



Effect of early, individualised and intensified follow-up after open heart valve surgery on unplanned cardiac hospital readmissions and all-cause mortality



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ABSTRACT

Background: Unplanned readmissions after heart valve surgery are common, and constitute a significant burden for the patient and the health care system. The objective was to investigate the effect of individualised follow-up after open heart valve surgery on a composite endpoint of first unplanned cardiac hospital readmission or all-cause mortality within 180 days of discharge.

Methods: The study is a prospective cohort study comparing the composite endpoint in patients undergoing early, individualised and intensified follow-up after heart valve surgery with a propensity matched historical control group. A total of 308 consecutive patients were enrolled in the prospective cohort study, 980 consecutive patients comprised the control group. The propensity matched group consisted of $n = 300$ (intervention) and $n = 580$ (controls).

Time to first event was analysed using uni- and multivariable Cox proportional hazard analysis. Kaplan-Meier survival curves were constructed to assess the probability of survival without readmission.

Results: After 180 days, the proportion of patients experiencing the composite endpoint was significantly lower in the intervention group compared with the controls for the overall, unmatched population (23% vs. 38%; HR 0.55; 95% CI, 0.42 to 0.73; $P < 0.001$). The effect did not change in the propensity matched population (HR 0.57; 95% CI 0.43; 0.75, $P < 0.001$). The difference was related to reduction in readmission rates, whereas death rates were similar in intervention and control group (1.6% vs. 1.8%).

Conclusion: An intervention consisting of early, individualised and intensified follow-up after open heart valve surgery reduced the risk of a composite endpoint of first, unplanned cardiac hospital readmission or all-cause mortality within 180 days.

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1. Introduction

Severe heart valve disease is associated with reduced exercise tolerability, shortness of breath, chest pain, heart failure and reduced lifespan unless timely treated [1,2]. However, the early period after heart valve surgery may be associated with complications due to the surgical procedure that increases the need for unplanned contacts and readmissions [3,4]. The most frequent causes of unplanned readmissions include pleural and pericardial effusions, heart rhythm

disturbances, but are also frequently caused by unspecific symptoms, including dizziness, chest pain and anxiety [3–5].

Readmission rates vary considerably internationally, especially between European countries and the United States [3,6–8]. This may likely be due to different discharge strategies with high utility of discharge to skilled nursing facilities compared with discharge directly to home, to economic penalties for high readmission rates [4,6,9]. A recent study highlighted the need for prospective testing of follow-up according to specific patient needs, to reduce readmissions [6].

Among patients with heart failure, studies have shown that monitoring of symptoms and follow-up adapted to individual needs can reduce readmissions [10,11]. Knowledge on the effect of similar interventions after heart valve surgery is sparse. Strategies to reduce readmission focusing on, e.g., closer outpatient follow-up and patient education have been suggested; none have been published [6]. Therefore, the hypothesis of the study was that early, individualised and intensified follow-up after open heart valve surgery, based on a structured triage of patients before discharge, can reduce the risk of unplanned cardiac hospital readmissions, compared with standard follow-up.

Thus, the objective of the study was to investigate the effect of an intervention consisting of early, individualised and intensified follow-up after open heart valve surgery on a composite endpoint of first, unplanned cardiac hospital readmission or all-cause mortality within 180 days of heart valve surgery.

2. Methods

2.1. Design

The *Individualised follow-up after valve surgery* (INVOLVE) study is a prospective cohort study comparing unplanned, cardiac readmissions and all-cause mortality in patients undergoing early, individualised and intensified follow-up after open heart valve surgery with a propensity matched historical control group.

2.2. Participants, setting and recruitment

The study was conducted at Odense University Hospital in the Southern Region of Denmark. All adults undergoing heart valve surgery were consecutively enrolled in two groups from August 2013 to November 2017 (control group from August 2013 and July 2016, intervention group from November 2016 and November 2017). Patients not living in the Region of Southern Denmark were excluded for logistical reasons. Furthermore, the study excluded; Patient receiving transapical and transaortic valve procedures ($n = 100/n = 26$), patients treated for endocarditis during index admission (as their admission were prolonged with 6 weeks due to intravenous antibiotic in-hospital treatment) ($n = 11/n = 10$) and patients transferred directly from surgical ward to neurological rehabilitation facility due to serious perioperative stroke (prolonged admission due to rehabilitation and specialised follow-up) ($n = 25/n = 4$), Fig. 1 in [12].

2.3. Control and intervention group

All patients in both groups were referred to their general practitioner for removal of stitches 7–10 days after surgery. Moreover, patients in both intervention and control group received a comprehensive echocardiography performed as an outpatient procedure at local referring hospital 4–6 weeks after surgery. This was performed according to European recommendations [2]. All patients were encouraged to participate in cardiac rehabilitation thereafter.

2.3.1. The control group

All unmatched control patients underwent a follow-up program consisting of: Routine discharge directly to home or to a local hospital and a short, unstructured telephone consultation performed by a surgical ward nurse within seven days after discharge. General practitioner was primary care person after discharge.

2.3.2. The intervention

The intervention was multidisciplinary; follow-up was planned in collaboration between specialised nurses and cardiologists, and the outpatient consultations were nurse-led with the possibility of consulting a specialist cardiologist or heart surgeon, when necessary.

Prior to discharge, a clinical examination was made for each patient comprising: A frailty test (based on a modified version of the frailty-test by Fried [13], consisting of: shrinking, exhaustion, weakness, slowness and low activity level, by Katz [13,14]), a focused chest ultrasound to assess pleural and pericardial effusion, screening of electrocardiogram (ECG) for rhythm disorders, and evaluation of the medical treatment. Furthermore, patient education was performed. The patient education comprised

information on results of the clinical assessment, how to react to symptoms, symptom awareness, and information on whom to contact after discharge, if needed.

Based on the above, an overall individual risk assessment was performed. Patients with more than trivial pericardial effusion were considered at high risk, whereas patients with pleural effusions and no other symptoms were considered at intermediate risk. Frail patients were grouped according to other symptoms as well, but were never considered to be at low risk. Due to risk of readmissions caused by anxiety, physiological and psychological distress, the overall clinical perception of the patients coping with postoperative challenges were included in the assessment. Thus, patients without specific findings or symptoms could be considered at high or intermediate risk due to the overall clinical presentation, including expression of worries or anxiety about discharge. Follow-up was planned based on initial triage, but could be changed according to specific patient needs, Fig. 2 in [12].

Patients considered to be at high risk of readmission were contacted by telephone within three days of discharge, seen in the outpatient clinic within one week and thereafter every week during the intervention (up to four outpatient consultations). Patients in the intermediate risk group were contacted after one week by telephone, seen within two weeks and after four weeks (two outpatient consultations). Patients with presumed low risk of readmission were also contacted by telephone after one week, and seen in an outpatient clinic after four weeks (one outpatient consultation). The telephone consultations were based on a specific guide and the outpatient visits were symptom-driven, including chest ultrasound, ECG and blood samples, when indicated. When clinically indicated (symptom-driven), pericardiocentesis and thoracocentesis were performed at the outpatient clinic.

Empowerment of the patient was essential during every consultation, including education to improve understanding and awareness of possible symptoms and how to properly react on them.

The nurse-led intervention lasted for four weeks after discharge. After the final consultation at four weeks, uncomplicated patients underwent echocardiography as recommended and referred to cardiac rehabilitation. Contrary, patients with a more complicated follow-up trajectory could be followed as required in the outpatient clinic after the four weeks. The patients could contact the outpatient clinic by telephone whenever they felt the need.

2.4. Primary outcome

The primary outcome was a composite of first, unplanned cardiac hospital readmission or all-cause mortality within 180 days of discharge. The composite endpoint was chosen to capture both possible positive (avoidance of cardiac readmission) and negative (increased mortality rates with reduced readmissions) effects of the intervention.

An unplanned cardiac hospital readmission was defined as: a) Admission occurring >24 h after discharge and within 180 days after discharge; b) overnight stay; and c) unplanned readmissions due to cardiac causes/causes related to the surgery. An elective cardiac readmission was defined as an intentional admission that was scheduled as a part of the patient's plan of care. Causes of elective cardiac readmissions were similar to the ones of unplanned readmission, but furthermore included e.g., pacemaker implantation, new valve procedures or mediastinitis. When the cause of readmission was uncertain, an event committee, consisting of two cardiologists and a heart surgeon, determined the cause of readmission. Registration of all readmissions (both cardiac and all-cause) was based on electronic medical records, and included the hospital, where the surgery was performed, but also both follow-up and readmissions at all other hospitals within the Region.

Demographics and clinical characteristics were obtained from both electronic medical records and from the Western Denmark Heart Registry [15]. Data on mortality were obtained from electronic medical records. Data were entered in the electronic REDCap database [16].

The investigation conforms with the principles outlined in the Declaration of Helsinki [17], approved by the Danish Data Protection Agency (18/19152), Danish Patient Safety Authority, and registered at [ClinicalTrials.gov](https://www.clinicaltrials.gov) (NCT03053778). Patients in the prospective group gave verbal and written consent and the Danish Patient Safety Authority approved the study (historical group).

2.5. Statistical analyses

Sample size estimation was performed based on primary endpoint. It was estimated that the rate of the primary endpoint was at least 40% after 180 days [3,18] and that the intervention would result in a 25% relative reduction (10% absolute reduction) in the primary endpoint. Further, for each patient in the intervention group, two matched patients from the control group were included. With α 0.05 and β 0.8, 1069 patients were required.

Continuous data were presented as mean and standard deviation (SD) or as median and 25th to 75th percentiles (IQR) when appropriate, and were compared using two-sample *t*-test or Mann-Whitney *U* test, respectively. Normality was tested with the Shapiro-Wilks test. Categorical outcome measures were compared using χ^2 and expressed as number of patients and percentages.

Analyses of the primary outcome were conducted according to the intention-to-treat principle. To account for possible differences in baseline characteristics between the intervention group and control group, a propensity score matching was performed [19]. The model included: Sex, age, acute/unplanned surgery, primary diagnosis, type of surgery,

Table 1
Demographic and clinical characteristics of the total population.

| Characteristics | Overall, unmatched population | | | Propensity matched population | | |
|--|---------------------------------|----------------------------|---------|---------------------------------|----------------------------|---------|
| | Intervention group (n = 308) | Control group (n = 980) | P* | Intervention group (n = 300) | Control group (n = 580) | P** |
| Sex (male, n (%)) | 217 (71) | 676 (69) | 0.624 | 209 (70) | 400 (69) | 0.831 |
| Age (median (IQR)) | 70 (62;75) | 71 (63;76) | 0.627 | 70 (63;76) | 71 (63;76) | 0.815 |
| Living alone (n (%)) | 79 (26) | 263 (27) | 0.681 | 79 (26) | 147 (25) | 0.750 |
| Pre-operative information | | | | | | |
| Reduced pulmonary function ^a (n (%)) | 111 (36) | 361 (37) | 0.800 | 109 (36) | 213 (37) | 0.909 |
| EuroScore II (logistic) (median (IQR)) | 2.0 (1.1;3.5) | 2.1 (1.3;3.6) | 0.327 | 2.0 (1.1;3.5) | 1.9 (1.2;3.6) | 0.963 |
| Estimated glomerular filtration rate ml/min ^b (median (IQR)) | 76 (60;99) | 76 (59;95) | 0.330 | 75 (60;98) | 78 (60;97) | 0.749 |
| Prior percutaneous coronary intervention (n (%)) | 25 (8) | 93 (100) | 0.466 | 25 (8) | 51 (9) | 0.818 |
| Prior cardiac surgery (n (%)) | 16 (5) | 67 (7) | 0.306 | 15 (5) | 41 (7) | 0.233 |
| Permanent pacemaker (n (%)) | 9 (3) | 25 (3) | 0.723 | 7 (2) | 18 (3) | 0.515 |
| Atrial fibrillation (n (%)) | 64 (21) | 240 (25) | 0.181 | 62 (21) | 122 (21) | 0.899 |
| Diabetes ^c (n (%)) | 38 (12) | 124 (13) | 0.884 | 38 (13) | 68 (12) | 0.684 |
| Ejection fraction (median (IQR)) | 60 (50;60) | 60 (50;60) | 0.855 | 60 (50;60) | 60 (50;60) | 0.745 |
| Ejection fraction ≤ 50% (n (%)) | 86 (28) | 293 (30) | 0.507 | 82 (27) | 173 (30) | 0.439 |
| NYHA class ≥ 2 (n (%)) | 291 (95) | 899 (92) | 0.113 | 284 (95) | 546 (94) | 0.748 |
| Body Mass Index (median, (IQR)) | 26 (24;29) | 27 (24;30) | 0.310 | 26 (24;29) | 27 (24;29) | 0.501 |
| Current or former smoker (n (%)) | 181 (59) | 561 (57) | 0.637 | 175 (58) | 335 (58) | 0.870 |
| Alcohol intake above national recommendations (n (%)) | 36 (12) | 111 (11) | 0.862 | 35 (12) | 67 (12) | 0.960 |
| Primary diagnosis, n (%) ^d | | | | | | |
| Aortic stenosis | 185 (60) | 620 (63) | 0.312 | 185 (62) | 378 (65) | 0.304 |
| Aortic regurgitation | 61 (20) | 143 (15) | 0.029* | 55 (18) | 105 (18) | 0.933 |
| Mitral stenosis or regurgitation | 61 (20) | 212 (22) | 0.494 | 59 (20) | 94 (16) | 0.199 |
| Acute/unplanned surgery (n (%)) | 9 (3) | 20 (2) | 0.363 | 9 (3) | 13 (2) | 0.494 |
| Type of valve procedure, (n (%)) | | | | | | |
| Aortic valve, biological | 201 (65) | 612 (62) | 0.372 | 201 (67) | 381 (66) | 0.697 |
| Aortic valve, mechanical | 42 (14) | 152 (16) | 0.423 | 42 (14) | 99 (17) | 0.239 |
| Aortic valve, repair | 10 (3) | 7 (1) | 0.001* | 4 (1) | 5 (1) | 0.499 |
| Mitral valve, replacement ^e | 29 (9) | 57 (6) | 0.027* | 27 (9) | 47 (8) | 0.650 |
| Mitral valve, repair | 25 (8) | 147 (15) | 0.002* | 25 (8) | 45 (8) | 0.765 |
| Concomitant CABG (n (%)) | 68 (22) | 269 (27) | 0.061 | 68 (23) | 137 (24) | 0.751 |
| Duration of ECC (min., median (IQR)) | 101 (78;128) | 112 (93;147) | <0.001* | 101 (78;128) | 109 (90;140) | <0.001* |
| Re-operation (n (%)) | 28 (9) | 84 (9) | 0.778 | 28 (9) | 50 (9) | 0.724 |
| Length of stay, intensive care unit (median (IQR)) | 1 (1;1) | 1 (1;1) | 0.655 | 1 (1;1) | 1 (1;1) | 0.990 |
| Blood transfusion during surgery and/or at intensive care unit, (n (%)) | 122 (40) | 509 (52) | <0.001* | 120 (40) | 291 (51) | 0.002* |
| Units of blood among patients receiving blood transfusion (ml, median (IQR)) | 0 (0;500) | 100 (0;712) | 0.005* | 0 (0;500) | 100 (0;710) | 0.015* |
| Thoracocentesis (n (%)) | 49 (16) | 164 (17) | 0.734 | 49 (16) | 93 (16) | 0.909 |
| Pericardiocentesis (n (%)) | 20 (7) | 96 (10) | 0.077 | 19 (6) | 57 (10) | 0.080 |
| Postoperatively atrial fibrillation ^f (n (%)) | 138 (45) | 400 (41) | 0.216 | 135 (45) | 251 (43) | 0.625 |
| Length of stay (median (IQR)) | 9 (7;12) | 9 (7;13) | 0.313 | 9 (7;12) | 9 (7;13) | 0.362 |

IQR = interquartile range, 25th to 75th quartile.

^a Patients with forced expiratory volume₁ ≤ 80% of predicted value and/or a history of chronic obstructive pulmonary disease.

^b Estimated glomerular filtration rate estimated by the Cockcroft-Gault Equation.

^c Patients with diabetes; insulin, per oral and non-pharmacological treatment.

^d Six patients had a tricuspid-valve disease and are not shown in the table.

^e Both biological and mechanical mitral valve replacement.

^f Without known atrial fibrillation before surgery.

* P < 0.05 between the intervention group and the historical control group (all).

** P < 0.05 between the intervention group and the propensity matched historical control group.

concomitant coronary artery bypass surgery, obstructive or restrictive lung disease, New York Heart Association class (NYHA), EuroScore II (logistic), estimated glomerular filtration rate, permanent pacemaker prior to surgery, atrial fibrillation and body mass index (BMI). The propensity match was performed with a 1:2 matching without replacement, using a caliper width of 0.2 SD and the nearest-neighbour approach, as previously recommended [20].

The effect of the intervention was analysed using univariable Cox proportional hazard regression model, for both unmatched and propensity matched patients. In addition, a multivariable Cox proportional hazard analysis was performed. Results were reported as hazard ratios (HR) with 95% confidence intervals (CI). Kaplan–Meier survival curves were constructed to assess the probability of survival without readmission during the follow-up period. Follow-up was calculated from time of discharge to time of event or 180 days, whichever occurred first. To investigate possible sustained effect of the intervention, Kaplan–Meier curves beginning from the first day after last consultation in the intervention were presented with time to event from the last consultation (after 30 days) until event or 180 days.

Time to first event (among patients with an event occurring) and event-free time (for the total population) were presented as mean and SD. The effect of the intervention on the individual components in the composite outcome was assessed separately in post-hoc analyses. Due to possible competing risk of readmission and all-cause mortality, the incidence of readmission was evaluated using a cumulative incidence function in an

univariable Fine and Gray Proportional Hazard Model, with death as competing event [21]. In addition, a Cox proportional hazard model to estimate unadjusted hazard ratios for all-cause mortality was performed.

Sensitivity-analyses were performed, investigating differences among groups; including differences in number of unplanned/planned readmission, mean length of stay per readmission, number of readmissions per patient and total number of readmissions, Table 2 in [12].

The P value was set at 0.05. SPSS 24 (IBM Corp, Armonk, NY) and R 3.2.2 (R Foundation for Statistical Computing) were used for the analyses.

3. Results

3.1. Patient and baseline demographics

During the time periods, 1518 patients underwent heart valve surgery at Odense University Hospital, 48 patients were excluded in the intervention group and 182 patients in the control group, Fig. 1 in [12]. In total, 1288 were eligible for inclusion. In the intervention group of 308

consecutive patients, all but two patients completed the intervention. The control group consisted of 980 patients. No patients were lost to follow-up.

The median age was 71, 69% were men; the majority underwent aorta valve replacement (78%), 20% had a mitral valve procedure and 6 patients (0.5%) had primary surgery on the tricuspid valve (not shown in table).

Except for a higher prevalence of patients diagnosed with aortic regurgitation in the intervention group, preoperative clinical characteristics were similar among intervention group and unmatched control group; Table 1. In addition, more patients in the intervention group underwent aortic valve repair and surgery on the mitral valve. Median time on extracorporeal circulation (ECC) was significantly shorter in the intervention group and fewer patients received blood transfusions, compared with the unmatched control group, Table 1.

The propensity matched population consisted of 300 patients in the intervention group and 580 controls. No significant differences in baseline characteristics were found among groups, Table 1. Differences in patient management during admission were reduced to differences in time on ECC and units of blood transfusion, Table 1.

3.2. The intervention

Risk assessment was performed at discharge for 308 patients in the intervention group. Of those, 102 patients (33%) were considered to

be at high risk of readmission, 176 patients (57%) at intermediate risk and 30 patients (10%) at low risk. No differences in age or sex were found between risk groups. Frailty score was measured for 266 patients (86%). Frailty status varied across risk groups, with 24 (24%) of the high-risk patients being frail, 16 (9%) in the intermediate, and no patients (0%) in the low-risk group, $P < 0.001$. After four weeks, 14 patients (5%) were scheduled for further contact with the outpatient clinic.

3.3. Primary outcome, readmission and mortality

At 180 days, the proportion of patients with the composite endpoint of unplanned, cardiac hospital readmission or death was significantly lower in the intervention group compared with the unmatched control group (HR 0.55; 95% CI, 0.42 to 0.73; $P < 0.001$), Fig. 1A. The difference was related to reduction in readmission rates with 70 patients (23%) being readmitted in the intervention group vs. 366 patients (37%) in the unmatched control group, $P < 0.001$. Death rates were similar in intervention and unmatched control group: 1.6% vs. 1.8%, HR 0.88 (95% CI: 0.33; 2.38, $P = 0.81$) and propensity matched population HR 1.08 (95% CI 0.36; 3.21, $P = 0.90$).

Among the propensity matched population analysis of primary endpoint showed similar results (HR 0.57; 95% CI 0.43; 0.75, $P < 0.001$), Fig. 1B. Pre-specified subgroup analyses revealed consistent results across all the subgroups, including sex, age, surgery on aortic or on mitral valve respectively, co-morbidity, and higher EuroScore, Fig. 2.

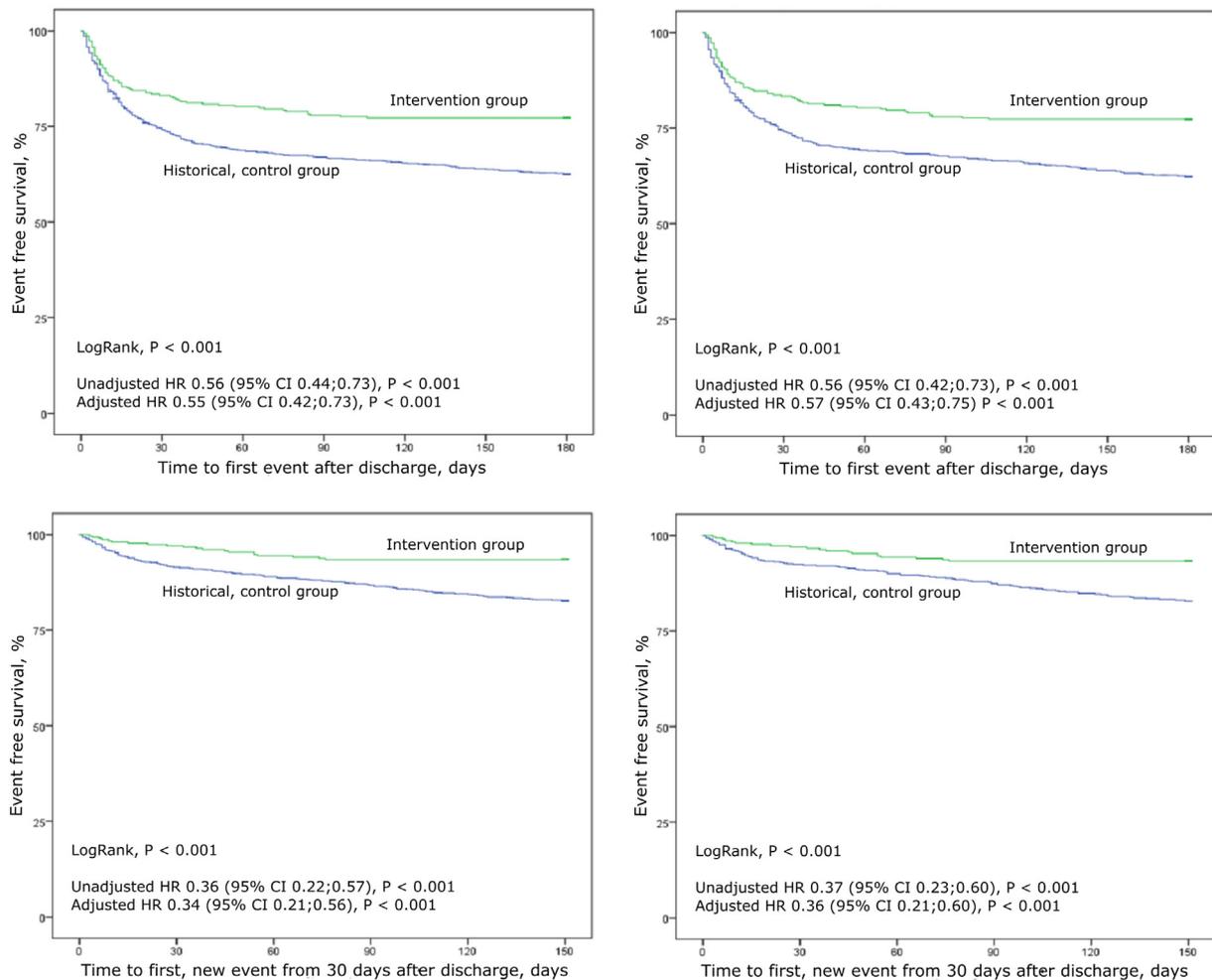


Fig. 1. Effects of the intervention on time to first event (unplanned readmission or all-cause mortality) within 180 days. Shown are Kaplan Meier curves with time to event of the primary composite outcome (unplanned readmission or all-cause mortality) within 180 days of discharge for the total population (panel A) and for the propensity matched population (panel B). In panel C and D time to first new event from termination of the intervention for the total population (panel C) and the propensity matched population (panel D) until 180 days after discharge. The multivariable analyses were adjusted for sex, age, duration of extra corporeal circulation and number of blood transfusions.

Early, unplanned cardiac hospital readmission (within 30 days) occurred in 52 patients (17%) in the intervention group and in 249 patients (25%) in the control group, $P = 0.002$.

No difference in duration from discharge to first event was found between the intervention group and the control group (mean 23 days (SD 27) vs. 33 days (SD 43), $P = 0.053$). For the overall, unmatched population, days without an event were significantly different among groups: Intervention group mean 144 days (SD 67) and control group mean 124 days (SD 76), $P < 0.001$. After completion of the intervention, the proportion of patients with an event remained lower in the intervention group, adjusted HR 0.34, 95% CI 0.21;0.56, $P < 0.001$ for the total population; adjusted HR 0.36, 95% CI 0.21;0.60, $P < 0.001$ for the propensity matched population, Fig. 1C and Fig. 1D.

3.4. Causes of readmission and subgroup analyses

Causes of readmission were similar among groups, Table 1 in [12], but with statistically significant fewer readmission due to pericardial effusion (3.2% vs 6.9%, $P = 0.018$) and unspecific cardiac symptoms (1.6% vs 3.8%, $P = 0.041$). Furthermore, there were no statistically differences in non-cardiac readmission among patients in the intervention group compared with controls (3.9% vs 4.8%, $P = 0.510$), Table 2 in [12].

The sensitivity analyses revealed no differences in number or type of readmissions, or days readmitted among groups, Table 2 in [12].

The incidence of readmission alone, evaluated with a cumulative incidence function, with death as competing event confirmed the primary

analysis. The cumulative incidences of readmission were significantly lower in the intervention group compared with the control group; Total, unmatched population HR 0.54 (95% CI: 0.41; 0.70, $P < 0.001$), propensity matched population HR 0.53 (95% CI: 0.40;0.70, $P < 0.001$), Fig. 3.

4. Discussion

This is the first study to describe a prospective intervention in the early period post-discharge following open heart valve surgery to avoid early unplanned, cardiac hospital readmissions. We found that an intervention consisting of early, individualised and intensified follow-up, including patient empowerment after open heart valve surgery, was associated with a significant reduction in the composite endpoint of first, unplanned cardiac hospital readmission or all-cause mortality, compared with a propensity matched historical control group. The intervention was associated with reduced risk of readmission, whereas mortality remained unchanged. The effect of the intervention was consistent in all relevant subgroups and was sustained after completion of the intervention.

Readmissions after heart valve surgery vary greatly across countries and hospitals [3,8]. Among patients undergoing aortic valve replacement a recent review and meta-analysis reported 30-day readmission rates varying from 7% to 23% (pooled estimate 17%) [8], whereas others have found even higher rates of readmission [3,18]. The varying proportions of readmission in previous studies are multifactorial [3,4,6,7,9], but seemingly related to different ways of organising management after discharge and enforcement of economic penalties in case of readmission.

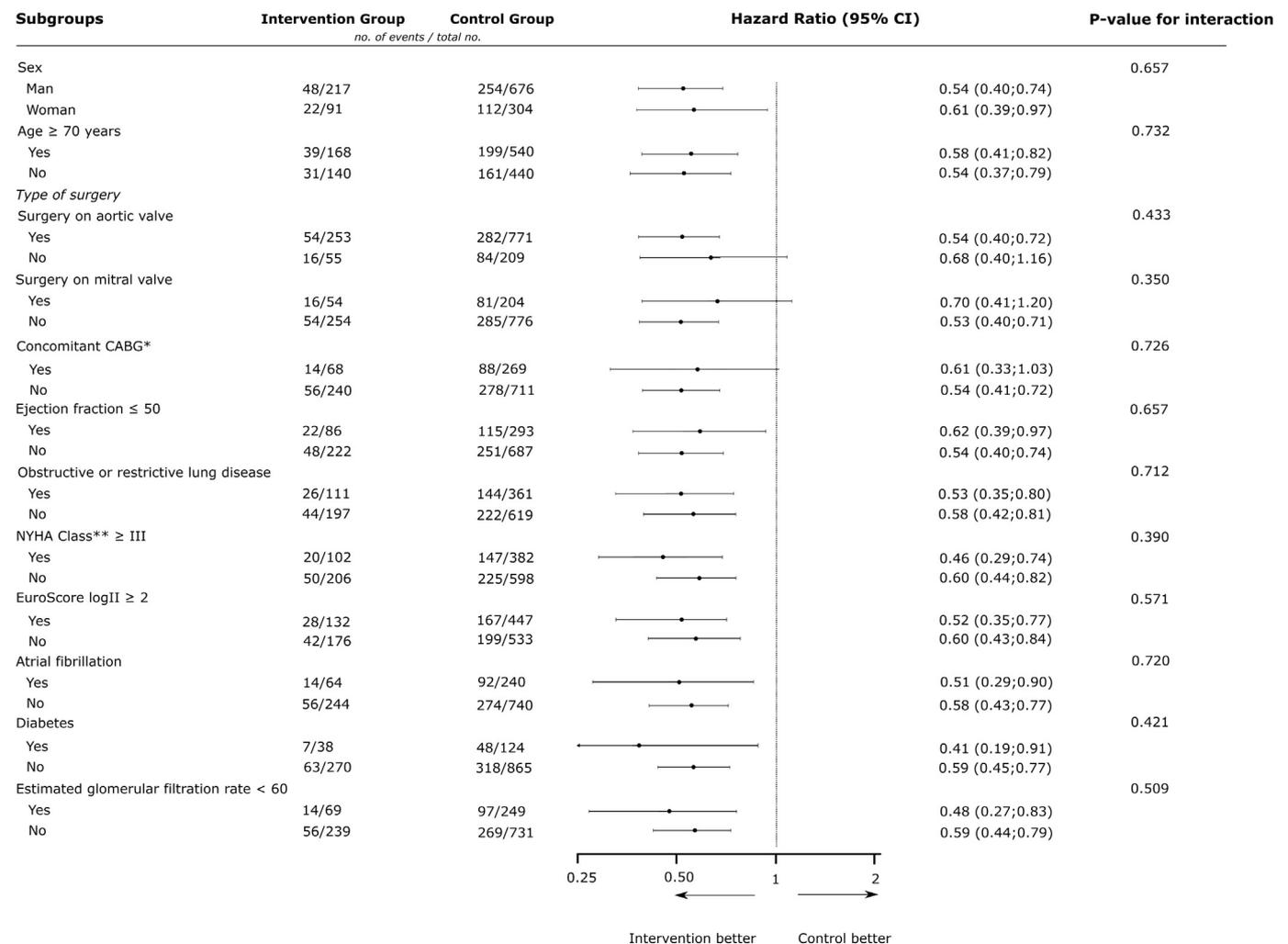


Fig. 2. Rate of events (primary outcome) in pre-specified subgroups. Forest plot of hazard ratios for the primary composite outcome (unplanned readmissions or all-cause mortality) in pre-specified subgroups. P values for the interaction. *CABG, coronary artery bypass surgery. **NYHA, New York Heart Association Class.

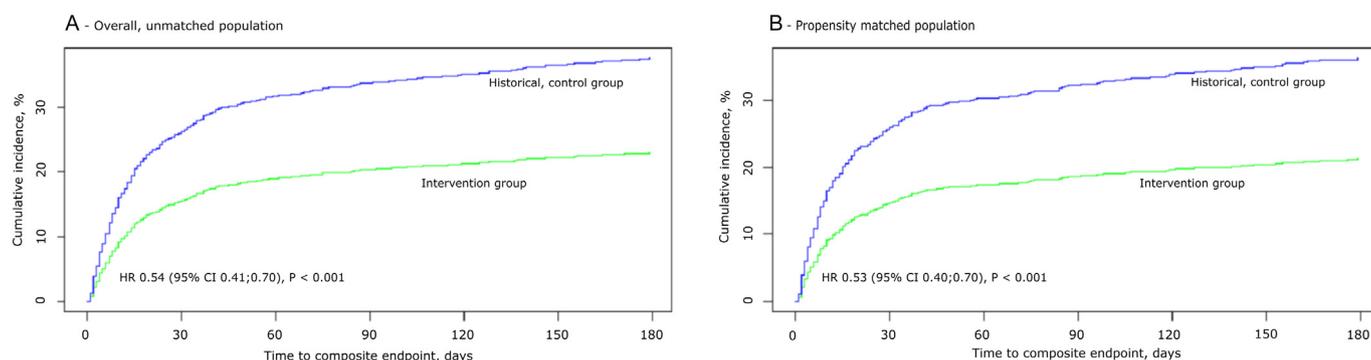


Fig. 3. Cause-specific univariate cumulative incidence of readmission censoring death at date of death, post-hoc analysis. Shown are cumulative incidence curves with time to first, unplanned cardiac readmission within 180 days of discharge for the total, unadjusted population (panel A) and for the propensity matched population (panel B).

Transparency regarding how readmission rates are obtained, causes of readmissions and organisation of follow-up is, however, essential in order to make future comparisons.

Follow-up after discharge for the control group was performed as recommended in recent European guidelines on management of patients with valvular heart disease [2], and comprises current usual care in European countries [2]. By introducing the intervention in the present study, the risk of readmission was reduced by 45%. The effect of the intervention was shown as a reduction especially driven by fewer unplanned readmissions caused by pericardial effusion and readmission caused by unspecific cardiac symptoms without other obvious underlying causes. After surgery, patients undergoing heart valve surgery can experience physiological and psychological distress after discharge [4,5], thus increasing the likelihood of readmission. This type of readmission is potentially avoidable with interventions aiming at empowering the patient by targeted education on symptom management [4,22]. A central element in the current study, different to previous studies, was follow-up according to specific patient needs and the intensified patient education, from the view point that “one size does not fit all”.

To investigate any potentially harmful effect of the intervention, all-cause mortality was included in the composite outcome. Although mortality was low, with low power to detect differences between groups, mortality rates were similar across groups.

4.1. Strengths and limitations

The study was conducted as a prospective cohort study, where all patients in the specific time period were included, with complete follow-up for all patients. This ensures a high representability of the study. Furthermore, data on readmissions was gathered from electronic patient records and not from registers, which ensures completeness of data. In addition, readmissions were validated independently by two researchers.

The results should be considered and interpreted in the context of the study design and its limitations. First, the key limitations of the study include those associated with the non-randomised design and its inability to account for unmeasured confounders. The chosen design aimed at ensuring that all patients were enrolled. Furthermore, blinding of the intervention could obviously not be performed. During the control and intervention periods, the management of patients was carried out by the same surgeons, in the same operating theatres and in the same stationary ward, which reduces bias. Power calculation was performed based on primary outcome for the overall, unmatched population. We further performed a propensity score matching to adjust for confounders and render the included patient groups as balanced as possible, and we eliminated most differences – leaving two well-balanced populations. However, although an analysis with propensity score matching addresses known confounding, it cannot control for confounding because of unmeasured characteristics. We find it unlikely, though, that an unmeasured bias can account for an effect of the magnitude as seen in the present study.

We believe that the individualisation of the intervention is both a strength and a limitation. A strength, as we believe that it is of great importance to look at each patient individually and treat the patient according to this, but also a limitation as it lowers the reproducibility of the triage system.

Despite significant reduction in readmission rates in the intervention group, one out of every four patients has an unplanned, cardiac hospital readmission within 180 days after heart valve surgery, thus, there is a continuous need for more research and attention in daily clinical practice. Furthermore, the current study focus on readmissions related to cardiac causes. We acknowledge though, how non-cardiac problems related to existing comorbidities are a problem that might increase in the future due to an ageing population. This calls for more multidisciplinary cooperation.

5. Conclusion

An intervention consisting of early individualised and intensified follow-up after open heart valve surgery can substantially reduce the risk of a composite outcome of unplanned, cardiac hospital readmissions or all-cause mortality within 180 days. The effect was sustained after the end of the intervention period. The effect was alone driven by a reduction in readmission rates, alone, whereas death rates were identical.

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Conflict of interest

None.

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