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CLINICAL EXPERIENCES IN GASTRIC FREEZING FOR PEPTIC ULCER

A Preliminary Report

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GASTRIC cooling for the control of hemorrhage from the upper gastrointestinal tract has enjoyed variable popularity for many years.[1,2] Cooling has been attempted by external application of ice packs to the abdomen, or by lavage of the stomach with ice water to which epinephrine and other medications sometimes have been added. In 1958 the method was improved and standardized by Wangensteen, with the goal of depressing gastric secretion and digestion.[3] In 1962, he and his associates[4] reported the use of still lower temperatures for gastric hypothermia ("freezing") in the definitive treatment of duodenal ulcer, the goal being permanent suppression of gastric secretion.

Research and clinical experiences at the Cleveland Clinic since 1960 with gastric cooling in animal and human subjects,† respectively, and six months' experience with gastric freezing in animals, encouraged us to commence in March, 1963, the treatment of peptic ulcers by gastric cooling in a series of selected patients. Dr. Owen H. Wangensteen kindly permitted a visit to his department to observe the technic of his group. The reference gives complete details of the technic,[5] which is described briefly here. A specially shaped deflated balloon is passed into the

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stomach and is then filled with the coolant, 95 percent alcohol, to a volume of 400 to 950 ml. depending on gastric size and tolerance. The coolant is circulated constantly between the balloon and a reservoir in a specially constructed refrigerator. The temperature of the coolant entering the balloon is approximately −17 C., and leaving the balloon, about −10 C. The period of freezing in our patients was 50 minutes, and after this a 10-minute period of thawing was allowed before the balloon was emptied and withdrawn.

Comprehensive studies to evaluate adequately the physiologic effects of gastric freezing were undertaken. The studies included gastroscopy, gastric biopsy,* cinefluoroscopy,† and 12-hour overnight and betazole hydrochloride‡ stimulated gastric acidity determinations before and after freezing. The data are briefly summarized in this paper, with emphasis on the clinical results in our first 36 patients, as well as on the difficulties encountered.

Indications for Gastric Freezing

Patients to undergo gastric freezing were carefully selected largely from a group of more than 125 patients who had requested this form of treatment. Most of those who requested freezing were considered inacceptable subjects for such reasons as the following: the patient was obviously responding well to the therapeutic program and did not require supplemental treatment; the patient had ulcer symptoms for many years, but was found to have chronic obstruction or severe gastroduodenal deformity necessitating surgery rather than freezing; the patient (sometimes psychoneurotic) had ulcer-like symptoms without definite evidence of an ulcer. A group of 36 patients qualified for treatment of peptic ulcers with gastric freezing.

Indications for gastric freezing were those usually required for operative treatment, namely recurrent peptic ulcer with or without a history of hemorrhage. Obstruction, however, was considered a contraindication. All patients received the usual clinical appraisal including anamnesis, physical examination, and routine laboratory studies including gastric analysis and upper gastrointestinal roentgenographic examination. Surgical consultation was obtained for all patients considered for gastric freezing, and the decision depended upon agreement between the consultant and the attending gastroenterologist.

Clinical Results

Since each patient had a severe ulcer diathesis, we deemed inadvisable the discontinuance of standard medical treatment after freezing, and considered freezing an adjunct to medical management for those patients whose disease otherwise would have warranted operative treatment. Hence, all patients were advised to continue their hourly ulcer regimen for three weeks after freezing, although anti-

Pathologic evaluation was done by Lawrence J. McCormack, M.D.
†Radiologic studies were made by Thomas F. Meaney, M.D.
‡Histalog, Eli Lilly and Company.

cholinergics, if previously administered, were usually discontinued. Thereafter patients were advised to change to a modified ulcer regimen consisting of meals, feedings, or antacids, every two or three hours.

Each patient was observed one week and again six weeks after treatment (*Table 1*). Of the 29 patients who were asymptomatic one week after freezing, the

Table 1.—*Symptomatic results of gastric freezing in 36 patients*

Time after freezing	Status, number of patients	
	Asymptomatic	Symptomatic
One week	29	7
Six weeks	26	10

majority were still on an hourly feeding program although they were having no ulcer distress. Of the 26 who were asymptomatic six weeks after freezing, 13 had discontinued all treatment either the third week or earlier, and 13 were on only the modified treatment.

Of the seven patients who had ulcer symptoms one week after freezing, one patient had further bleeding, having previously had persistent slight bleeding from a marginal ulcer. Since he continued to have symptoms after the six-week postfreezing evaluation, he underwent gastric freezing at another institution, and currently is on strict medical management. The other six patients reported moderate recurrent ulcer symptoms requiring hourly antacids or feedings for relief of distress. Most of these patients were much improved at six weeks after freezing.

Of the 10 patients who had ulcer symptoms at six weeks after freezing, four have followed medical treatment and have gradually improved. Evaluation of repeated gastric freezing is under study in the remaining patients. (It is interesting that most of the patients who reported recurrence of ulcer symptoms at the six-week evaluation had noted a remission for four or five weeks before the recurrence.)

The first 21 patients of our series have now been seen or contacted six months after gastric freezing. Fourteen were asymptomatic; seven had noted recurrent ulcer symptoms.

Evaluation of Patients With Demonstrable Ulcer Craters

Of the 36 patients in this series, 21 had roentgenographically demonstrable ulcer craters. Some physicians think that these patients ought to comprise a special group for evaluation. Indeed most of the patients who underwent repeated gastric freezing were in this group. However 15 of the 21 patients with demonstrable ulcer craters were asymptomatic at six weeks after freezing. Of these 15, eight had discontinued all treatment and seven continued on a modified ulcer program.

Complications

Adverse reactions have occurred only twice in our gastric freezing experience. We have carried out gastric freezing 40 times in 36 patients, of whom one patient had recurrence of bleeding within one week, which may be considered a complication of the procedure, and a recurrent ulcer at six weeks after freezing. Gastric freezing was attempted in one other patient who is not included in the series for clinical follow-up, since he is the only patient who did not tolerate the procedure. Within a few minutes after the balloon was filled with the coolant he complained of cramping of the muscles in the extremities, and shortly thereafter hyperventilation, carpopedal spasm, hypotension, and bradycardia occurred. One-half hour after the freezing was interrupted by this reaction the patient felt normal. All of the findings could be explained as acute anxiety reaction with associated hyperventilation and vasovagal reaction. It is noteworthy that this particular gastric freezing was attempted a day after publication, by a medical writer in the lay press, of the dangers of gastric freezing; the information was relayed to the patient by his wife.

Summary of Our Other Studies

Gastroscopic observations at one week after freezing in 34 of 36 patients, compared with the prefreezing appearance, showed an increase in friability in four patients. At six weeks postfreezing, slight increase in friability was again noted. A few patients were examined within a day or two after freezing; edema was prominent. Gastric biopsy was done at one-week postfreezing in 26 patients: 21 showed normal findings and 5, minor changes. At six weeks postfreezing in 21 patients, 14 showed normal findings, and 7, minor changes. In no patient was there a significant diminution in parietal cells.

Motility was evaluated by cinefluoroscopy because of the possibility that an alteration would affect either the pain pattern and/or the gastric emptying. At one week after freezing there was decreased motility in 4 of 11 patients; at six weeks after freezing, no hypomotility was seen in 12 patients but one instance of hypermotility was encountered.

Twelve-hour basal nocturnal gastric secretion of free hydrochloric acid was decreased by more than 50 percent in 12 of 30 patients at six weeks after freezing, compared with the prefreezing secretory study; betazole hydrochloride stimulated secretion, however, was decreased in only two patients in this same series.

Comment

Initial optimism concerning the control of peptic ulcer by gastric freezing has been restrained by instances of strictly brief control of symptoms and the early recurrence of ulcer. Nevertheless, the results suggest that gastric freezing may become a useful adjunct in peptic ulcer therapy. Possibly it may provide a means of control in those situations in which surgery is temporarily or permanently contrain-

dicated. Perhaps it will permit a period of respite from the rigors of ulcer therapy in some patients. Although occasionally prolonged remission may follow its use, certainly the number of recurrences noted at evaluation, one week and six weeks after freezing, emphasizes how brief the period of control of peptic ulcer may be.

Peptic ulcer is frequently a lifetime disease and certainly five years is a necessary period for any satisfactory evaluation, and the first patient underwent freezing only approximately two and one-half years ago.[4] While it has been accepted by many patients and some physicians as a cure-all for ulcer, confirmation by longer periods of follow-up and controlled studies is needed before such acceptance is warranted.

Our experience indicates the necessity for meticulous care in the performance of this method of treatment. Casual attention would undoubtedly be followed by incidents that could easily be disastrous. The physician who decides to utilize this form of therapy should have a period of orientation and should carefully study the instrument before commencing clinical use. Trial of the instrument in laboratory animals is worthwhile, particularly in demonstrating the dangers of the procedure; for example, lengthening the duration or increasing the extent of freezing often is lethal in dogs. The physician should have the opportunity to apply this treatment frequently so as to attain facility in its use. Finally, he should be prepared to abandon the procedure readily if any untoward reaction is noted, and should have immediately available the qualified personnel capable of dealing with any medical or surgical emergency that could arise.

Conclusions

Preliminary observations on a series of 36 peptic ulcer patients who were treated with gastric freezing, warrant the following conclusions: (1) gastric acidity, and the results of biopsy, cinefluoroscopy, and gastroscopy show little change; (2) symptomatic response, although sometimes striking, may be followed by early relapse; (3) freezing may permit delay or avoidance of surgical treatment in selected patients, but further time is required for evaluation; (4) at the present stage of development, freezing is not a cure-all for peptic ulcer, nor does it replace standard medical treatment.

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