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Impact of telephone follow-up and 24/7 hotline on 30-day readmission rates following aortic valve replacement -A randomized controlled trial

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ABSTRACT

Background: Thirty-day all-cause readmissions are high after aortic valve replacement (AVR). We aimed to assess the effectiveness of a structured telephone follow-up (TFU) and a 24/7 hotline on reducing 30-day all-cause readmission (30-DACR) after AVR, on reducing symptoms of anxiety and depression and on improving perceived health state.
Methods: A prospective randomized controlled trial was conducted. Patients (n = 288) were randomly allocated to either post-discharge usual care or to care that provided TFU and access to a 24/7 hotline after AVR. Ancillary endpoints were time-to-event (readmission), proportion of avoidable versus unavoidable readmissions after AVR, and predictors of 30-DACR after AVR.
Results: 30-DACR was 22.3%. The structured TFU and 24/7 hotline intervention failed to reduce 30-DACR rates after AVR ($P = 0.274$). Symptoms of anxiety were significantly reduced 30 days after surgery ($P = 0.031$), an effect that did not persist one year after surgery ($P = 0.108$). Most readmissions occurred before 15 days post-discharge, and 75% of them were deemed to be unavoidable. Pleural drainage before hospital discharge ($P = 0.027$) and symptoms of anxiety before surgery ($P = 0.003$) were predictors of 30-DACR after AVR.
Conclusion: The TFU and 24/7 hotline had no effect on reducing 30-DACR after AVR. However, we did measure reduced symptoms of anxiety the first month after AVR. Anxiety reduction appeared to be an important target for intervention, because we found it to be a risk factor for readmission. Future research should focus on the effectiveness of interventions to prevent avoidable unplanned readmissions.
Trial registration: ClinicalTrial.gov, NCT02522663.

1. Introduction

Severe aortic stenosis (AS) caused by calcification of the aortic valve is the prominent reason for aortic valve replacement (AVR) treatment [1]. The prevalence of AS increases with age [2], and is estimated to reach about 10% in 80–89 year old's [3]. In developed countries, a growing older population will expectedly increase the prevalence of AS and the number of invasive treatments [1]. Untreated symptomatic AS has a high mortality rate (up to 85%) within 5 years after onset of symptoms [4]. However, when AVR is done early in the disease course, patients have approximately the same life expectancy as their non-AS counterparts from the general population [3]. In-hospital mortality after AVR is 2–5% [5,6], and increases up to 6–7% for patients >85 years [5]. Postoperative atrial fibrillation and heart failure are common cardiac complications after AVR and causes of readmissions [7].

A recent meta-analysis showed that hospital readmissions following AVR occur in 17% of patients (range 7–23%) [8], and AVR have higher readmissions than coronary-artery-bypass-surgery [9]. Because of the economic impact of readmissions and its increased burden on the

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quality of life of patients and their caregivers [10], preventing hospital readmissions are of paramount importance.

Interventions to reduce readmissions after discharge can be divided into mainly pre-and post-discharge types, and “bridge” interventions (both pre- and post-discharge targets) [11]. Pre-discharge interventions typically include discharge planning and patient education. Interventions done in the post-discharge phase are often telephone follow-ups (TFUs), home visits, or telephone “hotlines” for patients. Few interventions have proven successful in reducing hospital readmissions [11]. TFU and monitoring and managing symptoms after discharge (e.g., home visits) are suggested to have favorable effects in reducing readmission rates [11]. However, such follow-up and support are seldom offered “off-hours,” triggering avoidable readmissions when AVR-related symptoms occur in the evenings, at night, or during the weekend. Therefore, a 24/7 hotline in combination with structured TFU is hypothesized to provide a critical resource of support in the immediate post-discharge period [12]. However, to the best of our knowledge, the effectiveness of a 24/7 hotline staffed with specialized professionals and combined with TFU to reduce readmissions has not been investigated to date. Therefore, we conducted a randomized controlled trial to examine the efficacy of such a telephone support system for patients following AVR. The primary objective of the present study was to test the effectiveness of the 24/7 hotline and structured TFU on the 30-day all-cause readmission (30-DACR) rate after discharge for AVR. The secondary objectives were to determine whether this kind of support system would reduce symptoms of anxiety and depression and improve perceived health state. As ancillary objectives, we examined the proportion of avoidable and unavoidable readmissions and predictors of 30-DACR after AVR.

2. Methods

2.1. Participants

We conducted a prospective, randomized controlled trial with parallel groups, following the CONSORT guidelines for reporting [13]. Patients aged 18 and older assigned to the following AVR treatments were eligible for inclusion: First-time isolated AVR, AVR with concomitant coronary artery bypass grafting (CABG), or AVR with concomitant supra-coronary tube graft (SCG). Further, patients had to be available by telephone after discharge, and had mastered the Norwegian language verbally and in written form. We excluded patients who were admitted to the intensive care unit >24 h postoperatively, or patients who experienced physical and/or cognitive impairment following complications after AVR treatment [12]. Patients were operated in two cardiac surgery locations within Oslo University Hospital in Norway. After initial treatment at the tertiary hospital, most patients were transferred to a local hospital (as part of the elective stay and treatment) for medical follow-up until discharge to home. Participants gave written informed consent.

2.2. Intervention

The telephone-support intervention consisted of two parts. First, the project coordinator actively called each intervention patient on day 2 and day 9 after hospital discharge to home (telephone follow-up). Structured telephone calls, comprising advice on the importance of physical activity in the early rehabilitation phase after AVR, were made to remind the participant about the availability of 24/7-telephone support and to answer questions they might have had about their present health condition (patient-centered instructions and/or reassurance). Second, the patients could call a dedicated phone number to receive information whenever they wanted during the first 30 days after discharge (patient-activated hotline). The 24/7-phone hotline was staffed by a group of dedicated and experienced advanced nurse practitioners trained for this service. Participants assigned to the intervention are the experimental group.

Both groups received standard discharge care, which included a scheduled consultation with the treating surgeon before discharge from the tertiary hospital. Individual information was given to each patient about the treatment and the present health condition. The nurses coordinated the transport to local hospital and ensured that necessary documentation followed. A cardiologist in charge at the local hospital, in cooperation with nurses, discharged the patient after a planned final consultation to ensure follow-up and a safe return to home. The patients' general practitioners got notified by email from the tertiary hospital to inform them about the given treatment before the patient was returning home. As part of the discharge care, a short pamphlet about the treatment and early rehabilitation was given all patients before surgery.

2.3. Outcomes

The primary outcome was 30-DACR rate after discharge for AVR treatment, which was defined as an unplanned readmission for any cause to any hospital at least 8 h, and up to 30 days, after discharge from the local hospital. Readmission data were obtained through the patients' medical records from all hospital stays.

Secondary outcomes were symptoms of anxiety, depression, and self-perceived health status. We used the Hospital Anxiety and Depression Scale (HADS) to measure symptoms of anxiety and depression [14].

We used the EuroQol (5D-3L) to assess participants' self-perceived health status [15,16]. EQ-5D-3L assesses five dimensions of health: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The descriptive health state was converted to a single index value using the time-trade-off (TTO) technique, which was based on the UK population [17]. The EQ-5D-3L additionally has a visual analogue scale (EQ-VAS), ranging from 0 (worst imaginable health state) to 100 (best imaginable health state). EQ-5D-3L is validated for the use of assessing patients' self-perceived health after heart valve surgery [18].

Assessments of HADS and EQ-5D-3L were conducted before surgery, and at 1, 3, 6, and 12 months after the surgical treatment.

The assessment of avoidable versus unavoidable readmissions was performed by a cardiac surgeon (T.T.), a cardiologist (S.S.), and a nurse with expertise in the field of discharge management (I.L.). They had available for evaluation the relevant clinical pre-, per- and postoperative information of each patient in addition to readmission data. They were blinded with regard to group assignment (i.e., experimental vs. control).

2.4. Study overview

The AVRre Study was approved by the Regional Committees for Medical and Health Research Ethics, Health East South, Norway (approval 2013/2031-3), and complied with the Declaration of Helsinki principles.

2.5. Randomization

Randomization was performed by using a web-based randomization system developed and administered by the Norwegian University of Science and Technology, Trondheim, Norway.[15] Patients were randomly assigned in a 1:1 ratio, block-randomized with block-size randomly varied between 8 and 12 [12].

2.6. Statistical analysis

Sample size and power calculation was published in a protocol [12]. Categorical values are presented as numbers and percentages, and continuous data are presented as means or medians with the standard deviation (SD). To characterize the sample and evaluate differences between the intervention and control groups, we used Pearson Chi-square or Fisher's exact tests for categorical variables. Independent *t*-tests or Mann-Whitney *U* tests were used to test for significant differences between groups on continuous variables.

Assessment of the primary objective was conducted by comparing the 30-DACR rates of the intervention and control groups, using a Chi-square test (per protocol analysis, N = 260). Intention-to-treat (ITT) analysis (N = 282) was performed as part of the sensitivity analysis. For analyses of secondary outcomes at the first month post-discharge, we first performed analysis of covariance (ANCOVA) as per protocol, adjusting for baseline scores as a covariate. Assumptions for ANCOVA were checked and were adequately met. Furthermore, a linear mixed model (LMM) was used to evaluate the difference in HADS-A and HADS-D and in EQ-5D-3L VAS and EQ-5D-3L index value (TTO) scores between the groups on repeated measures, up to one year after surgery (N = 260). In each model, the baseline score, time variable, and group were specified as fixed factors, while the intercept was specified as a random effect. The percentage of missing values in HADS-A and HADS-D index scores was 6.5% and 6.4%, respectively. For the EQ-5D-3L VAS and TTO index scores, the percentages of missing index values were 10.31% and 8.23%, respectively. Missing index values in HADS and EQ-5D-3L were substituted by means of multiple imputation with 20 iterations and analyzed under the missing-at-random assumption [19]. The assumptions underlying mixed-model analysis were checked and were adequately met.

We conducted ancillary analyses. First, we described the use of the 24/7 hotline within the intervention and the readmission cohort. Second, we analyzed whether the readmissions were avoidable or unavoidable. Third, we performed a time-to-event analysis using Kaplan-Meier survival curves. The survival analysis was stratified by group to quantify the time to readmission within 30 days after discharge, censored at day 31 and tested for significance by the log-rank test. Finally, we performed a Cox proportional hazards regression analysis to examine the predictors associated with 30-DACR after AVR (complete analysis without imputation). The assumptions underlying the Cox regression analysis were checked and were adequately met. We examined first predictors in a univariate analysis. Variables with *P* values <0.2 were included in a multivariate model, using a stepwise approach. The multivariate model contained the following variables: women, age, group assignment, pleural drainage before discharge, and anxiety at baseline.

Statistical significance was evaluated using a two-sided *P* value of <0.05. Analyses were performed with the Statistical Package for Social Sciences (SPSS), version 25.

3. Results

3.1. Study population

Overall, 482 patients were screened for participation from late August 2015 to mid-February 2017, 288 of which were randomly assigned to either usual care (control group) or to the 24/7-phone support group (intervention group) (Suppl Fig. 1). A total of 27 of these allocated patients were excluded before they were discharged, 16 in the intervention group and 11 in the control group. In the intervention group, 9 were excluded because they were admitted to the ICU >24 h postoperatively, 4 were receiving prolonged care, 2 underwent a non-AVR procedure instead, and 1 moved to another hospital. In the control group, 5 patients were excluded because they were admitted to the ICU > 24 h postoperatively, 3 underwent a non-AVR-procedure, and 3 withdrew from the trial. Table 1 shows the distribution of baseline characteristics of participants, stratified by group assignments. In-hospital outcomes are shown in Table 2. In this sample, 30-day mortality was 0, and 1-year mortality was 0.7% (2/282).

3.2. Use of the 24/7 hotline

During the trial, 58 of the 127 (46%) participants in the intervention group used the 24/7-phone support hotline (including two caregivers calling for their spouses). More women than men ($P = 0.046$) used the 24/7 hotline, and callers were more often readmitted compared with non-callers ($P = 0.001$). Supplement Table 1 shows the characteristics of the intervention participants before the trial and outcomes related to the use of the 24/7 hotline.

3.3. Primary outcome: 30-DACR

A total number of 58 participants (22.3%) experienced an unplanned 30-DACR. In the intervention group, 32 participants (25.2%) were readmitted compared to 26 participants (19.5%) in the control group. This difference, however, was not statistically significant (χ^2 [1, $N =$ 260] $= 1.196$, $P = 0.274$). The ITT analysis on 30-DACR yielded a non-significant result also ($N = 282$, $P = 0.317$). Readmissions to local hospitals accounted for 86.2% of the total numbers of readmissions and 13.8% to the tertiary hospital. A few patients were discharged direct to rehabilitation ward (9%). The characteristics of participants with and

Table 1
Baseline characteristics of participants in the AVRre study (N = 282).

Variables	Intervention group[a]	N	Control group	N
Demography				
Age, y, mean (SD)	65.8 (11.1)	141	67.3 (9.8)	141
Male gender, n (%)	101 (71.6)	141	100 (70.9)	141
Married or partner, n (%)	105 (75.5)	139	96 (76.8)	125
Medical history		141		141
Non-rheumatic aortic stenosis, n (%)	118 (83.7)	–	111 (78.7)	–
Hypertension, n (%)	61 (43.3)	–	52 (39.6)	–
Atrial fibrillation, n (%)	13 (9.2)	–	25 (17.7)	–
Diabetes, type I and II, n (%)	23 (16.3)	–	16 (11.3)	–
Coronary artery disease, n (%)	55 (39)	–	55 (39)	–
Heart failure, n (%)	13 (9.2)	–	8 (5.7)	–
Pulmonary disease, n (%)	8 (5.7)	–	5 (3.5)	–
Thoracic aortic aneurysm, n (%)	16 (11.3)	–	20 (14.2)	–
Medications at baseline		141		141
Anticoagulants/antiplatelets, n (%)	88 (62.4)	–	85 (60.2)	–
Statins, n (%)	89 (53.1)	–	79 (56)	–
Beta-blockers, n (%)	59 (41.8)	–	53 (37.6)	–
Diuretics, n (%)	19 (13.5)	–	15 (10.6)	–
Risk factors				
Charlson Comorbidity Index, n (%)		138		138
0, n (%)	53 (38.4)	–	53 (37.6)	–
1–2, n (%)	69 (50)	–	72 (52.2)	–
≥ 3, n (%)	16 (11.6)	–	13 (9.4)	–
EuroScore, mean (SD)	5.40 (2.1)	130	5.5 (2.2)	127
NYHA classification		131		129
Class I, n (%)	2 (1.5)	–	2 (1.6)	–
Class II, n (%)	59 (45)	–	54 (41.9)	–
Class III, n (%)	65 (49.6)	–	72 (55.8)	–
Class IV, n (%)	5 (3.8)	–	1 (0.8)	–
Ejection fraction		126		128
Normal >50%, n (%)	101 (80.2)	–	109 (85.2)	–
Moderate ≥30–50%, n (%)	22 (17.5)	–	15 (11.7)	–
Low <30%, n (%)	3 (2.4)	–	4 (3.1)	–
Echocardiographic measures at baseline				
Aortic valve area, cm^2, mean (SD)	0.9 (0.5)	123	0.9 (0.6)	127
Aortic peak velocity, m/s, mean (SD)	4.30 (0.9)	131	4.32 (1)	132
Aortic mean gradient, mmHg, mean (SD)	49.62 (16.7)	125	50.96 (18.6)	118
End diastolic diameter of left ventricle, cm, mean (SD)	5.3 (0.9)	125	5.27 (0.9)	130

NYHA, New York Heart Association; SD, standard deviation.
[a] 24/7-telephone support hotline (control group received usual care).

Table 2
In-hospital outcomes of participants in the AVRre study.

Variables	N	Intervention group	N	Control group	N	*P*
Surgery	279		141		138	
Mechanical single valve, n (%)		22 (15.6)		26 (18.4)		0.641
Biological single valve, n (%)		61 (43.3)		56 (39.7)		0.741
Valve with concomitant surgery, n (%)	279	58 (41.1)	141	56 (40.6)	138	0.925
Total surgery time, min, mean (SD)	272	182.5 (43.7)	137	179.1 (45.2)	135	0.302
Ischemic time, min, mean (SD); range (34–166 min)	275	87.3 (23.6)	137	83.7 (23.7)	138	0.381
Total time on heart-lung machine, min, mean (SD)	275	117 (32.4)	138	114.8 (33.7)	137	0.254
Maximum troponin, ng/L, mean (SD)	240	630 (409)	117	670 (362)	123	0.828
Maximum CK-MB, μg/L, mean (SD)	274	27.4 (16.5)	137	27.4 (16.9)	137	0.363
Complications						
Reoperation, n (%)	279	5 (3.5)	141	7 (5.1)	138	0.530
Atrial fibrillation, n (%)	282	79 (56.8)	139	77 (56.6)	136	0.971
Heart blocks, n (%)	258	12 (9.4)	127	11 (8.5)	131	0.767
Pleural drainage, n (%)	282	32 (22.7)	141	37 (26.2)	141	0.489
Pericardial drainage, n (%)	282	6 (2.1)	141	6 (2.1)	141	1.000
Infection treatment, n (%)	281	19 (13.6)	140	32 (22.7)	141	**0.047***
Permanent pacemaker implantation, n (%)	268	12 (8.9)	135	6 (4.3)	133	0.152
Postoperative delirium, n (%)	260	11 (8.7)	127	11 (8.3)	133	0.705
Stroke/TIA, n (%)	282	5 (3.5)	141	2 (1.4)	141	0.447
Echocardiographic measures at discharge						
Aortic valve area, cm^2, mean (SD)	205	1.95 (0.6)	100	1.9 (0.6)	105	0.879
Aortic peak velocity, m/s, mean (SD)	258	2.45 (0.6)	129	2.42 (0.5)	129	0.195
Aortic mean gradient, mmHg, mean (SD)	196	15 (7.1)	99	14.5 (5.7)	97	0.284
Length of elective stay						
In university hospital, da, mean (SD)	277	5.2 (3.2)	139	4.91 (2.7)	138	0.148
Total elective hospital stay, da, including local hospital, mean (SD)	275	11 (6.6)	137	10 (4.1)	138	**0.006***

SD, standard deviation; TIA, transient ischemic attack.
* Statistically significant.

without a readmission are summarized in Supplement Table 2. In Supplemental Table 3 are the causes of 30-DACR given.

3.4. Secondary outcomes

3.4.1. Symptoms of anxiety and depression

The intervention group experienced significantly fewer symptoms of anxiety compared to the control group one month after surgery (N = 260, *P* = 0.031; adjusted for baseline score). The partial eta-squared score was 0.019, indicating a small effect size. There was no statistically significant difference between the groups on symptoms of anxiety at the one-year assessment (N = 260, *P* = 0.108). The LMM analysis done without multiple imputations also showed no effect of the intervention on anxiety at the one-year assessment (N = 260, *P* = 0.096). The time course of all participants' HADS-Anxiety scores is presented in Suppl Fig. 2A of the online-only Data Supplement.

Participants in the control group had more symptoms of depression before surgery compared to those in the intervention group; however, this difference was not statistically significant different (N = 260, *P* = 0.213). Up to one year after surgery, there was no statistical difference between the groups on symptoms of depression (N = 260, *P* = 0.758). The progression of the HADS-Depression scores over time is presented in Suppl Fig. 2B of the online-only Data Supplement.

3.4.2. Perceived health state

There were no statistically significant differences between the groups on perceived health state, as measured by EQ-5D-3L VAS (N = 260, *P* = 0.636). There was also no significant difference between the groups on perceived health state, as measured by EQ-5D-3L index value TTO up to one year after surgery (N = 260, *P* = 0.485). The time course of EQ-5D-3L VAS and index value (TTO) scores are presented in Suppl Fig. 3A, B of the online-only Data Supplement.

3.5. Ancillary analyses

3.5.1. Avoidable vs. unavoidable readmissions after AVR

Overall, the proportion of unavoidable readmissions was 75%. In the intervention group, 26 out of 32 readmissions (81%) were unavoidable. In the control group, 18 out of 26 readmissions (69%) were considered unavoidable. Non-adherence to medication (33%) and chest discomfort or pain (67%) were the reasons for the readmissions assessed avoidable.

3.5.2. Time-to-event analysis of readmissions

Construction of Kaplan-Meier survival curves showed that 45% and 83% of all 30-DACR occurred within 7 days and 14 days after discharge, respectively (Fig. 1). The calculated readmission-free survival of the intervention and control groups was not significantly different (log rank χ^2 (1) = 1.439, *P* = 0.230).

3.5.3. Predictors of 30-DACR after AVR

The Cox proportional hazards multivariate analysis demonstrated that participants' symptoms of anxiety before surgery (95% CI: 1.333–4.022, *P* = 0.003) and pleural drainage before hospital discharge (95% CI: 1.072–3.213, *P* = 0.027) were independent predictors of 30-DACR after AVR, when adjusted for other variables (Fig. 2). Participants' age was borderline statistically significant (HR = 0.979, *P* = 0.067). Moreover, 30-DACR showed a downward trend in risk with increasing age; that is, as age increased in our sample, risk of readmission decreased.

4. Discussion

To reduce 30-DACRs after AVR, we developed and evaluated an intervention that used a structured TFU accompanied by a 24/7 hotline. We hypothesized that a 24/7 hotline would strengthen the promising effects of TFU in reducing readmissions. However, with this study population, our study results failed to find this hypothesis. Our findings did not show a significant difference in readmission rates between the intervention group and control group after discharge for AVR. The intervention was effective, however, in reducing symptoms of anxiety within the first month after surgery. This reduction did not persist. One year after discharge there were no differences in anxiety between the intervention and control group. The intervention also did not affect symptoms of depression or perceived health status. Symptoms of anxiety before surgery and pleural drainage before discharge predicted well 30-DACR. Three quarters of the readmissions were evaluated to be unavoidable.

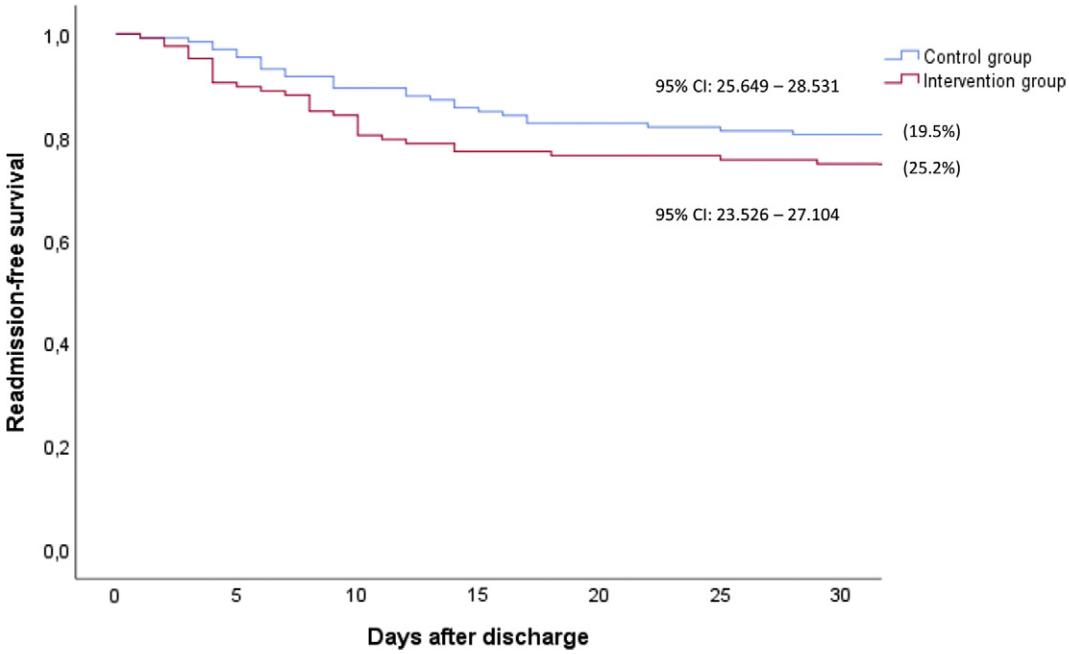

Fig. 1. Kaplan-Meier curves illustrating the results of the time-to-event analysis on the thirty-day all-cause readmission rate between the groups in the AVRre study.

In this trial, the 30-DACR rate was 22.3%. This readmission rate is higher than the pooled 30-DACR rate of 17%, as found in a recent meta-analysis [8]. However, the readmission rate in the present study is somewhat lower than that of an earlier study in our hospital (26%) [20]. Hospitals within and between countries vary on readmissions rates, and this is often attributed to differences in healthcare systems, policies, or hospital volumes, which evolve over time [21–23]. Achieving the lowest readmission rate is not necessarily an indicator of good-quality care. Indeed, in the USA, implementation of the Hospital Readmission Reduction Program is associated with fewer readmissions but with higher mortality [24]. Therefore, it would be more useful to focus on appropriate versus inappropriate readmissions, or avoidable and unavoidable readmissions.

This study is the first to report on the proportion of avoidable versus unavoidable readmissions after AVR. Three quarters of the readmissions in our trial were unavoidable. The most common reasons for readmission were atrial fibrillation, pericardial and pleural effusions, and infections, which is in line with prior studies [25–27]. Obviously, such complications cannot be managed or averted using a 24/7 hotline or TFU. Conversely, TFU can act as an appropriate gateway to needed readmissions. Indeed, participants in the intervention group who called the 24/7 hotline were more often readmitted than those who did not call. We observed that our intervention referred 10 patients to readmission, and only 3 of these might have been avoidable. Furthermore, two of the referred patients had tamponade and were invasively treated acutely. This suggests that our intervention might have the potential for enhancing patient safety post-discharge. It would be useful to investigate the effectiveness of our intervention specifically on the prevention of avoidable readmissions. Unfortunately, our trial was not powered to do this analysis. Greater emphasize on the causes for the avoidable readmissions might have prevented the avoidable readmissions.

Our intervention succeeded in reducing symptoms of anxiety in the first month after AVR. This effect did not last up to one year after surgery. Interventions (including TFU) delivered post-discharge have been shown to reduce anxiety after cardiac surgery [28]. Personal

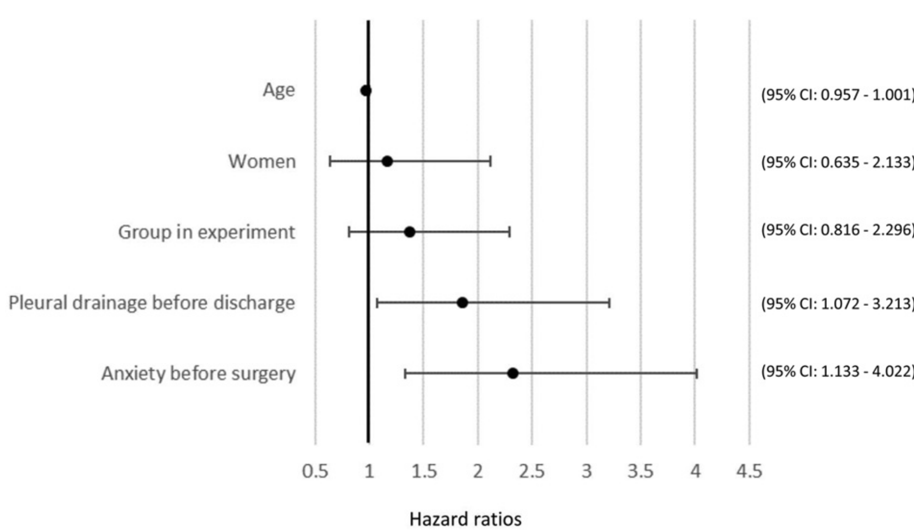

Fig. 2. Hazard ratios from Cox regression analyses. The analyses were adjusted for the following variables: Living alone, Charlson Comorbidity Index, hypertension, atrial fibrillation, and diabetes before surgery, length of stay in tertiary hospital, and depression score before surgery.

contact with patients before discharge from the tertiary hospital, opportunities to directly contact at any time post-discharge professionals at the tertiary hospital (24/7 hotline), and satisfaction with the structured TFU may be responsible for the lower level of symptoms of anxiety after surgery. However, with a small effect size present the result must be interpreted with caution. Targeting anxiety is important, because anxiety is as an independent risk factor for mortality and major morbidity after cardiac surgery [29]. In the present trial, anxiety levels before surgery predicted readmissions. Hence, in order to improve other outcomes, anxiety would be an appropriate target for an intervention.

Another risk factor for readmission that emerged from the present trial was pleural drainage before discharge. Knowing the impact of pleural drainage before discharge on readmissions after AVR should lead to heightened attention toward these patients in the discharge planning. Enhanced cooperation with local hospitals and primary care, including effective communication and systematically pre-scheduled outpatient consultations, could enhance the follow-up of AVR patients whose pleural cavities are drained before discharge [30].

4.1. Methodological considerations

The AVRre study has several strengths. First, it is the first study that aimed to use a 24/7 hotline to reduce readmissions after AVR. The methods and statistical approaches are transparently reported in order to be replicable. Second, we accessed and tabulated necessary medical information and had complete data on the primary outcome. Third, we used well-established, valid, and reliable instruments to assess changes in the secondary outcomes over time. Forth, we had high response rates on the questionnaires, which were a result of the planned logistics and our conscious choice to use only two small self-report questionnaires to assess these patients. Fifth, we perceive this as a low-cost intervention because no extra personnel needed to be hired for the intervention, and it can be implemented as a part of the 24/7 patient care provided by experienced nurses of cardiovascular wards.

Nevertheless, the interpretations of the findings in our study must be used cautiously because of some limitations. First, the study was conducted at a single center, which could limit the external validity of the results. Second, there was likely some heterogeneity in the way the intervention was delivered; e.g., a learning effect of TFU over time and possible differences in the way different nurses staffed the hotline. Third, the heterogeneity of multiple local hospitals (some were rural requiring >4-hour drive time from the tertiary hospital), with different discharge procedures and rehabilitation offers, must be considered when interpreting the findings. Fourth, different quality of services among primary care providers might have contributed to differences in the post-discharge phase and readmission rates of the AVR patients. Fifth, the intervention might have introduced a bias effect, in which more attention was paid toward a patient's health condition during a sensitive phase of his early rehabilitation. This might have led to slightly more readmissions in the intervention group compared to the control group. Sixth, our trial was powered on the reduction of 30-DACRs with 10 percentage points. Given our finding that only 10%–25% are avoidable, the study was insufficiently powered to carry out analyses on the effect of the intervention on avoidable readmissions. Future studies should target avoidable readmissions and evaluate whether our intervention is capable of reducing this type of readmission. Seventh, we cannot provide evidence on the costs of the intervention, yet. However, we are preparing a cost-utility study to investigate the benefit-burden ratio of the intervention.

5. Conclusions

Our findings did not support the hypothesis that a structured TFU and a 24/7-patient-support hotline intervention would reduce post-discharge readmissions after AVR. The intervention was effective, however, in reducing symptoms of anxiety within the first month after AVR surgery. We found that a three-quarter of the readmissions were unavoidable. Therefore, our results indicate that it could be promising to shift our focus from reducing all-cause readmissions to reducing avoidable readmissions and test the effect of interventions on such avoidable readmissions. Such future studies would, at the very least, preclude the possibility that unavoidable readmissions are reduced at the cost of increased mortality.

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Declaration of competing interest

None of the authors have any connections with industry or financial associations that pose a conflict of interest in relation with this study. Conflict of interest: none declared. The authors report no relationships that could be construed as a conflict of interest.

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