

Introduction

Resources to promote recovery following common cardiovascular surgical procedures such as coronary artery bypass grafting (CABG), valve replacement (VR), and CABG in combination with VR are made available in the form of patient education initiatives and cardiac rehabilitation programs.¹ However, over a quarter of all CABG and/or VR patients are being readmitted to hospitals with post-operative complications experienced during the first three months of recovery.² A possible reason for the development of post-operative complications during the post-discharge recovery period is insufficient self-care behavior performance.

Patient education is an essential health intervention to promote self-care behaviour change, but may often lack required effectiveness. Specifically, the mode, dose, and timing of delivery of the educational intervention may not be optimal in promoting self-care behaviours, resulting in the onset of complications and increased hospitalizations, leading to reduced health related quality of life. Patient education formats vary depending on the degree of standardization versus individualization.³ Patient education delivered in a standardized format involve the delivery of the same content to all patients, while individualized format encompass education being tailored to reflect the learning needs of the individual.

Learning needs are defined as the topical areas of interest perceived by the individual as important to learn.³ The inclusion of learning needs into the design of the patient education teaching session is a key element in the process of teaching and learning, as they reflect the patient's personal health experience.³ Theoretically, incorporating patients' perceived learning needs, beliefs, and/or values into the design of patient education interventions should yield significant outcomes through the acquisition of relevant knowledge, resulting in a change in cognitive states.³ Enhanced change in cognitive state has been shown to reduce levels of

depression and/or anxiety³ which can result in an increase in the performance of self-care behaviors.³ Enhanced self-care behaviours speeds up recovery, resulting in a decreased likelihood for re-hospitalizations, thus, enhancing individuals overall health related quality of life.⁴

Education based on an individual's perceived learning needs is the focus of this systematic review as it is commonly viewed as the most pragmatic and feasible intervention to administer within the clinical setting.³ Alternative interventions such as knowledge transfer through coaching, follow-up telephone calls, and group counselling are more costly and difficult to implement in financially unstable environments.³⁻¹⁶

An existing systematic review¹⁷ has been completed to examine the effect of patient education on mortality, onset of total cardiovascular events, revascularization, hospitalization, and health care costs in the management of coronary heart disease. This review included trials that enrolled study participants who had suffered a myocardial infarction (MI), underwent revascularization, or who had angina pectoris or coronary heart disease. Mixed results were reported in relation to outcomes that include: health related quality of life, self-care, and mood following CABG and/or VR surgery.

The aim of this systematic review was to determine the effects of individualized patient education interventions compared to standardized education on rate of re-hospitalizations, performance of self-care behaviors, changes in mood (depression/anxiety), and cognitive states during the post-hospital discharge recovery period following cardiovascular surgery.

Methods

Design

A systematic review of randomized controlled trials was conducted, using a meta-analytic approach for the synthesis of the estimates on the effectiveness of individualized patient education. Studies that included patients undergoing first CABG and/or VR procedure, were eighteen years or older, and received standardized education for the determination of its effectiveness were included. This systematic review is based on a Cochrane Review, in which the protocol outlining the plan for conducting the review has already been published.¹⁹ No amendments have been made to the final review compared to the original protocol.¹⁹

The investigation conforms with the principles outlined in the Declaration of Helsinki.²¹

Inclusion and exclusion criteria

Target Population

Studies that incorporated individuals who underwent their first CABG and/or VR procedure, who were eighteen years of age or older, and who were recovering in the community or in a convalescent home were included within this review. Individuals were excluded if they had previous CABG and/or VR surgeries, underwent emergency surgery, and/or received a heart transplant or ventricular assist device. These individuals tend to have divergent learning needs and/or higher levels of complication risk compared to patients experiencing an elective CABG and/or VR for the first time.

Study designs

Studies that included randomized controlled trials were included in this systematic review. Cross over trials were excluded as they are typically longitudinal studies that examine the effect of a number of different interventions. Thus, to be able to determine the effectiveness of individualized educational interventions, cross over trials were excluded.

Types of interventions

Studies that included an individualized patient education intervention provided to individuals following cardiovascular surgery were included in this review. Studies that were excluded are those that did not examine a post-operative patient education intervention. Individualized patient education interventions are education-based interventions in which the education is individualized to reflect the individual's learning needs. They differ from individualized psychological/behavioural support and cognitive behavioural therapy in that the intervention consists of teaching rather than counselling and support.^{1,9,18,20-26} Individualised patient education interventions were considered eligible regardless of the length of the intervention period. Furthermore, individualized patient education interventions that address any or all of the following content areas were included: complications, activities, medication, nutrition, symptom management and control, and psychological symptoms.²³

The focus of the education was on post-operative recovery initiatives and involved direct or indirect contact (face-to-face, email, phone interaction, chat rooms) with a health care provider and patient following cardiovascular surgery, either in isolation or in the presence of family members following hospital discharge. The education could be provided using a combination of formats that included brochures, pamphlets, online, books, audiotape, videotape, and/or Skype³ and range between one to seven sessions in terms of number of times delivered, with variability in the length of time for delivery of each individualized education session. The individualized patient education intervention had to have been delivered during the patient's post-hospital discharge period either in a community settings or programs (for example convalescent hospitals), or within their home environment. Trials that included individualized patient education interventions that were delivered during the patient's hospitalization and then

delivered during their post-discharge recovery were also included, as long as the focus of the education was on post-operative recovery initiatives.

Studies in which the intervention consisted of a multi-component (education plus psychological support) treatment were excluded, to avoid confounding the effects. Thus, only studies that included standalone individualized education delivered post-operatively were included in this systematic review.

Studies with comparators that were identified as standard of care, routine care, or usual care were also included in this review and consisted of education provided in a standardized format via an information booklet, small group discussion, or video. Comparators that included individualized interventions were excluded to avoid confounding the results.

Outcomes

This review included studies that reported on re-hospitalization (primary outcome)³⁵, mood (depression/anxiety)^{26, 31, 32}, health related quality of life, and performance of specific self-care behaviours (for example smoking and physical activity)^{4, 9, 33, 34}. Cognition²⁷⁻³⁰ represents an intermediate variable in the prevention of secondary complications.

For each outcome of interest, all outcome data claimed by the original authors to measure the construct of interest were considered eligible regardless of the measurement methods and/or type of data source used (e.g. extraction of objective clinical data taken from patient records or self-administered questionnaires or standardized measurement instruments applied in patient interviews).

Trials that evaluated this intervention, with or without a follow-up period, which ranged between one week post-hospital discharge up to two years, were also included in this review. For

inclusion in this review, no restrictions were applied in terms of the length of follow-up, method used or frequency of outcome measurement.

Search methods for identification of studies

CENTRAL (2012-2015) (The Cochrane Library), MEDLINE (OVID, 1990 to March week 3 2015), EBM Reviews (including Cochrane Database, 1990 to March week 3 2015), CINAHL (1990 to March week 3 2015) and Web of Science (1990 to March week 3 2015) databases were searched for relevant studies. Medical subject headings (MeSH) or equivalent and text word terms were used and language or date restrictions were not applied. Oxford Reference and Springer Platforms and Databases, and Proquest and Sage Platforms and Databases were used to conduct these searches using the following search terms: health education, patient education, telemedicine, cardiopulmonary bypass, cardiovascular surgical procedures, aortic valve, and health literature (Web Appendix – Search Strategy).

Additionally, the following trial registries were searched in March 2012 and again in December 2014 to identify any relevant ongoing trials: meta-Register of controlled trials (mRCT), clinicaltrials.gov, WHO International Clinical Trials Registry Platform (ICTRP). The same search terms that were used in the electronic literature databases were used to search the trial registries. Reference lists of articles were searched for additional studies that fit the inclusion criteria. Moreover, experts in the field were contacted for unpublished and ongoing trials. Authors were also contacted where necessary for additional information.

Study selection

The process for selecting studies were as follows: search results were merged using reference management software, and duplicate records of the same report were removed, titles and abstracts were examined to remove irrelevant reports; full text of the potentially relevant

reports were retrieved, multiple reports of the same study were combined, and full-text reports were examined for compliance of studies with eligibility criteria. Lead investigators were contacted to obtain missing data. Both authors were involved in all phases of this systematic review, inclusive of the final selection of studies. First, all references were scrutinized by one author, followed by cross checks by the second author. In cases of disagreement arbitration by a third person was used.

Studies, rather than reports were considered the unit of interest. Thus, multiple reports of the same study were identified and linked together.

Data extraction

Assessment of eligible studies, data extraction, and data entry were performed by two members of the research team and the results were compared until 100% agreement was achieved. In cases of disagreement between authors, arbitration by another person was used. For each outcome of interest, the following data were extracted: sample size, missing participants, summary data for each intervention group (for example a 2×2 table for dichotomous data; means and SDs for continuous data), estimate of effect with 95% confidence interval; P value. Raw estimates of between group differences at follow-up were extracted. For studies that did not contain the intended effect estimates, these were computed by hand. The final follow-up measuring point was used, when more than one effect estimate was reported. No pre-specified hierarchy of length of follow-up was applied.

Risk of bias assessment

The Cochrane Collaboration's tool for assessing risk of bias was used.³⁶ Sources of bias included: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment

(detection bias), incomplete outcome data (attrition bias), selective reporting bias, and other sources of bias (i.e. investigator bias). Risk of bias for each included study was assessed via judgement and a support for the judgment for each entry in a 'Risk of bias' table, where each entry addressed a specific feature of the study. Categories of risk of bias included: 'low risk', 'high risk, or 'unclear risk', with the last category indicating either lack of information or uncertainty over the potential for bias.

Data analysis

For all planned comparisons, data was entered based on the principle of intention to treat. To be included in a given comparison, outcome data had to have been available for at least 80% of those who were randomized. In trials in which some participants had interventions such as education prior to enrolment, only those outcome data assessed after randomization were included in the meta-analysis.

Relative risks as the measures of effect size for binary outcomes were calculated. Weighted (unadjusted) mean differences for most continuous outcome measures was used. If trials used different ways of measuring the same outcome, standardized mean differences were used. Scores from rating scales were either analysed as continuous variables, if the scale is sufficiently long for this to be reasonable; or converted to dichotomous variables.

Measures of treatment effect

Forest plots were calculated in RevMan. Effect measures were estimated based on either the usual difference between the study groups' means or the standardized mean difference for continuous outcomes depending on whether the measurement scale was the same or varied across studies. Effect measures were estimated based on odds ratios for binary outcomes.

Estimates and their standard errors were entered directly into RevMan under the 'Generic inverse variance'.

The trials within this review contained divergent follow-up periods and used varied outcome measurement instruments. Thus, random-effects meta-analysis was used to account for the between-trial heterogeneity. Chi-square and I statistic were used to estimate the size and statistical impact of cross trial heterogeneity in the outcome data.

Sensitivity analysis

Sensitivity analyses were pre-planned to explore the impact of noted risks of bias on pooled effect sizes within the body of included studies by means of funnel plots (Figure 3). These analyses were also conducted to determine the likelihood prevalent sources of bias may impact the direction or size of pooled effect estimates. However, due to the insufficient number of studies and outcome data, the minimum number of trials required to justify the conduct of sensitivity analyses including funnel plots for the primary outcome of readmission was four^{6,11,18,44} Only trials were included which met all of the pre-specified eligibility criteria.

Results

Description of search retrievals

A total of 585 studies were retrieved, excluding 1453 duplicates. In total, 17 studies^{6,9,11,13,14,16,36-44} were eventually included (Figure 1).

Included studies

Seven studies (Table 1: Web Appendix: Summary of Study Characteristics), published between 1989 and 2010, were based in the United States,^{6,7,13,14,40-42} seven in Canada,^{9,18,37-39,44} and one from Norway,¹¹ Iran,⁴⁵ and Thailand.¹⁶ Proportions were calculated based on raw data retrieved from each study (Table 1: Web Appendix: Summary of Study Characteristics).

Overall, 2624 study participants were included in the trials. The median of the individual trials' mean values for age was 63.2 years (range: 59.1 – 70.4). Seven out of the seventeen trials included primarily male, while 15 of 17 trials contained samples that were of Caucasian decent, with at least a high school education. The exact cultural distribution and various levels of education within trials were rarely identified, as individuals were described as either Caucasian or non-Caucasian; and having at least a high school education or less than a high school education. Approximately 16 of the 17 trials contained samples diagnosed and living with a co-morbid condition. The exact type of co-morbid condition is not known, as this information was not routinely collected across all trials. The median of the individual trials' mean values for length of hospitalization was 3.7 days (range: 3.1 – 6.4). More than three quarters (13 out of 17) of the studies included patients who underwent CABG procedures, while 4 out of 17 trials^{43,44} contained study participants who underwent either CABG and/or VR.

Telephone (8/17) with use of audiotape (5/17) or an assistive device (4/17) such as a Health Buddy recorder which is connected to patients' telephones with pre-recorded messages, was used to deliver the individualized education. For the most part, the content addressed CABG recovery behaviours (15/17), assessment and management of symptoms (14/17), and self-efficacy and self-regulation activities to promote the performance of self-care post-operative recovery behaviours (9/17). The intervention was delivered via one-on-one individualized conversations (13/17) by either a trained research assistant (8/17) or study nurse (8/17), on a weekly basis (14/17) for up to 8 weeks (2/17). However, the intervention was typically delivered over a period of one week (6/17). The delivery of the intervention was variable (6/17), with 10 (4/17) to 30 (6/17) minutes being the range of time for which the intervention was provided. More than half of the trials (10/17) provided patients with access to help and additional resources

in the form of a contact nurse (14/17) during the delivery of the intervention. The role of the contact nurse encompassed responding to patients' questions related to the individualized education and/or clarifying and expanding on the individualized patient education content.

The control group received standard of care (17/17) that encompassed usual standardized patient education (17/17) delivered in the form of a booklet/brochure (6/17), just prior to hospital discharge (17/17). The standard of care was variable (14/17) in its length of time for delivery. Content addressed: medication management (12/17), follow-up appointments (12/17), and activity performance (12/17).

The follow-up periods varied across included trials between 5 days³⁹ to 5.5 years⁴² with the most commonly reported follow-up period being 3 months (5/17).^{18,41}

Assessment tools varied across studies, however appeared to be reliable and valid.

Excluded studies

Nineteen studies were excluded for either not having an individualized patient educational intervention,^{10,12,14,46-49} the sample underwent a cardiovascular surgical procedure other than CABG and/or VR,^{50,51} the outcomes were not of interest,⁷ used interventions that were delivered pre-operatively,^{40,41} or they did not contain a RCT.⁵⁴⁻⁶¹

Summary of risk of bias distribution across studies

Assessment of all included studies with respect to the defined risk of bias sources was performed. However, we were not always able to precisely judge the risk of bias due to lack of information, thus leaving the risk of bias unclear in a number of cases. Risk of bias results are summarized in Figure 2 and Web Appendix 2 (titled: Risk of Bias in Web Appendix).

Allocation (selection bias)

Eleven studies provided evidence of sufficient random sequence generation^{6,7,9,11,13,15,16,18,37-45} with 7 of these studies reporting adequate concealment.^{6,9,11,13,15,18,37}

Blinding (performance bias and detection bias)

Complete blinding of persons delivering the intervention, in addition to study participants receiving the intervention was confirmed in four studies.^{14,38, 40, 44}

Incomplete outcome data (attrition bias)

Risk of bias due to incomplete outcome data was relatively low across all studies with the exception of Weaver (2001), Miller (2007), and Watt-Watson (2004) in which this information was not provided.

Selective reporting (reporting bias)

The reported outcomes in the results sections of the published paper. No attempt was made to identify original study protocols and to compare these to reported outcomes. Three studies^{6,40-41} did not provide adequate information to assess reporting bias.

Publication bias

Due to the limited number of included studies, statistics tests of the symmetry of reported effect sizes were not performed. However, upon visual inspection, the effects sizes do appear to be symmetrical.

Other potential sources of bias

A main source of bias related to the potential confounding effect of co-interventions received by the intervention and control group study participants. In addition to the individualized education, the study participants appeared to receive other co-interventions that included: confidence building activities^{6,40} psychosocial counselling⁴, and social and/or

psychological support.^{9, 46} In these studies it was often unclear how much of these co-interventions were received by control patients resulting in a performance bias.

Effect of interventions

Four studies that included 930 participants reported on hospital readmissions.^{6,11,18,44} It was possible to pool the results for these studies. An effect of the individualized patient education in reducing hospital readmission rates (Mean Difference: -1.28, 95% CI -1.87 to -0.68, $p < 0.00$) was noted. The heterogeneity among the studies was minimal ($I^2 = 99\%$) (Figure 3).

Eight studies that included 1053 participants reported on depression.^{6,11,13,14,16,42-44} It was possible to pool the results for these studies. An effect of the individualized patient education in reducing depression (Mean Difference: -23.32, 95% CI -23.70 to -22.95, $p < 0.00$) was noted. The heterogeneity among the studies was minimal ($I^2 = 100\%$) (Figure 3).

Eight studies that included 1281 participants reported on anxiety.^{9,11,14,16,37,42,45} It was possible to pool the results for these studies. An effect of the individualized patient education in reducing anxiety (Mean Difference: -19.34, 95% CI -20.46 to -18.23, $p < 0.00$) was noted. The heterogeneity among the studies was minimal ($I^2 = 86\%$) (Figure 3).

Ten studies that included 1808 participants reported on self-care behaviours.^{6,7,13,16,37-39} It was possible to pool the results for these studies. An effect of the individualized patient education in enhancing health behaviours (Mean Difference: 3.45, 95% CI 3.27 to 3.63, $p < 0.00$) was noted. The heterogeneity among the studies was minimal ($I^2 = 96\%$) (Figure 3).

Two studies that included 488 participants reported on cognitive mental health functioning.^{6,7} It was possible to pool the results for these studies. An effect of the individualized patient education in enhancing cognitive mental health functioning (Mean

Difference: 11.17, 95% CI 10.66 to 11.68, $p < 0.00$) was noted. The heterogeneity among the studies was minimal ($I^2 = 0\%$) (Figure 3).

No studies reported all-cause mortality data.

Discussion

Summary of main results

Among the 17 studies included in this meta-analysis, the majority were of adequate quality as demonstrated by the use of adequate concealment, blinding, publication, and reporting techniques. Evaluated education programs varied in the degree of individualization of the teaching methods, approach to teaching, type of medium to facilitate education delivery, length of time for education delivery, amount of times for provision of intervention, and number of follow-up educational sessions. Key findings suggest individualized patient education was effective in reducing readmission rates, anxiety, and depression, while enhancing performance of self-care behaviours and cognitive mental health functioning.

Based on four trials involving almost 1,000 patients, the pooled effect estimate regarding the impact on the admission rates suggests at best, one readmission may be prevented through patient education. Financially, decreasing readmission rates by one is of significance, however the rates are still high within the first year of recovery. Thus, there is a need to continue to redesign patient education interventions so that the delivery extends beyond 8 weeks post-operatively.

Overall completeness and applicability of evidence

The narrow eligibility criteria reduced clinical relevance and applicability of findings. Even though these limitations were crucial in reducing the potential risk for heterogeneity;

diversity in the educational intervention and patient presentation still existed which can result in the intervention effects being different across studies.

As well, even though all study participants in the experimental intervention group received some form of individualized patient education, it appeared that some study participants (i.e. member of the intervention and/or control group) may have received other interventions such as confidence building activities,^{14, 42} psychosocial counselling,⁴ and social and/or psychological support,^{9, 47, 62} which may have acted as a confounding variable resulting in effect sizes that may not be an accurate representation of the effectiveness of the intervention. In these studies, it was often unclear how much of these co-interventions were received by these study participants. Also, in many instances, there was not a lot of clarity pertaining to how the experimental intervention was delivered. That is, the effect of the instructor, variability in teaching methodology, and training of the instructor were rarely reported across the studies which may have influenced the outcomes achieved.

Previous reviews that have examined post-operative cardiac patient education interventions^{15, 63, 64} have reported the lack of inclusion of cultural diversity in sample representation. This has led to skewed results obtained from homogeneous looking groups. That is, results reflect a narrow sub-section of the population. Findings from this meta-analysis reinforces this notion; as the samples consisted primarily of patients who were of Caucasian (63.2%) decent. Non-white individuals remain under-represented, thus decreasing the generalizability of these findings. Use of purposeful or quota sampling to enhance the representation of samples and thus the generalizability of results is needed for future studies.

Limitations

A major limitation of the findings is the small number of studies meeting the eligibility criteria, especially with regard to the "hard" outcomes readmission rate and mortality. Due to the small number of studies and thus small sample sizes, corresponding effect estimates are prone to statistical uncertainty as it is reflected by wide confidence intervals (also with regard to the outcome measures anxiety, depression and).

Details pertaining to the methodological risk of bias of the studies were either often not reported or poorly identified, and confirmation of methodology had to be sought from authors. With the exception of Fredericks³⁷; Parry 2009³⁸; Watt-Watson 2004³⁹, we did not receive a response from authors that we contacted resulting in missing data. Two areas of potential risk of bias were identified: performance and detection bias. Few studies provided sufficient details to judge if the outcomes were assessed by the researchers blinded or independent of the trial. As well, training of the interventionist was not clearly described across the included studies, which could have influenced outcomes achieved. Finally, it appears that the control group may have received co-interventions that may have resulted in results that were in favour of this group.

Furthermore, unpublished data was requested for this review, however no relevant studies were identified.

Implications for practice

The findings from this meta-analytic review are consistent with the theoretical assumption that individualized patient education interventions are effective for patients following CABG and/or VR. The transfer of knowledge to patients resulting in changes in their behaviours within the clinical setting can be achieved through the implementation of patient education interventions. Thus, a health care provider who is trained to deliver patient education interventions, can provide the education in such a way that it results in changes in patients'

behaviours. In order for changes in patients' behaviours to occur, these professionals should be taught how to use open communication strategies to facilitate an individualized patient education session. These education sessions should ideally begin immediately following surgery or when the patient is able to consciously interact with their health care provider. When responding to patients' questions, the health care provider should use easy to understand terms; as well as communication pathways so that the responses are tailored to reflect the patient's needs.

Implications for research

Continued investigation into the "optimal" patient education intervention is needed. The effect of co-interventions need to be more carefully examined for their potential effect on health-related outcomes. In addition, attempts should be made to increase the representation of culturally diverse patients to gain a better perspective of the effect of patient educational interventions on these sub-groups. Thus, to ensure trial samples sufficiently reflect relevant patient populations, it is important that eligibility criteria cover these populations and are combined with sufficiently broad and effective recruitment strategies and probabilistic sampling methods (e.g. consecutive sampling). Finally, well defined RCTs that incorporates strategies to minimize the risk of bias due to selection, performance, detection, attrition, and reporting need to be designed and implemented.

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