General Practice Observed

Long-term digoxin treatment in general practice

P CURTIS

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Summary

A questionnaire was sent to several general practitioners and specialists in an attempt to obtain a consensus on standards of care for patients receiving long-term digoxin treatment. The consultants' suggested standards were slightly more stringent than those of the general practitioners. The records of 42 patients taking digoxin under the care of two general practitioners were studied to see how far their actual care matched up to the suggested standards. The models of management proposed by these patients' doctors were only slightly different from those suggested by other practitioners, but measured against these models the patients' care was in some cases inadequate. Nevertheless, there was little relationship between the recorded levels of care and the health of the patient, and it may have been the standard of recording rather than the care that was inadequate. Measuring plasma digoxin levels in these patients proved to be of little value. Medical audit is thus a useful tool in helping the general practitioner to review his work and improve his knowledge, but it may not be a practical or true way of measuring the quality of care.

"The correct use of digitalis is a clinical art which can only be learned at the bedside."¹

Medical audit has been suggested as a method of monitoring the effectiveness and quality of care in general practice, and some possible methods of appraisal have been described.² Quality control in medicine is being developed in North America for mainly economic reasons and its effect has not yet been evaluated. There is much discussion on this subject in Britain²⁻³ and the assessment of quality is one of the growing points in academic general practice. Acheson⁴ suggests that any quality control system should be run by the doctors themselves. To be realistic acceptable quality control in general practice must be aimed at a reasonable level of adequate care provided by the doctor, rather than the ideal, and it must be undertaken with as little disturbance of the general practitioner's normal professional activities as possible.

Objectives

The purpose of this study was to assess the quality of care given to a group of patients on long-term digoxin treatment

according to standards suggested by their family doctors, other general practitioners, and a few hospital specialists. Serum digoxin levels were estimated to discover whether this investigation was of value in therapeutic control. The patients were selected for the following reasons: (1) The repeat prescription card system easily identified all patients on digoxin. A disease register was not relied on and the selection method could be used by most doctors. (2) There have been several recent reports of a significant incidence of toxicity in patients on this drug, particularly the elderly, but most published work is hospital-oriented and little is known of the problem in general practice.⁵⁻⁹ (3) The study group was small and consequently caused little disturbance to normal practice routine. (4) I hoped that criteria for the adequate care of patients stabilised on digoxin could be established as a guideline, perhaps for trainees and as a basis for discussion among general practitioners.

Methods

The patients were identified by the practice dispenser, who recorded the names of all patients presenting repeat prescription cards for digoxin tablets. This drug was prescribed by the doctors every one or two months. Over three months 42 patients were selected for study. These patients represented 1.2% of the total practice population (5200); 39 were aged 65 years or over and they represented 6.2% of all patients over 65. In 11 patients treatment had been started by a specialist, but only three were subsequently seen regularly at the hospital. The general practitioners were responsible for the initial diagnosis and treatment in 31 patients although they had obtained a specialist opinion in 12 cases.

To establish a consensus on standards of care for patients stabilised on digoxin over a long period a questionnaire was sent to local general practitioners and hospital consultants. It was also completed by the two doctors caring for the patients under study. Thirty-four general practitioners and six consultant physicians replied but not all the questions were answered.

Results of questionnaire

Taking the majority view from the survey (table I) the general practitioners proposed that patients on digoxin should be seen every three months. At these consultations the doctor should ask about four or more of the following symptoms: breathing, chest pain, irregular heart beat, oedema, work, and gastric symptoms and should perform at least three of the following examinations to determine signs: measure pulse rate, measure blood pressure, look for oedema, and auscultate the heart and chest. The general practitioners thought that no biochemical tests need be undertaken unless there was evidence of cardiac failure and no regular electrocardiogram (ECG) or chest x-ray examination should be undertaken.

The consultants agreed with the general practitioners over the frequency of consultation, the history, and examination for signs, but they disagreed over tests. The consultants thought that blood urea and electrolytes should be estimated and a blood picture constructed each year and also if there was evidence of cardiac failure. They also thought that a chest x-ray examination should be undertaken regularly.

TABLE I—Standards of care suggested by consultants and general practitioners. Results are numbers of doctors giving each response to questions asked

	Consultants (n = 6)	General practitioners (n = 34)
Frequency of consultation:		
Weekly	0	0
Monthly	0	0
3 Monthly	4	22
6 Monthly	1	8
Yearly	1	4
At each visit ask about:		
≥4 of following	6	22
<4 of following		12
Breathing, irregular heart beat, oedema, gastric symptoms, work capacity		
At each visit check clinical signs (pulse, blood pressure, oedema, auscultation of heart/lungs):		
All	5	22
Pulse and oedema	1	11
Pulse only	0	1
Biochemical tests undertaken on patients on established treatment:		
None	1	16
Blood urea and electrolytes	2	13
Urea, electrolytes, and blood picture	2	5
Frequency of biochemical tests:		
Each visit	0	0
Every 6 months	2	6
If evidence of cardiac failure	4	17
ECG undertaken regularly	2	0
Chest x-ray examination undertaken regularly	3	1

INTRAPRACTICE AUDIT

The proposed standards of the doctors in the practice differed slightly from those of the majority. The adequacy of the care given to their patients as measured by their own standards is shown in table II. There was an obvious lack of correlation between the doctors' own suggested standards of care and their actual practice. Dr X did not see his patients as often as he said he should and both doctors did not see some patients at all for long periods. Table III shows details of the 42 patients on long-term digoxin therapy. Dr X looked after 14 patients and Dr Y 28 patients. Three patients were only seen annually and the records of four others showed no evidence of diagnosis or treatment. There was little evidence from the notes that digoxin treatment had been reviewed in any patient. The drug was not stopped and then restarted in any case, although it has been suggested that digoxin may be discontinued in up to 70% of patients with ischaemic heart disease without detriment.¹⁰ Despite the apparent inadequacy of monitoring most patients remained fairly well (table III).

PLASMA DIGOXIN LEVELS

The plasma digoxin level was estimated to discover whether it could be used as an objective indicator of adequate treatment. A radioimmunoassay method (¹²⁵I) was used; 7 ml of blood was obtained from each of 33 patients about five hours after the morning dose of digoxin. This produced a reading that correlated closely with the therapeutic dose in the patient.¹¹ Serum urea and creatinine levels (table III) were also estimated as digoxin toxicity rises rapidly in the face of poor renal function.^{7, 12} In patients with a serum creatinine level greater than 133 μmol/l (1.5 mg/100 ml) blood serum electrolytes were also estimated. These were all within normal limits.

The satisfactory therapeutic level of serum digoxin is 1.3-2.6

nmol/l (1-2 ng/ml), but the correlation between serum levels and toxicity is poor,^{7, 8} and the degree of overlap between toxic and non-toxic levels may be considerable. Toxicity depends on many factors, including other drugs, the type of cardiac disease, and serum potassium, calcium, and magnesium levels.¹³ Of the 33 patients investigated 12 had digoxin levels above 2.6 nmol/l and six had levels below 1.3 nmol/l. Only 46% of the patients achieved the accepted therapeutic range.

Serum digoxin levels bore no relation to the patients' health. A feeling of well-being was regarded as being a good outcome of long-term digoxin treatment and was assessed at an interview with the patient. Each person was asked how they felt and, particularly, about their activity, breathlessness, and symptoms of toxicity.¹⁴ These rather vague measurements were used because they reflected the type of information usually obtained and recorded in general practice. The state of health of patients is shown in Table III graded as follows: +++ = well and mobile; ++ = fair and mobile (occasional symptoms, such as angina, indigestion, breathlessness); + = moderate (recurrent symptoms, poor exercise tolerance); — = poor (housebound, continuous ill-health). Five patients were housebound. Two of these were incapacitated by rheumatoid arthritis and two by obstructive airways disease. Only one had severe cardiac disease. The patient with asthma (case 4) and the one with severe cardiac disease (case 27) had toxic digoxin levels with symptoms attributable to the drug. It seems, therefore, that estimating serum digoxin in general practice is of little value as a measure of the quality of care.

Discussion

Most of the patients studied were in good or fairly good health and were only occasionally disturbed by cardiac symptoms, and most remained perfectly well on digoxin despite inadequate monitoring by the doctors' own standards. Thomas¹⁵ states that the practice of giving digoxin and a diuretic together over a long period is contraindicated in the elderly and should be regularly reviewed. In this study digoxin and diuretics were prescribed for most of the patients and the indications for treatment were rarely reviewed.

Once a patient had been put on digoxin the drug was likely to be prescribed indefinitely without critical appraisal in spite of regular monitoring by the doctor. This suggests that the standards of care recommended by the general practitioners and specialists may contribute only slightly to the health of patients who are stabilised on digoxin. Easy and rapid access to the doctor in the event of mild ill-health may be of greater value as a measure of quality than the regular three-monthly consultation.

The appraisal of Dr X's and Dr Y's performances against their own suggested standards highlighted a major problem with this method of quality control.³ In general practice many questions are asked and clinical signs noted without a record being made at the consultation. Thus inadequate records probably created an unjustifiably gloomy picture of the doctor's standards of care, particularly in relation to the accuracy of diagnosis. This method of audit may also be unfair if recording habits vary.

TABLE II—Adequacy of care received by 42 patients as measured by their general practitioners' own standards

	Doctor	Standard	No of patients receiving:		
			More than adequate care	Adequate care	Inadequate care
Frequency of consultation	X Y	6 Monthly 3 Monthly	3 8	0 12	11 8
Questions to ask at each visit	X Y	All All	0 0	4 10	6 18
Clinical signs to look for	X Y	All All	1 0	3 8	10 28
Biochemical tests	X Y	None Electrolytes	0 0	14 8	0 20
Frequency of laboratory tests	X Y	If in cardiac failure If in cardiac failure	0 0	4 22	3 6
Regular ECG and x-ray examination	X Y	No No	0 0	14 28	0 0

TABLE III—Data on 42 patients studied

Case No	Doctor	Age	Serum creatinine ($\mu\text{mol/l}$)	Blood urea (mmol/l)	Serum digoxin (nmol/l)	Recorded diagnosis	Time on treatment (years)	Frequency seen in previous year	Health status†	Diuretic treatment
Men										
1	X	75	124	6.0	2.6	IHD	8	9 monthly	++	
2	X	73	97	6.5	1.2	AF	7	3 monthly	+++	
3	X	43	88	6.8	2.9*	AF	1	3 monthly	+++	
4	Y	76	133	6.6	3.3*	IHD	2	3 monthly	—	+
5	Y	80	106	4.7	1.2	No record	9	2 monthly	++	
6	Y	77	88	5.6	2.1	AF	5	3 monthly	+++	
7	Y	75	106	6.1	2.6	IHD	3	2 monthly	+++	
8	X	70	88	5.3	1.4	LVF	4	3 monthly	+++	
9	X	68	88	7.0	2.9*	Arrhythmia	2	12 monthly	+++	+
10	X	68	124	5.8	1.8	IHD	5	1 monthly	++	+
11	Y	75	115	7.1	1.0	IHD	3	12 monthly	++	+
12	Y	72	97	5.5	0.4	IHD	5	Twice weekly	—	+
13	X	83	150	8.0	3.6*	IHD	3	No record	++	+
14	Y	68	97	6.0	2.3	IHD	3	6 monthly	+++	
15	X	85	76	6.0		No record				
16	Y	76	133	6.0		AF	5	12 monthly		+
17	X	73	97	6.1		No record	5	Every 2 years		
Women										
18	X	77	133	5.6	3.1*	Cardiac failure	16	3 monthly	++	+
19	Y	80	124	5.0	2.9*	LVF, IHD	3	3 monthly	++	+
20	Y	79	88	6.6	2.1	LVF, IHD	5	9 monthly	++	+
21	Y	56	80	6.3	2.4	AF	7	Weekly	—	+
22	Y	74	106	6.1	1.9	LVF, IHD	4	4 monthly	+++	
23	Y	60	80	6.6	2.8*	RHD	15	1 monthly	++	+
24	Y	85	124	5.0	2.6	LVF, IHD	6 months	3 monthly	++	+
25	Y	80	115		1.8	LVF, IHD	8	6 monthly	+++	+
26	Y	72	88	7.5	3.7*	IHD	3	2 monthly	+++	+
27	Y	80	115	8.3	3.8*	IHD	7	3 monthly	—	+
28	X	76	62	5.8	2.6	No record	?	Not seen	++	
29	Y	83	88	5.8	2.9*	LVF	4	6 monthly	++	+
30	Y	79	88	6.6	1.9	Cardiac failure	4	3 monthly	++	+
31	Y	80	97	4.8	0.9	IHD	3	12 monthly	++	+
32	Y	75	106	5.3	3.1*	No record	5	6 monthly	++	+
33	Y	77	124	6.3		Cardiac failure	1	2 monthly	+	+
34	Y	78	141	7.0		No record	5	3 monthly	++	+
35	Y	43	133	5.2		RHD	6	3 monthly	+++	+
36	Y	76	168	6.1	3.1*	IHD	10	3 monthly	++	+
37	X	84	97	5.8		LVF, IHD	3		++	
38	Y	83	115	6.0		LVF, IHD	4	3 monthly	—	+
39	Y	86	88	5.0	1.8	IHD	10	9 monthly	++	+
40	X	87	106	6.6		No record	1½	No record	++	+
41	X	75	106	6.1	2.3	IHD		9 monthly	++	+
42	X	83	80	5.3		No record		No record	+++	+

*Toxic levels of digoxin. +++ = Well. ++ = Fair. + = Moderate. — = Poor. (See text.)

IHD = Ischaemic heart disease. AF = Atrial fibrillation. LVF = Left ventricular failure. RHD = Rheumatic heart disease.

Conversion: SI to traditional units—Creatinine: $1 \mu\text{mol/l} \approx 0.0113 \text{ mg/100 ml}$. Urea: $1 \text{ mmol/l} \approx 6 \text{ mg/100 ml}$. Digoxin: $1 \text{ nmol/l} \approx 0.78 \text{ ng/ml}$.

VALUE OF AUDIT

Nevertheless, the development of standards applied to a small group of high-risk patients in general practice has shown areas where improvement in clinical management is needed, and much has been learnt about the clinical activity of the doctors in relation to digoxin treatment. Medical audit is therefore an educational tool and consequently should, in time, change methods of clinical practice.

As a result of this study, the following modifications to the clinical management of patients receiving long-term digoxin treatment have been suggested: (a) there should be six-monthly consultations with the doctor or health visitor; (b) consultations should be initiated by the repeat prescription card system through the ancillary staff; (c) recording methods with regard to cardiac disease, especially diagnosis, should be improved; (d) doctors should ensure that patients are aware of the symptoms of digoxin toxicity and encourage them to report these; and (e) the need for digoxin treatment should be reviewed critically by reducing the dose or stopping the drug for a time.

The investigation of plasma digoxin levels was time consuming and of little relevance to the quality of care. The time taken to apply the standards proposed by Dr X and Dr Y to 42 case records was three hours and would seem a feasible undertaking in any practice.

The creation of a set of standards for a particular disease or management problem is fraught with difficulties and the contribution of those standards to the health of patients may be minimal. Family doctors still look to the standards of hospital medicine when appraising their own work, although those standards may not be attainable or practical in general practice. The consequence may be a feeling of inadequacy or underachievement in spite of the provision of perfectly adequate care to their patients. It would therefore be unwise to use medical

audit as an arbiter of "good" or "bad" medicine, but it seems to be a useful method of intrapractice analysis.

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A patient with collagen disease and taking steroids suffers from severe cramps at night. What treatment do you advise?

Muscle cramps in bed at night are common in perfectly normal people with no illness of any sort. They may, nevertheless, be most unpleasant and interfere with sleep. Many patients think that an 0.3-g tablet of quinine hydrochloride or bisulphate on retiring will help but this is debatable. When venous insufficiency is responsible raising the legs in bed at night often proves helpful.