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Declarations

Authors' contributions:

SC developed the survey, analysed, and interpreted the data. He was also involved in drafting the paper.

TJ analysed and interpreted the data and was responsible for drafting the paper.

DS developed the survey and reviewed the draft paper for publication.

JS developed the survey, collected data, and reviewed the draft paper.

SJL and GR developed the survey, collected data, interpreted the data and reviewed the draft paper.

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ABSTRACT

OBJECTIVES: To investigate relationships between factors influencing medication taking and behavioural determinants in patients who have undergone percutaneous coronary intervention (PCI).

METHODS: A cross-sectional survey using a postal questionnaire distributed to PCI patients. The questionnaire was iteratively developed by the research team with reference to the Theoretical Domains Framework (TDF) of behavioural determinants, reviewed for face and content validity and piloted. Data were analysed using descriptive and Principal Component Analysis (PCA). Inferential analysis explored relationships between PCA component scores and factors influencing medicating taking behaviour.

KEY FINDINGS: Adjusted response rate was 62.4% (325/521). PCA gave 3 components: (C1) Self-perceptions of knowledge and abilities in relation to medication taking; (C2) Aspects relating to activities and support in medication taking; (C3) Emotional aspects in taking medication. Generally, respondents held very positive views. Statistically significant relationships between all three components and self-reported chest pain/discomfort indicated patients with ongoing chest pain/discomfort post-PCI are more likely to have behavioural determinants and beliefs which make medication-taking challenging. Respondents who were on 10 or more medications had lower levels of agreement to the C2 and C3 statements

indicating challenges associated with their activities / support and anxieties in medication taking.

CONCLUSIONS: PCI patients show links between TDF behavioural determinants and factors influencing medication taking for those reporting chest pain or polypharmacy. Further research needs to explore the effective design and implementation of behavioural change interventions to reduce the challenge of medication-taking.

KEYWORDS: coronary heart disease, adherence

BACKGROUND

Percutaneous coronary intervention (PCI) is the dominant form of revascularisation in patients with myocardial infarction (MI) or symptomatic angina. Effective pharmacological management is mandated after PCI to prevent acute stent thrombosis and associated morbidity and mortality.[1] Poor adherence to medication is associated with worse outcomes.[2,3]

Medication adherence has been defined as 'the process by which patients take their medications as prescribed, composed of initiation, implementation and discontinuation'.[4] In their review of 51 systematic reviews exploring the determinants of medication taking adherence, Kardas, Lewek and Matyjaszczyk identified 771 individual factors, grouped into eight clusters, for non-adherence to chronic medication.[5] The determinants with a negative impact on adherence were then further clustered according to the modified World Health Organization five dimensions of adherence; socio-economic-related factors, healthcare team- and system-related factors, condition-related factors, therapy-related factors, and patient-related factors.[6] Medication taking has been noted to be particularly poor in patients after MI treated with PCI; with a high rate of discontinuation of therapy occurring during the 12-month follow-up.[7] There are numerous predicting factors associated with non-adherence to antiplatelet therapy in patients after PCI including; a lack of education on antiplatelet treatment, various comorbidities and depression[8] as well as misconceptions around treatment[9]. It has been noted that adherence to medication is associated with adherence to lifestyle modification post-MI.[10]

A limitation of the evidence base around medications adherence behaviour is the omission of behaviour change theory within the stages of research design, data collection, analysis, and interpretation. Considering theory in research processes

enhances robustness and rigour, and the relevance and impact of the findings. Incorporation of behaviour change theory also permits the identification of possible theoretical mechanisms that can drive behavioural change leading to the development of targeted interventions.[11]

However, changing human behaviour is complex and challenging and can be influenced by a multitude of factors and thus any development work to understand potential influences on behavioural determinants should have a theoretical underpinning.[12] The Theoretical Domains Framework (TDF) was developed and validated by a group of psychological theorists, health psychologists, health service researchers and behavioural experts. It aims to "simplify and integrate a plethora of behaviour change theories and make theory more accessible to, and usable by, other disciplines".[13,14] TDF is not one theory but a framework of 33 psychological theories, organised into 14 theoretical domains, that facilitate investigation of behavioural determinants.[11,14]

In order to develop relevant and effective interventions that improve medication taking behaviours, and so outcomes, it is essential to understand what influences behavioural determinants in specific therapeutic areas. Thus, the aim of this study was to investigate the relationships between factors influencing medication taking and behavioural determinants in patients who have had PCI.

METHODS

A cross-sectional survey using a postal questionnaire was adopted. The study was approved by North East - Newcastle & North Tyneside 2 NHS Research Ethics Committee (Reference: 160480). NHS Research and Development approval was granted by NHS Highland R&D office (ID 1059).

Participant identification, sampling, and recruitment

All patients who received PCI within NHS Highland over a 12-month period between November 2013 and October 2014 were included in the study with no exclusions (N=526). Participants were identified by clinical staff with access to the Cardiac Unit PCI database. It was calculated that two hundred and twenty-seven responses were required to give an error rate of 5% with confidence of intervals of 95%. The questionnaire was piloted before a final version was mailed to all patients in November 2014.

Data Collection

The questionnaire was developed in several iterative stages by the research team and reviewed for face and content validity by an independent expert panel with extensive expertise in policy, practice and research related to cardiovascular medication and medication adherence. The questionnaire was piloted by mailing to a random sample of 50 patients on the PCI database, along with a letter inviting participation stating the research background and aims as well as including a reply-paid envelope. A reminder was sent to non-responders 3 weeks later. Piloting resulted in minimal changes to questionnaire wording and format and so the same distribution approach was used for the main study. The responses to the pilot were then included in the main sample. All patients were assigned a study number by the clinician with access to the PCI database. The clinician wrote to all the patients giving along with the participant information letter and explained the nature of the collaboration between university and NHS. All responses were labelled with the study number. Only the clinician held the list of patients and associated study numbers. Follow up letters were then targeted to non-respondents by the clinician. Responses were anonymised and university researchers were not given access to clinical details.

The questionnaire contained twelve items on patient characteristics including full postcode, number of visits to GP and community pharmacies and clinical information such as age, sex, smoking status, chest pain, nature of PCI procedure. Clinical Iinformation on PCI-type was obtained from the PCI database held within the Cardiology department. Attitudinal statements (19 items) were developed with reference to the Theoretical Domains Framework (TDF) to explore behavioural determinants of medication taking.[14] The Determinants of Implementation Behavior Questionnaire (DIBQ), which was developed based on the TDF items, was used to guide the development of the TDF linked attitudinal statements.[15] Item responses were a combination of closed options, 5-point Likert scales (strongly agree to strongly disagree).

Data Analysis

Data were entered into IBM SPSS version 21.0 by a researcher and independently checked for outliers before being analysed using descriptive and inferential statistics. Respondent postcodes were used to determine their Scottish Index of Multiple Deprivation (SIMD) quintiles[16] and the Scottish Government 8-fold Urban Rural Classification[17].

Questionnaire items were subjected to exploratory factor analysis (principal component analysis (PCA) with varimax rotation), to identify a smaller number of components of interrelated variables. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy and the Bartlett's Test of Sphericity were used to assess the suitability of the sample for PCA.[18] The number of components to be retained was decided based on:

- the Kaiser criterion (aiming for Eigenvalues ≥ 1)

- the scree plot, aiming for the point at which the 'elbow' flattened
- meaningfulness of component items in relation to TDF.[19,20]

Analysis included items that were not freestanding, cross-loading or decreasing the scale's internal consistency, and that displayed acceptable communalities, with factor pattern/structure coefficients above 0.4.[19, 21-23]

Following PCA, internal consistency was determined by Cronbach's alpha for each component, with negatively worded items being reverse scored.[24] Cronbach's alpha gives an indication of the average correlation among all of the items within the component scale.[25] Nunnally suggests a minimum level of 0.7 for the component scale to be considered reliable.[26]

If shown to be reliable, total component scores were obtained by assigning scores of 1 (strongly disagree) to 5 (strongly agree) to each of the Likert statement responses, with negatively worded items being reverse scored. The median and IQR scores of each reliable component were determined and compared to the mid-point of the component.

Non-parametric statistics were used to determine any significant relationships between respondent characteristics and responses with the WHO 5 dimensions of adherence (Table 1) such as age, gender, living arrangements, deprivation, rurality, number of medications, and the scores for each component. Independent samples Mann-Whitney U tests (two variables), Kruskal Wallis tests (more than two variables), and Pearson correlation were used to determine the association between the component scores and key demographic variables.

[Insert Table 1 - **WHO Dimensions of Adherence and related respondent characteristics**]

RESULTS

Demographics

The overall response rate was 61.8% (325/526) with five returned undelivered giving an adjusted response rate of 62.4% (325/521). The demographics are given in Table 2. The majority were male (262, 80.6%) with a mean age of 66.9 years (SD 10.94), a minority lived alone (69, 21.2%), the majority were living in areas of deprivation category 3 or 4 (29.8% (n=97), 33.8% (n=110 respectively). Presence of chest pain or discomfort was reported by 138 (42.5%) respondents. The median number of medications taken by patients was six (interquartile range (IQR) 5-9), with the majority of patients prescribed five or more medications (263/325, 80.9%). Table 2 also shows that around 54.5% of respondents were prescribed at least five medications.

[Insert Table 2 - **Respondent demographics (N=325)**]

TDF Behavioural determinants

When attitudinal items were subjected to PCA, the correlation matrix contained multiple coefficients above 0.3. The Kaiser–Meyer–Olkin measure of sampling adequacy (0.868) and Bartlett's test of sphericity (significance < 0.001) confirmed the factorability of the items. Three components had eigenvalues exceeding 1.0, for which varimax rotation was used a resultant 3-factor solution emerged explaining 52.7% of the variance. The three components were labelled: Self-perceptions of knowledge and abilities in relation to medication taking (Cronbach's alpha internal consistency 0.805); Aspects relating to activities and support in medication taking (Cronbach's alpha internal consistency 0.851); and Emotional aspects in taking medication (Cronbach's alpha internal consistency 0.642). Despite this last

component scale alpha value being just less than 0.7 the team decided to proceed to use it in analysis given it was a short four-item scale. Alpha is dependent on the number of items composing the scale with shorter scales being more difficult to achieve reliability.[26] Responses to items of these three components are given in Table 3.

[Insert Table 3 - **Responses to attitudinal items on behaviours relating to medication taking (N=325)**]

Component 1 – Self-perceptions of knowledge and abilities in relation to medication taking

Table 3 shows that respondents generally held very positive views, with a median overall score of 28 (IQR 27-31) [range possible 7-35 (midpoint 21), with 35 representing the highest possible positive score]. The 7 statements included in this component mainly related to the TDF domains of knowledge, skills, and beliefs about capabilities.

The median (IQR) score for component 1 for males was 28 (27 – 30) and females 29 (27 – 34). Scores for component 1 were statistically significantly lower in male patients (Mann-Whitney U, p=0.028). There were also weak negative correlations between the component 1 score and the number of times respondents visited a pharmacy for advice (Pearson Correlation, r=-0.16, p=0.015) and number of times seen by a GP in past three months (r=-0.119, p=0.044). Statistical analysis also showed that those with lower component 1 scores (i.e. expressing lower levels of agreement with statements) were more likely to have continuing chest pain or discomfort (Mann-Whitney U, p= 0.031) indicating that those with chest pain or discomfort or those on multiple medications perceived themselves to have less

knowledge and less ability in medication-taking as well as having lower levels of belief about the benefit of medication.

Component 2 –Aspects relating to activities and support in medication taking

Respondents generally held positive views, with a median overall score of 32 (IQR 30-35) [range possible 8-40 (midpoint 24), with 40 representing the highest possible positive score] (Table 3). The eight statements that loaded to this component mainly related to the TDF domains around: beliefs of consequences; environmental context and resources; and social influences/support.

Scores for component 2 were statistically significantly lower for those who received an elective PCI procedure (Mann-Whitney U, $p=0.034$). There were also weak negative correlations between the component 2 score and the number times seen by a GP in the past three months (Pearson Correlation, $r=-0.129$, $p=0.003$). Similar to component 1, statistical analysis also showed that those with lower component 2 scores (i.e. expressing lower levels of agreement with statements) were more likely to have continuing chest pain or discomfort (Mann-Whitney U, $p<0.001$) or to have polypharmacy with 10 or more medications (Kruskal Wallis, $p=0.013$) indicating that those with chest pain or discomfort or those on multiple medications perceived there to be generally less to gain from taking medicines as prescribed and perceived less support from healthcare professionals and family in respect of taking medication.

Component 3 – Emotional aspects in taking medication

Table 3 shows that respondents generally disagreed with the statements used for this PCA component. These four statements included in this component were written

to address the 'emotions' domain within the TDF and as such were designed to explore concern and anxiety in relation to medication taking.

In view of the negative wording of these statements the scoring was reversed for the PCA analysis. So, higher component scores indicate respondents had lower degrees of concern and difficulty in medication taking. The median overall PCA Component score was 16 (IQR 14-18) [range possible 4-20 (midpoint 12), with 20 representing the highest possible positive score].

Negative correlation was also observed between component 3 score and the number of times seen by a GP in the last three months (Pearson Correlation, $r=-0.280$, $p<0.001$). This indicates that higher component score sand so less concerns meant that these individuals visited their GP less frequently. Again, analysis also showed that those with lower component 3 scores (i.e. expressing lower levels of agreement with reverse scored statements) were statistically more likely to have chest pain or discomfort (Mann-Whitney U, $p=0.001$) or to have polypharmacy with 10 or more medications (Kruskal Wallis, $p<0.001$) indicating that those with chest pain / discomfort or on more medications had more concerns and difficulty in medication taking.

DISCUSSION

Key findings

PCA of the TDF items of behavioural aspects of medication taking gave three components: (C1) Self-perceptions of knowledge and abilities in relation to medication taking; (C2) Aspects relating to activities and support in medication taking; (C3) Emotional aspects in taking medication. Generally, respondents held positive views. There were four key findings:

There were statistically significant relationships between all three components and self-reported chest pain/discomfort with respondents having lower scores for each component if they indicated they had continuing chest pain or discomfort. This indicates that patients with ongoing chest pain/discomfort post-PCI are more likely to have behavioural determinants and beliefs which make medication-taking challenging.

There was a statistically significant relationship between C2 or C3 scores and 'number of medications' with respondents who were on 10 or more medications having lower levels of agreement to the statements. This indicates that those with polypharmacy ($\geq$10 meds in this study) were more likely to have challenges associated with their medication-taking activities/support and have more concerns and anxieties about medication in general.

Scores for C1 were statistically significantly lower in male versus female patients indicating less knowledge and less confidence in medication and medication-taking abilities.

A weak negative correlation was observed with number of visits to pharmacy (C1) and GP (C1 and C2). This indicated that those with higher C1 scores had stronger perceptions of knowledge/understanding and confidence and so less need to use pharmacy/GP for advice.

Strengths and Limitations

The first strength of this research was the response rate which was high considering the geographical area and population targeted. Secondly, the questionnaire used was developed based on a theoretical framework thus ensuring that all key aspects related to medication taking behaviour in this population were explored.[12]

Data were collected from one geographical area within Scotland potentially limiting their generalisability. However, there was a good representation within the recruited sample in terms of demographics (e.g. number of acute and elective PCI patients). Although data collection started in 2014, there have been no clinically significant changes in treatment or practice in the interim that would affect the results reported here.

Consideration of chest pain/discomfort has to be interpreted in the context of this being self-reported rather than clinically assessed, so may not necessarily relate solely to cardiac chest pain.

One of the component scales, namely 'Concerns and Difficulties in taking medications' has a Cronbach's alpha just less than 0.7, the subjective normal 'cut off' for reliability,[26] but a decision was made to proceed to use it in analysis given that it comprised only 4 items. Achieving reliability in shorter scales is more challenging and

therefore it was considered that a Cronbach's alpha of 0.642 was acceptable for the purposes of this study.

Interpretation of findings

It is expected, given the cohort, there would already be a proactive focus on identification of ongoing chest pain/discomfort. The results that those with self-reported pain are more likely to have behavioural determinants and beliefs which make medication-taking challenging should be of some interest to clinicians. While it is important to explore this signal further and to differentiate those with medically-diagnosed (rather than self-assessed) post-PCI cardiac vs non-cardiac chest pain; clinicians should be cognisant that from the patient's perspective, this differentiation may not be as important as the presence of pain itself as an indicator of potential challenges to medication-taking.[27]

The United Kingdom Medical Research Council guidance on 'Developing and implementing complex interventions' highlights the role of cognitive, behavioural and organisational theoretical lenses in research focusing on complex interventions.[28] For example, it is often important to study changes in behaviour around interventions to provide information on if and how an intervention has been successful. Embedding behaviour change theories will generate findings which can be related to how and why a change has occurred (or not). Thus, in the current study, incorporating the TDF was deemed essential in developing the questionnaire in order to ensure that all potential influences on medication taking behaviour are examined. TDF determinants can be mapped to relevant Behaviour Change Techniques (BCTs)[29,30] which in turn can form part of an intervention. Given the apparent links between behavioural determinants, self-reported chest pain / discomfort and polypharmacy shown in this study, consideration should be given to the role of the pharmacist. Pharmacists, in

particular, have been shown to have a role in providing interventions for cardiovascular patients[31] which could be extended to include questioning on chest pain / discomfort in any identified PCI patients and also rationalisation and management of polypharmacy[32,33]. To enable this, there needs to be significant changes made to allow closer working relationships and additional clinical/consultation skills training for pharmacists.[34]

CONCLUSIONS

This study revealed that patients who underwent PCI in NHS Highland broadly perceived themselves to have the knowledge, abilities, and support to take their medications as prescribed with no or limited concerns or difficulties. However, mixed feelings were expressed in those who experienced chest pain/discomfort; were prescribed >10 medications; were male; or who had less contact with healthcare services. Clinicians should be aware that those with pain are more likely to have behavioural determinants and beliefs which make medication-taking challenging and so take time to assess and address these. Further research needs should focus on the relationship between pain post-PCI and behavioural determinants for medication taking, including adherence, given the high risk of future life threatening events in non-adherence.

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