- 1 Support from next of kin and nurses are significant predictors of long-term adherence to
- 2 treatment in post-PCI patients
- 3 Abstract
- 4 **Background:** Adherence to treatment is a crucial factor in preventing the progression of coronary
- 5 heart disease (CHD). More evidence of the factors associated with long-term adherence is needed.
- 6 Aims: To identify the factors associated with adherence six years after percutaneous coronary
- 7 intervention (PCI).
- 8 Methods: Baseline data (n = 416) was collected in 2013 and follow-up data in 2019 (n = 169) at
- 9 two university hospitals and three central hospitals in Finland. The self-reported Adherence of
- 10 Patients with Chronic Disease Instrument was used. Data were analysed using descriptive statistics
- and binary logistic regression analysis.
- 12 **Results:** The respondents reported higher adherence six years after PCI in comparison to four
- months post-PCI. Smoking and alcohol consumption were decreased statistical significantly.
- Support from next of kin was associated with higher physical activity and normal cholesterol levels;
- this outcome was associated with close relationships, which also was associated with willingness to
- be responsible for one's own care. Women perceived lower support from nurses and physicians, and
- they had more fear of complications. Fear was more common among respondents with a longer
- duration of CHD. Physical activity and male gender were associated with the better results of care.
- 19 **Conclusion:** Adherence to medication was at a high level, but adherence to a healthy lifestyle did
- 20 not meet Clinical Practise Guidelines among post-PCI patients. Support from next of kin and
- 21 nurses, results of care, and participating to the follow-up controls predicted adherence. Special
- attention should be given to women, patients without a close relationship, physically inactive and
- 23 those with a longer duration of CHD.

1 Keywords: Adherence, percutaneous coronary intervention, coronary heart disease

Introduction

- 3 Ageing populations and increasing rates of survival following acute coronary syndrome (ACS) have
- 4 resulted in large numbers of people living with cardiovascular disease (CVD). 1,2 Adherence to
- 5 treatment is a key factor in preventing the progression of coronary heart disease (CHD), which
- 6 remains a leading cause of death and disability in adults worldwide, despite the enhanced prognoses
- 7 of cardiac patients over the past several decades.³
- 8 According to the Theory of Adherence of People with Chronic Disease, adherence is a patient's
- 9 active, goal-oriented self-management of his/her health status as required by collaboration with
- 10 healthcare professionals. ⁴ This theory has been tested and confirmed to be suitable for evaluating
- post- percutaneous coronary intervention (PCI) patients' adherence to treatment.⁵ Adherence to
- treatment includes adherence to medication and a healthy lifestyle, which are predicted by a
- patient's sense of responsibility, cooperation with healthcare professionals, sense of normality,
- motivation, results of care, fear of complications and support from family, nurses and physicians.^{5,7}
- Adherence to treatment has been studied in terms of medication and a healthy lifestyle. Post-PCI
- patients' non-adherence to treatment may be intentional or unintentional. Intentional non-adherence
- is associated with a patient's decision to stop taking or reduce the dosage of their medication;
- unintentional non-adherence refers to a patient's lack of capacity or cognitive resources, which can
- 19 lead to non-adherence.²
- Adherence to treatment is challenging, although the effects on long-term outcomes are undeniable.
- 21 Smoking cessation halves the risk of mortality and increased physical activity and recommended
- diet reduces that risk by almost one-third.⁸⁻⁹ Additionally, failure to adhere to the prescribed

- 1 medication regimen is associated with poor clinical outcomes, higher readmission rates, increased
- 2 healthcare costs and increased morbidity and mortality. 10
- 3 Despite strong evidence supporting the importance of adherence, non-adherence to treatment
- 4 represents a common and significant public health problem among post-PCI patients.¹¹
- 5 Approximately 25% of post-PCI patients have at least two modifiable cardiovascular risk factors,⁸
- 6 but only about 50% of CHD patients make lifestyle changes. 12
- 7 Many studies have shown that adherence to treatment declines over time especially regarding
- 8 adherence to a healthy lifestyle. Uncontrolled risk factors have been found in 20%-40% of our
- 9 patients at the 1-year follow-up. 15-17 However, long-time adherence to medication have been found
- to be high among post-PCI patients, ^{18,15,17} especially among high risk population. ¹⁹ Long-term
- follow-up data about predictors of adherence among post-PCI patients is scarce; thus, effort must be
- made to focus on interventions that induce changes in adherence change that can be sustained for
- long periods of time. 18 The present study aims to produce new data about long-term adherence
- based on a follow-up research design. Toward that end, the study investigated and identified the
- level of adherence, predictors of adherence to treatment and s sociodemographic, health behavioural
- and disease-specific factors associated with them in patients with CHD six years after PCI. The
- study sought to answer the following research questions:
- 1) What is the level of adherence in patients with CHD six years after PCI in comparison to the
- baseline levels four months after PCI?
- 20 2) What are the predictive factors and sociodemographic, disease specific and health behavioural
- background variables associated them in patients with CHD six years after PCI in comparison to the
- baseline factors four months after PCI?

Methods

1 Design

- 2 This explanatory and descriptive survey is a six-year follow-up study of an initial study that was
- 3 conducted in five hospitals in 2013 with the aim of identifying the predictive factors of adherence to
- 4 treatment and sociodemographic, disease specific and health behavioural background variables
- 5 associated them in patients with CHD after an elective or acute PCI procedure (angioplasty or
- 6 stent).

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Participants

- 8 Hospitalised post-PCI patients, ranging in age from 18 to 75, with CHD and no diagnosed memory
- 9 disorders, were recruited from medical wards at two university hospitals and three central hospitals
- in Finland in 2013 four months after PCI. At the baseline in 2013, convenience sampling was used
- to select the study participants. Thus, every patient who was treated with PCI and met the inclusion
- criteria was invited to participate in the study. A total of 572 patients met the inclusion criteria.
- Nurses working in the medical wards gave the participants information about the study. The nurses
- asked the prospective participants for informed consent, and 520 (91%) of the patients agreed to
- participate. The response rate was 80% (n = 416) for the initial study. At baseline, the participants
- were asked permission to contact them regarding the follow-up study, and 352 (84.6%) of the
- 17 respondents gave their informed consent. After six years, the final response rate was 48.3% (n =
- 18 169).

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Data collection

- 20 Data were collected using questionnaires mailed via the postal service six years after PCI using the
- same Adherence of People with Chronic Disease Instrument (ACDI) that was employed in the 2013
- baseline study, which is based on the Theory of Adherence of Patients with Chronic Diseases
- developed by Kyngäs. ⁴ The ACDI have been tested, developed further and used among patients with
- 24 different chronic diseases. 4-7 The ACDI⁴ consisted of eleven mean sum variables: Two mean sum

variables measuring adherence to medication (2 items) and a healthy lifestyle (4 items), which were 1 2 explained with nine mean sum variables: responsibility (2 items), motivation (2 items), cooperation 3 (2 items), results of care (2 items), fear of complications (2 items), sense of normality (7 items), support from next of kin (5 items), support from nurses (4 items) and support from physicians (4 4 items). 5 6 In the baseline study, the construct validity of the ACDI was verified with an exploratory factor 7 analysis (EFA) using Principal Axis Factoring and Promax rotation, which produced a factor solution 8 with satisfactory statistical values (Table 1). Missing values were replaced with each item's mean 9 value. Eleven factors explained 65 % of the total variance, communalities varied between 0.20 - 0.80, 10 and the factor loadings were between 0.30 - 0.90. One original item related to responsibility was 11 removed, because it did not load on any factor. The final questionnaire included 37 items measuring 12 adherence. Internal consistency of the mean sum variables was evaluated by Cronbach's alpha values, which varied between 0.40 - 0.90. The alpha of the whole instrument was 0.84, which represent 13 acceptable value. 19 14 15 Based on the EFA results 11 mean sum variables were formatted: These mean sum variables were rated on a 5-point Likert scale ranging from 'definitely disagree' (1), 'disagree' (2), 'uncertain' (3), 16 'agree' (4) and 'definitely agree' (5). Additionally, the instrument contained 18 questions about 17 demographic details (age, gender, relationship, profession, employment status and length of 18 education), disease-specific information (duration of CHD, previous AMI, previous PCI, previous 19 20 CABG, systolic and diastolic blood pressure, total cholesterol, LDL-cholesterol) and health behaviour (physical activity, smoking, consumption of vegetables and alcohol) 21

Data analysis

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- 1 According to the initial study, ⁷ the mean sum variables were categorised into two classes. Good
- 2 adherence with a range < 3.5 was combined and assigned a value of 1; reduced adherence with
- 3 values ranging from 3.51 to 5.0 were combined and assigned a value of 2. Missing values were
- 4 replaced with each item's mean value for the mean sum variables. Descriptive statistics
- 5 (frequencies, percentages, means, standard deviation [SD]) were used to describe the respondents'
- 6 sociodemographic, health behavioural and disease-specific factors, just as they were in the initial
- 7 parent study.
- 8 At the beginning, cross tabulation and the chi-square test were used to identify the relationship
- 9 between the independent sociodemographic, health behavioural and disease-specific factors and the
- dependent mean sum variables that explain adherence to treatment (the univariate model; Table 2:
- electronic background material). In cases in which a chi-square test was not appropriate, Fisher's
- exact test was used. In the second phase, multivariate logistic regression was used to determine
- which sociodemographic, health behavioural and disease-specific factors predicted factors known to
- predicting adherence to treatment in the standardised model. All statistically significant variables in
- the univariate model were entered into the multivariate logistic regression using backward stepwise
- selection. This standardised method facilitated the confirmation of the results of the earlier
- univariate analysis. P-values < 0.05 were considered to be statistically significant. Differences
- between the baseline and follow-up groups were analysed using Wilcoxon-test and McNemar's test.
- 19 In this study, the goodness-of-fit was evaluated using the chi-squared distribution and Nagelkerke
- 20 R-square values. 19 Data analysis was conducted using Statistical Package for Social Sciences
- 21 software for Windows (SPSS 25).

Ethical considerations

- 23 Approval for the study was obtained from each research centre and the Ethical Review Board of the
- 24 University Hospital of Kuopio (Ref. 226/2015). In accordance with the Declaration of Helsinki,

- 1 participants received verbal and written information about the study, which was provided by a
- 2 registered nurse, before signing the consent forms and being discharged. This information included
- 3 the purpose and procedures of the study, the voluntary nature of participation and the option to
- 4 withdraw at any point.

5 Validity and reliability

- 6 In the 2013 initial study, the face validity of the questionnaire was evaluated by three nurses and 15
- 7 patients with CHD in a medical ward, and an explanatory factor analysis was conducted to ensure
- 8 the construct validity of the instrument. 8 In the initial study, the alpha coefficients ranged from 0.40
- 9 to 0.90, indicating sufficient-to-high internal consistency, and the alpha coefficient of the entire
- scale was 0.84, which indicates high internal consistency. 19

11 Results

12 Sample characteristics

- Of the final sample of 169 respondents (Table 3), most were male with a mean age of 68.2 years;
- just over three-quarters were married or in a close personal relationship.
- 15 Prevalence of good adherence to treatment and explanatory factors of adherence among
- 16 patients with CHD after PCI
- 17 The majority of the respondents (Table 3) reported a high level of adherence to medication and a
- healthy lifestyle six years after PCI in the follow-up study in comparison to the 2013 baseline
- values obtained, four months after PCI. Adherence to a healthy lifestyle was statistically
- significantly higher in the follow-up study than the baseline study (baseline 2013 mean 3.27, 25th-
- 21 75^{th} percentile 2.81 3.75; follow-up 2019 mean 3.40, 25^{th} - 75^{th} percentile 3.0 3.75; p = 0.05).
- The predictors of adherence (Table 4) did not differ significantly from the 2013 baseline findings,
- 23 although a different model explained adherence to treatment six years after PCI. In the baseline

- study, the sense of normality, cooperation and motivation predicted adherence, explaining 28–32%
- of the model. In this follow-up study, support from next of kin and nurses and results of care were
- 3 the strongest predictors of adherence to a healthy lifestyle explaining 30–50% of the model.
- 4 Sociodemographic, health behavioural and disease-specific factors associated with predictors
- 5 of adherence to treatment
- 6 In the follow-up study (Table 2), inspection of the respondents' health behaviours confirmed higher
- 7 levels of adherence to a healthy lifestyle in comparison to the baseline. Results in the follow-up
- 8 study (Table 4) indicated that the number of respondents that smoked was statistically lower six
- 9 years after PCI than four months after PCI. In the 2013 baseline study, one-fourth of the smokers
- 10 had stopped smoking after PCI. Additionally, alcohol consumption (based on recommendations of
- a maximum of two portions at a time²⁵) was statistical significantly lower than the baseline finding.
- Additionally (Table 3), in the follow-up study in 2019 42% of the respondents reported engaging in
- at least 120 minutes of moderate levels of physical exercise; in the baseline study, that number was
- 14 38.2%. Instead, respondents consumed vegetables in their diet on average 2.5 decilitre (dl)/day in
- 2019, and 6.5% of the respondents achieved the recommend consumption of 5 dl/day. In
- 16 comparison, in the 2013 study, 8.9% of the respondents consumed vegetables at least 5 dl/day.
- While the differences are not statistically significant, they are clinically noteworthy.
- Multivariate logistic regression (Table 6) was conducted to determine whether sociodemographic,
- 19 health behavioural and disease-specific factors were associated with factors predicting adherence to
- treatment. Support from next of kin was associated with a close personal relationship, normal total
- 21 cholesterol and physical activity. Thus, support from next of kin was the strongest predictor of
- 22 adherence to treatment. Support from nurses was the second strongest predictor of adherence to
- treatment six years after PCI. Male respondents and respondents with normal total cholesterol were
- 24 more likely to receive a high level of support from nurses.

- 1 Better perceived results of care were associated with higher physical activity and male gender.
- 2 Responsibility of patients own care was more likely among those who were in a close personal.
- 3 Lower support from physicians and higher fear of complications were more common among female
- 4 respondents. Additionally, fear of complications was associated with a longer history of CHD.
- 5 The binary logistic regression analysis results indicate a statistically significant model for predictors
- 6 of adherence to treatment and sociodemographic, health behavioural and disease-specific factors
- 7 associated with them. The effect size indicators showed a satisfactory explanatory power with
- 8 respect to the factors predicting adherence to treatment and sociodemographic, health behavioural
- 9 and disease-specific factors associated with them (Nagelkerke R2 0.12–0.50)¹⁹ (Table 6).
- 10 Three-quarters of the respondents received regular follow-up controls in a primary healthcare,
- specialised medical care or occupational healthcare setting, which was found to be statistically
- significant association with better adherence to treatment in multivariate logistic regression.
- Additionally, one-third of the respondents participated in cardiac rehabilitation, which was
- associated with adherence to blood pressure medication.

Discussion

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2 This study produced new data about the long-term follow-up results of the predictors of adherence 3 to treatment and sociodemographic, health behavioural and disease-specific factors associated with 4 them among CHD patients six years after PCI. Similar to the 2013 baseline study, the respondents in this follow-up study reported good adherence to medication in line with the results of Griffo et al. 5 (2013) one year after PCI.²⁰ However, numerous previous studies have reported contradictory 6 results, indicating that a substantial number of post-PCI patients exhibit non-adherence to 7 cardiovascular medications in long-term observations. ²¹⁻²³ Brieger et al. (2018) have indicated that 8 9 non-adherence was observed over 30% of post-PCI patients six months after PCI and with a 3-year follow-up non-adherence appeared even 48% of the post-PCI patients. ²¹ High adherence to 10 medication in the present study is significant because failure to adhere to medication is associated 11 with poorer clinical outcomes, higher hospitalisation rates and increased morbidity and mortality 12 among post-PCI patients. 10,24 13 14 Although the respondents' self-reported adherence to a healthy lifestyle and health behaviours were 15 somewhat better in the follow-up study than in the 2013 baseline study, there was a significant conflict between the respondents' health behaviours and secondary prevention guidelines, as also 16 noted by Perk et al. (2015), who reported that patients overestimate their adherence to a healthy 17 lifestyle.¹⁸ It the present study, adherence to a healthy lifestyle was significantly higher regarding 18 smoking in line with previous finding. ^{18,20} Additionally, alcohol consumption in comparison to the 19 baseline data, was decreased but it is still does not met the Clinical Practice Guidelines.²⁴ Instead, 20 21 consumption of vegetables was lower in the follow-up study than the baseline study in contrast to prior studies, which have indicated significantly higher adherence to a healthy diet one year after 22 PCI.²⁰ 23

- 1 According the results of the present study, slight improvement in physical activity was seen among
- 2 the post-PCI patients in comparison to the baseline results although the level of physical activity
- 3 was still far from the recommendations of the Clinical Practice Guidelines. ²⁴ Only about half of the
- 4 respondents reported engaging in physical activity as recommended, which in in line with the
- 5 previous studies after one-year follow-up. 18,20 This is important to note because physical activity is
- 6 a key factor in managing modifiable CHD risk factors, such as hypercholesterolaemia, hypertension
- 7 and being overweight. A moderate level of physical activity decreases the risk of premature death
- 8 and improves cardiorespiratory fitness, cardiac output, muscle strength and endurance and
- 9 functional capacity. Additionally, it may improve recovery of physical function after cardiac
- procedures and enhance health-related quality of life among post-acute myocardial infarction
- patients; hence, the importance of physical activity should be emphasised in counselling.²⁵
- Respondents that were married or in a close personal relationship received support from next of kin,
- took responsibility for their own care and were physically more active in comparison to respondents
- who were unmarried or not in a close personal relationship. Additionally, their blood pressure and
- cholesterol levels were more likely to be in line with medical guidelines. Previous evidence
- 16 confirms that support from next of kin is as an important resource for future lifestyle changes
- among post-PCI patients, ²⁵ it also has a protective effect in maintaining a healthy lifestyle resulting
- in better overall health status.²⁶ In nursing science, this means that person-centred care should be
- 19 the established practice; patients should be involved in their care and next of kin should have the
- 20 opportunity to participate in caring for patients, if the patients so choose. In contrast, support of
- 21 patients who do not have a close personal relationship should be ensured and strengthen through
- other means, such as peer support.
- 23 In accordance with our 2013 baseline results, female gender was associated with higher fear of
- 24 complications six years after PCI. This finding is clinically important because previous studies have
- 25 indicated a possible connection between fear of complications and activation of the autonomous

nervous system, resulting in a lower immune response, impaired heart rate, endothelial dysfunction 1 and vascular inflammation, which could have a negative impact on clinical outcomes.²⁷ It is 2 3 disconcerting that, in this study, female gender was associated with lower perceived support from nurses and physicians. On the other hand, this result may indicate gender differences regarding 4 support, as previously reported. In particular, women's higher need for support should be 5 6 addressed in counselling, because conventional CHD risk factors, such as smoking, hypertension 7 and dyslipidaemia, have been found to be more harmful to the development and progression of 8 CHD in women than in men. Additionally, the accumulation of risk factors and the increasing 9 prevalence of hypertension, obesity and diabetes are more common among women compared to men.29 10 It is interesting to note that, in the 2013 baseline study, support from nurses was not a statistically 11 significant predictor of adherence to treatment, but support from physicians was a significant 12 predictor of females' motivation to adhere to treatment. However, six years after PCI, both support 13 from nurses and support from physicians were significant predictors of adherence. This finding 14 15 highlights the importance of multi-professional collaboration to predict patient adherence, which was also reported by Valaker et al. (2017) In the acute phase, after PCI, the therapeutic relationship 16 between patients and their cardiologist is an important predictor for adherence to treatment,⁷ and the 17 18 resources for this should be guaranteed despite the scarce number of cardiologists. This result is in line with Du et al. (2016), who confirmed that counselling coordinated by a cardiologist is effective 19 for decreasing cardiovascular risk factors and promoting adherence to treatment. In the present 20 study, support from nurses was associated with lower total cholesterol in line with the finding 21 reported in numerous of studies that confirmed that nursing interventions had a positive impact on 22 improving patients' health behaviour and managing risk factors. ¹² Thus, nursing interventions 23

should be emphasised as a part of secondary prevention programmes.

- 1 It has been extensively documented that continuum of care and cardiac rehabilitation are not
- 2 sufficiently implemented as a part of secondary prevention, although their benefits are undeniable
- 3 ^{18,30}. In this study, one-third of the respondents participated in cardiac rehabilitation, and one-third
- 4 did not have regular follow-up controls. The respondents that received continuum of care in
- 5 secondary prevention had better adherence to treatment, as also noted by Thomas et al. 82019), who
- 6 reported an association between continuum of care and lower frequency of hospital admissions. In
- 7 future, it will be important to focus the research on the barriers and opportunities for follow-up care,
- 8 as well as the relationship between counselling and adherence to treatment.

Conclusion

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- Self-reported adherence to medication was at a high level, but adherence to a healthy lifestyle did
- 11 not meet Clinical Practise Guidelines among post-PCI patients. Support from next of kin and
- nurses, results of care, and participating to the follow-up controls predicted adherence. Special
- attention should be given to women, patients without a close relationship, physically inactive and
- those with a longer duration of CHD.

Limitations

- 16 The present study has some limitations. First, when using self-reported data collection methods, there
- is always a risk of the social desirability effect in which patients provide answers they think are
- 18 favourable instead of saying what they actually believe or sharing information about the actions they
- 19 actually take. The second limitation relates to the bias associated with the recruitment process in the
- 20 2013 baseline study, because, in general, patients are discharged 24 hours after PCI. Due to this rapid
- 21 turnover, there is a risk that patients who met the inclusion criteria for the study were overlooked.
- 22 Third, respondents bias is a significant limitation. At baseline, the participants were asked permission
- 23 to contact them regarding the follow-up study, and 352 (84.6%) of the respondents gave their
- informed consent. After six years, the final response rate was 48.3% (n = 169). Additionally, it is

- 1 known that patients who adhere well to treatment are more likely to respond to the questionnaire.
- 2 Fourth, the results have been analysed, according to the research plan, at the group level which can
- 3 be limitation also; thus, the generalisability of the results have to be treated with caution.

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- 8 research.

9 Declaration of conflicting interests

10 The authors have no conflict of interest to declare.

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14 Implications for Practice

- Next of kin should have possibility to participate post-PCI patients care and counselling
- Regular follow-up controls should be an established part of the care path after PCI
- Although post-PCI patients experienced a high self-reported adherence, their health

behaviour was not in accordance with the clinical guidelines. Thus, post- PCI patients'

understanding of their risk factors and target values have to ensure in multi-professional

person-centred counselling.

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