

Controlled Trial of Vagotomy and Gastro-enterostomy, Vagotomy and Antrectomy, and Subtotal Gastrectomy in Elective Treatment of Duodenal Ulcer: Interim Report*

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Until fairly recently, like many other clinicians in this country, we accepted so-called subtotal gastric resection, despite its defects, as the procedure of choice in the elective surgical treatment of duodenal ulcer. But some four and a half years ago, influenced by the tremendous resurgence of interest in vagotomy in the management of this condition in America and Britain, we decided that we ought to reconsider this latter operation. However, we felt that if we were going to take it up we should make a serious attempt to evaluate it in one or more of its combinations against the hitherto standard operation of high partial gastrectomy. Accordingly we instituted a controlled clinical trial, the essential features of which were that patients with duodenal ulcer were allotted in random fashion to the different operations, and that a very careful and uniform follow-up system was maintained subsequently. In this paper we describe briefly the organization of the trial and give an interim report on the findings obtained to date.

Organization of Trial

Operative Procedures under Trial

The types of operation are three in number (see Diagram):

Vagotomy and Posterior Gastro-enterostomy.—The vagotomy is a complete subdiaphragmatic or per-hiatal division of the vagi, and the gastro-enterostomy a posterior no-loop or short-loop operation, with the stoma lying vertically, obliquely, or transversely according to the preference of the individual surgeon, and usually sited at the most dependent part of the stomach and not, as advised by Dragstedt (1962), as close as possible to the pylorus.

Vagotomy and Antrectomy.—Again the vagotomy is, or is intended to be, a complete subdiaphragmatic division. The

antrectomy is achieved by what is judged at laparotomy to be a distal third or half gastrectomy, invariably including the ulcer and completed by the Polya method, though the precise details of the anastomosis—whether antecolic or retrocolic, afferent jejunal limb to the lesser curve or the greater curve, or a total or partial gastric stoma—are left to individual surgical preference.

Ordinary Subtotal Gastrectomy.—This is a standard, distal two-thirds or three-fourths resection, invariably of Polya type but allowing for technical variations from surgeon to surgeon within this framework.

Selection of Cases for the Trial

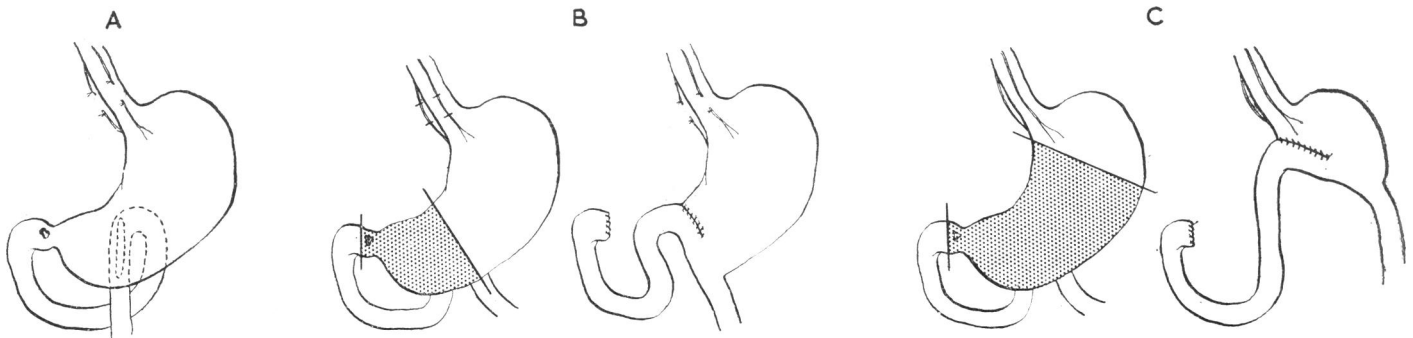
We have restricted the trial to cases undergoing "cold" or elective surgical treatment for duodenal ulcer. So far as assessment of the relative advantages and disadvantages of the three operations is concerned, one would have liked to include all such cases handled by the nine surgeons contributing to the trial, and to divide them evenly into three groups, to be treated by each of the three methods. But it seemed to us that this would be incompatible with ethical clinical practice; for, whatever may be the ultimate verdict on the relative merits of these

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The three types of operation under trial. A, Vagotomy and posterior gastro-enterostomy. B, Vagotomy and antrectomy—that is, distal third or half resection always with Polya reconstruction. C, standard subtotal gastrectomy—that is, distal two-thirds or three-quarters resection always with Polya reconstruction.

different operations in the treatment of duodenal ulcer, it is already clear that under special circumstances each may have particular advantages which no surgeon should be forced by such a trial to ignore. Thus many surgeons whose usual elective operation for duodenal ulcer is high partial gastrectomy recognize that in dealing with very adherent posterior wall ulcers, vagotomy and posterior gastro-enterostomy, which appears to be capable of yielding quite good late results, saves the patient a specially hazardous resection and is the procedure of choice. Similarly in patients who have had pulmonary tuberculosis or are naturally very thin, a gastrectomy, because of its effects on nutrition, is better avoided. On the other hand, for patients with a history of a fairly recent haemorrhage some surgeons would, rightly or wrongly, consider a resection of the ulcer an essential part of surgical treatment.

It has been necessary, therefore, to allow surgeons to reject some of their cases from the trial either before laparotomy or in the light of the operative findings. But once the decision was made to put the case into the trial the choice of operation was out of the surgeon's control and he did not know in advance which of the three operations he would be given. The actual method of allocation was that, when a case of duodenal ulcer in which there were no obvious clinical contra-indications to inclusion in the trial such as have been mentioned above proceeded to laparotomy, the surgeon first of all confirmed the diagnosis. He then had to decide whether he could perform with reasonable safety any one of the three trial operations or not. If in his judgment he could not, the patient was rejected from the trial and treated by whatever was deemed to be the appropriate elective method—usually a vagotomy and gastro-enterostomy or pyloroplasty. If, on the contrary, the trial operations all seemed technically feasible, the case was entered in the trial and a sealed envelope of instruction was opened to discover which of the three operations was to be performed on this particular patient, the file of instruction letters having been prearranged by the secretariat to give a random distribution of the different procedures under trial. It is possible that after the patient had been put into the trial and a particular operation allotted, unforeseen technical difficulties might compel the surgeon to abandon this procedure in favour of another. Under these circumstances the case would be withdrawn from the trial and entered in the rejected group, the letter of instruction being subsequently reintroduced into the file and used on another occasion.

This method of randomization may strike some as very impersonal, but we would point out that during the time the trial has been in progress surgical opinion throughout the country on the choice of elective operation for duodenal ulceration has been so divided that in any large hospital several different methods were already in use. Which one would be performed on an individual patient has depended largely on the personal predilection of the particular surgeon to whom he happened to be referred and not on any accurate knowledge of the relative late results. Our trial has merely organized somewhat this pre-existing system of random usage in order to extract more reliable information from it. It seems to us that the provision of an "escape clause," which has allowed the surgeon to take his patient out of the trial when special indications were present for so doing, though to some extent weakening the trial, has established it on a firm ethical basis.

Documentation and Follow-up Arrangements

All patients with duodenal ulcer proceeding to elective surgical treatment, whether accepted for or rejected from the trial, have completed for them a special gastric follow-up card on which are entered full particulars of their clinical condition, the findings at operation, and the operative and post-operative treatment and complications. Subsequently when the patient reports for follow-up studies this card is available for recording

information about his state at each attendance. All the more common symptoms that may be encountered after gastric operations are listed and graded into four or five categories according to the degree of severity. The items on the card are so arranged that they can easily be transferred to a punched card to facilitate rapid sorting of data. Cards are repunched after each out-patient attendance to keep them up to date.

A few comments are required on the follow-up arrangements. As three hospitals are involved—namely, the General Infirmary at Leeds, St. James's Hospital, Leeds, and the County Hospital, York—it has been necessary to organize three separate follow-up clinics, which are run by J. C. Goligher, D. B. Feather (with G. Watkinson), and C. N. Pulvertaft respectively. We would emphasize that we have made certain by frequent discussions and attendance at each other's clinics that our criteria of assessment are quite uniform throughout. Patients attend the clinics at six months and one year after operation and thereafter annually. At the clinic they are usually interviewed by a small panel, who generally do not know which operation has been performed till after they have recorded their findings and verdict—and got some surprises when they discover what was done.

Immediate Results

Disposal of Patients in and out of Trial.—During the three years that patients were being accepted into the trial from April 1959 to August 1962 we have had 634 cases through our records. These include 127 women, who form too small a series to be subdivided into four groups and statistically analysed. Our further remarks will therefore all relate to the 507 men, and it will be seen from Table I how they have been disposed of in and out of the trial: 132, or just over a quarter of the cases, were rejected on various grounds listed in Table II ;

TABLE I.—*Disposal of 507 Male Duodenal Ulcer Patients In and Out of Trial During Period of Collection of Cases (April 1959 to August 1962), and Success of Subsequent Follow-up*

	Rejected (Mostly Treated by Vag. and G.E.)	Rejected and Treated by :		
		Vag. and G.E.	Vag. and Antr.	Subtotal Gastr.
No. in each group	132	126	132	117
Operative deaths	0	0	0	0
Subsequent deaths	3	4	6	3
Untraced cases	2	0	0	2
Traced cases	127	122	126	112

TABLE II.—*Reasons for Rejecting 132 Male Patients From Trial*

Reason Given	No. of Cases
Anticipated technical difficulties from adherent duodenum, obesity, etc.	33
Minimum lesion	29
Poor general condition due to age, chest disease, etc.	22
Undernutrition	12
Recent or repeated haemorrhage	6
History of pulmonary tuberculosis	4
Miscellaneous other reasons	26

of the 375 accepted, it will be noted in Table I that their allocation to the three trial operations has not been quite equal, owing to the fact that it was originally intended to keep the trial open for a rather longer period, during which time this unevenness would have automatically corrected itself.

Operative Mortality.—This is very simply dealt with because, as is shown in Table I, there have been no immediate or hospital deaths in these 507 male cases in and out of the trial (nor indeed in the entire group of 634 male and female patients). The absence of operative mortality in the 126 accepted and 96 rejected cases treated by vagotomy and gastro-enterostomy is not perhaps too surprising, for this is well known to be a very safe operation, but in the 249 trial patients submitted to gastrectomy or antrectomy (both of which carry the risks of duodenal stump closure) it is indeed somewhat remarkable. Undoubtedly some of the credit for the avoidance of cata-

strophes in these latter cases is due to the "escape clause" which allowed surgeons to reject patients on account of anticipated technical difficulties. But this is certainly not the sole reason, for some of the surgeons in the trial practically never rejected cases and in consequence had to treat many adherent ulcers by the trial operations, including the two forms of resection. None the less it must be admitted that the manner in which the trial is organized prevents our making a completely valid comparison of the inherent risks of the three operations.

Findings on Follow-up

Subsequent Deaths.—Sixteen patients died subsequently, and Table I indicates how they were distributed in the various groups of cases. These deaths occurred months or years after discharge from hospital and were all due to intercurrent conditions apparently quite unrelated to the operation or the ulcer for which it was performed—in five cases to coronary thrombosis; in two cases to carcinoma of the bronchus; and in one case each to aortic valvular stenosis, bronchopneumonia, lobar pneumonia, carcinoma of the biliary tract, carcinoma of the kidney, chronic hepatitis, disseminated sclerosis, pancreatitis, and suicide.

Untraced Cases.—Of the 491 male patients believed to be surviving, four are at present untraced—two after gastrectomy in the trial and two after vagotomy and gastro-enterostomy in the rejected group (see Table I). The reason for our failure to follow them up has been the same in each instance—namely, a change of address—and despite our utmost efforts along the usual lines these four cases remain untraced.

Traced Cases.—Though we have partial follow-up data on most of the foregoing patients who died subsequently or became otherwise untraceable, it has seemed to us simpler to exclude these cases entirely from consideration in assessing the later results. The latter have been determined solely on the findings in the 360 male patients in the trial with whom we are still in contact, either at the follow-up clinics or, in the case of a number of recalcitrant defaulters, by special visits to their homes during May and June 1963.

Length of Follow-up and Mode of Presentation of Results

As the trial began in April 1959 and closed in August 1962 it will be apparent that the follow-up period has ranged from four years to one year, with a mean of just under two years. We have information about most of the patients at six months after operation and annually thereafter, so that it would be possible to assess the results at these intervals, but we have preferred in the first instance to make a composite statement based on the *latest follow-up findings available on each of the 360 traced male cases in the trial*. Later we give some data on the comparative results at different periods after operation.

Thorough assessment of the late results of operations for peptic ulcer is a complex process involving consideration of several factors—the frequency of symptoms due to alimentary dysfunction, the incidence of recurrent ulceration, the occurrence of disturbances of metabolism and haemopoiesis, and the overall fitness of the patients for work and enjoyment of life. It is common knowledge that many years may elapse before recurrent ulceration manifests itself, and anaemia may take a very long while to develop. Clearly our present survey of the results at a mean period of two years after operation does not enable us to obtain a fair measure of the incidence of either of these latter two complications. In fact, we are unable on the basis of our inadequate haematological data to make a worth-while report on the incidence of anaemia at this stage. As for recurrence of ulceration, our information, though complete to date, must be considered to provide an incomplete picture of the tendency to recurrence after these operations.

On the other hand, we believe that our survey does permit us to form a reliable impression of the functional and nutritional state of the patients after these various operations and to make valid comparisons. It is on these aspects of the late results that we shall mainly concentrate our attention in this communication.

Frequency of Symptoms due to Alimentary Dysfunction after Operation

The incidence of the various symptoms of this kind commonly encountered after the three trial operations is given in Table III. It will be seen that many of the symptoms, such as post-prandial epigastric fullness without vasomotor accompaniments, nausea, flatulence, food-vomiting, and bile-vomiting, were more or less equally common after the three operations. But with four symptoms—namely, heartburn, early dumping, late dumping, and diarrhoea—there was an obvious difference in the frequency after subtotal gastrectomy and after the other two operations. Early dumping and diarrhoea are of particular importance and are examined in detail.

TABLE III.—Symptoms Due to Disturbance of Alimentary Function After Operation

Symptom	After Vag. and G.E. (Percentage of about *122 Cases)	After Vag. and Antr. (Percentage of about *126 Cases)	After*Subtot. Gastr. (Percentage of about *112 Cases)
Epigastric fullness without vasomotor phenomena	37.2	36.0	39.4
Early dumping	11.5	13.7	20.4
Late dumping	2.5	4.0	1.0
Nausea	18.0	18.4	21.3
Food-vomiting	5.0	7.2	9.3
Bile-vomiting	10.7	12.8	14.7
Heartburn	16.7	12.0	5.6
Flatulence	18.3	22.4	17.6
Dysphagia	0.8	1.6	0.0
Diarrhoea	27.0	20.7	10.7

* The percentages are out of the total number of cases in which the particular symptom was elicited, which in some instances are a few less than the numbers indicated.

Early Dumping

Though the overall incidence of early dumping after subtotal gastrectomy was considerably higher than after vagotomy with either gastro-enterostomy or antrectomy (Table III), this difference was not statistically significant at the 5% level. If, however, the occurrence of the symptom is considered according to its severity (Table IV) a significant difference does emerge.

TABLE IV.—Early Dumping

Severity	After Vag. and G.E. (Percentage of 122 Cases)	After Vag. and Antr. (Percentage of 124 Cases)	After Subtot. Gastr. (Percentage of 108 Cases)
Very mild	7.4	11.3	10.2
Moderate	3.3	2.4	9.3
Severe	0.8	0.0	0.9
Total	11.5	13.7	20.4

Three grades of severity are recognized in this table, and these should be defined. By *very mild* is meant the patient did not volunteer information about it, for he had learnt to avoid the complaint completely by very slight restriction of the size of his meals, and it was only on careful interrogation that the defect was brought to light. *Moderate* implied that the symptom was freely mentioned by the patient and gave him a fair amount of trouble, which he could only partly obviate by dietetic or medical care. *Severe* indicated that the patient was considerably inconvenienced by the dumping to the extent of doubting whether the operation had been worth while.

It will be noted that a very mild degree of dumping was fairly common after all three operations; the slight differences

in incidence between them are not significant. Perhaps surprisingly, moderate and severe dumping did occur occasionally after the two vagotomy procedures as well as after gastrectomy, but, if both grades are taken together, the frequency was significantly greater ($P < 0.02$) after the latter operation.

Alteration of Bowel Habit

The simple statement of incidence of diarrhoea contained in Table III could be deceptive if not amplified. The effects of these operations on bowel habits are examined more comprehensively in Table V. In comparison with the pre-operative state three sorts of result have been recognized:

Unchanged (or costive), where bowel function has either not altered at all since operation or has shown a very slight tendency to constipation.

Slightly improved, which means that the motions are a trifle looser than before operation, and possibly a little more frequent—for example, the patient may find that, instead of having one very hard, difficult motion every two or three days as before operation, he now enjoys a perfectly easy normal bowel action with regularity every day. By no stretch of imagination could this change be described as a diarrhoea or in any way unpleasant. On the contrary it is usually regarded by the patient as one of the most agreeable effects of the operation.

Diarrhoea of varying degrees of severity, ranging from mild with three or four motions daily to more severe with five, six, or more stools in the 24 hours. In only a few of the patients who complained of actual diarrhoea has it been continuous or very frequent; much more usual has been *episodic* diarrhoea, where the symptoms have occurred in short attacks lasting perhaps a few hours or a day or so, and interspersed with long periods of normal bowel habits of several weeks' or months' duration. Indeed, it has often been difficult to decide on the relationship of the bouts of looseness to the operation. Where there has been a consistent correlation between the diarrhoea and some dietetic indiscretion or idiosyncrasy, such as excessive beer-drinking, particularly if similar attacks occurred before operation, we have ignored the episodes and classified the patient according to his basic bowel condition as "unchanged" or "improved." But in all other instances, unless the attacks were very infrequent, we have put the cases in the categories of "mild" or "severe episodic diarrhoea." Probably by so doing we have included some patients under these headings whose rare bowel disturbances were not attributable at all to their operation, but we preferred to frame our criteria too liberally in the recognition of post-operative diarrhoea, for we hoped that the presence of a group of cases treated by ordinary subtotal gastrectomy in our series would provide a valuable yardstick for comparison.

It will be seen from Table V that after all three operations between roughly a third and a half of the cases claim a slight improvement in the ease and regularity of their bowel actions. As regards diarrhoea the overall incidence according to the liberal criteria already described varied considerably, depending on the nature of the operation performed, being 27.0% and 20.7% after vagotomy with gastro-enterostomy and antrectomy respectively, but only 10.7% after gastrectomy—a difference that is statistically significant ($P < 0.01$). However, it is important to emphasize that these figures include very many patients with an extremely mild, usually intermittent form of

TABLE V.—*Bowel Habit After Operation*

Bowel Habit	After Vag. and G.E. (Percentage of 122 Cases)	After Vag. and Antr. (Percentage of 126 Cases)	After Subtot. Gastr. (Percentage of 112 Cases)
Unchanged or more costive	44.3	33.3	54.5
Slightly improved	28.7	46.0	34.8
Diarrhoea:			
Mild continuous	4.9	4.0	0.0
Mild episodic	15.6	11.1	9.8
Mild (total)	20.5	15.1	9.8
Severe continuous	0.8	1.6	0.9
Severe episodic	5.7	4.0	0.0
Severe (total)	6.5	5.6	0.9
All forms	27.0	20.7	10.7
Total	100.0	100.0	100.0

looseness, which certainly constitutes no inconvenience to them and is usually regarded as a preferable state of affairs to the chronic constipation that often beset them before operation. If one considers only the cases of more severe diarrhoea the incidence is very much lower—6.5% and 5.6% after vagotomy with gastro-enterostomy and antrectomy respectively, but only 0.9% after subtotal gastrectomy—a difference that is just significant at the 5% level. Even here, owing to the fact that the diarrhoea was often confined to short attacks with long intervals of freedom between them, it caused less disturbance to the patient than might have been expected. But some of the patients found it to be definitely incapacitating while present—two after each of the vagotomy operations and one after gastrectomy, a difference that is not statistically significant.

Inquiry was also made of any *change in the character of the stools* after operation. As for *consistency*, 21.0% after vagotomy and gastro-enterostomy, 12.6% after vagotomy and antrectomy, and 5.4% after subtotal gastrectomy stated that the stools were on occasion frankly liquid. Regarding *colour* of the motions, many patients were very vague and uncertain on this point, but approximately 30% after each of the three operations thought that the stools were paler than before operation.

Clearly in respect of bowel function subtotal gastrectomy enjoys an advantage over the two vagotomy operations, the results of which are unquestionably marred to a slight extent by the occurrence of post-operative diarrhoea.

State of Patients' Weight after Operation

In estimating the effect of gastric operations on the patients' nutritional state a difficulty is encountered because these patients have often been much below their normal weight before operation, so that a simple comparison of pre- and post-operative weights could be misleading. We have preferred to compare the post-operative weight with the optimal weight for a patient of the same age, sex, and height, as worked out on Life Assurance Tables. Employing this method on the 284 trial patients who attended the follow-up clinics for review where accurate measurements could be made (Table VI), but

TABLE VI.—*State of Patients' Weight Compared with Optimum Weight Given in Life Assurance Tables*

Operation	Mean Percentage Below Optimal Weight, with Standard Error
Vagotomy and G.E. (98 cases)	1.8 ± 1.1
Vagotomy and Antr. (104 cases)	3.9 ± 1.0
Subtotal gastrectomy (82 cases)	6.1 ± 1.2

N.B. 1% of the weight of an 11-stone man is about 1½ lb.

not on those who had to be traced to their homes, it will be seen that the mean percentage below optimal weight was significantly greater after gastrectomy than after vagotomy and gastro-enterostomy or both types of vagotomy operation together. The difference between the mean percentage below optimal weight after gastrectomy and that after vagotomy with antrectomy just fails to be statistically significant.

Overall Assessment of Patients' Functional Condition and Capacity for Work and Enjoyment of Life

For this purpose we have used a slight modification of the well-known Visick classification, which we have found extremely helpful (Table VII). It should be explained, however, that this system of grading does not directly concern itself with nutritional disturbances, anaemia, or even recurrence, though these ill-effects are indirectly considered in so far as they impair function or reduce the patients' fitness for work or pleasure, which, presumably, is what really counts. The results obtained in our cases are shown in Table VIII. From the practical point of view categories I and II can both be regarded as highly satisfactory and are therefore grouped together in this

table. It will be seen that gastrectomy can point to rather more cases in these top two categories than can the other two operations and fewer in category IV, but these differences are not statistically significant. We must reckon, therefore, that

TABLE VII.—Overall Grading of Functional Results (Based on Visick's Classification)

Excellent	Absolutely no symptoms. Perfect result.
Very good	Patient considers result perfect, but interrogation elicits mild occasional symptoms easily controlled by minor adjustments of diet.
Satisfactory	Mild or moderate symptoms not controlled by care, causing slight discomfort; but doctor and patient satisfied with result, which does not interfere with life or work.
Unsatisfactory	Moderate or severe symptoms or complications which interfere considerably with work or enjoyment of life; patient or doctor not satisfied with result.

TABLE VIII.—Overall Grading of Functional Results at Latest Follow-up

Result	After Vag. and G.E. (Percentage of 119 Cases)	After Vag. and Antr. (Percentage of 126 Cases)	After Subtot. Gastr. (Percentage of 112 Cases)
Excellent (no symptoms)	57.1	61.1	54.4
Very good (virtually no symptoms)	17.7	18.2	25.9
Satisfactory (mod. symptoms, patient satisfied)	17.6	15.1	17.0
Unsatisfactory (severe symptoms, patient dissatisfied)	7.6	5.6	2.7

none of the three operations has so far shown a definite superiority as regards the overall functional condition of the patients.

The category IV cases are of special interest in that they represent the failures of surgery. It is pertinent to examine the reasons for deeming operation to have failed in these cases and to discover why more patients were relegated to this category after the two lesser operations than after subtotal gastrectomy—was it due to a higher incidence of recurrent ulceration or to other unfavourable developments? The causes of failure in each of the category IV cases have therefore been determined (Table IX). In most instances a combination of sequelae was responsible for regarding the operation as having failed, and in respect of each patient these are listed in order of relative importance in contributing to the downgrading. It will be seen that the major factor contributing to the greater number of failures after vagotomy with antrectomy, and especially with gastro-enterostomy, has been, not a higher incidence of recurrent ulceration, but the more frequent occurrence of disabling symptoms due to disturbance of alimentary function, such as bile-vomiting, postprandial epigastric fullness, heartburn, flatulence, and diarrhoea.

TABLE IX.—Causes of Failure of Operation in 19 Trial Patients

Case and Nature of Operation	Sequelae Responsible for Placing Case in Category IV (unsatisfactory)
No. 1 Vag. and G.E.	Proved recurrent ulcer, bile-vomiting, nausea, flatulence, heartburn
" 2 " "	Suspected recurrent ulcer, dumping
" 3 " "	Bile-vomiting, flatulence, heartburn, diarrhoea
" 4 " "	Bile-vomiting, flatulence, heartburn, diarrhoea
" 5 " "	Bile-vomiting, nausea, epigastric fullness, food-vomiting
" 6 " "	Epigastric fullness, nausea, bile-vomiting, diarrhoea
" 7 " "	Epigastric fullness, flatulence, bile-vomiting
" 8 " "	Epigastric fullness, dumping, nausea, bile-vomiting, diarrhoea
" 9 " "	Nausea, epigastric fullness, dumping, flatulence, diarrhoea
" 10 Vag. and Antr.	Suspected recurrent ulcer, bile-vomiting, nausea, epigastric fullness
" 11 " "	Bile-vomiting, epigastric fullness, heartburn
" 12 " "	Bile-vomiting, nausea, epigastric fullness, dumping
" 13 " "	Bile-vomiting, nausea, epigastric fullness, flatulence
" 14 " "	Bile-vomiting, nausea, diarrhoea
" 15 " "	Bile-vomiting, nausea, epigastric fullness, dumping, heartburn, flatulence
" 16 " "	Bile-vomiting, epigastric fullness, flatulence, diarrhoea
" 17 Subtot. Gastr.	Proved recurrent ulcer, bile-vomiting, epigastric fullness, flatulence
" 18 " "	Suspected recurrent ulcer, epigastric fullness, dumping, flatulence, diarrhoea
" 19 " "	Nausea

We thought it would also be interesting to observe whether the overall grading of the functional results varied with the length of time that had elapsed since operation. Accordingly the Visick grading has been applied to patients at six months, one year, two years, and three years after operation for each of the three procedures on trial (see Tables X, XI, XII, and XIII). Though subtotal gastrectomy seems to maintain its high proportion of excellent and very good results and its negligible number of unsatisfactory results slightly better than the other two operations, the variations are too small to be of significance.

TABLE X.—Overall Functional Results at Six Months After Operation

Visick Scale	After Vag. and G.E. (Percentage of 116 Cases)	After Vag. and Antr. (Percentage of 111 Cases)	After Subtot. Gastr. (Percentage of 91 Cases)
I }	79.1	80.2	85.1
II }	15.4	16.8	12.6
III }	5.5	3.0	2.3
IV }			

TABLE XI.—Overall Functional Results at One Year After Operation

Visick Scale	After Vag. and G.E. (Percentage of 114 Cases)	After Vag. and Antr. (Percentage of 102 Cases)	After Subtot. Gastr. (Percentage of 89 Cases)
I }	80.8	79.6	82.8
II }	11.0	16.3	14.9
III }	8.2	4.1	2.3
IV }			

TABLE XII.—Overall Functional Results at Two Years After Operation

Visick Scale	After Vag. and G.E. (Percentage of 91 Cases)	After Vag. and Antr. (Percentage of 79 Cases)	After Subtot. Gastr. (Percentage of 63 Cases)
I }	75.6	82.3	79.4
II }	17.7	12.7	19.0
III }	6.7	5.0	1.6
IV }			

TABLE XIII.—Overall Functional Results at Three Years After Operation

Visick Scale	After Vag. and G.E. (Percentage of 40 Cases)	After Vag. and Antr. (Percentage of 39 Cases)	After Subtot. Gastr. (Percentage of 30 Cases)
I }	71.8	74.4	80.0
II }	17.9	15.4	16.7
III }	10.3	10.2	3.3
IV }			

Recurrent Ulceration

Though suspicion of recurrent ulceration has at some stage been aroused in a number of patients in the trial by the occurrence of abdominal pain not unlike that experienced before operation, or by the development of a small haematemesis or melaena, in the majority of these cases this tentative diagnosis has not been confirmed by radiological or gastroscopic investigation, and the symptoms have subsequently subsided. The proportion of patients in whom suspicion still lingers at their follow-up attendance or who have been definitely established to have recurrent ulcers is quite small, as shown in Table XIV. It is indeed gratifying that the overall incidence of further ulceration remains so far so low, but these figures are obviously too small to bear any detailed comparative examination.

TABLE XIV.—Recurrent Ulceration at Latest Follow-up (1-4 Years)

Presence of Ulceration	After Vag. and G.E. (122 Cases)	After Vag. and Antr. (126 Cases)	After Subtot. Gastr. (112 Cases)
Suspected	3 cases	1 case	2 cases
Proved	2 { 1 by x-ray 1 at lap.	0	1 case at lap.
Total	5 cases	1 case	3 cases

Conclusions

The interim nature of this report must be emphasized. Clearly no final comprehensive verdict can be reached at this early stage regarding the relative worth of these three operations in the elective treatment of duodenal ulcer, but the following conclusions seem justified.

1. Because of the way in which the trial is conducted, the complete absence of operative mortality almost certainly does not accurately reflect the relative hazards of the three operations if used exclusively, but it shows that, with a certain amount of selection, even resection procedures can in the hands of experienced gastrectomists be remarkably safe at the present time.

2. There is significantly less nutritional upset after vagotomy and gastro-enterostomy than after subtotal gastrectomy. In its effect on nutrition vagotomy and antrectomy apparently occupies a position midway between these two operations.

3. With the exception of early dumping, diarrhoea, and heartburn, most of the common symptoms due to post-operative disturbance of alimentary function occurred with roughly equal frequency after the three operations. Early dumping was encountered a good deal more often after subtotal gastrectomy than after vagotomy and gastro-enterostomy or antrectomy; overall, the difference was not statistically significant, but if only the moderate and severe grades of the symptoms are considered there is a significant difference. On the other hand, diarrhoea was much more frequent after vagotomy, particularly with gastro-enterostomy, than after subtotal gastric resection, and this latter difference was significant. It is only fair to add that the number of patients inconvenienced by post-vagotomy diarrhoea, which was often episodic, very mild, and infrequent, was quite small.

4. So far the incidence of proved or strongly suspected recurrent ulceration, which has amounted to only 9 instances in the 360 traced cases in the trial and occurred after all three operations, is too small to permit of any deductions concerning the relative effectiveness of the different methods in curing the ulcer diathesis.

5. If the overall functional state and general well-being of the patients are assessed by the Visick system of grading, the results of subtotal gastrectomy seem slightly better than in those of either of the other two operations, and especially of vagotomy and gastro-enterostomy, but these differences are not statistically significant. The reason for the greater number of failures after the latter two procedures is not a higher incidence of recurrent ulceration but the more frequent development of symptoms due to alimentary dysfunction, such as bile-vomiting, postprandial epigastric fullness, flatulence, heartburn, and diarrhoea. It would be reasonable to speculate whether fewer troubles of this kind might not have been encountered if

pyloroplasty had replaced gastro-enterostomy as the drainage operation, if a Billroth I reconstruction had replaced that of Polya after antrectomy, and if selective vagotomy had been used instead of total abdominal vagotomy as the method of denervation. The merits of these alternative techniques are now under investigation.

Summary

Provided no special contraindication existed, such as a very adherent posterior-wall ulcer, cases coming to elective surgery were allotted in random fashion at laparotomy to the three methods under trial. Between 1959 and 1962 360 patients were thus distributed more or less evenly to the trial operations. There were no operative deaths, but 13 subsequent deaths occurred, unrelated to operation; two patients were untraced. The results in this study were determined on the latest follow-up findings available on each case, which ranged from one to four years. At follow-up patients were usually interviewed "blindly" by a small panel.

Recurrence has been infrequent to date after all three operations, making worth-while comparison impossible.

The incidence of most "*post-gastrectomy*" syndromes was roughly the same after the three operations. But early dumping was significantly more common after subtotal gastrectomy, and diarrhoea (usually mild and episodic) after vagotomy, especially with gastro-enterostomy.

Weight loss was significantly greater after subtotal gastrectomy than after vagotomy and gastro-enterostomy; vagotomy and antrectomy occupied an intermediate position in this respect.

Grading of the *overall results* on the Visick scale showed no significant difference in the outcome after the three operations.

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Bowel Habit After Vagotomy and Gastrojejunostomy

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The surgical treatment of chronic duodenal ulcer continues to pose many difficult and as yet unsolved problems. Chief among these is the choice of procedure which meets the three main requirements of low mortality rate, low recurrence rate, and freedom from troublesome sequelae such as impaired nutrition, dumping symptoms, and bilious vomiting. No gastric operation is entirely blameless in all respects, but vagotomy with a drainage procedure now finds favour with many surgeons who

hold that it provides the best combination of these aims. However, vagotomy has been criticized as leading to an allegedly high incidence of diarrhoea, but, despite many references to this complication, disagreement continues regarding its cause

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