

- 12 Kallings LO. Bacteriological aspects of infections of the upper respiratory tract. *Scand J Infect Dis* 1983;39(suppl):9-13.
- 13 Stammberger H. Endoscopic endonasal surgery. Concepts in treatment of recurring rhinosinusitis. I. Anatomic and pathophysiologic considerations. *Otolaryngol Head Neck Surg* 1986;94:143-56.
- 14 Lund VJ, Mackay IA. Staging in rhinosinusitis. *Rhinology* 1993;31:183-4.
- 15 Hansen JG, Schmidt H, Rosborg J, Lund E. Predicting acute maxillary sinusitis in a general practice population. *BMJ* 1995;311:233-6.
- 16 Lindbæk M, Hjørtedahl P, Johnsen U. Use of symptoms, signs, and blood tests to diagnose acute sinus infections in primary care: comparison with computed tomography. *Fam Med* 1996;28:181-6.
- 17 Facer GW, Kern EB. Sinusitis: Current concepts and management. In: BJ Bailey, ed. *Head and neck surgery otolaryngology*. Philadelphia: Lippincott, 1993:366-76.
- 18 Lindbæk M, Johnsen U, Kaastad E, Dolvik S, Møll P, Lærum E, et al. CT-findings in general practice patients with suspected acute sinusitis. *Acta Radiologica* 1996 (in press).
- 19 Berg O, Carenfeldt C. Analysis of symptoms and clinical signs in the maxillary sinus empyema. *Acta Otolaryngol* 1988;105:343-9.
- 20 Williams JW, Simel DL. Does this patient have sinusitis? Diagnosing acute sinusitis by history and physical examination. *JAMA* 1993;270:1242-6.
- 21 Zeifer BA. Sinus imaging. In: BJ Bailey, ed. *Head and neck surgery otolaryngology*. Philadelphia: Lippincott, 1993:350-65.
- 22 Laine FJ, Smoker WRK. The osteomeatal unit and endoscopic surgery: anatomy, variations, and imaging findings in inflammatory diseases. *AJR Am J Roentgenol* 1992;159:849-57.
- 23 Pollei S, Harnsberger HR. The radiologic evaluation of the sinonasal region. *Postgraduate Radiology* 1989;9:242-66.
- 24 Havas TE, Motbey JA, Gullane PJ. Prevalence of incidental abnormalities on computed tomographic scans of the paranasal sinuses. *Arch Otolaryngol Head Neck Surg* 1988;114: 856-9.
- 25 Cooke LD, Hadley DM. MRI on the paranasal sinuses: incidental abnormalities and their relationship to symptoms. *J Laryngol Otol* 1991;105:278-81.
- 26 Sackett DL, Haynes RB, Guyatt GH, Tugwell P. *Clinical epidemiology—a basic science for clinical medicine*. Boston: Little, Brown, 1991:187-248.
- 27 Soderström M, Blomberg J, Christensen P, Hovelius B. Erythromycin and phenoxymethylpenicillin (penicillin V) in the treatment of respiratory tract infections as related to microbiological findings and serum C-reactive protein. *Scand J Infect Dis* 1991;23:347-54.
- 28 Goodman A, Gilman A, Rall TW, Nies AS, Taylor P, eds. *Goodman and Gilman's pharmacological basis of therapeutics*. 8th ed. New York: McGraw Hill, 1990.

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Opening Pandora's box: the unpredictability of reassurance by a normal test result

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Abstract

Objectives—To determine the rate of failure of patient reassurance after a normal test result and study the determinants of failure.

Design—Replicated single case study with qualitative and quantitative data analysis.

Setting—University teaching hospital.

Subjects—40 consecutive patients referred for echocardiography either because of symptoms (10 patients) or because of a heart murmur (30). 39 were shown to have a normal heart.

Interventions—Medical consultations and semistructured patient interviews were tape recorded. Structured interviews with consultant cardiologists were recorded in survey form.

Main outcome measures—Patient recall of the explanation and residual understanding, doubt, and anxiety about the heart after the test and post-test consultation.

Results—All 10 patients presenting with symptoms were left with anxiety about the heart despite a normal test result and reassurance by the consultant. Of 28 patients referred because of a murmur but shown to have no heart abnormality, 20 became anxious after detection of the murmur; 11 had residual anxiety despite the normal test result.

Conclusions—Reassurance of the “worried well”—anxious patients with symptoms or patients concerned by a health query resulting from a routine medical examination or from screening—constitutes a large part of medical practice. It seems to be widely assumed that explaining that tests have shown no abnormality is enough to reassure. The results of this study refute this and emphasise the importance of personal and social factors as obstacles to reassurance.

Introduction

Reassurance of patients concerned about a possible health problem is perhaps the commonest clinical transaction of all. Clinicians and textbooks generally assume that reassurance must logically follow a clear and confident statement that no disease has been found. Failure of reassurance may then be ascribed to neurosis or labelled as abnormal illness behaviour.¹ The anxiety which remains can seriously impair quality of life and result in unnecessary reinvestigations, which are a bur-

den on both the patient and the healthcare system. Despite the manifest importance of patient reassurance there has been remarkably little empirical study. We investigated this issue on the assumption that “The scientific resolution of most problems in clinical medical management will come from analyses of events and observations that occur in non-experimental circumstances during the interaction of nature, people, technological artefacts and clinical practitioners.”²

Study population and methods

Six cardiologists in private practice and with university affiliation were each asked to recruit 10 consecutive patients who were referred to one of three laboratories (one public, two private) for the exclusion of heart disease. No cardiologist refused. Three recruited patients as requested and the remainder provided 10 patients between them. The sample of 40 patients recruited was sufficient to allow analysis in each major data category according to the principle of theoretical sampling.³ Twenty five patients were female and 15 male, and their average age was 32 years (range 3-74).

The symptomatic group (10 patients) presented because they were worried by symptoms, usually palpitations or chest pain or both. In the incidental group (30 patients) referral was for assessment of a systolic murmur detected during a routine examination in primary care (21 patients) or in the course of a pre-employment or insurance check (nine patients). A systolic murmur had been heard in 36 patients. Doubt had previously been raised about the heart in 13 patients—in one no fewer than four times—and echocardiography had been performed previously in six. Three patients had previously taken medication for the heart.

DATA ACQUISITION AND ANALYSIS

Data analysed consisted of medical records, transcripts of tape recordings of the medical consultation in which the cardiologist had explained the test result, structured interviews with the cardiologists, and semistructured patient interviews.

The *cardiologist interview*, conducted by a consultant cardiologist, utilised a questionnaire developed for a previous study.⁴ Data recorded included the reason for ordering the test, plans for patient management, and gradings of perceived patient anxiety before and after the test. The pretest likelihood of cardiac normality was

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expressed as a grading on an ordinal scale of probabilities developed by a consensus method for the earlier study,⁴ in which "probable" represented a subjective probability estimate between 0.65 and 0.89, "almost certain" a subjective probability estimate between 0.90 and 0.99, and "certain" a subjective probability estimate of more than 0.99. Patients were interviewed twice by a sociologist.

Patient interviews—The initial home interview was conducted as soon as possible after the medical consultation in which the test result had been explained (average 6.3 days). The follow up home interview, conducted nine to 12 months later, concentrated on subsequent progress and related medical events. One patient could not be located for the initial interview. Four patients were unavailable for follow up; all had changed address (one had moved interstate, one overseas).

These home interviews, roughly two hours long, were structured along the lines of routine medical history taking. Thus patients were encouraged to give a free account of their perceptions and problems and leading questions were kept to a minimum to ensure that the issues discussed were those of most concern to the patient. A short check list of direct questions, introduced as necessary at the end of the interview, was analogous to the clinical review of systems.

Analysis of transcripts—The protocol used for analysis of transcripts drew on an earlier study of patient responses.⁵ Definitions of study variables and of the criteria used for their classification and grading have been reported.⁶ So too have the details of the method and the results of qualitative analysis of the data.⁷

Grading quality of consultation—For the clinical consultations the important issues were what the cardiologist actually told the patient and generation of a grading of the quality of the consultation. An aggregate score was constructed as follows. A consultation was graded as "good" if (a) explicit information about the heart was stated clearly and with confidence, (b) the patient was provided with clear and persuasive reasons for the query and referral, and (c) the patient's views were elicited and discussed. The grading was "fair" if criterion (a) was met plus either (b) or (c). In all other cases the grading was "poor."

Patient recall and understanding—At issue in the initial patient home interview were the accuracy of the patient's recall of what the cardiologist had said, level of understanding concerning the normality of the heart, and evidence of anxiety related to doubt or misunderstanding. Patient recall of the consultation was compared with what the cardiologist had actually said according to the transcript. From the patient's own account we graded pretest understanding as a composite index taking account of (a) understanding of the reason for the heart query and (b) understanding of the fact that serious disease was possible but unlikely. Post-test understanding was graded with respect to (a) understanding of the nature of the presenting symptoms or murmur and (b) appropriate acceptance that the heart was normal and the consequent implications for health. We graded the level of patient anxiety both before the test and after explanation of the normal result.

Observer agreement determined by comparison of the independent gradings made by a cardiologist (IMcD) and a sociologist (JD) has been presented in detail elsewhere.⁶ Differences in mean observer gradings were not significant at the 5% level for any variable (Mann-Whitney U test).⁸ When results for all four level grading scales were pooled there was complete agreement between observers⁹ for 75.0% of gradings, minor disagreement (one grade) for 17.4%, and serious disagreement (two grades) for 7.7% (Cohen's weighted κ 0.78; 95% confidence interval 0.73 to 0.81).¹⁰ Agreement was therefore deemed to be satisfactory for 92.3%

of gradings. Having documented the reproducibility of our application of the study protocol, the cardiologist and sociologist then graded each variable by consensus using direct quotations from the transcripts as supporting evidence. Of a total of 106 variables measured in the original study, consensus could not be reached on two, which were then eliminated from the study.

Results

We examined the impact of the echocardiography result on clinical diagnosis, treatment, patient anxiety, understanding, and symptoms. Patient recall, clinical presentation, and the quality of the consultation were explored as factors which could influence the success of reassurance.

IMPACT ON DIAGNOSIS AND TREATMENT

In 17 cases the main reason for ordering the test was to rule out organic heart disease. However, in almost as many patients (16) the test was performed by the consultant cardiologist in deference to the explicit or perceived wish of the referring doctor. Less commonly (seven patients) the test was aimed primarily at bolstering reassurance as a kind of placebo. The clinical diagnosis before the test was "certainly normal" in 15 patients, "almost certainly normal" in 16, and "probably normal" in nine. The test result was unequivocally normal in 37 patients. Only one definite abnormality was found—a bicuspid aortic valve with trivial regurgitation and no stenosis. In two patients doubt was expressed about the presence of mild mitral valve prolapse, but the result was reported as normal. All three patients had been classified as probably normal before the test; all were given antibiotic prophylaxis against infective endocarditis after the test. Providing evidence for managing the "probably normal" group was the greatest clinical gain from the test. However, it is noteworthy that in one case antibiotic prophylaxis was instituted by the referring doctor despite an unequivocally normal test result.

IMPACT ON PATIENTS

Of the 38 patients followed up after a normal test result, eight claimed that they had not experienced any anxiety as a result of the query raised about the heart or referral for echocardiography (fig 1). Two had been pre-occupied with other pressing life events. The remaining six were fit, athletic, and resistant to the suggestion that they could have heart disease. All eight remained free of anxiety after the test and at the follow up interview.

The remaining 30 patients reported anxiety after the query but before the test. After the doctor's explanation that the test result was normal anxiety had been reduced in most (27 cases). In six patients anxiety had been completely relieved; however, 21 reported residual doubt and anxiety about the heart and three stated that

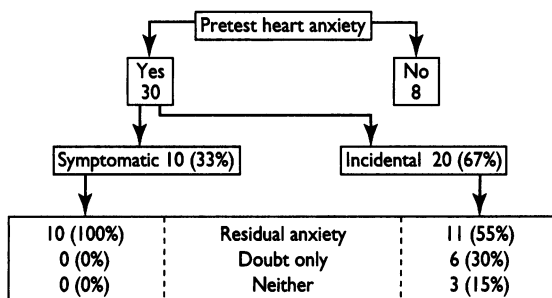


Fig 1—Patient's responses to test (echocardiogram) and explanation of normal result

they were just as anxious after the test as before. An important correlate of continuing anxiety about the heart was lack of adequate patient understanding that the murmur itself and symptoms could persist even though the heart was normal. Thus residual anxiety was inversely related to post-test understanding ($r_s = -0.43$; $P = 0.006$) and reduction of anxiety was directly related to patient gain in understanding ($r_s = 0.65$; $P = 0.001$). Symptoms persisted in three patients who were symptomatic on presentation. After the discovery of a murmur seven patients interpreted chest pain, fatigue, or breathlessness as possibly related to heart disease, and one still had symptoms at follow up.

We could emphasise the positive finding that most patients benefited from a reduction of anxiety after the test. However, in a broader context we note that this anxiety had been induced by the heart query and referral for testing in 21 people who had not previously been concerned about their heart (fig 1). Hence the need for referral for evaluation has to be critically appraised.

FACTORS INFLUENCING SUCCESS OF REASSURANCE

Patient recall of what the cardiologist had said in the post-test consultation was remarkably accurate. Altogether there were 71 transactions which included the communication of information from doctor to patient. These concerned diagnosis in 38 cases, treatment implications in 19, prevention of unnecessary retesting in 11, and the possible social implications of the normal test result in three. In most cases (53) the patient's recall was an accurate version of what the doctor had said or did not differ in any important respect (10). In only two cases was there a difference of potential clinical importance.

Manner of presentation—The manner of a patient's presentation was related to the likelihood that reassurance would be successful in the longer term. Thus the 21 patients still anxious about the heart at the initial interview included all 10 who had presented with symptoms (fig 1), despite the fact that the consultant had believed that anxiety had been abolished in seven. Follow up at nine to 12 months showed that one patient had retired from work because of a perceived heart condition without going back to a doctor, four had returned to the family doctor with symptoms, two had been referred for another cardiologist opinion, and one had been referred for another echocardiogram. In contrast, of those 28 patients without symptoms whose heart had been queried incidentally, 11 had some residual anxiety but only one (with persistent chest pain) had returned to her doctor at the time of the later interview. Of 20 patients in this group with pretest anxiety about the heart, over half had residual anxiety (fig 1).

The *quality of the consultation* was classified as good in nine patients, fair in 17, and poor in 13. The relation between quality and success of reassurance was not significant. However, the sample size was small, so that failure to achieve significance should not be taken to mean that no relation existed. Thus successful reassurance rarely followed a poor consultation (1/13), and a good consultation technique offered no guarantee of abolishing patient anxiety about the heart (3/9). The most likely explanation was that past experiences, subsequent eventualities, or social context contribute to a patient's ultimate interpretation of events, influencing the outcome of attempted reassurance. In some cases such effects become evident months after the test.

We encountered some striking examples of the longer term effect of a personal belief or social event acting as an impediment to effective reassurance. Thus a middle aged woman who took up jogging and became breathless on hills attributed this to a heart murmur detected 30 years previously, when she had been "too busy" to give it any credence. Similarly a young woman

with a murmur detected in childhood became alarmed when a television programme showed the heroine dying of heart disease after detection of a heart murmur. A man previously reassured after echocardiography returned for another test because his wife had become concerned about the possibility of having to raise two children on her own. A woman, initially successfully reassured, became mistrustful of the normal test result after she learnt that her sister had developed metastatic cancer despite earlier negative ultrasound and computed tomography scans; this belief was reinforced by her conviction that computers were often prone to error. A normal test result was not enough to allay the fears held by the parents of a 3 year old boy, their only child; they linked the murmur to a heart attack recently suffered by the father and feared hereditary disease. As occurrences such as these could not readily be predicted by doctor or patient we refer to them as "wild card effects."

Discussion

There have been remarkably few empirical studies of reassurance in any clinical setting.^{11 12} A false positive test result will not allow reassurance, and an inconclusive result may leave doubt and anxiety. Both are statistical risks inherent in the ordering of an imaging test to rule out disease in a population with a low prevalence of disease.¹³ Our study warns of an additional problem, more common and more subtle, whereby reassurance may not be entirely successful despite a normal test result. This is particularly unfortunate when the patient's anxiety was engendered in the first place by a query raised in the course of a routine examination.

The suspicion of heart disease can arouse fear rivalled only by cancer, so that patients can become very alarmed either by symptoms thought to be related to the heart or by the finding of a heart murmur. Referral for a consultant opinion and for a test lends credence to this fear. The patient's credulity may then be strained by the cardiologist's claim that the continued presence of the murmur or persistence of symptoms is unrelated to heart disease. Wild card effects attributable to unpredictable specific patient circumstances or beliefs can lead to resistance to believing that the heart is normal despite a normal test result. Under these circumstances the best possible doctor-patient communication might not be equal to the task of reassurance. Even when reassurance is initially successful we find that doubt and anxiety may recur later in the context of a further query related to the murmur, recurrence of symptoms at a time of stress, media publicity about the heart, or some occurrence which sows doubt in the patient's mind about the reliability of the evaluation. In patients with murmurs there is also the possibility of further tests which could reactivate anxiety. More than one third of patients in this category had been queried at least once before; half of these had a previous echocardiogram.

OBSTACLES TO REASSURANCE

Much has been written about the importance of better communication between doctor and patient. In the study consultations only limited attempts were made to determine patients' views and doubts, and doctors often remained unaware of important barriers to acceptance of reassurance. Perhaps some of the misunderstandings and doubts after investigation could have been resolved by careful interactive discussion of patients' concerns, together with a concerted effort to persuade which took these concerns into account. However, it should be kept in mind that evidence of such barriers emerged only in the course of a much longer home interview under conditions quite different from those in medical practice.

Key messages

- Reassuring patients with symptoms or a murmur in whom an echocardiogram is normal often leaves doubt and anxiety
- Obstacles to reassurance relate not only to problems of doctor-patient communication but also to the patient's past experience and social circumstances
- Because of the risk of residual anxiety and the epidemiological hazard of a false positive or inconclusive test result, referral for the test should be avoided if an expert clinical opinion will suffice
- Clinical skills in recognising anxiety and identifying innocent murmurs should be reinforced to minimise unnecessary referrals
- The consequences of possible residual doubt and anxiety must be factored into measurements of cost effectiveness of echocardiography and of other imaging technologies

In addition, we found evidence that unwarranted fears can grow, suggesting that prompt reassurance is desirable.^{14 15} Nevertheless, in light of the fact that the risk of harm which can arise from misdiagnosis, from doubt about image interpretation, or from a wild card effect is largely unpredictable, an important implication of our results is that preventive measures should be aimed at keeping queries about the heart and referrals for testing to the necessary minimum.

MINIMISING UNNECESSARY TESTS

An important issue underlying the assessment of systolic murmurs is the risk of endocarditis, to which even patients with minor and asymptomatic heart defects are exposed. The magnitude of this risk needs constant re-evaluation in the face of continuing controversy concerning the extent to which antibiotic prophylaxis is effective.^{16 17} In light of our findings it is clearly important that the benefit of any reduction of risk for the few patients who have asymptomatic heart lesions should always be weighed against the significant risk of iatrogenic harm to the many who do not.

The proportion of patients in whom the normality of the heart is questioned and who are referred for echocardiography could be kept to a necessary minimum by increased emphasis in medical training on the auscultation normal range and on the characteristics and classification of innocent murmurs. Doctors in primary care could be trained to have a keener appreciation of the high prevalence of murmurs in young, pregnant, athletic, anxious, and elderly patients and to be more confident in their recognition.¹⁸ Consultants also could be asked to rely more often on clinical judgment than risk inducing or exacerbating concern by ordering an echocardiogram.

We can attest to the accuracy of the experienced cardiologist's confident diagnosis of a normal heart. When we add the patients in this report to those making up a patient population recruited in exactly the same way in an earlier survey (unpublished data), we have tested the accuracy of clinical examination against that of echocardiography in a total of 105 patients. The only heart abnormality found was a bicuspid aortic valve with regurgitation of no haemodynamic consequence,

about which the clinician was not confident, pronouncing the heart as "probably normal." These results extend to adults the finding of high accuracy of the clinical examination reported by Newburger *et al* in children.¹⁹ What makes it more difficult for clinicians to avoid ordering an echocardiogram is that missing organic disease will inevitably be criticised whereas diagnostic restraint is rarely praised regardless of its overall minimisation of harm and greater cost effectiveness. There is also the temptation to order the test in deference to the wish of a referring doctor in the interests of good practice relations.

IMPLICATIONS FOR EVALUATION OF IMAGING TESTS

Similar studies are needed for other tests in other organs before further generalising from our results in other clinical contexts. Nevertheless, on the basis of clinical experience a *prima facie* case can be made that our findings are likely to apply to other imaging tests commonly used for reassurance in ruling out disease or for detecting minor asymptomatic disease such as diagnostic ultrasound, nuclear medicine, computed tomography, and magnetic resonance imaging. It is also important that evaluation of the cost effectiveness of these tests should take account of possible harm such as we have recorded in the case of echocardiography. In particular, a survey of subsequent medical consultations and tests after failure of reassurance could provide valuable information both on morbidity and on direct and indirect costs.

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- 1 Pilowsky I. Abnormal illness behaviour *Br J Med Psychol* 1969;42:347-51.
- 2 Feinstein AR. An additional basic science for clinical medicine: II. The limitations of randomized trials. *Ann Intern Med* 1983;99:544-50.
- 3 Strauss AL. *Qualitative analysis for social scientists*. Cambridge: Cambridge University Press, 1987.
- 4 McDonald IG, Guyatt GH, Gutman JM, Jelinek VM, Fox P, Daly J. Contribution of a non-invasive test to clinical care: the impact of echocardiography on diagnosis, management and patient anxiety. *J Clin Epidemiol* 1988;41:151-61.
- 5 Tuckett D, Boulton M, Olson C, Williams A. *Meetings between experts: an approach to sharing ideas in medical consultations*. London: Tavistock, 1985.
- 6 Daly JM, McDonald IG. *The social impact of echocardiography: opening Pandora's box*. Canberra: Australian Government Publishing Service, 1993. (Health care technology series, No9.)
- 7 Daly J. Innocent murmurs: echocardiography and the diagnosis of cardiac normality. *Sociology of Health and Illness* 1989;11:99-116.
- 8 Howell DC. *Statistical methods for psychology*. 2nd ed. Boston: PWS-Kent, 1987.
- 9 Kramer MS, Feinstein AR. Clinical biostatistics: LIV. The biostatistics of concordance. *Clin Pharmacol Ther* 1981;29:111-23.
- 10 Cohen J. Weighted kappa: normal scale agreement with provision for scaled disagreement or partial credit. *Psychol Bull* 1968;70:213-20.
- 11 Fitzpatrick R, Hopkins A. Referrals to neurologists for headaches not due to structural disease. *J Neurol Neurosurg Psychiatry* 1981;44:1061-7.
- 12 Bass C. Chest pain and breathlessness relationships to psychiatric illness. *Am J Med*. 1992;92(suppl 1A):125-75.
- 13 Fletcher RH, Fletcher SW, Wagner EH. *Clinical epidemiology: the essentials*. Baltimore: Williams and Wilkins, 1982:54.
- 14 Hunt LM, Jordan B, Irwin S. Views of what's wrong: diagnosis and patients' concepts of illness. *Soc Sci Med* 1989;28:945-56.
- 15 McKinlay JB. Social network influences on morbid episodes and the career of help seeking. In: Eisenberg L, Kleinman A, eds. *The relevance of social science for medicine*. Dordrecht: Reidel, 1981:77-110.
- 16 Chemoprophylaxis for infective endocarditis: faith, hope, and charity challenged [editorial]. *Lancet* 1992;339:525-6.
- 17 Oakley CM. Controversies in the prophylaxis of infective endocarditis: a cardiological view. *J Antimicrob Chemother* 1987;20(suppl A):99-104.
- 18 Caceres CA, Perry LW. *The innocent murmur: a problem in clinical practice*. Boston: Little, Brown, 1967:75-82.
- 19 Newburger JW, Rosenthal A, Williams RG, Fellows K, Miettinen OS. Non-invasive tests in the initial evaluation of heart murmurs in children. *N Engl J Med* 1983;308:61-4.

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