Does the Early Feedback of Results Improve Reassurance Following Diagnostic Testing? A Randomized Controlled Trial in Patients Undergoing Cardiac Investigation

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Objective: Providing reassurance is often a critical component of the medical consultation. An important area that has not been addressed in the literature is how delay in providing the results of medical tests affects patient reassurance. In this study we investigated whether the early provision of a normal diagnostic result immediately following medical testing improves patient reassurance compared to results provided 4 weeks later.

Method: We conducted a longitudinal randomized controlled trial and 1-month follow-up. Fifty-one cardiology outpatients with no known cardiac pathology referred for an echocardiogram test were randomized following normal test results to receive their test results from a cardiologist either immediately following testing or 4 weeks later. Measures of symptoms, anxiety, and health perceptions were taken prior to diagnostic testing. Reassurance was assessed immediately after the results were provided and 1 month later.

Results: Data analysis showed that the provision of early results had no impact on patient reassurance. Cardiac anxiety was strongly associated with lower reassurance; patients who were more anxious about their heart were significantly less reassured by a normal test result, both immediately following feedback and 1 month later.

Conclusions: The early provision of test results had no impact on patient reassurance. The study suggests the identification and targeting of patients high in cardiac anxiety may be a better method for improving reassurance than reducing the waiting time for results following medical testing.

Keywords: reassurance, medical testing, diagnosis, cardiac anxiety, noncardiac chest pain

Providing reassurance has become one of the most important interventions of the medical consultation due to its powerful effects on patient health beliefs and recovery (Petrie et al., 2007). Yet studies have demonstrated that many patients remain anxious about their symptoms following medical consultations (Howard & Wessely, 1996; McDonald, Daly, Jelinek, Panetta, & Gutman, 1996). Patients who are not reassured are more likely to suffer persistent health anxiety, use drugs inappropriately, and be more disabled by their physical symptoms (Buchsbaum, 1986; Petrie et al., 2007). In turn, these patients increase the burden on health care resources through unnecessary medical consultations and investigations (Fitzpatrick & Hopkins, 1981). Despite the fact that reassurance is a widely used medical intervention, there is a great deal we don’t know about what influences the effect of a reassuring message on patients. An important area that has not been addressed in the literature is how delay in providing the results of medical tests affects reassurance. Delay in the provision of results can lead to higher levels of anxiety and dissatisfaction (Jones, 1995; Leddy, Kaldenberg, & Becker, 2003; Thompson & Yarnold, 1995). However, to date no study has directly examined whether delay directly influences reassurance.

Diagnostic testing and the subsequent provision of normal test results have been identified as major components of the medical consultation that promote reassurance (van Ravesteijn, et al., 2012). However, a large number of patients experiencing chest pain fail to be reassured by a normal result following a cardiac investigation (Donkin et al., 2006). Potts and Bass (1993) found that 75% of patients who had undergone coronary angiograms and
received a normal test result 11 years earlier continued to experience chest pain and 44% continued to believe they had heart disease. Follow-up studies of patients with normal exercise stress testing results have shown that patients continue to worry about their chest pain 1 month later (Channer, James, Papouchado, & Rees, 1987; Goodacre, Mason, Arnold, & Angelini, 2001).

Research into the timeliness of the communication of diagnostic test results shows that longer wait times for consultations and testing are related to higher levels of patient dissatisfaction (Leddy et al., 2003; Thompson & Yarnold, 1995). Further research suggests that by the time patients undergo diagnostic testing, many already hold negative beliefs about their symptoms, and that a delay in undergoing investigations or receiving results may act as an incubator for unhelpful illness beliefs that interfere with reassurance (Broadbent, Ellis, Gamble, & Petrie, 2006; Donkin et al., 2006; Petrie et al., 2007). Thus, the early provision of normal test results may be a worthwhile intervention to increase reassurance.

The effect of delays in receiving diagnostic test results on reassurance may be influenced by the patient’s existing level of health anxiety (Meechan, Collins, Moss-Morris, & Petrie, 2005; Howard & Wessely, 1996). Previous studies have shown that anxious patients are harder to reassure, and this finding has been demonstrated across diverse clinical areas. Preexisting high levels of health anxiety are associated with poor reassurance in patients with benign breast symptoms (Meechan et al., 2005), osteoporosis (Rimes & Salkovskis, 2002) and gastrointestinal symptoms (Lucock, Morley, White, & Peake, 1997). In cardiac research, patient anxiety has been associated with the continuation of heart symptoms and functional disability following the provision of normal test results (Channer et al., 1987; Potts, & Bass, 1993). Health anxiety measured before cardiac investigations may represent a method for practitioners to identify patients that necessitate a more intensive reassurance intervention.

In the current study, we used a randomized controlled design to test whether prompt feedback of a normal echocardiogram test result would improve self-reported reassurance among patients, and whether this reassurance could be sustained in the long term. Patients with noncardiac chest pain were randomized into two groups receiving either immediate feedback of results or a 4-week wait for feedback (current standard care). Reassurance was measured immediately following feedback and at 1-month follow-up. We hypothesized that the early feedback group would show greater levels of reassurance compared to the standard feedback group, and that higher preexisting levels of cardiac anxiety would hinder patient reassurance.

**Method**

**Participants**

Participants were adult outpatients referred to the Cardiology Clinic at Waitakere Hospital, Auckland, New Zealand for an echocardiogram test. Patients were eligible for the study if the reason for referral included chest pain, palpitations, or suspected heart murmur but they were not suffering any significant illness, as judged by their medical records. Those patients who were known to have existing cardiac pathology, diabetes mellitus, or other serious illnesses were excluded from the study. Also excluded were patients unable to communicate in English, and patients with impaired cognitive ability.

A CONSORT diagram showing the flow of patients through the trial is shown in Figure 1. Sixty eligible patients were approached for the study. Of these, nine were found to have abnormal echocardiogram results, and were subsequently excluded from the trial. The final sample of 51 patients comprised 25 participants randomized to the early feedback group and 26 to the standard feedback group. Two patients were lost to follow-up because of either a cardiac event or because they were unable to be contacted.

**Design and Procedure**

This was a longitudinal, parallel-group, randomized controlled trial conducted to test whether early versus standard timing of the provision of normal echocardiogram results influenced the self-reported reassurance of patients. Ethical approval was granted by the New Zealand Ministry of Health Regional Ethics Committee (reference: NTY/09/02/013). Prior to their hospital appointment, eligible patients were mailed information that provided a brief outline of the study. After arrival at the hospital clinic patients were provided with further information and a consent form. Those willing to participate provided demographic details and completed baseline questionnaires prior to undergoing their echocardiogram. Patients were then randomly allocated to either an early feedback group or a standard feedback group using a computer-generated number sequence. Group allocation was concealed in sequentially numbered, sealed, opaque envelopes by a person blind to study aims. Group allocation was not revealed until the baseline measurements and echocardiogram had been conducted.

Patients in both groups received their results from the same cardiologist who was asked to present the reassurance message in a consistent manner during the course of the study. Patients in the early condition received their results from the cardiologist immediately following the echocardiogram test and subsequently completed the posttest questionnaire. The patients in the standard feedback condition received their results during a consultation with the cardiologist 4 weeks following their diagnostic test, after which they, too, completed the posttest questionnaire. One month after receiving their test results participants completed a follow-up questionnaire administered over the phone by a research assistant blind to the aims of the study.

**Measures**

Data were collected from participants at three time points. Baseline questionnaires were administered prior to the patient undergoing the echocardiogram procedure; postechocardiogram questionnaires were issued after patients received a normal test result; and a follow-up questionnaire was administered at one month. The measures included in each questionnaire are detailed below.

**Baseline questionnaire.**

**Demographic data.** Participants were asked to provide basic information regarding their gender, age, ethnicity, marital status, living arrangement, education level, and employment status.

**Heart-related symptoms.** Respondents were required to identify which of 21 common symptoms they had experienced in the last month, and whether they believed the symptoms were related
to their heart. This measure incorporated the symptoms of the 14-item illness identity subscale of the Revised Illness Perceptions Questionnaire (IPQ-R; Moss-Morris et al., 2002), as well as a further seven relevant symptoms (including chest pain, irregular heartbeat, muscle soreness or pain, heartburn or indigestion, coughing, migraine, difficulty concentrating). Total scores were calculated by summing the number of symptoms patients believed to be related to their heart.

**Cardiac Anxiety Questionnaire.** The Cardiac Anxiety Questionnaire (Eifert et al., 2000) is a 18-item measure designed to assess the degree to which patients experience heart-related anxiety, ranging from never to always on a 5-point scale. Examples from this scale include: “I pay attention to my heartbeat” and “I avoid activities that make my heartbeat faster.” The total score is a relative frequency rating of all items calculated by summing the responses to each item and dividing by the total number of items. Scores therefore range between 0 and 4 with higher scores indicating higher levels of heart-related anxiety. Good internal reliability has been reported for the questionnaire (Eifert et al., 2000). In the present study Cronbach’s alpha for the scale was .61.

**Heart worry.** Two items were devised to assess the extent to which patients were worried about their health and the extent to which they believed something was seriously wrong with their heart. Participants were asked to rate these statements on a 7-point Likert scale ranging from 0 (not at all) to 6 (extremely). These items were correlated at $r = .52, p = .001$.

**Postechocardiogram questionnaire.** After receiving their echocardiogram results from the cardiologist, participants completed a 4-item reassurance questionnaire measuring the degree to which they felt reassured by their normal result (Donkin et al., 2006). Items included: how worried they were about their health after receiving their results, how reassured their results left them feeling, whether they believed they needed further investigations for their symptoms, and how accurate they believed the echocardiogram test to be at detecting problems. Scores for each item ranged from 1 (indicating low level of reassurance) to 10 (indicating high level of reassurance). Scores summed to give final score ranging from 4 to 40, with higher scores indicating higher levels of reassurance. The Cronbach’s alpha for the scale in this sample was .62.

Participants also completed four questions asking how satisfied they were with the echocardiogram procedure. They were asked to respond on a 10-point scale how well they thought the procedure was explained, how well they thought their results were explained, how thoroughly the procedure was conducted, and how seriously they thought their concerns were dealt with. These items ranged from 1 (not at all) to 10 (very well), providing a total out of 40 with

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**Figure 1.** Flow of participants through the study.
higher scores indicating greater satisfaction (Cronbach’s alpha in this sample was .75).

**Follow-up questionnaire.** One month following receiving feedback about their normal results, participants were administered a follow-up questionnaire consisting of the Reassurance Scale (Donkin et al., 2006) and the Cardiac Anxiety Questionnaire (Eifert et al., 2000). Participants also answered whether or not they continued to experience symptoms, whether their day-to-day activity was limited by their symptoms, whether or not they had been taking medication, and whether or not they had undergone further cardiac investigations.

**Data Analysis**

We estimated that two groups of 25 participants each were required to achieve adequate power (80% at the 5% significance level) to detect a difference of one third of the baseline reassurance score observed in Petrie et al. (2007; M = 36, SD = 15) between the early and standard reassurance arms of the trial at the first visit. This constitutes a medium effect (r = .34), Cohen’s d = 0.73. The data were analyzed using SPSS/PASW version 20. The demographic and symptom reporting data was analyzed to obtain means and frequencies. Missing data were replaced with mean values. Data are presented as mean and standard deviation, or median and range or n (%) for descriptive statistics, while measures of effect are presented as mean and 95% confidence intervals. Differences between normally distributed continuous variables were sought and type III sums of squares were used for the significance tests; Tukey’s HSD was used to explore significant main and/or interaction effects. Fisher’s exact test and chi-square tests were used as indicated. Results are presented as least squares adjustment means and type III sums of squares were used for the significance tests; p < .05 was considered significant and all tests were two-tailed.

**Results**

The total sample of 51 patients had a mean age of 45.4 years and comprised 12 males and 39 females. Seventy percent of participants were European; 11.8% were Asian; 6% were Pacific Islander; 4% were Maori, and 7.8% described themselves as an “other” ethnicity. Most were married or in de facto relationships (63%) and in paid employment (64%). Forty percent were living with their spouse and children, 23% with a spouse and no children, 12% lived alone, 20% lived with other adults and 5% were a sole adult with children. In terms of education, 2% had only a primary school education, 54% had completed secondary school, 8% had a technical or trade certificate, 10% had a university or polytechnic diploma, 17% had a university degree, and 10% held a postgraduate degree. There were no significant differences between the intervention group and standard care group on age, gender, marital status, ethnicity, living arrangement, educational level, or employment status.

The baseline psychological data are presented in Table 1. There were no significant differences between the groups in the number of physical symptoms reported, heart-related symptoms reported, or the extent of health worry and heart worry. However, there was a significant difference in cardiac anxiety among patients in the two groups. Also, there were nine patients in the standard care group who had previously undergone an echocardiogram compared to two in the early feedback group, x^2(1, N = 51) = 5.34, p = .038. Thus, having had an echocardiogram in the past and cardiac anxiety were variables controlled in subsequent analyses.

We investigated the effect of early versus standard feedback of echocardiogram results on reassurance in patients. The independent variable was the time of receiving normal echocardiogram results (early, standard), and the dependent variable was the score on the reassurance scale administered after the intervention. Participants’ baseline scores on cardiac anxiety and whether or not they had previously had an echocardiogram were used as the covariates in an analysis of covariance (ANCOVA). Marginal, least squares adjusted means are presented.

The results did not support our hypothesis. In the assessment immediately following receiving feedback about their normal test results, there was no difference in reassurance scores between the early feedback (M = 34.60, 95% CI = 32.29–36.91) and standard feedback groups (M = 33.14, 95% CI = 30.88–35.41), F(1, 47) = .75, p = .39. Also at this assessment the early (M = 37.81, 95% CI = 35.88–39.73) and standard feedback groups (M = 35.92, 95% CI = 34.04–37.80) did not differ in satisfaction with the echocardiogram procedure, F(1, 47) = 1.82, p = .18.

Similarly, at 1-month follow-up, no difference in reassurance scores were observed between the early (M = 34.49, 95% CI = 32.82–36.16) and standard groups (M = 34.65, 95% CI = 33.05–36.25), F(1, 44) = .02, p = .89. There was also no difference in cardiac anxiety between the early feedback and standard feedback groups at the 1-month follow-up, F(1, 42) = 2.34, p = .13. The groups also did not differ on whether their day-to-day activity was limited by their chest pain, t(49) = 1.58, p = .12, whether they continued to experience symptoms, χ^2(1, N = 49) = 1.05, p = .31, whether they were taking cardiac medication, χ^2(1, N = 49) = 0.004, p = .95, or whether they had undergone further cardiac investigations, χ^2(1, N = 49) = 4.40, p = .11. These results indicate that the timing of feedback did not affect patient reassurance levels either following test feedback or 1 month later nor did it influence satisfaction, cardiac anxiety, functioning, medication taking, ongoing symptoms, or further investigations.

The results of the ANCOVA indicated that there was a significant main effect of cardiac anxiety on the posttest measure of reassurance, F(1, 47) = 5.69, p = .02 as well as on the 1-month follow-up measure of reassurance, F(1, 44) = 17.08, p < .001. To explore this main effect, scores on the Cardiac Anxiety Questionnaire were dichotomized into a low anxiety group (those scores

<table>
<thead>
<tr>
<th>Baseline psychological variables</th>
<th>Early (n = 25)</th>
<th>Standard (n = 26)</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical symptoms reported</td>
<td>7.0 (3.75)</td>
<td>6.46 (3.79)</td>
<td>.61</td>
</tr>
<tr>
<td>Heart-related symptoms reported</td>
<td>1.80 (1.38)</td>
<td>1.65 (2.13)</td>
<td>.77</td>
</tr>
<tr>
<td>Health worry</td>
<td>2.84 (1.21)</td>
<td>2.54 (1.35)</td>
<td>.41</td>
</tr>
<tr>
<td>Heart worry</td>
<td>1.98 (1.31)</td>
<td>1.88 (1.35)</td>
<td>.79</td>
</tr>
<tr>
<td>Cardiac anxiety</td>
<td>1.23 (0.47)</td>
<td>0.94 (0.41)</td>
<td>.02</td>
</tr>
</tbody>
</table>
equal to or below the median of 1 for the total sample at baseline), and a high anxiety group (scores above 1). ANCOVAs were conducted to investigate the differences in reassurance scores between the low and high anxiety groups, as well as any interactions between cardiac anxiety and timing of feedback about normal test results while controlling for previous echocardiogram. Immediately following the provision of normal test results a significant difference in reassurance scores were seen between the low ($M = 36.45$ 95% CI = 34.23–38.66) and high cardiac anxiety group ($M = 31.53$ 95% CI = 29.38–33.68), $F(1, 46) = 10.26, p = .002$. Similarly, at the 1-month follow-up measure, the results indicated a significant difference in reassurance scores between the low ($M = 36.50$, 95% CI = 34.77–38.23) and high cardiac anxiety groups ($M = 32.64$, 95% CI = 30.93–34.35), $F(1, 43) = 10.26, p = .003$. No significant interaction effects were seen between cardiac anxiety level and the timing of feedback after provision of normal results and at follow-up ($ps > .75$). These results indicate that patients who are more anxious about their heart are significantly less reassured by a normal test result, both immediately following feedback and 1 month later.

**Discussion**

The current study found that providing noncardiac chest pain patients with normal echocardiogram test results either immediately or 1 month following testing had no effect on the degree of reassurance reported by patients. Overall, regardless of condition allocation, patients reported experiencing a high level of reassurance at both the initial measurement and the 1-month follow-up. Both groups’ fears were allayed at equal levels. We also did not find any effect of the early provision of results on patient satisfaction, reported functioning, medication taking, ongoing symptoms or further investigations. Thus, the early provision of normal results does not seem to improve patient reassurance in a clinical setting. The study’s findings also indicated that anxiety was a stronger predictor of reassurance among patients than the timeliness of result feedback. Patients with higher levels of preexisting cardiac anxiety were more difficult to reassure compared to those with lower levels of cardiac anxiety, regardless of whether results were provided immediately or at the usual 1-month time point. These results confirm that anxiety plays a key role in reassurance following normal test results.

Previous research argues that negative symptom interpretations and health anxieties can become entrenched over time; for example, while waiting for test results (Nijher, Weinman, Bass, & Chambers, 2001). However, the current findings demonstrate that waiting for results does not decrease the ability of normal results to allay patient fears. Research examining patients’ perceptions before and after a coronary angiography and CT angiography has shown how these beliefs changed upon receiving either a normal diagnosis or a diseased-artery diagnosis (Devich, Ellis, Broadbent, Gamble, & Petrie, 2012; Devich, Ellis, Gamble, & Petrie, 2008). Results indicated that illness beliefs are sensitive and immediately affected following a cardiac diagnosis. In this way, an individual’s initial views of their condition can be immediately adjusted following diagnosis. Relating this to the current study’s findings, if patients in the standard group did indeed experience more negative views during their 4-week wait, these were effectively allayed upon receiving a normal echocardiogram result.

The current findings confirm the results of earlier investigations that have identified poor reassurance to be associated with preexisting high levels of health anxiety. Women who were not reassured by a benign breast symptom diagnosis were more likely to score highly on health anxiety and general anxiety measures (Meechan et al., 2005). Other studies have reported that patients who were higher on health anxiety before undergoing bone screening for osteoporosis were less successfully reassured (Rimes & Salkovskis, 2002), and patients high in health anxiety have shown strong resurgences in worry and negative illness beliefs 24 hours after a gastroscopy showing no serious illness (Lucock et al., 1997). Trait characteristics can be difficult to shift, which provides one explanation as to why these individuals were not reassured. Furthermore, people tend to hear and filter health information in light of their health schemas, meaning what a doctor says and what a patient hears can be different (Rief, Heitmuller, Reisberg, & Ruddel, 2006).

It should be noted that the researchers in the present study had no control over the dose of reassurance given by the cardiologist; thus, there was no direct way of assessing its adequacy. However, patients did seem to receive adequate reassurance as indicated by the pattern of scores on the reassurance scale. The sample generally had low levels of worry about their health and heart, as well as low cardiac anxiety. This may be due to the fact that the inclusion criteria required that they had not been previously diagnosed with any cardiac condition or serious illness. It should also be noted that while the study was powered to detect a moderate effect, it may be that the effect of the timing on reassurance is at a smaller level.

The strengths of the study also warrant mention. The study was conducted in a standard hospital cardiology clinic and participants were referred because of a variety of cardiac-related reasons. While some patients complained of chest pain, others had heart palpitations or had suspected heart murmur. The resulting heterogeneity within the sample grants the study greater external validity. One aspect that deserves further attention in future research on reassurance is examining the role of delay in feedback on different types of medical testing. Some testing is aimed at ruling out serious disease, such as cancer, while other medical testing is directed at explaining the cause of symptoms that may be less serious in nature.

Overall, the study’s findings have important clinical implications in that they suggest it is crucial that practitioners endeavor to identify patients who are anxious about their health, so that more intensive reassurance can be offered to such patients. Attending medical consultations is naturally worrying for most people, and even more so for those who are predisposed to high levels of trait anxiety. Given that patients’ anxiety levels at baseline were found to be the most predictive of successful reassurance, the results provide support for the importance of intervening early on in the investigative process. These implications are consistent with previous work. Lucock et al., (1997) suggested clinicians screen for highly anxious patients prior to consultations, and early intervention to productively manage anxiety in noncardiac chest pain patients is encouraged by Bass and Mayou (2002). It is possible that more effective reassurance may be achieved through tailored interventions or better communication between doctor and the anxious patient (Lucock et al., 1997; Bass & Mayou, 2002). Providing intensive reassurance to anxious patients may mean that...
fewer patients suffer persistent health anxiety, use drugs inappropriately, or are left disabled by their physical symptoms (Buchsbaum, 1986).

Reassurance is an important intervention in the medical consultation. While this study has not demonstrated that the timeliness of result feedback is an integral component of reassurance, it has highlighted individual variation in anxiety as a key factor in reassurance. Future work could develop interventions specifically for patients high in health anxiety. Indeed, the use of information sheets to prepare patients for normal results has been found to be effective among cardiology patients (Petrie et al., 2007). Tailored interventions for anxious patients may provide benefits in terms of improving reassurance outcomes and reducing subsequent needless investigations and clinic appointments.

References


Received August 12, 2013
Revision received April 14, 2014
Accepted April 15, 2014