The Outpatient Use of Digitalis: A Chart Audit

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In order to establish the appropriateness of the use of digitalis, the charts of 337 patients with heart disease from the Family Health Center at the University of Maryland were reviewed. The results revealed that several patients were on digitalis for weak or borderline reasons or for poorly documented reasons. Although few attempts had been made to discontinue digitalis, a high percentage of those patients who had discontinued digitalis did so without morbidity or mortality, and without having to have digitalis reinstituted. The necessity for continuous evaluation and reassessment of each patient's need for digitalis was clearly illustrated. Chart audit was also a significant means of self as well as group education, through dissemination of the information obtained. Ideally, chart audits will improve patient care, both immediately as a result of the audit and long term as a result of increased awareness of possible problems and pitfalls. Further study is needed to verify this latter premise.

Digitalis is one of the most valuable and commonly prescribed drugs. It is also potentially one of the most lethal drugs, with a low margin of safety.

Many patients may be on digitalis and never have the indications for its institution or its continuation reexamined. This is particularly true in the clinic situation where a patient may see a different physician on each visit. The concept of the model unit and ongoing care by a single resident at the University of Maryland Family Health Center lends itself to such an examination of the indications for digitalis by means of a chart audit.

The purposes of this paper are: (1) to examine the indications and proper use of digitalis in the outpatient setting; (2) to increase awareness of the potential danger of digitalis; and (3) to stress the necessity of continuing evaluation of the patient's need for digitalis.

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Methods

The charts of 337 patients with heart disease, as classified by the International Classification of Health Problems in Primary Care, were reviewed. These problems included rheumatic heart disease, chronic ischemic heart disease, healed myocardial infarction, angina pectoris, arteriosclerotic heart disease, valvular disease, right and left heart failure, atrial fibrillation or flutter, paroxysmal tachycardia, ectopic beats of all types, heart murmur, and all other heart disease including abnormal ECG, pericarditis, and cardiac arrest.

The IBM 370 computer was used to retrieve the information which had previously been coded on encounter forms filled out by the residents at each patient visit. The information stored is limited by the degree of cooperation of the residents in filling out encounter forms, and also limited to patients

Table 1. Method of Digitalization

Number of Patients	Digitalizing Dose	Where Digitalized	By Whom
13	Unknown: digitalized outside of Family Health Center (FHC) and were on digitalis when they entered program	Unknown	Unknown
12	0.25 mg q.d.	20 FHC	20 FHC residents
3	0.25 mg t.i.d. x 2d then q.d.	1 Emergency Room	1 4th year medical student rotating through FHC
2	0.25 mg b.i.d. x 3d, then q.d.		
1	0.125 mg q.d.		
1	0.5 mg b.i.d. x 7d, then 0.25 mg q.d.		
1	0.25 mg b.i.d. x 4d, then q.d.		
1	0.25 mg q.d.		

who have been seen for that specific problem since the initiation of the use of the encounter forms. There may be several other patients on digitalis, whose charts would not be retrievable by this method.

Since medications are not coded into the computer, charts with the above problems were reviewed to determine those patients taking digitalis and the indications for prescribing this medication. If a patient was not on digitalis, the chart was not further reviewed. For those patients on digitalis, special interest was paid to when, where, and how the patient was digitalized; signs, symptoms, laboratory studies, and assessment by the physician at the time of digitalization; follow-up visits including laboratory studies, signs of digitalis toxicity, and discontinuation or alteration of the dose of digitalis; and other concurrent health problems and medications of the patient. An audit sheet on each patient was then completed with the above information, as well as with conclusions and recommendations. The audit sheets were disseminated to the respective residents and included as a permanent record for each chart.

Results

From the 337 charts reviewed, 40 patients were found to be on a regimen of digitalis. All of the patients were receiving digoxin except one on digitoxin. Six patients were eliminated from the statistics. Four of these patients had not been seen in several years, and the other two were on a regimen of digitalis for atrial fibrillation with rapid ventricular response. Review of the latter two charts revealed an accurate diagnosis, good clinical response to digitalis, and adequate follow-up.

Thus, 34 patients who were receiving digitalis or who had been so recently were included in the statistics. The illness of 31 of these patients was diagnosed as congestive heart failure (CHF), that of two was diagnosed as angina, and that of one patient was diagnosed as both congestive heart failure and atrial fibrillation.

It was interesting to note that either the diagnosis and/or the dose of digitalis was not recorded on the problem list of 8 of the 34 patients. In a few cases this resulted in apparent unintentional changes in the dose of digitalis. In one case digitalis had been discontinued several months earlier, but not removed from the problem list. This apparently resulted in reinstitution of digitalis.

As seen in Table 1, approximately two thirds of the patients started receiving digitalis in the Family Health Center. This affords one an excellent opportunity to review the indications and use of digitalis. Tables 2 and 3 illustrate the signs and symptoms of CHF present at the time the patient was digitalized. The 13 patients not digitalized in the Family Health Center were obviously not included. It can be seen that several of the major criteria were either absent, or more notably, not described. Thus, several patients were started on digitalis therapy with either poor documentation and/or as a result of inaccurate diagnosis of their problem. Table 4 illustrates the laboratory evaluation obtained at the time of digitalization and indicates that several patients had an inadequate data base. Less than 50 percent had had an ECG prior to digitalization and only 23 percent had had a serum creatinine.

Return visit follow-up of patients was generally

Table 2. Symptoms of Congestive Heart Failure Present at Digitalization

Symptoms	Present	Absent	Not described as Present or Absent	Total % of Patients with Positive Symptoms
Fatigue	2	0	19	9.5
Shortness of breath	10	3	8	47
Dyspnea on exertion	11	2	8	52
Orthopnea	6	7	8	28
Paroxysmal nocturnal dyspnea	5	6	10	23
Nocturia	2	1	18	9.5

adequate. This was true with follow-up immediately after digitalization and long term follow-up. Documentation was generally poor concerning the patients' signs, symptoms, and evidence of significant improvement as a result of digitalis institution. The same lack of documentation was true for patients who had started receiving digitalis elsewhere. Reassessment of the original or the current need for digitalis had not been performed in the majority of cases. Thus, once put on a regimen of digitalis, patients were routinely continued on it.

Table 5 illustrates the follow-up of laboratory tests. These were obtained any time after starting digitalis. Thus the statistics do not indicate whether they had been obtained recently, at appropriate intervals, or for what indications. The indications for obtaining a serum digoxin level were reviewed and only 6 of 16 charts documented the reason for obtaining this test. All of the reasons documented were valid.

It was difficult to review for digitalis intoxication because of the nonspecificity and variability of the signs and symptoms. Only one patient was found to be digitalis toxic by serum digoxin level. She suffered no morbidity, outside of her presenting gastrointestinal symptoms. After the withholding of digoxin and the later institution of a lower dose, she had no further signs or symptoms of toxicity.

As stated above, the reassessment of the need for digitalis was poor. This is illustrated by an attempt to discontinue digitalis in only 6 of the 34 patients. Table 6 illustrates the outcome of these attempts. Three additional patients discontinued digitalis by their own noncompliance. All three were restarted on a regimen of digitalis at their next office visit despite the fact that two of the three patients had no signs of cardiac decompensation after several weeks without digitalis. Two other patients had had digitalis discontinued several years earlier and were not included in the statistics. They have not taken digitalis for periods of three and five years, respectively, and have done well. It can be seen that a significant percentage of the patients in whom digitalis was discontinued demonstrated no need for the drug.

It was noted that the dose of digitalis was changed in eleven patients. Eight charts lacked documentation for dosage change, leaving the reviewer to question whether this was intentional and poorly documented, a typographical error, or an error in renewal of the medication.

Table 7 shows the major concurrent problems and medications appearing in the problem list. No significant drug interactions were discovered. Although several patients were on diuretics, they were also on a potassium-chloride preparation, a potassium-sparing diuretic, or had their serum potassium level checked at routine intervals without evidence of hypokalemia. A few patients were taking antacids when necessary; however, no effect was noted symptomatically by the patients to indicate that digitalis absorption was impaired.

Using the criteria in Tables 2 and 3 for the diagnosis of congestive heart failure, it was determined that 13 patients had weak indications for taking digitalis and might be candidates for discontinuation of the medication. Twelve patients were found to have well-documented evidence for the use of digitalis. In six patients it could not be determined whether the indications for digitalis use were sound, as they had been digitalized elsewhere and old records were not available. Finally, three patients had had digitalis discontinued and have remained off the drug without evidence

Table 3. Signs of Congestive Heart Failure Present at Digitalization

Signs	Present	Absent	Not described as Present or Absent	Total % of patients with positive signs
Rales	8	13	0	38
S_3 gallop	3	15	3	14
Jugular venous distension (JVD)	2	8	11	9.5
Hepatojugular reflux (HJR)	1	2	18	5
Edema	7	7	7	33
Hepatomegaly	0	3	18	0
Pulsus alternans	0	0	21	0
Cardiomegaly				
Clinical	1	0	20	5
X-ray	11	3	7	52
Tachycardia	5	7	9	24
Tachypnea	2	3	16	9.5

of morbidity.

Discussion

Not long ago digitalis was administered almost routinely to patients with any kind of heart disease. Furthermore, long-term or life-long therapy was considered essential for most patients who started taking the drug; hence the dictum, "once on digitalis, always on digitalis."[1] Recently, however, the appropriateness of digitalis therapy in a number of disease states and the need for continuing therapy once it has started have been receiving increasingly critical scrutiny.[1-4] Cohn emphasizes the necessity of evaluating the patient's response to digitalis instead of initiating the therapy and continuing it for life. Cohn recommends that when one starts a patient on digitalis, one should see him one or two weeks later to determine whether the patient shows any improvement. Even more important is to stop the drug after the patient has stabilized on it and observe whether anything changes.[5]

Digitalis remains the drug of choice in the control of atrial fibrillation with a rapid ventricular response, atrial flutter, and certain paroxysmal supraventricular tachyarrhythmias. Although digitalis is also of unquestioned value in the treatment of congestive heart failure, the concept that digitalis is essential for all patients with CHF is no longer tenable. Clinical experience increasingly suggests that many cases of CHF can be managed adequately with diuretics alone. No controlled studies are available to indicate whether digitalis or a combination of digitalis and diuretics is safer or more effective than diuretics alone.[1,6] The indications for use of digitalis are less clearly established in patients with CHF who are in sinus rhythm and clinically compensated. Under such conditions digitalis may be useful because of its inotropic effects. In a truly compensated heart, however, this effect does not occur, and usefulness of the drug under these circumstances is questionable. There is also no evidence that the use of digitalis will ward off the progression of the underlying heart disease.[7]

A danger of using digitalis in all cases of CHF is that too much reliance may be placed on the drug treatment to the exclusion of other measures to conserve cardiac reserve, ie, weight reduction, sodium restriction, discontinuation of smoking, and correction of underlying conditions such as anemia, thyroid malfunction, etc. Oftentimes CHF is precipitated by an acute illness or other problem causing transient cardiovascular stress. Treatment of the intercurrent problem may be sufficient to treat the decompensated heart, or it may be necessary to treat with digitalis for short-term adjunctive management. Life-long therapy is not necessarily required.

Risk/benefit analysis of other indications for digitalis therapy suggests that its value may be questionable and that it is probably overpre-

Table 4. Laboratory Tests Obtained at Time of Digitalization or in Soon Before Digitalization

Test	Obtained	Not Obtained	Total % of Patients' Laboratory Tests Obtained
Chest x-ray	13	8	62
ECG	10	11	48
Electrolytes and BUN	16	5	76
Creatinine	5	16	24
T_3, T_4, FTI	1	20	5
Complete blood count	16	5	76

scribed.[1] Studies indicate that digitalis is of no benefit in anginal patients with a normal-sized heart or without nocturnal angina. A therapeutic trial may be indicated in patients with nocturnal angina. In one study, a variable response was noted with the condition of some patients improving, some with worsening of symptoms, and others with no change.[8] Digitalis was also of no benefit when combined with propranolol in the therapy of angina, unless abnormal left ventricular function was demonstrated. In this instance improved exercise tolerance was noted.[9] Digitalis is contraindicated in sinus or atrioventricular block, asymmetric septal hypertrophy, or digitalis toxicity. It should be administered with caution in the presence of renal failure, hypothyroidism, hypokalemia, and hypoxic pulmonary disease.

Even though digitalis is said to be the fourth most commonly prescribed drug in the United States, it is one of the drugs most poorly and improperly used.[10] In one study digitalis toxicity was estimated to occur in 8 to 22 percent of patients taking digitalis, with a mortality rate of 3 to 11 percent.[11] Another study estimated that 23 percent of hospital patients taking digitalis were digitalis-intoxicated with a mortality rate of up to 41 percent.[12] Only one study was noted in direct contrast to the above. Shapiro reported absence of fatal digitalis toxicity in his study.[13] Fonrose also described several cases of unrecognized digitalis toxicity in elderly patients in an extended care facility. When digitalis was discontinued several patients showed increased vitality and appetite and were less withdrawn and quarrelsome.[14]

In the same Fonrose study, it was demonstrated that 50 percent of the patients studied and 17 percent of the patients taking digitalis in that facility were exposed to the dangers of digitalis without the benefit of a therapeutic effect. The reasons that so many patients were taking a drug that was not needed were uncertain. It was suggested that the original reason for starting digitalis therapy may have been questionable or may no longer exist. In any case, it was apparent that the cardiac status had not been reviewed or reassessed. A study by Dall revealed that 75 percent of 80 elderly patients did not need digitalis.[15] In both studies all patients were able to discontinue digitalis without detrimental effects. Those patients who needed to restart digitalis because of cardiac decompensation had no morbidity beyond early decompensatory symptoms.

Curtis performed a medical audit in England, looking at long-term digoxin treatment in general practice by auditing the charts of two general practitioners.[16] Their care was compared with standards of care as determined by a questionnaire sent both to specialists and general practitioners. He found that in many cases the charts of the two general practitioners were inadequate when measured against these standards. There appeared to be little relationship, however, between the recorded levels of care and the health of the patient. Curtis concluded that a medical audit is an excellent means of improving knowledge, although it is of questionable validity as a way of measuring quality of care. He felt this was particularly true in a busy general practice where many questions are

Table 5. Follow-up Laboratory Tests Obtained After Digitalization

Test	Obtained	Not Obtained	Percent of Follow-up Laboratory Tests Obtained
CXR	24	10	71
ECG	24	10	71
SMA_6	30	4	88
Creatinine	16	18	47
Digoxin level	16	-	-

asked and signs are noted without being recorded.

It appears clear, from both the literature and the chart audit, that digitalis is overprescribed and used in many patients who may be receiving no benefit from the drug. Aagaard states, "The decision to begin or continue digitalis therapy may be difficult. In doubtful cases the benefit to be derived from its use should clearly outweigh the risks. The following questions are suggested as the basis for reviewing the administration of digitalis.

1. In sinus rhythm, was there evidence of CHF when digitalis was prescribed?
2. In acute myocardial infarction, for what indication was digitalis prescribed?
3. In hypertensive heart disease, was digitalis prescribed when diuretics and other antihypertensive drugs might have achieved control?
4. In concomitant administration of digitalis and diuretic, were steps taken to prevent, detect, or correct hypokalemia?
5. In elderly patients given digitalis, what effort was made to appraise renal function?"[10]

Therefore, the cornerstone of rational use of digitalis therapy should include the continuous reevaluation and reassessment of the patient's need for digitalis. With this in mind the incidence of digitalis toxicity should be reduced so that many patients will no longer be taking digitalis for life.

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