Høgskulen på Vestlandet

Masteroppgave

MKS590

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Høgskulen på Vestlandet

Mekanisk aortaklaff, klikkelyd og søvnforstyrrelser

Mechanical Aortic Valve Sound and Sleep Disturbance

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Master's Degree in Clinical Nursing part II

Department of Health & Social Studies, HvL 29.05.2019

Supervisors: Associate Professor II Kjersti Oterhals, PhD & Professor II Tone M. Norekvål, PhD

Jeg bekrefter at arbeidet er selvstendig utarbeidet, og at referanser/kildehenvisninger til alle kilder som er brukt i arbeidet er oppgitt, *jf. Forskrift om studium og eksamen ved Høgskulen på Vestlandet, § 10.*

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Stavanger, May 2019

Kristin Liland

Sammendrag

Bakgrunn: Aortastenose (AS) er den mest vanlige hjerteklaffe-sykdommen blant voksne i Europa og Nord-Amerika i dag. Rundt 1-2% blir født med bikuspid aortaklaff, som er den vanligste årsaken til aortaklaffe-operasjon (AVR) i ung alder. Yngre pasienter får vanligvis implantert mekanisk klaffeprotese, med visse krav til tilpasningsdyktighet. Tidligere forskning viser at personer med mekanisk klaffeprotese rapporterer søvnforstyrrelser.

Hensikt: Hensikten med denne studien er å undersøke sammenhenger mellom klikkelyden fra en mekanisk aortaklaff og søvnforstyrrelser, og om der er forskjeller med hensyn til alder.

Metode: Data ble samlet ved hjelp av et spørreskjema som ble sendt per post til 1191 pasienter som var klaffeoperert ved et universitetssykehussykehus i Norge fra januar 2000 til desember 2012. Kliniske data ble innhentet fra sykehusets hjertekirurgiregister. Spørsmål om grad av forstyrrelse fra klikkelyd og minimal insomnia symptom scale (MISS) ble brukt for å innhente data. Assosiasjoner mellom grad av forstyrrelse fra klikkelyd (skala 0-10) og insomnia sum score som avhengige variabler, samt mulige aldersforskjeller ble undersøkt. I tillegg ble åtte uavhengige forklaringsvariabler inkludert og evaluert i en lineær regresjonsanalyse: kjønn, alder, utdanning, røyk, tid siden operasjon, rehabilitering, erstatte klaff med lydløs, og grad av forstyrrelse (skala 0-10).

Resultat: Responsraten var 77%, derav 245 pasienter som hadde mekanisk klaffeprotese. Gjennomsnittlig (SD) alder på disse var 61 (11) år, 47% var <60 år, og 186 (76%) var menn. Over 50% rapporterte at de ofte hørte klikkelyden fra klaffeprotesen. Søvnforstyrrelser relatert til klikkelyden ble rapportert som «sjelden/noen ganger» hos 44% av pasientene i begge aldersgrupper, og som «ofte» hos 6% av pasientene ≤60 år og hos 9% av pasientene >60 år. En av ti rapporterte alvorlige problemer med å falle i søvn. Lineær regresjonsanalyse viser at insomnia øker med alder (p=0.005) og med økt forstyrrelse fra klikkelyden (p=0.001). Opplevelsen av klikkelyd ble redusert med tid siden operasjon (p=0.050) og der var en signifikant, positiv assosiasjon mellom grad av forstyrrelse og ønsket om å erstatte klaffen med en lydløs klaff (p=0.001).

Konklusjon: Pasienter med mekanisk klaffeprotese opplever søvnforstyrrelser i varierende grad. Pasienter >60 år opplever mer søvnforstyrrelser, mens pasienter som er 60 år eller yngre ønsker oftere å erstatte klaffen med en lydløs klaff. De aller fleste som får implantert

mekanisk hjerteklaff tilpasser seg klikkelyden godt, mens noen har utfordringer i lang tid etter operasjon. Ved å sette fokus på utfordringene som kan oppstå etter mekanisk klaffeoperasjon, som på søvnforstyrrelser, kan sykepleiere arbeide forebyggende og bidra til pasientens mestring og håndtering av sine utfordringer.

Abstract

Background: Aortic stenosis (AS) is the most common valvular heart disease (VHD) among adults in Europe and Northern- America. About 1–2% are born with a bicuspid aortic valve, which is the most common reason for aortic valve replacement (AVR) in young age. Young patients mostly receive mechanical heart valve prostheses, which sets certain requirements regarding adaptability. Previous research shows that people with mechanical valve prostheses report insomnia.

Aims: To investigate the association between valve noise perception and insomnia, and possible age differences.

Methods: A survey questionnaire was sent to 1191 patients who had undergone AVR from 2000-12. Clinical data were obtained from the local cardiac surgery database. Seven questions regarding valve sound perception and minimal insomnia symptom scale (MISS) were analysed. Associations between valve noise perception (scale 0-10) and insomnia sum score as dependent variables, and possible age differences were investigated. In addition, eight independent explanatory variables were included, and evaluated in linear regression analysis: gender, age, edication, smoking, time since surgery, rehabilitation, replace valve with soundless and disruption (scale 0-10).

Results: The response rate was 912 (77%) of which 245 patients had mechanical valve. Mean (SD) age was 61 (11) years, 47% were <60 years and 186 (76%) were men. More than 50% reported they often could hear the closing sound from their mechanical valve. Sleep disturbance due to valve sound were reported as «seldom/sometimes» in 44% of the patients in both age groups, and «often» in 6% ≤60 years and 9% of patients >60 years. One out of ten reported severe difficulties initiating sleep. Linear regression shows that insomnia increase with increasing age (p=0.005) and with increased disturbance from the valve sound (p=<0.001). Valve sound perception decreased by time since surgery (p=0.050) and a

significant, positive association was shown between extent of noise disturbance and the wish to replace valve with soundless valve (p=0.001).

Conclusion: Patients with mechanical valve prostheses, experience sleep disturbance in varied extent. Patients >60 years experience more sleep disturbances, while patients 60 years or younger more often wish to replace their valve with a soundless valve. Most patients who receive mechanical heart valve prosthesis adjust well, while the remaining group experience challenges for a long time after the surgery. With this knowledge, health workers can prepare and contribute to patients' adaption. Preventive work may help patients master their challenges.

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1.0 Introduction

Valvular heart disease (VHD) is a common cause of reduced heart function and increased mortality (Woods, Forelicher, Motzer, Bridges, 2010, p.705). The number of patients presenting with VHD in developed countries is growing, primarily due to the increasing age of the population (Nishimura et al, 2014, p.e69). Aortic stenosis (AS) is the most common VHD among adults in Europe and in North America (Lam & Henry, 2004 p.307). The treatment is aortic valve replacement (AVR). Both bioprosthetic and mechanical heart valve prostheses are implanted today, and the main question for patients that require AVR remains whether a mechanical or bioprosthetic valve should be implanted (Head & Kappetein, 2017, p.2183). Adolescents and young adults with more than 10 years life expectancy most commonly receive mechanical valve prostheses, because of longer durability compared to bioprosthetic valve prostheses (Sedrakyan et al, 2004, p.266).

Mechanical valve prostheses make a characteristic sound when the valve closes, which patients must adapt to and learn to live with. Previous research shows that sleep disturbance are in several cases the main challenge for patients who struggle to adapt to the existence with a constant valve noise (Golczyk, Kompis, Englberger, Carrel, Stalder, 2010; Laurens, Wit, Ebels, 1992; Limb, Kay, Moritz et al, 1992; Murday, 1992). However, none of the studies are focusing specifically on associations regarding valve noise perception and sleep disturbance, nor related to possible age differences. Previous research also indicates that disturbance from mechanical valve prostheses and sleep disturbance may vary in different age groups, though these associations have not been investigated. Research is needed to obtain knowledge and awareness on the subject. The psychological aspect around the closing sound, and how it is affecting the patients' sleep quality, is the background of this study.

1.2 Background

1.2.1 VHD and indications for surgery

Well-functioning heart valves leads the blood flow through the heart to the pulmonary circulation, the big cycle and to all organs in the body (Camm, Lüscher, Serruys, 2009, p.764). Rheumatic fever was in the earlier years a common cause to stenosis and regurgitation of the valves, but most VHD's today are in the Western world degenerative conditions in elderly people (Forfang & Rasmussen, 2007 p.165). More elderly get surgical treatment compared to earlier years, especially due to AS (Forfang & Rasmussen, 2007 p.165). VHD in one or more valves can primarily come from stenosis (the valve does not open properly),

regurgitation (the valve does not close properly) or a mix of these two conditions (Woods et al, 2010, p.705). AS has become the most common VHD among adults in Europe and in North America (Lam & Henry, 2004, p.307). The other heart valves can also develop disease, but aortic- and mitral valve disease cause most of the symptoms and make up most of the heart valve diseases (Woods et al, 2010, p.705). Heart valve stenosis is most common in people older than 65 years, followed by younger people with congenital valve failure/disease. The most common indicator for valve surgery in young people is congenital heart disease with bicuspid aortic valve. About 1–2% of infants are born with a bicuspid aortic valve, which is sometimes associated with coarctation of the aorta. Most of these affected infants are male (Carabello & Paulus, 2009, p.956). A bicuspid aortic valve has only two leaflets instead of three, which is most common in human anatomy. The bicuspid aortic valves are more exposed to valve calcification and aortic stenosis (Jacobsen, Kjeldsen, Ingvaldsen, Buanes, Røise, 2012, p.81). These patients will mostly in young age, or when the valve is starting to cause symptoms, need AVR (Jacobsen et al, 2012, p.82). Onset of severe symptoms of AS - angina, synope and heart failure, remains the major demarcation point in the disease's course (fig.1). The asymptomatic patient has a good outlook even with severe obstruction, whereas an individual with symptoms has a mortality rate of about 25% per year (Carabello & Paulus, 2009, p.957).

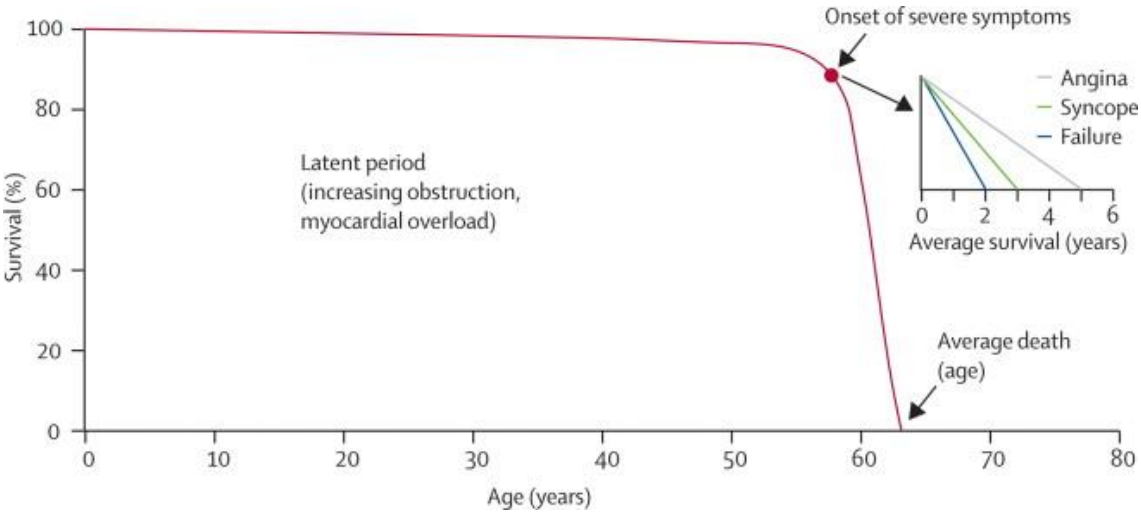


Figure 1. *Survival of patients with AS over time (Carabello & Paulus, 2009, p.957).*

After a long latent asymptomatic period, during which time survival is nearly normal, survival declines precipitously once symptoms develop (Carabello & Paulus, 2009, p.957).

With acute symptomatic severe aortic regurgitation, acute surgery is indicated (Vahanian et al, 2012, p.11). The primary cause of acute aortic regurgitation is infective endocarditis and aortic dissection (Baumgartner et al, 2017 p.2749). With chronic aortic regurgitation that causes symptoms, surgery is recommended regardless of left ventricle ejection fraction (LVEF) (Baumgartner et al, 2017, p.2749). Statistics show that most of the VHD treatments in Norway involves the aortic valve, and the number of treatments have increased. The number of treatments of the other heart valves is relatively constant (Fiane, Bjørnstad, Geiran, Svennevig, 2018, p.16).

1.2.2 Treatment of AS

The alternatives in treatment of severe AS is conservative, medical treatment, surgical aortic valve replacement (SAVR), or transcatheter aortic valve implantation (TAVI) with bioprosthetic valve prostheses. The only effective treatment of symptomatic AS is replacement of the valve: SAVR or TAVI (Carabello & Paulus, 2009, p.960). In SAVR, mechanical heart valves are implanted via open- heart surgery with sternum split. The patient is connected to a heart and lung machine that maintains the blood circulation throughout the body, while the heart is temporarily stopped from beating. TAVI makes it possible to implant bioprosthetic valves without having to go through open- heart surgery. The procedure is now more common in elderly, high-risk patients with indications for AVR (Camm et al, 2009, p.774). With a bioprosthetic valve, patients do not have to use anti-coagulation medication, and the valve is functioning naturally without valve noise. The disadvantage is the risk of reoperation after four to 15 years (Zipes, Libby, Bonow, Braunwald, 2005, p.1611). Durability beyond 20 years for the commonly used bioprosthetic valves can occasionally be expected when implanted at ages >60 years. However, these results cannot be extrapolated to all designs or to younger ages at implantation (Briffa & Chambers, 2017, p.1101). The number of bioprosthetic valves has increased above the number of mechanical valves since 2005 (Fig.2). In most cases, mechanical valve prostheses last a lifetime, and there is a much lower risk of reoperation (though not absent) compared with bioprosthetic valves (Korteland et al, 2016, p.727).

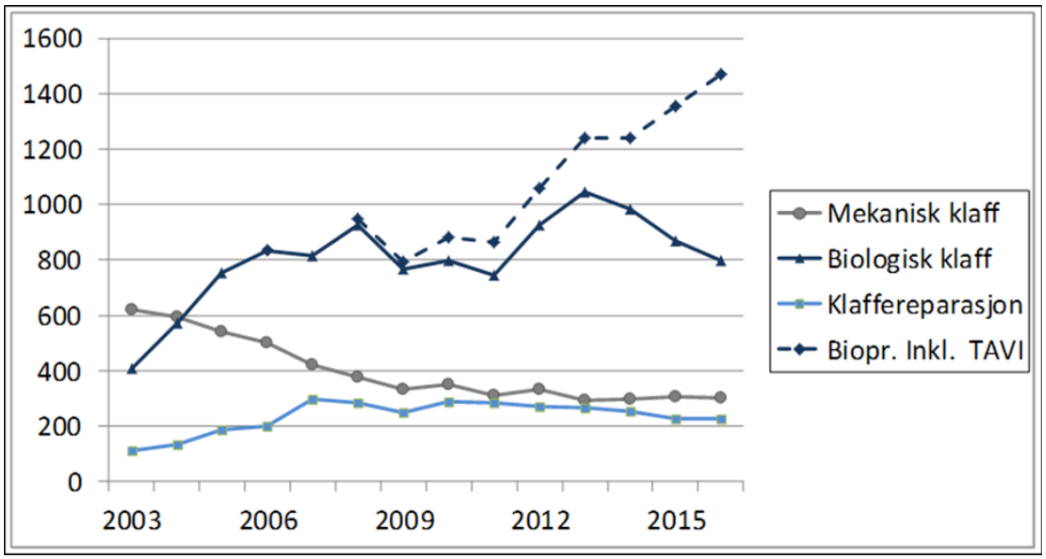


Figure 2. *The relation between the number of mechanical valves, bioprsothetic valves, valve reparations and bioprosthetic valves including TAVI in Norway 2003-2016 (Fiane, Geiran, Svennevig, 2017, p.20).*

As it appears in figure 2, the number of bioprosthetic valves have increased above the number of mechanical valves since 2005, and the number of TAVI procedures have been increasing the last 10 years (Fiane et al, 2017, p.20). Guidelines from American Heart Association/American College of Cardiology (AHA/ACC) recommend, after taking patient preferences into consideration, that mechanical valve prostheses should be implanted in patients <50 years of age. Patients <50 years at the time of valve implantation incur a higher and earlier risk of bioprosthetic valve deterioration (Nishimura et al, 2017, p.266-267). According to European Guidelines, the choice of prosthetic valve in adults is determined mainly by estimating the risk of anticoagulation-related bleeding and thromboembolism with a mechanical valve versus the risk of structural valve deterioration with a bioprostheses, and by considering the patient's lifestyle and preferences (Baumgartner et al, 2017, p.2769).

Uncertainty exists regarding the optimum type of prosthesis for patients 50 to 70 years of age. There are conflicting data on survival benefit of mechanical versus bioprosthetic valves in this age group, with equivalent stroke and thromboembolic outcomes (Nishimura et al, 2017, p.266). Patients receiving a mechanical valve incur greater risk of bleeding, and those undergoing bioprosthetic valve replacement more often require repeat valve surgery (Nishimura et al, 2017, p.266.). The choice of type of prosthetic heart valve should always be a shared decision-making process that accounts for the patient's values and preferences. For

patients between 50 and 70 years of age, it is reasonable to individualize the choice of either a mechanical or a bioprosthetic valve prosthesis. This should be on the based on individual patient factors and preferences, after a full discussion of the trade- offs involved (Nishimura et al, 2017, p.266). Despite recommendations, there is a tendency in younger patients, to wish for a bioprosthetic valve due to requirements living with mechanical heart valve prostheses (Briffa & Chambers, 2017 p.1101).

1.2.3 Sleep disturbance

Sleep is essential for health and well-being (Magee, Caputi, Iverson, 2011, p.348-349). The human body and brain need sleep, as important hormones that keep us fit and able to reduce stress, are produced in our body during sleep (Heier & Wolland, 2005, p.323). Good sleep restores both psychological and physical energy, and is a process necessary for recovery after surgery (Liao, Huang, Huang, Hwang, 2011, p.276). However, the need for sleep is individual and there is no golden standard for how many hours of sleep a person needs.

Coping with stress is an important factor in sleep quality. Methods for coping with stress should be a part of treatment of sleep disturbance (Heier & Wolland, 2005, p.321). The consequences of chronic lack of sleep are many. Studies of young men show that reduced sleep over an amount of time affects metabolism and hormonal conditions (Heier & Wolland, 2005, p.322). Findings indicate that reduced sleep over time, contributes to or hastens development of diabetes type 2 and hypertension (Spiegel, Leproult, Van Cauter, 1999, p.1438). Lack of sleep can cause reduced function during daytime, tiredness, irritability, impaired memory, and reduced performance (Wolland & Heier, 2009, p.31). Sleep disturbance can also impair the immunity of the body, prolong the mechanical ventilation duration, reduce cognitive functions, increase the risk of infections, aggravate the disease and increase the mortality (Cooper et al, 2000; Orwelius, Nordlund A, Nordlund P, Edéll-Gustafsson, Sjöberg, 2008). In addition to contributing to poor mood and decreased quality of life, disrupted sleep has also shown to increase mortality risk (Cappuccio, D'Elia, Strazzullo, 2010; Hsu, Ko, Liao, 2010; Magee et al, 2011).

Previous studies have shown that sleep disturbance can be one of the main challenges in patients after mechanical heart valve implantation (Laurens et al, 1992; Limb et al, 1992; Oterhals, Fridlund, Nordrehaug, Haaverstad, Norekvål, 2012). In addition, sleep disturbance in patients partners are reported (Kottmaier et al, 2017, p.203; Limb et al, 1992, p.619).

Patients use numerous methods of reducing the valve noise at night; sleeping on one specific side does, for some patients make the sound to appear quieter, clutching the bedclothes close to the chest or ears, playing music, herbal remedies, alcohol, tranquillisers, or sleeping with the mouth open are some methods reported in previous research (Limb et al, 1992, p.619).

2.0 Theoretical framework

2.1 Roy's Adaption Model

To adapt to a new lifestyle with the restrictions that follows is crucial for the patients who amongst other requirements, are dealing with the closing sound from the mechanical valve for the rest of their lives. In Roy's adaption model, humans are viewed as biopsychosocial adaptive systems who cope with environmental change through the process of adaption (Polit & Beck, 2017, p.122). The model describes four subsystems within the human system:

1) Physiologic/physical: The way people as individuals interact as physical beings with the environment, in this case with the mechanical valve and the click sound.

2) Self-concept/group identity: Psychical and spiritual integrity. The composite of beliefs and feelings that an individual hold about him- or herself at a given time (Roy, 2009, p.44). The patients' need to interpret him- or herself as the same person as before the valve surgery, - and need others to view the patient as the same person they knew before.

3) Role function: The roles that the individual occupies in the society. Some patients may experience a change in their role function after receiving a valve implant and some may get social isolated - they avoid situations that can lead to increased pulse and louder closing sound (Kottmaier et al, 2016; Laurens et al, 1992; Limb et al, 1992; Oterhals et al, 2012). Basic need: social integrity and the need to know who one is in relation to others so that one can act (Roy, 2009, p.44).

4) Interdependence: Giving and receiving love, respect and value. One own and others acceptance of a new state and new conditions. Interaction between the patient and friends, family and others – the extent to which one allow the click sound to affect relations as well as new relations on professional and private base. Basic need: termed relational integrity, the feeling of security in nurturing relationships (Roy, 2009, p.45).

These four subsystems constitute adaptive modes that provide mechanisms for coping with environmental stimuli and change. Nurses can be an important part of the adaption process. Nursing regulates stimuli affecting adaption. The goal of nursing, according to this model, is to promote client adaption. Nursing interventions usually take the form of increasing, decreasing, modifying, removing or maintaining internal and external stimuli that affect adaption (Polit & Beck, 2017, p.122).

3.0 Aim

The aim of this study was to investigate the association between valve noise perception and insomnia, and possible age differences.

4.0 Materials and methods

4.1 Design and setting

To collect data, a cross-sectional design was used. The cross-sectional design is economical and appropriate for describing the status of phenomena or relationships among phenomena (Polit & Beck, 2017, p.168). The design involves the collection of data once the phenomena under study is captured during a single period of data collection (Polit & Beck, 2012, p.184). A postal survey questionnaire was sent out to 1191 patients who had undergone AVR with or without concomitant coronary artery bypass graft (CABG) at a University Hospital in Western Norway between January 2000 and December 2012.

4.2 Study population

Hospital information- system registries at the university hospital and patient records were used to identify patients eligible for the present study. Inclusion criteria other than AVR were age ≥18 years and Norwegian language. The registries were also used to exclude cognitively impaired or deceased patients.

4.3 Data Collection

Data were collected from the postal survey questionnaire that was sent along with a pre-stamped envelope to 1191 patients treated during the last 13 years, in April 2013. The questionnaire was completed and returned by 912 (77%) patients, and a total of 245 of the patients who returned the questionnaire had mechanical aortic heart valve prostheses and were included in this study. Information on baseline clinical characteristics, cardiovascular risk

factors and postoperative outcome, including complications, were obtained from the local cardiac surgery database.

4.4 Instruments

From the data collection, research was conducted on the patient self-reported data of the closing sound and sleep disturbance. The questionnaire regarding heart valve sound and disturbance was translated to Norwegian for this study (Oterhals et al, 2015).

4.4.1 Heart valve sound and disturbance

The questionnaire includes seven items on how patients perceive the valve sound from mechanical heart valve, developed by Sezai et al. in 2000. The following was ascertained:

1.	your valve sound is audible to yourself
2.	your valve sound is audible to others; when audible
3.	you sometimes feel uneased about the valve sound
4.	the valve sound disturbs you during daytime
5.	the valve sound disturbs your sleep
6.	you want to replace it with a soundless prosthetic valve if possible
7.	noise index (a new quantitative indicator invented by the department to score the degree of sound stress imposed by prosthetic valves on the patients examined in the present study)

There are four alternative answers to the first six questions which scores different: “Never” = 0 points, “Seldom” = 1 point, “Sometimes” = 2 points and “Often” = 3 points. A valve sound perceived by a patient was scored 10 points on the noise index when it was considered to put maximum stress on the patient, or 0 points when it did not disturb the patient at all (Sezai et al, 2000, p.508).

4.4.2 Minimal Insomnia Symptom Scale (MISS)

The MISS, a three-item screening instrument has been found to be psychometrically sound and capable of identifying insomnia in the general population (20-64 years). The original version of the MISS is valid and reliable (Hellström, Hagell, Fagerstöm, Willman, 2010, p.1-2). The three items are:

1.	Difficulties initiating sleep
2.	Waking up at night
3.	Not feeling refreshed by sleep in the morning

Each item has five response alternatives; no problem (0), small problems (1), moderate problems (2), severe problems (3), and very severe problems (4). A sum score of 0-3 indicates no insomnia, 4-6 subclinical insomnia, 7-9 moderate insomnia, and 10-12 severe insomnia (Hellström et al, 2010, p.2).

4.4.3 Sociodemographic and clinical variables

Age, gender, education, marital status, the New York Heart Association classification (NYHA), and comorbidities were obtained by patient self-report. NYHA classifies patients into four categories (I, II, III, IV), with higher classes indicating more severe symptoms and limitations in physical activity. This self-assessed NYHA classification tool asks patients to assign themselves to an NYHA class by ticking one of four boxes describing the category that best summarizes their ability to perform physical activity. This tool is a documented and valid way of assessing heart failure (Holland, Rechel, Stepien, Harvey, Brooksby, 2010). Acute myocardial infarction (AMI), pacemaker (PM) and atrial fibrillation (AF) were also obtained by patient self-reported. Clinical variables prior or related to the surgery, such as concomitant CABG, were obtained from the local cardiac surgery database.

4.5 Ethics

Scientific health research strives to provide generalizable knowledge about phenomena of the world (Lie, Svendsen, Gamlund, 2011, p.191). Our authority and legal system are a safety net, which provide rules to protect individuals. In Norway it is called Helseforskningsloven, Lov om personvern (NSD/personvernombud) and in addition we have the Regional Medical Ethics Committees (REK). The four ethical principles are in the center:

Autonomy	**Beneficience**	**Nonmaleficence**	**Justice**
Self-rule	Kindness	Do not act in a way that may hurt others	Selection Equality Relevance

(Polit & Beck, 2012)

The main study was conducted in accordance with the ethical guidelines contained in the World Medical Association's Declaration and Helsinki (2004), and was approved by the Regional Medical Ethics Committee of Western Norway (No. 2010/01954). Information about the study, the possibility of withdrawing at any time, and confidentiality issues were included in the letter that accompanied the questionnaire. Informed consent was confirmed by the patients returning the completed questionnaire. In that way, the patient's autonomy were safeguarded, as well as their justice. The patients have a right by the law to sign an informed consent, in order to understand what they are participating in. The informed consent form must be understandable for all people, and the scientist must make sure that the participants understand what they are participating in. The questions regarding valve noise perception and insomnia, were included based on Oterhals et al's (2012) article; "Adapting to living with a mechanical aortic heart valve: a phenomenographic study". The questionnaire was tested for face validity in a sample of the participants that had participated in a previous interview study (Oterhals, 2015, p.46). There was no disadvantage related to nonmaleficence in this present study as the aim concerns a piece of what makes patient's well-being and quality of life hence sleep disturbance. The present study aims to benefit the patients, and that is the foundation of the thesis itself.

4.6 Statistical analysis

Descriptive statistics describe and summarize data (means, percentage). Univariate descriptions with frequency analysis was first conducted to get the description on each variable, and differences in age over/under 60 years. A 60-year cut off was found to be suitable due to the mean age and median in this study, that was slightly above 60 (round-up to 61). Comparisons between age under and over 60 years were performed with T-test and Chi-square test depending on the level of measurement of the variables. Linear regression analyses were conducted to investigate possible factors associated with level of stress from the valve

and insomnia, and to which extent the valve sound was disturbing. In the linear regression analysis, eight variables were included as independent variables. The variables were selected due to previous research, as well as clinical experiences.

In the second linear regression analysis, standard multiple regression was performed, with insomnia sum score as dependent variable. Eight independent variables were entered, where the categorical variables were collapsed into dichotomous variables before entered in the analysis. Age, gender, education, smoking, time since surgery, on a scale from 0-10; how disturbing is the valve noise on a daily basis and would you replace the valve with a soundless valve if it was possible, as dichotomous variables.

A two-sided p-value ≤ 0.05 was considered statistically significant. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 24.0 (SPSS, Inc., Chicago, IL, USA), which is suitable for analysing questionnaires.

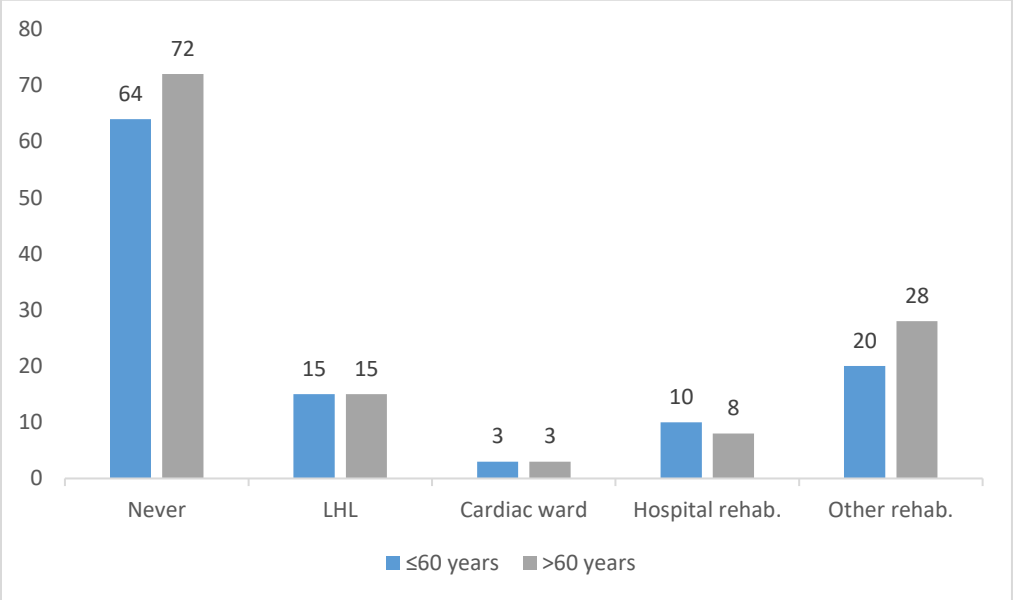
5.0 Results

Socio-demographic variables are presented in Table 1. At the time of the survey, the mean age (SD) of the 245 patients was 61 (11) years, and 114 (47%) were ≤60 years of age, 186 (76%) were men. In total, 192 (78%) were living with their spouse or cohabitant (Table 1). There were no significant age differences in the socio-demographic variables except for smoking, where 13% (15) ≤60 years contra 7% (9) >60 years were smoking (p=0.027). In all, 136 (57%) patients did never participate in heart rehabilitation and the majority of those who did not participate was >60 years of age (Fig.3). However, there were no significant differences in the age groups regarding heart rehabilitation (Table 1).

Table 1: Descriptive statistics on socio-demographic variables in a mechanical AVR population in Western Norway between 2000 and 2012.

	All patients (*N*=245) *n* (100%)	**≤60 years (*n*=114) *n* (47%)**	**>60 years (*n*=131) *n* (53%)**	***P*-value**
Age, mean, median (SD) range	61 (11) (20, 83)			
Gender, male	186 (76)	86 (75)	100 (76)	0.870
Married	190 (78)	84 (74)	106 (81)	0.176
Living alone	45 (18)	22 (19)	23 (18)	0.726
Education				0.855
High level	76 (31)	36 (32)	40 (31)	
University < 4 years				
University > 4 years				
Low level	167 (69)	77 (68)	90 (69)	
Elementary school				
College				
Employee	98 (40)	73 (64)	25 (19)	**<0.000**
Smoking	24 (10)	15 (13)	9 (7)	**0.027**
Rehabilitation	109 (45)	50 (44)	59 (45)	0.853

AVR: aortic valve replacement. *P*-values ≤0.05 shown in bold. **P*-values from Chi-Square test.



LHL: The Norwegian Federation of Heart- and Lung disease.

Figure 3. *Participation in heart rehabilitation.*

Twelve percent (29) of the patients have had acute myocardial infarction (AMI), and 15% (35) had coronary artery bypass graft (CABG), regarding 24% (35) of the patients >60, and only 5% (5) of those ≤60 years (p=0.001). Twice as many >60 had pacemaker (PM) (16%) compared to (8%) among those ≤60 years of age. One out of four (58) had intermittent atrial

fibrillation (AF) and 6% (13) had permanent AF. There were no age differences in NYHA classification, 92% (222) were in NYHA class I-II (Table 2).

Table 2: Descriptive statistics on comorbidities in a mechanical AVR population in Western Norway between 2000 and 2012.

	All patients (*N*=245) *n* (100%)	**≤60 years (*n*=114) *n* (47%)**	**>60 years (*n*=131) *n* (53%)**	***P*-value**
AMI	29 (12)	10 (9)	19 (15)	0.294
CABG	35 (15)	5 (5)	30 (24)	**<0.001**
PM	29 (12)	9 (8)	20 (16)	0.191
AF, intermittens	58 (25)	23 (21)	35 (28)	0.453
AF, permanent	13 (6)	4 (4)	9 (7)	0.476
NYHA				0.968
I-II	222 (92)	103 (92)	119 (92)	
III-IV	19 (8)	9 (8)	10 (8)	

AVR: aortic valve replacement; AMI: acute myocardial infarction; CABG: coronary artery bypass graft; PM: pacemaker; AF: atrial fibrillation, NYHA: New York heart association classification of symptomatic heart failure.
P-values ≤0.05 shown in bold. **P*-values from Chi-Square test.

More than 60% (68) of the patients ≤60 years reported that the valve sound often was audible to themselves, while 41% (49) >60 years reported the same. Twenty-six percent (28) of the patients ≤60 years reported it was also often audible to others, when audible, 20% (24) of the patients >60 years reported the same. One out of ten (12) ≤60 years would want to replace their valve with a soundless valve if possible, while the same applied for 17% (19) of the patients under 60 years (Table 3).

Table 3: Descriptive statistics on perception of valve noise, in a mechanical AVR population in Western Norway between 2000 and 2012.

Heart valve sound perception	**All patients (*N*=245) *n* (100%)**	**≤60 years (*n*=114) *n* (47%)**	**>60 years (*n*=131) *n* (53%)**	***P*-value**
Your valve is audible to yourself				**0.001**
Never	13 (6)	8 (7)	10 (8)	
Seldom/sometimes	101 (44)	39 (35)	62 (51)	
Often	117 (51)	68 (62)	49 (41)	
Your valve sound is audible to others; when audible				0.132
Never	23 (10)	7 (6)	16 (13)	
Seldom/sometimes	154 (67)	75 (68)	79 (66)	
Often	52 (23)	28 (26)	24 (20)	
You sometimes feel uneased about the valve sound				0.823
Never	131 (57)	60 (55)	71 (59)	
Seldom/sometimes	89 (39)	44 (40)	45 (38)	
Often	10 (4)	6 (6)	4 (3)	
The valve disturbs you during daytime				0.206
Never	146 (63)	62 (56)	84 (69)	
Seldom/sometimes	79 (34)	45 (41)	34 (28)	
Often	6 (3)	3 (3)	3 (3)	
The valve sound disturbs your sleep				0.710
Never	112 (49)	55 (50)	57 (47)	
Seldom/sometimes	101 (44)	48 (44)	53 (44)	
Often	18 (8)	7 (6)	11 (9)	
You want to replace valve with a Soundless prosthetic valve if possible				0.189
Never	110 (48)	45 (41)	65 (54)	
Seldom/sometimes	88 (38)	45 (41)	43 (36)	
Often	31 (14)	19 (17)	12 (10)	
Noise perception scale Mean (SD)	1.70 (2.215)	2.02 (2.4)	1.40 (2.0)	**0.036**

AVR: aortic valve replacement. *P*-values ≤0.05 shown in bold. **P*-values from Chi-Square test.

Regarding sleep disturbance, 6% (7) of patients ≤60 years, as well as 9% (11) >60 reported that the valve sound often disturbed their sleep at night. In all, one out of ten (24) reported they have severe difficulties initiating sleep. In addition, 17% (40) reported severe problems with waking up at night and 14% did not feel refreshed by sleep in the morning. Patients >60 years report some bigger challenges initiating sleep, and waking up at night than the patients ≤60 years, though the patients ≤60 years report somewhat bigger issues with not feeling refreshed by sleep in the morning (Table 4).

Table 4: Descriptive statistics on minimal insomnia symptom scale (MISS), in a mechanical AVR population in Western Norway between 2000 and 2012.

Minimal Insomnia Symptom Scale (MISS)	**All patients (*N*=245) *n* (100%)**	**≤60 years (*n*=114) *n* (47%)**	**>60 years (*n*=131) *n* (53%)**	***P*-value**
Difficulties initiating sleep				0.539
None	125 (53)	57 (52)	68 (55)	
Some	85 (36)	42 (38)	43 (35)	
Severe/very severe	24 (10)	11 (10)	13 (11)	
Waking up at night				0.235
None	66 (28)	39 (35)	27 (22)	
Some	130 (55)	55 (50)	75 (61)	
Severe/very severe	40 (17)	17 (15)	23 (18)	
Not feeling refreshed by sleep in the morning				0.999
None	81 (34)	37 (34)	44 (35)	
Some	121 (51)	57 (52)	64 (51)	
Severe/very severe	34 (14)	16 (15)	18 (14)	
Insomnia sum score Mean (SD)	3.55 (3.0)	3.41 (3.1)	3.68 (3.0)	0.491

AVR: aortic valve replacement. *P*-values ≤0.05 shown in bold. **P*-values from Chi-Square test.

Linear regression analysis was performed with valve noise perception (scale 1-10) as dependent variable, and age, gender, education, and smoking, time since surgery and replace valve if possible as independent variables. The valve noise perception decreased by time since surgery (p=0.050) and there was a significant, positive association between valve sound disturbance and the wish to replace the valve with a soundless valve (p=0.001) (Table 5).

Table 5: Results from linear regression of noise perception after AVR with mechanical valve, in 245 patients in Western Norway between 2000 and 2012.

Dependent variable: **noice perception (0-10)**			
Independent variables	*Beta*	95% CI	*P*
Gender	-0.092	(-1.579, 0.500)	0.306
Age	-0.069	(-0.060, 0.028)	0.464
Education	0.049	(-0.670, 1.160)	0.597
Smoking	-0.096	(-1.179, 0.383)	0.314
Time since surgery	-0.181	(-0.247, -0.000)	**0.050**
Rehabilitation	0.008	(-0.845, 0.921)	0.932
Replace valve with soundless	0.304	(0.680, 2.687)	**0.001**
R Square: 0.164 Adjusted R Square: 0.111 F: 3.110			

P-values ≤0.05 shown in bold.

Results from the second linear regression analysis shows that insomnia increased with increasing age (p=0.005) and there was a positive association between valve noise perception and insomnia (p=<0.001) (Table 6).

Table 6: Results from linear regression of Insomnia sum score in 245 patients after AVR with mechanical valve, in Western Norway between 2000 and 2012.

Dependent variable: **insomnia sum score**

Independent variables	*Beta*	95% CI	*P*
Gender	-0.091	(-1.991, 0.629)	0.305
Age	0.268	(0.025, 0.138)	**0.005**
Education	-0.129	(-1.996, 0.331)	0.159
Smoking	0.014	(-0.911, 1.064)	0.878
Time since surgery	0.086	(-0.084, 0.235)	0.349
Rehabilitation	-0.091	(-1.701, 0.544)	0.310
Disturbance (scale 0-10)	0.346	(0.208, 0.682)	**<0.001**
Replace valve with soundless	0.036	(-1.067, 1.572)	0.705
R Square: 0.215 Adjusted R Square: 0.157 F: 3.701			

P-values ≤0.05 shown in bold.

6.0 Discussion

6.1 Results

To the best of our knowledge, this is the first study to investigate a direct association between valve noise perception in patients with mechanical valve prostheses and sleep disturbance, with the valve-specific questionnaire in addition to the MISS. Comorbidities were obtained by patient self-report. Eight percent of the patients were classified as having symptoms equal to NYHA III-IV, 15% underwent CABG and 22% had intermittent atrial fibrillation (AF). Most of the patients in the present study were living with spouse or cohabitant.

Associations between valve noise perception and sleep disturbance, and possible age differences were investigated in this study. The main results indicate that there are associations between general disturbance from the mechanical valve prostheses and sleep disturbance, in addition to differences regarding age under/over 60 years. The majority of the patient's ≤60 years reported that the valve sound often was audible to themselves. More patient's ≤60 years reported it was also often audible to others, when audible. These findings are similar to previous studies who found that the closing sound is audible to the patients themselves, but also to their immediate surroundings (Golczyk et al, 2010; Nishi et al, 2010).

Only three percent reports that they often are disturbed by the valve sound during daytime, although 41% ≤60 years reported to «seldom or sometimes» be disturbed by the valve sound during daytime. Another study reported that 19% were disturbed during daytime (Sezai et al, 2000, p.508). In another study, 15% of the patients stated they "sometimes or often" were disturbed by the sound (22% in the first three to six months after operation) (Kottmaier et al, 2017, p.202). Being >60 years lowered the propability to be disturbed. Younger patients were

more likely to worry about the valve noise (Koertke et al, 2003, p.55). Recipients of mechanical valve prostheses are aware that the valve sound are audible to others (Nishi et al, 2010, p.416). Young patients often have a wide network in school, work and social happenings. Previous research show that mechanical valve recipients report difficulties with concentrating, embarrassment in relation to the closing sound, and they avoid situations that lead to increased heart rate (Kottmaier et al, 2017; Limb et al, 1992). Some of the previous research conducted in the past had the older valve prostheses, while the newer valve prostheses are making less noise. Nevertheless, the patients' noise perception has not changed much. In a previous study, surprisingly 12% replied that they felt disturbed by the valve sound, and these patients had received a bioprosthetic valve (Korteland et al, 2016, p.727).

In all patients, 39% reported to "seldom or sometimes feeling uneasy about the valve sound" with little differences in age groups, whereas a small group of 4% reported that they often felt uneasy, in which the majority was ≤60 years of age. The same valve- specific questions were used by Sezai et al (2000) who reported that among patients with ATS (ATS Medical, Inc, Minneapolis, Minn) and St. Jude Medical (SJM) valves, 46% often felt uneasy about the valve sound (Sezai et al, 2000, p.508-509). Age ≤60 years and being female were statistically significant factors for persisting unease caused by valve sounds (Koertke et al, 2003, p.52). In the present study, 10% of the patients over 60 years would want to replace their valve with a soundless valve if possible, while the same applied for 17% of the patients under 60 years. Sezai et al reported that nine percent wished to replace valve with soundless valve (Sezai et al, 2000, p.508-509).

The MISS consists of the three items; difficulties initiating sleep, difficulties maintaining sleep, and non-restorative sleep (not feeling refreshed by sleep in the morning). Results from another study suggests a close relationship between all three key symptoms in a normal population (Broman, Smedje, Mallon, Hetta, 2009, p.138). The closing sound from the valve are to some patients often disturbing when initiating sleep, reported by a majority over 60 years of age. It has been suggested that it is the individual's perspective of growing old that is significant for the experience of good or poor sleep (Hellström et al, 2010, p.5). In this study, patients reported waking up at night and not feeling refreshed by sleep in the morning. This was mostly reported by patients under 60 years of age. However, it is difficult to determine whether there could be other coherent factors of impact in both age groups, causing sleep disturbance regardless of the valve sounds. Previous research shows that problems created by

the valve sound were annoyance and sleep disturbance, the latter reported in 21% of the patients (Sezai et al, 2000, p.508-509). They also found that patients' partners reported sleep disturbance (Limb et al, 1992; Sezai et al, 2000). One study described that patients felt annoyed by the valve sound, and that both themselves and their partners felt disturbed during sleep (Limb et al, 1992, p.619). It has been argued in previous research that healthy elderly persons adjust their expectations of sleep, accepting the changes as a normal part of aging (Hellström et al, 2010, p.5). The presence of a medical disease or chronic illness has stronger correlations with poor sleep than chronological age per se (Bliwise, 1993; Zilli, Ficca, Salzarulo, 2009).

Results in the present study shows direct associations in valve noise perception, sleep disturbance and age. There is a positive association between valve noise perception and insomnia, and insomnia are increasing with increasing age. In addition, the valve noise perception decreased by time since surgery and there was a significant, positive association between valve sound disturbance and the wish to replace the valve with a soundless valve. Time since surgery have also been investigated in previous research, where it was reported that two years after operation, 6% classified their valve sounds as «quite» or «very much» disturbing (Koertke et al, 2003, p.52). The associations between time since surgery and extent of disturbance may indicate that coping mechanisms establishes with time.

Adapting to a new lifestyle with the restrictions that follows is crucial for the patients who amongst other requirements, are dealing with the closing sound from the valve for the rest of their lives. Health workers can be an important part of the patients' adaption process. Nursing regulates stimuli affecting adaption. The goal of nursing, according to Roy's adaption model, is to promote client adaption. Nursing interventions usually take the form of increasing, decreasing, modifying, removing or maintaining internal and external stimuli that affect adaption (Polit & Beck 2017; Roy, 2009). The role function and the roles that the patients occupies in the society may have an impact on adaption to a bodily change. The patients' need to interpret him- or herself as the same person as before the surgery, and need others to view them as the same person they knew before (Roy, 2009, p.44). Interdependence, giving and receiving love, respect and value, and the importance of accepting a new state and new conditions, affects adaption. Interaction between the patient and friends, family and others, and to which extent one allow the closing sound to affect, has impact on relations (Roy, 2009, p.45).

Humans are in Roy's adaption model, viewed as biopsychosocial adaptive systems who cope with environmental change through the process of adaption, both physiological and physical, concerning interaction with the environment as physical beings. The subsystems of Roy's adaption model constitute adaptive modes that provide mechanisms for coping with environmental stimuli and change (Polit & Beck, 2017, p.122). Comorbidities are important for the patient's physiological prerequisite, but also in relation to the psychological aspects, that comorbidity may have an impact on self-concept and group identity (Roy, 2009, p.44). The subject in this study has a great relevance for health workers in meeting with this patient group. The majority of the patients adapt and manage to deal with the closing sound without severe sleep disturbances. Nevertheless, patients need to receive information and be prepared for the closing sound and challenges that may follow, in order to be able to comprehend and to cope in a best possible way in the time after the surgery. The findings in the present study should make an important contribution to the field not only in cardiac nursing, but also to the several platforms where health workers meet patients that are facing, or have already faced AVR with mechanical valve prostheses.

6.2 Methodological considerations

6.2.1 Validity

The validity of a scale refers to the degree to which it measures what it is supposed to measure. There is no clear-cut indicator of a scale's validity. Content validity refers to the adequacy with which a measure or scale has sampled from the intended universe or domain of content. Criterion validity concerns the relationship between scores in a scale and some specified, measurable criterion (Pallant, 2010 p.7).

Internal validity concerns how the study is planned in order to avoid threats towards the ability to draw the correct conclusions from the results (Jacobsen, 2010, p.206; Martinussen et al, 2010, p.217). Internal validity must appear in the questionnaires in order to consider external validity (generazibility) of the findings based on the questionnaires. The questions are considered to which extent they are accurate, and easy to understand. A potential threat for the internal validity is selection bias. The sample must be representative for the population group that the study concerns. Drop-out; lack of response from the participants or incomplete questionnaires is another threat to internal validity (Martinussen et al, 2010, p.217, 219).

6.2.2 Generalizability

In cohort studies, there is always an insecurity related to whether the characteristics in a selection is generalizable. There was a response rate of 77% on the questionnaires in this study, which show strength regarding representativity of the study, and further on generalizability. External validity is related to the generalizability potential of the study; namely, can the results and findings relate to a bigger part of the population with the same background, and apply in different contexts (Jacobsen, 2010, p.20).

6.2.3 Reliability

The reliability of a scale indicates how free it is from random error. Cronbach's α is a frequent used index that estimates the internal consistency of a composite measure composed of several subparts. Cronbach's α is also called coefficient alpha (Polit & Beck, 2017, p.725). A common used indicator of internal consistency is Cronbach's coefficient alpha, which provides an indication of the average correlation amongst the items that make up the scale; Values range from 0.0 to 1.0, with higher values indicating greater reliability (Pallant, 2010, p.6+97). Cronbach alpha coefficient of a scale should be above 0.7, in order to assert the questions as correspondent (Pallant, 2010, p.97). In this present study, Cronbach's α was 0.80 for the noise perception questionnaire and 0.82 for the MISS. These Cronbach α values indicate that the questions in these questionnares are within the limit for validity.

6.2.4 Strengths and methodological limitations

The present study had several strengths and methodological limitations. The study has a retrospective study design. A disadvantage in cross-sectional studies may be that there are often alternative explanations for the findings (Polit & Beck, 2017, p.170), and inferring changes over time is problematic (Polit & Beck, 2012, p.186). As this was a single-centre study, it might decrease the generalizability of the results. The sample, however, represents patients from both densely populated and rural areas. The results can only indicate associations between variables, not causal relationships. The time since surgery (1-13 years) varied considerably and could have been problematic in the analyses. However, time since surgery became a valuable variable with relevant findings. The MISS instrument is a self-report questionnaire, reflecting subjective experiences rather than the prevalence of insomnia disorder, which may be problematic when comparing groups. The strength of this study is the large cohort, which allowed inclusion of a wide range of explanatory factors into the linear

regression analyses. Therefore, the predictive value of various socio-demographic characteristics, preoperative risk factors, surgical-related variables and comorbidities could be evaluated. Several former studies have used the validated questionnaires, which have proven to be appropriate for the target group (Amofah et al, 2016; Broman et al, 2008; Hellström et al, 2010; Sezai et al, 2000). The response rate was 77% in this study, which shows strength regarding the internal validity. No previous studies have investigated associations between valve noise perception, sleep disturbance and possible age differences. In addition, variables such as rehabilitation and comorbidities are important factors to include when investigating these associations.

7.0 Conclusions and implications for practice

The closing sounds from the mechanical valve prostheses have an impact on some patients' life after surgery. Valve noise perception varies in the age groups, and the majority of patients disturbed and wishing for a soundless valve was ≤60 years of age.

Sleep disturbance are to some patients with mechanical valve prostheses a severe challenge, and are experienced in varied extent. Insomnia increase with increasing age. One possible implication is that patients' sleep quality before surgery may be a factor of greater impact, in the time leading up to the choice in treatment of severe AS.

This study indicates associations in valve noise perception and sleep disturbance, in addition to age differences. The data reported appear to support the assumption that focus on valve noise perception and sleep disturbance in meeting with patients facing or have faced surgery with mechanical heart valve implantation, may improve patient care. Awareness on the possible age differences may lead to more patient- oriented directions of suitable interventions to help patients cope with their challenges individually. Coping with the closing sound from the mechanical heart valve and whether patients have sleep disturbance due to the sound are major aspects in health care of this patient group.

The aim was to establish a paper and submit to an international scientific journal so that the results are available to both health workers and patients. The findings should make an important contribution not only to the field of cardiac nursing, but also to other health workers. Hospitals, both medical and surgical wards, are platforms to use in dissemination. In addition, places for follow-up such as out- patient clinics and general practice are important

platforms where you meet patients in a different time and setting. Further research are required to investigate how to prevent disturbance and inconveniences, and how to manage the challenges in a health- promoting perspective.

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Article: ***Mechanical aortic valve sounds and sleep disturbance***

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Abstract

Background: Most patient's ≤60 years who undergo aortic valve replacement (AVR) receive mechanical valves. Patients report disruptions from closing sounds of the valve, and insomnia.

Objectives: To investigate associations between valve noise perception and insomnia, and possible age differences.

Methods: A questionnaire including valve-specific questions and the Minimal insomnia symptom scale (MISS) was sent to 1191 patients who received AVR from 2000-12. Assossiations between valve noise perception (scale 0-10) and insomnia sum score were investigated.

Results: The response rate was 77%, of which 245 patients with mechanical valve. Mean (SD) age was 61 (11) years, 47% were ≤60 years. Over 50% reported to often hear closing sounds, and positive associations was found between disruption and the wish to replace valve with soundless valve (p=0.001). Insomnia increased with age (p=0.005).

Conclusions: The associations between noise perception, insomnia and age may lead health workers to contribute to patient's adaption through preventive work.

Keywords: Valvular heart disease, aortic stenosis, aortic valve replacement, mechanical valve prostheses, valve sound, sleep disturbance.

Introduction

Valvular heart disease (VHD) is a common cause of reduced heart function and increased mortality.[1] The number of patients presenting with VHD in developed countries are growing, primarily due to increasing age.[2] Aortic stenosis (AS) is the most common VHD among adults in the Western world, due to degenerative conditions in elderly.[3, 4.] A common indicator for aortic valve replacement (AVR) in adolescents and young adults is bicuspid aortic valve. About 1–2% of infants, mostly male, are born with a bicuspid aortic valve, which is more exposed to AS.[5, 6] The alternatives in treatment of severe AS is conservative, medical treatment, surgical aortic valve replacement (SAVR) or transcatheter aortic valve implantation (TAVI) with bioprosthetic valve prostheses. Both mechanical and bioprosthetic valve prostheses are implanted today, and the main question for patients that require AVR remains whether a mechanical or bioprosthetic valve should be implanted.[7.] Guidelines from American Heart Association/American College of Cardiology (AHA/ACC) recommend, after taking patient preferences into consideration, that mechanical valves should be implanted in patients <50 years of age. Patients <50 years at the time of valve implantation incur a higher and earlier risk of bioprosthetic valve deterioration.[8.] According to European Guidelines, the choice between a mechanical and a bioprosthetic valve in adults is determined mainly by estimating the risk of anticoagulation-related bleeding and thromboembolism with a mechanical valve versus the risk of structural valve deterioration with a bioprostheses, in addition to considering the patient's lifestyle and preferences.[9.] Despite recommendations, there is a tendency in younger patients who wish for a bioprosthetic valve due to requirements living with mechanical valve prostheses.[10.]

Uncertainty exists about the optimum type of prosthesis for patients 50 to 70 years of age. There are conflicting data on survival benefit of mechanical versus bioprosthetic valves in this

age group, with equivalent stroke and thromboembolic outcomes. Patients receiving a mechanical valve incur greater risk of bleeding, and those who receive AVR with bioprosthetic prosthesis, more often require reoperation.[8.] In most cases, mechanical valves last a lifetime and there is a much lower risk of reoperation (though not absent) compared with bioprosthetic valves.[11.] Mechanical valves make a characteristic closing sound, and previous studies shows that sleep disturbance are in several cases, one of the main challenge for patients who struggle to adapt to the existence with a constant valve noise.[12, 13, 14, 15.] Sleep disturbance may impair the immunity of the body, prolong the mechanical ventilation duration, reduce cognitive functions, increase the risk of infections, and even aggravate the disease and increase the mortality.[16, 17.] Previous findings indicate that reduced sleep over time contributes to, or hastens development of diabetes type 2 and hypertension.[18.] However, none of the former studies has focused specifically on associations regarding valve noise perception and sleep disturbance. Previous research also indicates that disturbance from mechanical valves and sleep disturbance may vary in different age groups, although these associations have not been investigated specifically.[12, 13, 15, 19.] Therefore, the aims of this study was to investigate the associations between valve noise perception and insomnia, and possible age differences.

Material and methods

Design and setting

This study has a cross-sectional design. The patients was treated at a large and tertiary university hospital in Norway, in April 2013.

Patients

Hospital information- system registries at the university hospital, in addition to patient records was used to identify patients eligible for the study. Inclusion criteria were age ≥18 years and Norwegian language, and patients who had received AVR with or without concomitant coronary artery bypass graft (CABG). The registries and patient records was also used to exclude cognitively impaired or deceased patients.

Measures

A valve-specific, validated questionnaire was used to investigate patient's valve sound perception. The questionnaire includes seven items on how patients perceive the valve sound from mechanical heart valve, and was developed by Sezai et al, in 2000. The following was ascertained: 1) your valve sound is audible to yourself, 2) your valve sound is audible to others; when audible, 3) you sometimes feel uneased about the valve sound, 4) the valve sound disturbs you during daytime, 5) the valve sound disturbs your sleep, 6) you want to replace it with a soundless valve if possible. There are four alternative answers to the first six questions which scores different: "Never" = 0 points, "Seldom" = 1 point, "Sometimes" = 2 points and "Often" = 3 points. The seventh question was a noise index (a new quantitative indicator invented to score the degree of sound stress imposed by prosthetic valves on the patients.[20.] A valve sound perceived by a patient was scored 10 points on the noise index when it was considered to put maximum stress on the patient, or 0 points when it did not disturb the patient at all.[20.]

The Minimal Insomnia Symptom Scale (MISS) was used to investigate insomnia. MISS is a three-item screening instrument found to be psychometrically sound and capable of identifying insomnia in the general population (20-64 years).[21.] The three items are 1)

difficulties initiating sleep, 2) waking up at night, and 3) not feeling refreshed by sleep in the morning.[21] Each item has five response alternatives: no problem (0), small problems (1), moderate problems (2), severe problems (3), and very severe problems (4). A sum score of 0-3 indicates no insomnia, 4-6 subclinical insomnia, 7-9 moderate insomnia, and 10-12 severe insomnia.[21] The original version of the MISS is valid and reliable.[21]

Data collection

A postal survey questionnaire was sent along with a pre-stamped envelope to 1191 patients who had undergone AVR with or without concomitant coronary artery bypass graft (CABG) between January 2000 and December 2012. Clinical data and information on patients' baseline clinical characteristics, cardiovascular risk factors and postoperative outcome, including complications, was obtained from the local cardiac surgery database. Sociodemographic and clinical variables such as age, gender, education, marital status, NYHA classification and comorbidities were obtained by patient self-report. The questionnaire was piloted on a sample of the participants, for face validity. The questionnaires were completed and returned by 912 (77%), of which 245 patients had mechanical valve prostheses and were included in this study.

Data analysis

Descriptive statistics describes and summarize data (means, percentage). Univariate descriptions with frequency analysis was first conducted to get the description on each variable, and differences in age under/over 60 years. A 60-year cut off was found to be suitable due to the mean age and median in this study, that was slightly above 60 (round-up to 61). Comparisons between age under and over 60 years were performed with T-test and Chi-square test depending on the level of measurement of the variables. Linear regression analyses

was conducted to investigate possible factors associated with level of stress from the valve and insomnia, and the extent to which the valve sound was disturbing. In the first linear regression analysis, seven variables were included as independent variables: gender, age, education, smoking, time since surgery, rehabilitation and, would you replace the valve with a soundless valve if possible.

In the second linear regression analysis, standard multiple regression was performed, with insomnia sum score as dependent variable. Eight independent variables were included: gender, age, education, smoking, time since surgery, on a scale from 0-10; how disturbing is the valve noise on a daily basis and, would you replace the valve with a soundless valve if possible. The categorical variables were collapsed into dichotomous variables before entered in the regression analyses. The variables in each analysis was selected due to previous research, as well as clinical experiences. A two-sided P-value of ≤ 0.05 was considered statistically significant. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 24.0 (SPSS, Inc., Chicago, IL, USA) .

Ethics

The investigation conforms with the ethical guidelines contained in the World Medical Association's Declaration and Helsinki (2004) and was approved by the Regional Medical Ethics Committee of Western Norway (No. 2010/01954). Information about the study, the possibility of withdrawing at any time and confidentiality issues was included in the letter that accompanied the questionnaire. Informed consent was confirmed by the patients returning the completed questionnaire.

Results

Socio-demographic variables are presented in Table 1. At the time of the survey, the mean age (SD) of the 245 patients was 61 (11) years, 186 (76%) were men, and 114 (47%) were ≤60 years of age. In total, 192 (78%) were living with their spouse or cohabitant (Table 1).

Twelve percent (29) of the patients had acute myocardial infarction (AMI), 25% (58) had intermittent atrial fibrillation (AF) and 6% (13) had permanent AF. The majority (92%) were in NYHA class I-II. There were no significant age differences in comorbidities, except more patients >60 years had undergone CABG (p=0.001). Twice as many patients >60 years had pacemaker (PM), but these findings were not significant (Table 2).

More than 60% (68) of the patients ≤60 years reported that the valve sound often was audible to themselves, while 41% (49) >60 years reported the same. Twenty-six percent (28) of the patients ≤60 years reported it was also often audible to others, when audible, 20% (24) of the patients >60 years reported the same. One out of ten (12) of the patients ≤60 years would want to replace their valve with a soundless valve if possible, while the same applied for 17% (19) of the patients ≤60 years (Table 3).

Regarding sleep disturbance, 6% (7) of patients ≤60 years, as well as 9% (11) >60 reported that the valve sound often disturbed their sleep at night. In all, one out of ten (24) reported they have severe difficulties initiating sleep. In addition, 17% (40) reported severe problems with waking up at night and 14% did not feel refreshed by sleep in the morning. Patients >60 years report bigger challenges initiating sleep and waking up at night, than the patients ≤60 years. On the other hand, patients ≤60 years report bigger issues with not feeling refreshed by sleep in the morning (Table 4).

Linear regression analysis was performed with valve noise perception (scale 1-10) as dependent variable, and age, gender, education, and smoking, time since surgery and replace valve if possible as independent variables. The valve sound perception decreased by time since surgery (p=0.050) and there was a significant, positive association between valve sound disturbance and the wish to replace the valve with a soundless valve (p=0.001) (Table 5).

Results from the second linear regression analysis with insomnia as dependent variable, and gender, age, education, smoking, time since surgery, on a scale from 0-10; how disturbing is the valve noise on a daily basis and, would you replace the valve with a soundless valve if possible as independent variables. Results show that insomnia increase with increasing age (p=0.005) and there was a positive association between valve noise perception and insomnia (p=<0.001) (Table 6).

Discussion

To the best of our knowledge, this is the first study to investigate a direct association between valve noise perception in patients with mechanical valves and sleep disturbance, with the valve-specific questionnaire in addition to the MISS. Most of the patients in the present study were living with their spouse or cohabitant. Comorbidities were obtained by self-report. Eight percent of the patients were classified as having symptoms equal to NYHA III-IV, 15% had CABG and 22% had intermittent atrial fibrillation (AF).

Associations between valve noise perception and sleep disturbance, and possible age differences was investigated in this study. The main results indicate that there are associations between general disturbance from mechanical valve prostheses and sleep disturbance, and differences regarding age, under and over 60 years. The majority of the patient's ≤60 years reported that the valve sound often was audible to themselves. More patient's ≤60 years reported it was also often audible to others, when audible. These findings are similar to

previous studies who found that the closing sound is audible to the patients themselves, but also to their immediate surroundings.[14, 22]

Only three percent reported that they often are disturbed by the valve sound during daytime, although 41% ≤60 years reported to "seldom or sometimes" be disturbed by the valve sound during daytime. Another study reported that 19% were disturbed during daytime.[20] In another study reports that 15% of the patients in their study stated they "sometimes or often" were disturbed by the valve sound (22% in the first three to six months after operation).[23] Being >60 years lowered the propability to be disturbed. Younger patients were more likely to worry about the valve noise.[19] Recipients of mechanical valve prostheses are aware that the valve sound are audible to others.[22] Young patients often have a wide network in school, work and social happenings. Previous research show that mechanical valve recipients report difficulties with concentrating, embarrassment in relation to the closing sound, and they avoid situations that lead to increased heart rate.[12, 23.] Some of the previous research conducted some years back had the older valve prostheses, and the newer valve prostheses are making less noise. Nevertheless, the patients' noise perception has not changed much. In a previous study, surprisingly 12% replied that they felt disturbed by the valve sound, and these patients had received a bioprosthetic valve.[11.]

In all patients, 39% reported to "seldom or sometimes feeling uneasy about the valve sound" with little differences in age groups, whereas a small group of 4% reported that they often felt uneasy, in which the majority was ≤60 years of age. The same valve- specific questions were used by Sezai et al (2000) who reported that among patients with ATS (ATS Medical, Inc, Minneapolis, Minn) mechanical valves and St. Jude Medical (SJM) valves, 46% often felt uneasy about the valve sound.[20.] Age ≤60 years and being female were statistically significant factors for persisting unease caused by valve sounds.[19] In the present study, 10% of the

patients over 60 years would want to replace their valve with a soundless valve if possible, while the same applied for 17% of the patients under 60 years. Sezai et al reported that nine percent wished to replace valve with soundless valve.[20]

The closing sound from the valve are to some patients often disturbing when initiating sleep, reported by a majority over 60 years of age. It has been suggested that it is the individual's perspective of growing old that is significant for the experience of good or poor sleep.[21] In this study, patients reported waking up at night and to not feeling refreshed by sleep in the morning. This was mostly reported by the patients under 60 years of age. However, it is difficult to determine whether there could be other coherent factors of impact in both groups, causing sleep disturbance regardless of the valve sounds. Previous research shows that problems created by the sound were annoyance and sleep disturbance, the latter reported in 21% of the patients.[20] They also found that patients' partners reported sleep disturbance.[12, 20.] One study described that patients felt annoyed by the valve sound and that they and their partners felt disturbed during sleep.[12.] Previous studies have concluded that especially being younger increase the probability of severe disturbance due to mechanical valve sounds.[19, 24.] The present study shows that insomnia increases with increasing age and that there is a positive association between valve noise perception and insomnia. The results also show associations between increased insomnia with increased disturbance from the valve noise.

In the present study, valve noise perception decreased by time since surgery and there was a significant, positive association between valve sound disturbance and the wish to replace the valve with a soundless valve. In previous research, 6% classified their valve sounds as "quite" or "very much" disturbing two years after the surgery.[19] There are associations for some patients between time since surgery and extent of disturbance, which may indicate that coping mechanisms establishes with time. To adapt to a new lifestyle with the restrictions that

follows is crucial for the patients who amongst other requirements, are dealing with the closing sound for the rest of their lives. Healthcare workers can be an important part of the patients' adaption process. The majority of the patients adapt and manage to deal with the closing sound without severe sleep disturbances. Nevertheless, patients need to receive information and be prepared for the closing sound and challenges that may follow, in order to be able to comprehend and to cope in a best possible way in the time after the surgery.

Strengths and limitations

There were several strengths and methodological limitations in the present study. The generalizability of the results may have been decreased because of the fact that it was a single-centre study. However, the sample represents patients from both rural and densely populated areas. The study has a retrospective study design. The results can only indicate associations between variables, not causal relationships. The time since surgery (1-13 years) varied considerable. However, time since surgery became a valuable variable with relevant findings. The MISS instrument is a self-report questionnaire, reflecting subjective experiences rather than the prevalence of insomnia disorder, which may be problematic when comparing groups. The strength of this study is the large cohort in which the data was collected from, including all patients at a large university hospital, which allowed inclusion of a wide range of explanatory factors into the linear regression analyses. Therefore, the predictive value of various socio-demographic characteristics and comorbidities could be evaluated. Several former studies have used the MISS questionnaire, which have proven to be appropriate for the target group.[20, 21, 25, 26.] There was a response rate of 77% on the questionnaires in this study, which show strength regarding the representative of the study, and further on generalizability. To our knowledge, no previous studies have investigated associations between valve noise perception, sleep disturbance and possible age differences. In addition, variables such as

rehabilitation, comorbidities and sociodemographic variables are important factors to include when investigating these associations.

Conclusions

The closing sounds from the mechanical valve prostheses have an impact on some patients' life after surgery. Valve noise perception varies in different age groups, and the majority of patients feeling disturbed and wishing for a soundless valve was ≤60 years of age. Patients with mechanical valve prostheses experience sleep disturbance in varied extent. To some, sleep disturbance is a severe challenge. Results show that insomnia increase with age. One possible implication is that patients' sleep quality before surgery may be a factor of greater impact, in the time leading up to the choice in treatment of severe AS.

This study indicates associations in valve noise perception and sleep disturbance, in addition to age differences. The data reported appear to support the assumption that focus on valve noise perception and sleep disturbance in meeting with patients facing or have faced surgery with mechanical heart valve implantation, may improve patient care. Awareness on the possible age differences may lead to more patient- oriented directions of suitable interventions to help patients cope with their challenges individually, whether the platform of dissemination is in a hospital surgical ward, medical ward, out - patient clinics or in general practice.

Most patients who receive mechanical heart valve prosthesis adjust well, while the remaining group experience challenges for a long time after the surgery. With this knowledge, health workers can prepare and contribute to patients' adaption through preventive work. The findings should make an important contribution to not only the field of cardiac nursing, but also to other healthcare workers and patients. Further research are required to investigate how

to prevent disturbance and inconveniences, and how to manage the challenges in a health promoting perspective.

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Tables

Table 1: Descriptive statistics on socio-demographic variables in a mechanical AVR population in Western Norway between 2000 and 2012.

	All patients (*N*=245) *n* (100%)	**≤60 years (*n*=114) *n* (47%)**	**>60 years (*n*=131) *n* (53%)**	***P*-value**
Age, mean, median (SD) range	61 (11) (20, 83)			
Gender, male	186 (76)	86 (75)	100 (76)	0.870
Married	190 (78)	84 (74)	106 (81)	0.176
Living alone	45 (18)	22 (19)	23 (18)	0.726
Education				0.855
High level	76 (31)	36 (32)	40 (31)	
University < 4 years				
University > 4 years				
Low level	167 (69)	77 (68)	90 (69)	
Elementary school				
College				
Employee	98 (40)	73 (64)	25 (19)	**<0.000**
Smoking	24 (10)	15 (13)	9 (7)	**0.027**
Rehabilitation	109 (45)	50 (44)	59 (45)	0.853

AVR: aortic valve replacement. *P*-values ≤0.05 shown in bold. **P*-values from Chi-Square test.

Table 2: Descriptive statistics on comorbidities in a mechanical AVR population in Western Norway between 2000 and 2012.

	All patients (*N*=245) *n* (100%)	**≤60 years (*n*=114) *n* (47%)**	**>60 years (*n*=131) *n* (53%)**	***P*-value**
AMI	29 (12)	10 (9)	19 (15)	0.294
CABG	35 (15)	5 (5)	30 (24)	**<0.001**
PM	29 (12)	9 (8)	20 (16)	0.191
AF, intermittens	58 (25)	23 (21)	35 (28)	0.453
AF, permanent	13 (6)	4 (4)	9 (7)	0.476
NYHA				0.968
I-II	222 (92)	103 (92)	119 (92)	
III-IV	19 (8)	9 (8)	10 (8)	

AVR: aortic valve replacement; AMI: acute myocardial infarction; CABG: coronary artery bypass graft; PM: pacemaker; AF: atrial fibrillation, NYHA: New York heart association classification of symptomatic heart failure.
P-values ≤0.05 shown in bold. **P*-values from Chi-Square test.

Table 3: Descriptive statistics on perception of valve noise, in a mechanical AVR population in Western Norway between 2000 and 2012.

Heart valve sound perception	**All patients (*N*=245) *n* (100%)**	**≤60 years (*n*=114) *n* (47%)**	**>60 years (*n*=131) *n* (53%)**	***P*-value**
Your valve is audible to yourself				**0.001**
Never	13 (6)	8 (7)	10 (8)	
Seldom/sometimes	101 (44)	39 (35)	62 (51)	
Often	117 (51)	68 (62)	49 (41)	
Your valve sound is audible to others; when audible				0.132
Never	23 (10)	7 (6)	16 (13)	
Seldom/sometimes	154 (67)	75 (68)	79 (66)	
Often	52 (23)	28 (26)	24 (20)	
You sometimes feel uneased about the valve sound				0.823
Never	131 (57)	60 (55)	71 (59)	
Seldom/sometimes	89 (39)	44 (40)	45 (38)	
Often	10 (4)	6 (6)	4 (3)	
The valve disturbs you during daytime				0.206
Never	146 (63)	62 (56)	84 (69)	
Seldom/sometimes	79 (34)	45 (41)	34 (28)	
Often	6 (3)	3 (3)	3 (3)	
The valve sound disturbs your sleep				0.710
Never	112 (49)	55 (50)	57 (47)	
Seldom/sometimes	101 (44)	48 (44)	53 (44)	
Often	18 (8)	7 (6)	11 (9)	
You want to replace valve with a Soundless prosthetic valve if possible				0.189
Never	110 (48)	45 (41)	65 (54)	
Seldom/sometimes	88 (38)	45 (41)	43 (36)	
Often	31 (14)	19 (17)	12 (10)	
Noise perception scale Mean (SD)	1.70 (2.215)	2.02 (2.4)	1.40 (2.0)	**0.036**

AVR: aortic valve replacement. *P*-values ≤0.05 shown in bold. **P*-values from Chi-Square test.

Table 4: Descriptive statistics on minimal insomnia symptom scale (MISS), in a mechanical AVR population in Western Norway between 2000 and 2012.

Minimal Insomnia Symptom Scale (MISS)	**All patients (*N*=245) *n* (100%)**	**≤60 years (*n*=114) *n* (47%)**	**>60 years (*n*=131) *n* (53%)**	***P*-value**
Difficulties initiating sleep				0.539
None	125 (53)	57 (52)	68 (55)	
Some	85 (36)	42 (38)	43 (35)	
Severe/very severe	24 (10)	11 (10)	13 (11)	
Waking up at night				0.235
None	66 (28)	39 (35)	27 (22)	
Some	130 (55)	55 (50)	75 (61)	
Severe/very severe	40 (17)	17 (15)	23 (18)	
Not feeling refreshed by sleep in the morning				0.999
None	81 (34)	37 (34)	44 (35)	
Some	121 (51)	57 (52)	64 (51)	
Severe/very severe	34 (14)	16 (15)	18 (14)	
Insomnia sum score Mean (SD)	3.55 (3.0)	3.41 (3.1)	3.68 (3.0)	0.491

AVR: aortic valve replacement. *P*-values ≤0.05 shown in bold. **P*-values from Chi-Square test.

Table 5: Results from linear regression of noise perception after AVR with mechanical valve, in 245 patients in Western Norway between 2000 and 2012.

Dependent variable: **noice perception (0-10)**			
Independent variables	*Beta*	95% CI	*P*
Gender	-0.092	(-1.579, 0.500)	0.306
Age	-0.069	(-0.060, 0.028)	0.464
Education	0.049	(-0.670, 1.160)	0.597
Smoking	-0.096	(-1.179, 0.383)	0.314
Time since surgery	-0.181	(-0.247, -0.000)	**0.050**
Rehabilitation	0.008	(-0.845, 0.921)	0.932
Replace valve with soundless	0.304	(0.680, 2.687)	**0.001**
R Square: 0.164 Adjusted R Square: 0.111 F: 3.110			

P-values ≤0.05 shown in bold.

Table 6: Results from linear regression of Insomnia sum score in 245 patients after AVR with mechanical valve, in Western Norway between 2000 and 2012.

Dependent variable: **insomnia sum score**			
Independent variables	*Beta*	95% CI	*P*
Gender	-0.091	(-1.991, 0.629)	0.305
Age	0.268	(0.025, 0.138)	**0.005**
Education	-0.129	(-1.996, 0.331)	0.159
Smoking	0.014	(-0.911, 1.064)	0.878
Time since surgery	0.086	(-0.084, 0.235)	0.349
Rehabilitation	-0.091	(-1.701, 0.544)	0.310
Disturbance (scale 0-10)	0.346	(0.208, 0.682)	**<0.001**
Replace valve with soundless	0.036	(-1.067, 1.572)	0.705
R Square: 0.215 Adjusted R Square: 0.157 F: 3.701			

P-values ≤0.05 shown in bold.