common, usually occurs in elderly patients who have multiple co-morbidities, and is associated with high morbidity and mortality. Preoperative focused cardiac ultrasound (FCU) can alter diagnosis and management, but its impact on outcome remains uncertain. This pilot study assessed feasibility and group separation for a proposed large randomised clinical trial of the impact of preoperative FCU on patient outcome after hip fracture surgery. Adult patients requiring hip fracture surgery in four teaching hospitals in Australia were randomised to receive FCU before surgery or not. The primary composite outcome was any death, acute kidney injury, non-fatal myocardial infarction, cerebrovascular accident, pulmonary embolism or cardiopulmonary arrest within 30 days of surgery. Of the 175 patients screened, 100 were included as trial participants (screening:recruitment ratio 1.75:1), 49 in the FCU group and 51 as controls. There was 1 protocol failure among those recruited. The primary composite outcome occurred in 7 of the FCU group patients and 12 of the control group patients (relative group separation 39%); death, acute kidney injury and cerebrovascular accident were recorded, but no cases of myocardial infarction, pulmonary embolism or cardiopulmonary arrest were recorded. Focused cardiac ultrasound altered the management of 17 participants, suggesting an effect mechanism. This pilot study demonstrated that enrolment and the protocol are feasible, that the primary composite outcome is appropriate, and that there is a treatment effect favouring FCU - and therefore supports a large randomised clinical trial.

Introduction

Hip fracture patients are typically elderly and suffer from multiple co-morbid diseases. Despite advances in healthcare, both 30 day and 1-year postoperative mortality remain high at 7.1% (England and Wales) [1] and 20-35% (Europe) [2], respectively. Death mostly commonly results from co-morbidities rather than the hip fracture. Postoperative morbidity is common, often disabling and can require prolonged, expensive institutionalisation. Prolonged longevity suggests that the annual incidence of hip fracture worldwide could rise from 2.3 million currently to 6.3 million by 2050 [3].

Adequate preoperative assessment is prudent in patients having high risk of cardiac disease [4]. However, there is also evidence that delaying surgery increases postoperative mortality [5-7], constraining the time available for preoperative investigations. Clinical assessment of cardiac disease is unreliable, misdiagnosing significant cardiovascular disease in about half of all patients [8-10]. Transthoracic echocardiography (TTE) is a non-invasive investigation that identifies structural cardiac pathologies independently associated with postoperative mortality, such as cardiac failure [11], aortic stenosis [12], and pulmonary hypertension [13]. Transthoracic echocardiography also identifies abnormal haemodynamic states, including hypovolaemia, cardiac failure, and vasodilation [14], allowing rapid correction of these before anaesthesia and surgery.

However, formal TTE evaluation by cardiologists may not be routinely available in the short period required available before timely surgery [15]. Focused cardiac ultrasound (FCU) is a goal-directed, abbreviated form of TTE, which enhances bedside clinical assessment and guides acute medical decisions [16]. Without delaying surgery, FCU promotes diagnostic accuracy, often changing diagnosis and management [8, 17], for example, by guiding preoperative intravascular volume replacement, and rationalising the use of invasive monitoring, vasopressor infusions and planned postoperative intensive care.

In a two-centre retrospective cohort analysis of hip fracture patients, the use of FCU was associated with a 3-fold reduction in 30-day mortality, compared to a control group with similar risk factors [8]. This pilot study aims to inform the feasibility of conducting a larger multicentre, prospective randomised cohort comparison, to test the hypothesis that compared to controls, FCU alters the medical management of hip fracture patients and affects a collapsed composite of serious complications and 30-day postoperative mortality.

Methods

This parallel group, randomised, controlled, multicentre pilot study with 1:1 allocation ratio was approved by The Melbourne Health Research Ethics Committee (2015.309) and registered on ClinicalTrials.gov NCT02629484. Written consent was obtained from all participants or next of kin with power of attorney.

The main research site was a metropolitan tertiary university hospital with a high volume of acute orthopaedic surgery and sufficient clinicians proficient in FCU. Three similar centres participated in recruitment at varying times during the study period. The trial did not have per-participant funding which reduced the potential recruitment to days when researchers were available, and for some institutions, a limited duration of recruitment.

Adult participants were eligible for inclusion if they were scheduled for surgical repair of unilateral fractured neck of femur (fracture between the femoral head and a line 5cm below the lesser trochanter). Participants were excluded if they had received previous hip surgery on the affected side, were scheduled to receive surgery for other injuries, had metastatic cancer or a suspected pathological hip fracture, were not expected to survive longer than 24 hours, had had a TTE within one month of the current surgery, or had received a request for TTE before recruitment and randomisation in the study.

Research personnel, who monitored the emergency surgery operating theatre list for patients scheduled for hip fracture surgery, performed participant screening. Potential participants were assessed for eligibility by review of their medical notes and bedside assessment. After written informed consent, eligible participants were randomised to either receive preoperative FCU (FCU group) or not to receive preoperative FCU (control group). The screening researcher opened a sealed opaque envelope to reveal the group allocation, which was produced by computer generated random number software (<https://www.randomizer.org/>) arranged by a non-investigator.

Participants in the FCU group received FCU within 24 hours of planned surgery. The written FCU report (Appendix 1) was placed in a sealed envelope. At the time of surgery, the anaesthetist completed a diagnosis and management plan on a research form after their standard clinical assessment, which included access to the medical record and results of investigations. The anaesthetist then reviewed the concealed FCU report, before repeating their diagnosis and management plan. This allowed the research team to determine the influence, if any, on diagnosis and management influenced by the FCU findings. The FCU report was replaced in the opaque envelope and sealed, to blind researchers to the findings of the FCU. This is partial blinding as the perioperative staff could pass on the FCU information to other members of the treating team and the group allocation was not concealed from the

research nurses who performed patient recruitment, randomisation and outcome data collection

Participants in the control group did not receive FCU but the anaesthetist was still requested to complete the same diagnosis and management forms. Control group participants were not prohibited by the study protocol from having additional investigations after randomisation, including conventional TTE.

FCU was performed by clinicians who were trained in FCU according to the iHeartScan™ protocol (Haemodynamic Echocardiography Assessment in Real Time) [18], and who fulfilled the criteria for training in goal-focused cardiac ultrasound from the Australian and New Zealand College of Anaesthetists Professional recommendations [19]. This protocol uses pattern recognition of two-dimensional and colour flow Doppler images, to identify clinically important cardiac pathology, defined as: either left ventricular (LV) systolic or diastolic dysfunction, right ventricular (RV) systolic dysfunction, moderate or severe valve stenosis or regurgitation [20, 21], or pericardial effusion of greater than 0.5 cm. Left ventricular systolic dysfunction was defined as systolic fractional reduction in LV internal dimension less than 24% or a reduction in LV end diastolic area less than 50%. Left ventricular diastolic dysfunction was defined as normal LV systolic function with raised left atrial pressure determined by the presence of a fixed curvature of the interatrial septum towards the right atrium, as demonstrated by Haji et al. [22]. Right ventricular dysfunction was defined using FCU as dilation of the RV end diastolic area to greater than two thirds of the LV end diastolic area and reduced RV free wall motion with or without flattening of the interventricular septum. The haemodynamic state was assessed with FCU by categorisation into normal, empty, vasodilated, LV systolic and/or diastolic failure, or RV failure, as described previously [14] using the assessment of LV and RV volume and contractility and movement and position of the interatrial septum. Clinically insignificant findings included mild valvular stenosis or regurgitation or mild reduction in systolic ventricular function.

There were no guidelines or restrictions on the perioperative management of participants in the study by anaesthetists.

In all 4 participating hospitals, surgery is typically undertaken within 48 hours of hospital admission after hip fracture. Participants in both groups received review and management by internal medicine or orthogeriatricians as early as practicable during their hospital stay.

The feasibility outcomes of this 1-year pilot study were: to achieve a screening: recruitment ratio below 4:1, to quantify the protocol failure rate, to recruit at least 1

participant per site per week, to achieve group separation for the primary outcome of $\geq 20\%$, to determine whether FCU delayed surgery, to assess barriers to recruitment/site activation, to achieve $\geq 25\%$ change in cardiac diagnosis and clinical management in participants undergoing FCU compared to controls, and to determine a sample size in the main study based on primary outcome effect size, and recruitment ratio and protocol failure rates.

The primary outcome of the proposed trial is a 30-day postoperative composite outcome of all cause death, acute kidney injury [23] and cardiovascular morbidity (non-fatal myocardial infarction, stroke, pulmonary embolism or cardiac arrest [24]). Definitions of component outcomes are from the European Society of Anaesthesiologist's and Intensive Care Medicine joint taskforce on perioperative outcome measures [25] and are shown in Appendix 2. Research nurses obtained the morbidity and mortality data from the hospital records, general practitioner and medical residential facility where required. The cause of death was obtained from the death certificates. These outcomes were assessed by the principal researcher from the data collected by the research nurses, and by review of discharge summaries or case notes as required. A second clinician blinded to allocation performed primary outcome data verification; if there was disagreement, a third blinded reviewer would adjudicate outcome. In the definitive pragmatic trial there will be an independent data monitoring team of clinicians to adjudicate morbid end-points. The preoperative comorbidities were obtained from the medical record (including the preoperative assessment from the treating anaesthetist) and recorded by the research nurses.

The secondary outcomes of the proposed trial are shown in Appendix 2.

Results

Recruitment occurred between 1st February and 26th December 2016 at the primary study site, with four other sites activated during this time-period. One site did not recruit participants, as activation occurred just before conclusion of the recruitment for the pilot study (table 1). The mean (SD) screening: recruitment ratio was 1.7 (0.2), and all sites recruited at least 1 participant per week. There was one protocol violation where a participant randomised to the FCU group did not receive FCU before surgery due to unavailability of personnel to perform FCU; the participant remained in the FCU group on an intention-to-treat basis. After randomisation, two participants were excluded as the participants were subsequently deemed unfit for surgery by the treating team and palliative care ensued instead of surgery. These two participants were not deemed to be protocol violations.

A participant flowchart is shown in Fig. 1

Group demographic, comorbidity, preoperative length of stay and procedural characteristics of the 100 study participants are shown in table 2. The median (IQR [range]) age of the participants was 82 (74-88 [40-98]) years (FCU 82 (73-88 [47-98]) and control 83 (76-89 [40-98])). The median (IQR [range]) preoperative stay was 1 (1-1 [0-5]) days (FCU 1 (0-1 [0-3]) and control 1 (1-1 [0-5])). Their median (IQR [range]) ASA status was 3(3-4 [1-4]) (FCU 3 (3-4 [1-4]) and control 3 (3-4 [2-4])).

Preoperative comorbidities recorded included American Society of Anesthesiologists physical status [26], congestive cardiac failure [25], ischaemic heart disease (either documented previous myocardial infarction, abnormal coronary angiogram or coronary revascularisation) [27], valve disease of at least moderate severity [20, 21], pulmonary hypertension (mean pulmonary artery pressure >25mmHg or systolic pulmonary artery pressure >35mmHg [28]), dysrhythmia (documented atrial fibrillation, atrial flutter, ventricular tachycardia or ventricular fibrillation [25]), cerebrovascular disease (embolic, thrombotic or haemorrhagic cerebral event with persistent residual motor, sensory or cognitive dysfunction [27]), chronic obstructive pulmonary disease (use of bronchodilators or steroids [29]), diabetes mellitus requiring oral hypoglycaemic or insulin therapy [29], renal impairment (persistent elevated creatinine or requirement for intermittent peritoneal or haemodialysis [25]), and high level of dependence full time care.

Group primary and secondary outcomes are shown in table 3. The median (IQR [range]) length of inpatient stay was 8 (6-12 [0-30]) days (FCU 7 (5-13 [3-30]) and control 9 (6-14 [0-30])). The median (IQR [range]) ICU length of stay was 1 (1-1 [0-1]) days (FCU 0 (1-1 [0-1]) and control 0 (0-0 [0-0])). Group separation for the primary composite outcome at 30 days equated to a relative difference of 39%

Only the 30-day outcomes are reported, as the 90-day and 1-year outcome time points have not passed for all participants to date.

Although there were no participants recorded to have suffered a non-fatal myocardial infarction or cardiac arrest, two out of the three participants in the FCU group that died may have been due to myocardial infarction, as the cause of death were recorded as myocardial infarction (preoperative FCU revealed hypovolaemia) and cardiac failure (FCU revealed aortic stenosis with left and right ventricular failure). The cause of death in the third FCU patient was unknown (FCU revealed right ventricular failure, aortic and tricuspid regurgitation). The cause of death in the five participants in the control group participants was cerebrovascular accident, pulmonary embolism, surgical complications, and two unknown.

Focused cardiac ultrasound findings in the 49 participants in the FCU group are shown in table 4. Focused cardiac ultrasound led to a change in diagnosis in 26 and a change in management in 17 of the FCU group participants; in 9 cases, FCU identified significant unexpected pathology prompting stepped-up treatment, and in 8 cases, FCU excluded significant suspected pathology, prompting stepped-down treatment (table 5).

Discussion

This 1-year pilot study comparing 30-day outcomes between hip fracture patients receiving or not receiving preoperative focused cardiac ultrasound indicates that a larger, definitive study is feasible. The study achieved its aims, achieving a mean (SD) screening:recruitment ratio of 1.7 (0.2) and a mean recruitment rate of at least 1.2 patients.week⁻¹ in the four participating hospitals, with only 1 (/102) protocol violations, and group separation for the primary outcome of $\geq 20\%$ (39%). Focused cardiac ultrasound did not appear to delay surgery and changed diagnosis and/or management in $\geq 25\%$ (53% and 35%, respectively) of participants.

Based on a more conservative effect size of the primary outcome of 25% (39% in this pilot study) and control group incidence of primary outcome of 12/51, using a two-tailed design, alpha of 0.05 and power of 0.9, a sample size of 984 participants per group will be required, which will be rounded up to 1000 participants in each group to account for attrition other than that caused by death. Using a conservative recruitment rate of 1 participant per site per week, to complete the trial in 3 years will require 13 sites.

The primary outcome was designed to detect complications that could be primarily related to cardiac pathology, though other non-cardiac complications (such as pneumonia) could be indirectly influenced by cardiac disease (such as pulmonary venous congestion). Death was the most common contributor to the primary outcome and group separation (point estimates) occurred in favour of the FCU group. Of note, the cardiac pathology identified on FCU in the three FCU participants who died was very severe, and death may have been unavoidable. One of the secondary aims of the proposed definitive trial will be to identify patterns of cardiac pathology where death is inevitable, prompting non-operative management. This may assist in end of life decisions including whether or not to proceed with surgery if it is deemed futile from the FCU findings.

Composite endpoints consisting of binary events are frequently chosen as the primary outcome in medical trials of this nature and size, because no single outcome fully

characterises the disease or outcome of interest and individual outcomes may occur rarely, therefore the statistical power may be inadequate for any single outcome (eg. death) [30]. In our pilot study, the prevalence of the composite outcome (7/19) was more than double that of mortality alone (8/100). We chose a mortality and morbidity composite outcome based on the ENIGMA II trial [24], which involved patients at increased risk of cardiac disease undergoing non-cardiac surgery [24], representing a group with similar comorbid characteristics to the hip fracture population. We added mild acute kidney injury, as this occurs commonly and is associated with adverse outcomes after hip fracture surgery [31].

Non-fatal myocardial infarction and non-fatal cardiac arrest were not recorded in either pilot group, although myocardial infarction was reported as the cause of death in two participants and cardiac failure in one participant. We accept that our pilot study may have missed episodes of non-fatal myocardial infarction, the detection of which we hope to improve in the proposed larger trial by using serial serum troponin and ECG measurement.

Given the considerable financial burden of inpatient care for hip fracture patients, we intend to investigate the cost implications of assessing patients using FCU compared with conventional assessment. Focused cardiac ultrasound incurs additional costs, related to capital purchase and maintenance, training, process time and care expansion (eg intensive care provision, additional surgery such as valve replacement (+attendant costs)), which may be balanced by financial savings consequent to complication rates, duration of inpatient stay and life quality after hospital discharge.

This pilot study suggests that a larger, definitive randomised, controlled trial is feasible; recruitment rates were achievable, protocol violations were rare and group separation of the primary, composite endpoint was achieved. Focused cardiac ultrasound did not appear to delay surgery and changed diagnosis and/or management in $\geq 25\%$ (26/49 and 17/49, respectively) of participants. Based on a sample size of 2,000 participants in 13 hospitals over 3 years, we estimate the definitive trial would cost an estimated AU\$ 2.5 million (~£1.54 million, €1.67 million, US\$ 2 million) to conduct.

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Appendices

Appendix 1. Focused Cardiac Ultrasound report form – attached jpg file

Appendix 2. Definitions of primary and secondary outcomes of the proposed larger trial.

Primary outcome - 30-day postoperative composite outcome of all cause death, acute kidney injury [23] and cardiovascular morbidity (non-fatal myocardial infarction, stroke, pulmonary embolism or cardiac arrest [27]).

Definitions of component outcomes:

1. Acute Kidney Injury: (Risk, Injury, Failure, Loss, ESRD; RIFLE) 1 or greater (Cr 1.5–1.9 times baseline value within 7 days, or $\geq 27 \text{mmol.L}^{-1}$ (0.3mg.dL^{-1}) increase within 48 h, or Urine output $\leq 0.5 \text{mL.kg}^{-1}.\text{h}^{-1}$ for 6–12 h);
2. Non-fatal myocardial infarction: an increase in serum cardiac biomarker values (preferably cardiac troponin) with at least one value above the 99th percentile upper reference limit and at least one of symptoms of ischaemia, new or presumed new significant ST segment or T wave ECG changes or new left bundle branch block, development of pathological Q waves on ECG, radiological or echocardiographic evidence of new loss of viable myocardium or new regional wall motion abnormality, identification of an intracoronary thrombus at angiography, or need for coronary intervention;
3. Stroke: an embolic, thrombotic or haemorrhagic cerebral event with persistent residual motor, sensory or cognitive dysfunction (e.g. hemiplegia, hemiparesis, aphasia, sensory deficit, impaired memory);
4. Pulmonary embolus: new blood clot or thrombus within the pulmonary arterial system, confirmed on CT, angiography or echocardiography;

5. Non-fatal cardiac arrest: cessation of cardiac mechanical activity, as confirmed by the absence of signs of circulation.

Secondary outcomes

1. The incidence of composite outcome at 90 days and 1 year;
2. The incidence of other morbid outcomes as defined in the European Society of Anesthesiology and Intensive Care Medicine joint taskforce on perioperative outcome measures [25], including:
 - a. Congestive cardiac failure: signs or symptoms of dyspnoea or fatigue, orthopnoea, paroxysmal nocturnal dyspnoea, increased jugular venous pressure, pulmonary rales on physical examination, cardiomegaly or pulmonary vascular engorgement.
 - b. New cardiac dysrhythmia: documentation on electrocardiography or from the medical file of atrial fibrillation, atrial flutter, ventricular tachycardia or ventricular fibrillation.
 - c. Respiratory pathology diagnosed on chest X-Ray, CT scan or lung ultrasound, including pleural effusion, minor consolidation (atelectasis), consolidation, or pneumothorax.
 - d. Acute Kidney Injury severity; (Risk, Injury, Failure, Loss, ESRD; RIFLE) stage 1-3 (Cr = serum creatinine)
 - i. RIFLE 1 – Cr 1.5–1.9 times baseline value within 7 days, or $\geq 27 \text{ mmol.L}^{-1}$ (0.3 mg.dL^{-1}) increase within 48 h, or urine output $\leq 0.5 \text{ mL.kg}^{-1}.\text{h}^{-1}$ for 6–12 hours.
 - ii. RIFLE 2: Cr 2.0–2.9 times baseline value within 7 days, or urine output $\leq 0.5 \text{ mL.kg}^{-1}.\text{h}^{-1}$ for 12 hours.
 - iii. RIFLE 3: Cr 3.0 times baseline within 7 days, or increase in Cr $\geq 354 \text{ mmol.L}^{-1}$ ($\geq 4.0 \text{ mg.dL}^{-1}$ with an acute rise of $> 44 \text{ mmol.L}^{-1}$ (0.5 mg.dL^{-1})), or initiation of renal replacement therapy, or urine output $\leq 0.3 \text{ mL.kg}^{-1}.\text{h}^{-1}$ for 24 h, or anuria for 12 hours;
3. In-hospital infection (respiratory, superficial surgical site, deep surgical site infection, or urinary tract);
4. Hospital and ICU length of stay at 30-days, time until return to place of residence, number of days in new aged care facility (if presentation from home) at 90-days and 1 year;
5. Influence of diagnosis and perioperative management from the FCU, including any

change in the original cardiac diagnosis (haemodynamic state, valve pathology or pulmonary hypertension) or any change in the management plan after FCU had been performed [9], including both a step-up in treatment where FCU alerts the treating team to previously unsuspected cardiac pathology or abnormal haemodynamic state, and step-down in treatment where FCU reassures of the absence of clinic suspected cardiac pathology.

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Figure legend

Figure 1. Participant flow-chart.

Table legends

Table 1. Site recruitment.

Site	Study duration, weeks	Screened, n	Screened, n.week ⁻¹	Recruited, n	Recruited, n.week ⁻¹	Screening: recruitment ratio
Royal Melbourne	47	110	2.3	59	1.3	1.9
Western General	18	37	2.1	23	1.2	1.6
Prince Charles	6	21	3.5	15	2.5	1.4
Queen Elizabeth	2	7	5.0	5	3.6	1.4
Total	47	175	2.4	102	1.4	1.7

Table 2. Group demographic, comorbidity, preoperative length of stay and procedural characteristics of 100 study participants.

Variable	Total, n	FCU group, n	Control group, n
Number of participants	100	49	51
Female	70	31	39
Hypertension	55	29	26
Cardiac failure	13	7	6
Ischaemic heart disease	16	9	7
Pulmonary hypertension	1	0	1
Valve disease	6	1	5
Cardiac dysrhythmia	35	18	17
Cerebrovascular disease	16	8	8
Chronic obstructive pulmonary disease	20	7	13
Diabetes mellitus	15	9	6
Renal impairment	3	1	2
High level of dependence	22	11	11
Surgery type			
Dynamic hip screw	39	21	18
Proximal femoral nail	28	13	15
Hemiarthroplasty	26	10	16
Total hip replacement	7	5	2
Anaesthesia type			
General anaesthesia	85	48	37
Regional anaesthesia	15	1	14

Table 3. Group primary and secondary outcomes.

	Total, n	FCU group, n	Control group, n	Odds ratio	95%CI
Primary outcome					
Composite at 30 days	19	7	12	0.54	0.19-1.52
Secondary outcomes					
Mortality < 30 days	8	3	5	0.60	0.14-2.66
Morbidity < 30 days	11	4	7	0.56	0.15-2.04
Pulmonary embolus	4	2	2	1.04	0.14-7.71
Acute kidney injury (RIFLE 1)	6	1	5	0.19	0.02-1.70
Cardiac arrest	0	0	0	-	-
Cerebrovascular accident	1	1	0	-	-
Acute myocardial infarction	0	0	0	-	-
Congestive cardiac failure	8	0	8	-	-
New cardiac dysrhythmia	8	3	5	0.60	0.14-2.66
Respiratory failure	10	4	5	0.70	0.21-3.24
Pneumonia	15	4	11	0.32	0.10-1.10
Pulmonary aspiration	3	0	3	-	-
Pleural effusion(s)	8	2	6	0.32	0.06-1.67
Bronchospasm	1	0	1	-	-
Pneumothorax	0	0	0	-	-
Infection – uncertain origin	2	1	1	1.00	0.06-17.1
Infection – superficial surgical site	0	0	0	-	-
Infection – deep surgical site	0	0	0	-	-
Urinary tract infection	21	10	11	0.93	0.36-2.44

Table 4. FCU findings in 48 participants. Valve pathology indicates at least moderate stenosis or regurgitation according to recognised guidelines [20, 21]. LV left ventricle, RV right ventricle.

FCU findings	Number of participants, n
Normal	23
LV dysfunction	7
Systolic dysfunction	2
Diastolic dysfunction	3
Systolic + diastolic dysfunction	2
RV dysfunction	1
LV + RV dysfunction	1
Hypovolaemia	5
Vasodilation	1
Aortic stenosis	6
Isolated aortic stenosis	2
Aortic stenosis + ventricular dysfunction	4
Tricuspid regurgitation	4
Mitral regurgitation	1

Table 5. Stepped up/down treatment changes after rediagnosis using FCU. FCU focused cardiac ultrasound, LV left ventricle, RV right ventricle, PHT pulmonary hypertension, AS aortic stenosis, MR mitral regurgitation. Valve pathology indicates at least moderate stenosis or regurgitation according to recognised guidelines [20, 21].

Clinical findings	Change in diagnosis from FCU	Change in management
Significant unexpected pathology diagnosed + treatment stepped-up		
Normal	Alerted to aortic stenosis, LV systolic and diastolic dysfunction, RV dysfunction, tricuspid regurgitation and PHT	Change from spinal anaesthesia to general anaesthesia. Insertion of arterial catheter and commencement of vasopressor infusion before anaesthesia.
Normal	Alerted to vasodilation	Change from spinal anaesthesia to general anaesthesia. Commencement of vasopressor infusion before anaesthesia
Normal	Alerted to aortic stenosis and LV diastolic dysfunction	Vasopressor and inotrope infusions
Normal	Alerted to hypovolaemia, mitral and tricuspid regurgitation	Fluids given before anaesthesia
Normal	Alerted to LV diastolic dysfunction, mitral and tricuspid regurgitation and PHT	Less fluids given than planned
Normal	Alerted to tricuspid regurgitation	Less fluids given than planned
AS, MR, LV+RV systolic dysfunction	Alerted to PHT, confirmed LV and RV systolic dysfunction, reassured no aortic stenosis or mitral regurgitation	Delay surgery for haemodialysis
LV+RV systolic+diastolic dysfunction	Alerted to aortic stenosis, confirmed LV and RV systolic and diastolic dysfunction	ICU postoperative
LV systolic dysfunction	Alerted to right ventricular dysfunction, aortic and tricuspid regurgitation. Reassured no LV systolic dysfunction	Less fluids given
Significant pathology excluded, and treatment stepped down		

LV+RV systolic and diastolic dysfunction, aortic regurgitation	Reassured absence of RV failure and aortic regurgitation	No inotrope used
LV systolic dysfunction	Reassured absence of LV systolic dysfunction	More fluids given than planned
LV systolic dysfunction and hypovolaemia	Reassured absence of LV systolic dysfunction	More fluids given than planned
Pulmonary embolus and right ventricular dysfunction	Reassured absence of pulmonary embolus and right ventricular dysfunction. Alerted to LV diastolic dysfunction and pericardial effusion	More fluids given than planned
AS and regurgitation	Reassured absence of aortic regurgitation	More fluids given than planned
Hypovolaemia	Reassured absence of hypovolaemia	No fluids given before anaesthesia
Hypovolaemia and LV systolic dysfunction	Reassured absence of hypovolaemia and LV systolic dysfunction	Less fluids given than planned
AS and mitral regurgitation	Reassured absence of AS	No vasopressor infusion used

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Assessed for eligibility
(n = 175)

Not included (n=73)
- did not meet inclusion criteria (73)
- no consent (36)
- additional surgery (7)
- re-do surgery (2)
- not neck of femur fracture (4)
- TTE within 1 month (7)
- team requested preoperative TTE (1)
- FCU not available (2)
- in another research study (3)
- surgery delayed >48hr (3)
- surgery cancelled (2)
- not enough time to recruit (1)
- metastatic cancer (5)

Randomised
(n = 102)

Allocated to FCU group
(n = 50)

Received allocated intervention (n = 49)
(1 participant did not receive FCU but remained in the study in the FCU group)

Allocated to Control group
(n = 52)

Received allocated intervention (n = 52)

Lost to follow-up (n = 0)

Lost to follow-up (n = 0)

Excluded (n = 1)
No surgery (palliation)

Excluded (n = 1)
No surgery (palliation)

Complete data recorded
30 days 100% (n=49)

Complete data recorded
30 days 100% (n=51)

Enrolment

Allocation

Follow-up

Analysis

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