

Papers and Originals

Five- to Eight-year Results of Leeds/York Controlled Trial of Elective Surgery for Duodenal Ulcer*

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Surgical literature abounds in articles describing the results of the various operations currently or formerly in vogue for the treatment of peptic ulcer. But the value of most of these reports in assessing the comparative merits of different operative procedures has been much reduced by the circumstances of ordinary clinical practice, whereby any individual surgeon tends to favour one particular method and to reserve other methods to meet what he deems to be the special requirements of a few of his patients. The consequence is that any effort he may make to contrast the outcome of different operations in his hands is apt to be invalidated by personal bias and by the fact that he is comparing dissimilar groups of patients. Potentially fallacious also are the comparisons often made between the results of various operations performed by different surgeons in different centres, for there may be considerable variation in the methods of selecting patients for operation in these centres and in the criteria adopted for assessing the results.

Ideally what is required to make reasonably accurate comparisons of clinical results is a properly controlled prospective therapeutic trial in which patients are randomly allotted to different types of operation, performed by the same group of surgeons throughout, the results all being assessed "blindly" by the same group of investigators. But planned studies of this kind are excessively rare. In this article, however, we are able to report the findings of such a controlled trial of several different types of elective operation for duodenal ulcer which we have been running in Leeds and York for the past nine years (Goligher, Pulvertaft, and Watkinson, 1964; Goligher, Pulvertaft, and Franz, 1967).

Operative Procedures Under Trial

These were three in number:

Vagotomy and Gastroenterostomy (Fig. 1 A).—The vagotomy was a total subdiaphragmatic division of the vagal trunks, and the gastroenterostomy 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 (Fig. 1 B).—Again the vagotomy was a total abdominal division of the vagi. The antrectomy was achieved by what was judged at laparotomy to be a distal third or half gastrectomy, invariably including the ulcer and completed by the Polya method.

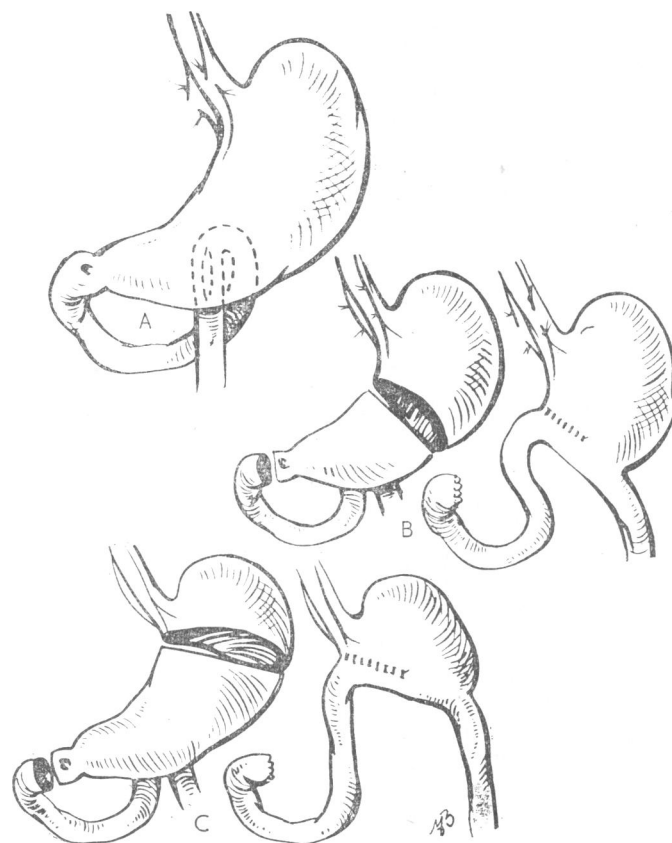


FIG. 1.—The three types of operation used in the Leeds/York controlled trial. A, Vagotomy and posterior gastroenterostomy. B, vagotomy and antrectomy—that is, distal third or half resection, always with Polya reconstruction. C, Standard subtotal gastrectomy—that is, distal two-thirds or three-quarters resection, always with Polya reconstruction.

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Ordinary So-called Subtotal Gastrectomy (Fig. 1 C).—This was a standard, distal two-thirds or three-quarters resection, always of Polya type and removing the ulcer.

One operation unfortunately *not* included was vagotomy and pyloroplasty, and we are unable to provide the sort of exact comparative data about the results of this procedure which would otherwise have been possible. However, in another publication (Goligher *et al.*, 1968) we do make some comments on our more recent experience with vagotomy and pyloroplasty in comparison with the results obtained with our trial operations.

Selection of Patients for Trial

We restricted ourselves to cases undergoing "cold" or elective surgical treatment for duodenal ulcer. The details of the method of randomization of patients to the trial operations have been described elsewhere (Goligher *et al.*, 1964), but we would like to stress that an "escape clause" was provided, allowing surgeons to reject cases—for example, with very adherent posterior wall ulcers or in a poor nutritional state—if in their opinion it was in the patient's interests to do so. Though the surgeon was able in this way to reject patients either before or at the actual laparotomy, it must be emphasized that once he decided to enter a patient in the trial the choice of operation was out of his control and he had no means of knowing in advance which of the three operations he would be given.

Assessment of Results

The assessment of results has been conducted yearly at special follow-up clinics at which the patient was interviewed by a small panel of clinicians who were not allowed to know which operation had been performed till after they had recorded their findings and verdict regarding the patient's grading, thus avoiding any bias from preconceived ideas of the relative advantages and disadvantages of the different operative methods.

Findings in Male Patients

The trial was open for the acceptance of new patients from April 1959 to midsummer 1962. During that period of about three years 634 cases passed through our records. These comprised 507 men and 127 women, and the results in the two sexes are considered separately.

The disposal of the 507 male patients in and out of the trial is shown in Table I. Just over one-quarter of them—132—were rejected on various grounds. Of the 375 patients accepted into

TABLE I.—Disposal of 507 Male Duodenal Ulcer Patients In and Out of Trial

	Accepted into Trial and Treated by:			Rejected from Trial (Mostly Treated by Vag. & G.E.)
	Vag. & G.E.	Vag. & Antr.	Subtot. Gastr.	
No. in each group ..	126	132	117	132
Operative deaths ..	0	0	0	0
Subsequent deaths ..	4	11	3	10
Untraced cases ..	3	5	7	2
Traced cases ..	119	116	107	120

Vag. & G.E. = Vagotomy and gastroenterostomy. Vag. & Antr. = Vagotomy and antrectomy. Subtot. Gastr. = Subtotal gastrectomy.

the trial it will be noted that the 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.

The *operative mortality* is indicated in Table I, from which it can be seen that there was no operative deaths among these 507 men. The absence of immediate mortality in the 126 accepted patients treated by vagotomy and gastroenterostomy

(and in the 96 rejected patients having the same operation) is not perhaps surprising, for this is well known to be a very safe procedure. But in the 117 trial patients submitted to gastrectomy and the 132 trial patients subjected to vagotomy and antrectomy (both of which operations carry the risks of duodenal stump closure) it is indeed somewhat remarkable. Undoubtedly some of the credit for the avoidance of fatalities 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 contributing to the trial practically never rejected cases, and in consequence had to treat many adherent ulcers by the trial operation, including the two forms of resection.

Subsequent Deaths.—Twenty-eight patients died subsequent to discharge from hospital (Table I), all from intercurrent conditions, such as coronary thrombosis, cerebrovascular accidents, bronchopneumonia, that were unrelated to the original ulcer or the operation used in its treatment.

Untraced Cases.—Despite every effort to make the follow-up complete, 17 patients, believed to be surviving, could not be traced owing to changes of address or migration overseas (Table I).

Traced Cases.—Though we have partial follow-up data on most of the patients who subsequently died or became otherwise untraceable, it has seemed to us simpler to exclude these cases entirely from consideration in assessing the late results. The latter have accordingly been determined solely on the findings in the 462 patients with whom we are still in contact, shown in the bottom row of Table I, who have all been followed up for a minimum of five years and a maximum of eight years.

Symptoms Due to Alimentary Dysfunction

These are the so-called "postgastrectomy" or "postgastric operation" syndromes.² Their incidence in the three trial groups is given in Table II, which also shows their frequency in rejected patients treated by vagotomy and gastroenterostomy,

TABLE II.—Frequency of Symptoms Due to Disturbances of Alimentary Function After Operation at Latest Follow-up (Five to Eight Years Postoperatively)

Symptom	Vag. & G.E. in Trial (% of About* 119 Cases)	Vag. & Antr. in Trial (% of About* 116 Cases)	Subtot. Gastrect. in Trial (% of About* 107 Cases)	Vag. & G.E. Rejected (% of About* 96 Cases)
Epigastric fullness ..	40.2	36.3	36.5	37.7
Early dumping ..	17.9	8.6	21.5	12.9
Late dumping ..	6.0	4.3	0.9	5.9
Nausea ..	12.8	17.2	23.4	12.8
Food vomiting ..	4.3	9.6	5.6	4.3
Bile vomiting ..	14.5	13.8	13.1	10.6
Heartburn ..	19.8	15.7	8.4	16.3
Flatulence ..	17.9	22.8	19.8	19.6
Dysphagia ..	1.1	0.0	0.0	1.3
Reflux ..	4.0	7.0	4.3	9.7
Diarrhoea ..	26.3	23.2	6.5	29.1

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

who make up the majority of the latter group. It will be seen that, contrary to popular belief, these complaints were certainly not the monopoly of gastrectomized patients. Most of them, indeed, occurred almost equally often after the three types of operation or were more common after the vagotomy operations—for example, epigastric fullness after meals, late dumping, bile vomiting or food vomiting, and flatulence. Even early dumping, generally considered to be a *bête noire* of gastrectomy,

² While most of these symptoms will be readily understood, the term "dumping" is used differently by different authors. We would define early dumping as a sensation of epigastric fullness accompanied by a feeling of faintness, sweating, or palpitation occurring immediately after a meal, and late dumping as a feeling of faintness and weakness coming on an hour or more after food, probably due to hypoglycaemia.

was recorded not uncommonly after vagotomy and gastroenterostomy, though for some inexplicable reason it occurred significantly less frequently after vagotomy and antrectomy. Furthermore, analysis of the severity of the dumping after gastrectomy, as after the other operations, shows that it was usually relatively mild. It would certainly be wrong to picture patients after subtotal resection as often being crippled by this complaint. It is particularly worthy of comment that late dumping and heartburn were significantly less common after gastrectomy than after vagotomy and gastroenterostomy in the trial.

Alteration of Bowel Habit

The exact frequency of disturbance of bowel function after vagotomy has evoked much controversy, and the simple statement of incidence of diarrhoea contained in Table II requires amplification. The effects of the three operations on bowel habit are examined more comprehensively in Table III. In

TABLE III.—*Bowel Habit Five to Eight Years After Operation*

Bowel Habit	Vag. & G.E. in Trial (% of 118 Cases)	Vag. & Antr. in Trial (% of 112 Cases)	Gastrectomy in Trial (% of 107 Cases)	Vag. & G.E. Rejected (% of 96 Cases)
No change ..	42.3	39.3	57.0	39.6
Improved ..	31.4	37.5	36.5	31.3
Diarrhoea ..	26.3	23.2	6.5	29.1

comparison with the preoperative state three sorts of result after operation have been recognized:

Unchanged (or more costive) where bowel function has either not altered at all since operation or has tended towards constipation.

Improved, which means that the motions have become 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 formed or slightly soft motion with regularity once or twice a day. By no stretch of imagination could this state of affairs be described as a diarrhoea or in any way unpleasant. On the contrary it is normally regarded by the patient as one of the most agreeable effects of the operation.

Diarrhoea of Varying Degrees of Severity, ranging from three or four softer liquid motions daily to eight to ten or more stools of liquid consistency in the 24 hours. Two features particularly characterized the diarrhoea in these cases. One was the great *urgency* of the call to stool often experienced by the patient, so that if he did not get to the lavatory very quickly he might not be able to control the motion. The second feature was that the diarrhoea was usually not continuous but *episodic*, the symptoms occurring in short attacks lasting perhaps a few hours or a day or so, interspersed with periods of normal bowel habits varying from a few days to several weeks or even two to three months.

In *grading patients according to the severity of their diarrhoea* we have taken into account not only the frequency and urgency of stools and the length of the episode and the intervals of freedom, but also—and more important—the amount of physical discomfort or inconvenience suffered by the patient, and whether he was incapacitated from following his work during attacks.

It will be seen from Table III that, after all three operations in the trial and after vagotomy and gastroenterostomy in rejected cases, between a third and just over one-half of the patients reported that bowel habit was quite unchanged, and a slightly smaller proportion claimed with some pride a slight improvement in the ease and regularity of their motions. As regards actual diarrhoea the overall incidence varied considerably according to the operation performed, being 26.3% after vagotomy and gastroenterostomy in the trial and 23.2% after vagotomy and antrectomy, but only 6.5% after subtotal gastrectomy—differences which are statistically significant. However, it is important to emphasize that these figures include

many patients with an extremely mild, usually episodic form of looseness (Table IV), which 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 (Table IV) the incidence is very much lower—5.1 and 2.7% after vagotomy and gastroenterostomy in the trial and vagotomy and antrectomy respectively (and 6.2% after vagotomy and gastroenterostomy in rejected cases), but only 0.9% after gastrectomy, differences which for the most part are not statistically significant.

TABLE IV.—*Severity and Type of Diarrhoea Five to Eight Years After Operation*

Severity	Vag. & G.E. (% of 118 Cases)	Vag. & Antr. (% of 112 Cases)	Subtot. Gastr. (% of 107 Cases)	Vag. & G.E. Rejected (% of 96 Cases)
Mild or moderate	21.2	20.5	5.6	22.9
Episodic ..	20.4	17.8		21.9
Continuous	0.8	2.7		1.0
Severe ..	5.1	2.7	0.9	6.2
Episodic ..	5.1	2.7	0.0	6.2
Continuous	0.0	0.0	0.9	0.0
All forms of diarrhoea ..	26.3	23.2	6.5	29.1

Obviously in respect of bowel function subtotal gastrectomy enjoys an advantage over the two vagotomy operations, the results of which are unquestionably marred to some extent by the occurrences of postoperative diarrhoea.

Patients' Weight After Operation

In gauging the nutritional effects of gastric surgery one difficulty encountered is that immediately before operation the patient's weight has often been much below his normal weight, so that a straightforward comparison of preoperative and postoperative weights could be misleading. For this reason we have elected to contrast the postoperative weight with the optimal weight for a patient of the same age, sex, and height, as worked out from the life assurance tables (Table V). It will be seen that the mean weight five to eight years after operation was not significantly different from the optimal weight in the cases submitted to vagotomy and gastroenterostomy (either in the trial or in rejected patients), but was significantly lower than the optimal weight in cases treated by vagotomy and antrectomy or subtotal gastrectomy. There seems to be no doubt, therefore, that gastric resection, whether in the form of a classical high gastrectomy or as an antrectomy in combination with vagotomy, impairs nutrition more severely than does vagotomy and a drainage operation.

TABLE V.—*Patients' Weight Five to Eight Years After Operation Compared with Optimal Weight as Given in Life Assurance Tables*

Operation Performed	No. of Cases	Recorded Weight in lb. (± 1 S.E.)		Mean Change in Weight after Operation		
		Mean Optimal	Mean Actual 5-8 Years after Operation	lb.	% of Opt. Wt.	P
Vag. & G.E. in trial ..	112	152.8 \pm 1.1	148.9 \pm 2.1	-3.9	-2.6	>0.1
Vag. & Antr. in trial ..	109	155.4 \pm 0.9	144.5 \pm 1.96	-10.9	-7.0	<0.0001
Subtot. Gastr. in trial ..	100	154.8 \pm 1.3	144.8 \pm 2.4	-10.0	-6.5	<0.001
Vag. & G.E. rejects ..	87	150.8 \pm 1.3	151.8 \pm 1.0	+1.0	+0.7	>0.8

Occurrence of Anaemia or Depletion of Vitamin B₁₂

The tendency of certain patients after gastric surgery to exhibit haematological abnormalities due to impaired absorption of iron or vitamin B₁₂ is well recognized, and it would

have been interesting to conduct a comprehensive survey of our cases from this point of view. Unfortunately administrative difficulties handicapped us in so doing, and we have regretfully to report that the data on this aspect of our patients' condition are too incomplete to be worth recording.

Incidence of Recurrent Ulceration

Though suspicion of recurrent ulcer has at some stage been aroused in a number of patients in the trial and in the reject groups, in the majority of instances this tentative diagnosis has not been confirmed by radiological or gastroscopic examination (or in some cases gastric analysis to show incomplete vagotomy), and the symptoms have subsequently subsided. The proportion of patients in whom any suspicion still lingers at the time of the latest follow-up or who have been definitely established by laparotomy to have recurrent ulcers is quite small (Table VI). Particularly gratifying is our finding that the incidence of recurrence five to eight years after vagotomy and gastroenterostomy is relatively low (7–10%), certainly if the very dubious cases are excluded. One has to admit that further ulceration could still occur after this operation on longer follow-up, but probably the main incidence has not been revealed. There is a lesser incidence of recurrence after subtotal gastrectomy (2–5%), and from other extensive follow-up studies which we have conducted on gastrectomy patients (Goligher *et al.*, 1956; Pulvertaft, 1964), it seems unlikely that this figure will now increase. The frequency of recurrent ulcer after vagotomy and antrectomy (2–6%) is almost identical with that after subtotal gastrectomy without vagotomy.

TABLE VI.—*Recurrent Ulceration at Latest Follow-up (Five to Eight Years After Operation)*

Degree of Certainty	Vag. & G.E. (119 Cases)	Vag. & Antr. (116 Cases)	Subtot. Gastr. (107 Cases)	Vag. & G.E. Reject (96 Cases)
Proved	3; lap.	0	1; lap.	3; lap.
Suspected*	2 melaena	1 melaena	1 melaena	4 rec. pain
Very dubious*	2 rec. pain	1 rec. pain	3 rec. pain	3 rec. pain
	3 rec. pain	4 rec. pain		
Total	7 (10)	2 (6)	2 (5)	7 (10)

lap. = Laparotomy. rec. = Recurrent.
* All these cases were x-ray negative.

Overall Assessment of Patient's Fitness

For this purpose we have used a slight modification of the well-known Visick (1948) classification, which recognizes essentially four categories of result (Table VII). From the practical point of view categories I and II can both be regarded as highly satisfactory, and they are grouped together in our analysis. Category IV comprises the failures. It should be explained that this system of grading does not directly concern itself with postoperative disturbances of nutrition or anaemia, though these ill-effects are indirectly considered in so far as they may impair function or reduce the patient's fitness for work or pleasure, which presumably is what really counts. We have arbitrarily placed patients with proved recurrent ulcer permanently in category IV, regardless of the success of subsequent surgical treatment, and have likewise categorized those

TABLE VII.—*Overall Grading of Results (Modified Visick Classification)*

Category	Definition
I. Excellent	Absolutely no symptoms. Perfect result
II. Very good	Patient considers result perfect, but interrogation elicits mild occasional symptoms easily controlled by minor adjustment to diet
III. Satisfactory	Mild or moderate symptoms not controlled by care, causing some discomfort, but patient and surgeon satisfied with result, which does not interfere seriously with life or work
IV. Unsatisfactory	Moderate or severe symptoms or complication which interfere considerably with work or enjoyment of life; patient or doctor dissatisfied with result. Includes all cases with proved recurrent ulcer and those submitted to further operation, even though the latter may have been followed by considerable symptomatic improvement

individuals who have required reoperation for bilious vomiting, dumping, etc., even though they may have secured a reasonably good result after their second operation.

Applying this classification to our cases at their latest follow-up five to eight years after operation (Table VIII), we have shown that subtotal gastrectomy has fewer patients in category IV than any other operation but this difference is significant only in comparison with vagotomy and gastroenterostomy in reject cases. Both gastrectomy and vagotomy and antrectomy can also point to more cases in categories I and II than can either of the vagotomy and gastroenterostomy groups, but these differences are not statistically significant at the usually accepted level.

TABLE VIII.—*Visick Grading of Functional Results at Latest Follow-up Five to Eight Years After Operation*

Category	Vag. & G.E. (% of 119 Cases)	Vag. & Antr. (% of 116 Cases)	Subtot. Gastrect. (% of 107 Cases)	Vag. & G.E. Reject (% of 96 Cases)
I	44	50	49	46
II	26	28	28	27
III	19	14	17	10
IV	11	8	6	17

The category IV cases are of special interest in that they represent the failures of surgery—though it must be admitted that the dividing line between category III and IV is sometimes very difficult to draw. It is pertinent to examine the reasons for regarding operations as having failed in each of the category IV cases after the three operations. The 13 category IV cases after vagotomy and gastroenterostomy in the trial are listed in Table IX. Though the cause of failure in six of these patients was proved or strongly suspected recurrent ulcer, in seven it was the occurrence in severe form of one or more of the various symptoms due to disturbances of alimentary function, such as epigastric fullness, nausea, bile vomiting, or diarrhoea. The distribution of the 16 category IV cases after vagotomy and gastroenterostomy in reject patients (Table X) as between those having recurrent ulcer and those suffering from severe post-gastric operation syndromes was similar, with seven in the former group and nine in the latter. In the nine category IV cases after vagotomy and antrectomy (Table XI) and seven category IV cases after subtotal gastrectomy (Table XII) there were only two in each group with recurrent ulcer, the remainder having been downgraded mostly because of disorders of

TABLE IX.—*Thirteen Category IV Cases After Vagotomy and Gastroenterostomy in the Trial*

1 } Recurrent ulcer leading to re-laparotomy—gastrectomy	{ (IV)*
2 } Recurrent ulcer leading to re-laparotomy—gastrectomy	{ (IV)*
3 } Recurrent ulcer leading to re-laparotomy—gastrectomy	{ (IV)*
4 } Severe melaena, x-ray and gastroscopy negative for recurrent ulcer	
5 } Persisting pain, x-ray and gastroscopy negative for recurrent ulcer	
6 } Early dumping, flatulence, nausea, and persistent pain, but x-ray negative for recurrent ulcer	
7 } Bile vomiting, epigastric fullness, and dumping—conversion to pyloroplasty	{ (III)*
8 } Bile vomiting, epigastric fullness, and dumping—conversion to pyloroplasty	{ (IV)*
9 } Early dumping, epigastric fullness, heartburn, and bile vomiting	
10 } Early dumping and severe diarrhoea	
11 } Severe diarrhoea	
12 } Severe diarrhoea	
13 } Severe diarrhoea	

* Indicates what would be the patient's Visick grading since reoperation if he were not by convention retained in category IV.

TABLE X.—*Sixteen Category IV Cases After Vagotomy and Gastroenterostomy Rejects from Trial*

1 } Recurrent ulcer, proved at laparotomy—gastrectomy	{ (II)*
2 } Recurrent ulcer, proved at laparotomy—gastrectomy	{ (III)*
3 } Recurrent ulcer, proved at laparotomy—gastrectomy	{ (IV)*
4 } Persistent pain, x-ray and gastroscopy negative for recurrent ulcer	
5 } Persistent pain, x-ray and gastroscopy negative for recurrent ulcer	
6 } Persistent pain, x-ray and gastroscopy negative for recurrent ulcer	
7 } Bile vomiting, epigastric fullness, and dumping—conversion to pyloroplasty	{ (III)*
8 } Bile vomiting, epigastric fullness, and dumping—conversion to pyloroplasty	{ (IV)*
9 } Bile vomiting, epigastric fullness, and dumping—conversion to pyloroplasty	{ (IV)*
10 } Bile vomiting, epigastric fullness, and dumping—conversion to pyloroplasty	{ (IV)*
11 } Bile vomiting, epigastric fullness, and dumping—conversion to pyloroplasty	{ (IV)*
12 } Bile vomiting, epigastric fullness, and dumping—conversion to pyloroplasty	{ (IV)*
13 } Nausea, epigastric fullness and dumping, and diarrhoea	{ (III)*
14 } Severe diarrhoea	
15 } Severe diarrhoea	
16 } Severe diarrhoea	

* Indicates what would be the patient's Visick grading since reoperation if he were not by convention retained in category IV.

alimentary function; but it is to be noted that two of the patients in category IV after gastrectomy were so graded because of the postoperative development of pulmonary tuberculosis (Table XII).

TABLE XI.—Nine Category IV Cases After Vagotomy and Antrectomy in the Trial

1	Severe melaena; x-ray and gastroscopy negative for recurrent ulcer, but insulin test = incomplete vagotomy	(I)* (IV)* (II)* (II)*
2	Persistent pain, but x-ray and gastroscopy negative for recurrent ulcer	
3	Bile vomiting, epigastric fullness, and dumping—conversion to Roux-en-Y anastomosis	
4		
5		
6	Severe diarrhoea—conversion to Billroth I anastomosis	
7		
8		
9	Nausea, epigastric fullness and dumping, flatulence, and bile vomiting	

* Indicates what would be the patient's Visick grading since reoperation if he were not by convention retained in category IV.

TABLE XII.—Seven Category IV Cases After Subtotal Gastrectomy in the Trial

1	Recurrent ulcer proved at laparotomy—vagotomy	(III)*
2	Severe melaena	(III)*
3	Bile vomiting, epigastric fullness and dumping, nausea, and flatulence—conversion to Billroth I or Roux-en-Y anastomosis	(III)*
4		(III)*
5		(III)*
6	Development of pulmonary tuberculosis	(III)*
7		(III)*

* Indicates what would be the patient's Visick grading since reoperation if he were not by convention retained in category IV.

It will be noted that no fewer than 24 of the total number of 45 category IV cases after all operations came to further operation (Tables IX–XII). In 15 instances this second surgical intervention was successful in raising the patient's symptomatic state to that of a higher category, though, according to the convention enunciated in Table VII, these cases having further operations remain permanently in category IV in our records. The effect of incorporating such upgrading in the assessment of the overall results is shown in Table XIII.

TABLE XIII.—Visick Grading of Functional Results Five to Eight Years After Original Operation, Incorporating the Results of Any Reoperations

Category	Vag. & G.E. (% of 119 Cases)	Vag. & Antr. (% of 116 Cases)	Subtot. Gastr. (% of 107 Cases)	Vag. & G.E. Reject (% of 96 Cases)
I	44 } 70	51 } 81	49 } 77	46 } 76
II	26 } 70	30 } 81	28 } 77	30 } 76
III	20 } 70	16 } 81	21 } 77	14 } 76
IV	10 } 70	5 } 81	2 } 77	10 } 76

It is interesting to examine whether the overall grading of functional results has varied with the length of time that has elapsed since operation. Fig. 2 indicates in graphic form the changes that have taken place in the proportion of combined category I and II cases from one to six years after each type of operation. The first point that emerges from this illustration is that for all but the initial 12 months subtotal gastrectomy and vagotomy and antrectomy score consistently better marks than vagotomy and gastroenterostomy either in or out of the trial, the poorest results being at all stages those of vagotomy and

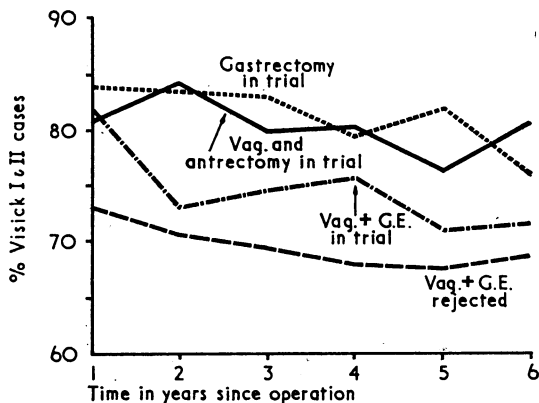


FIG. 2.—Comparison of proportion of combined Visick I and II male cases from one to six years after each type of operation.

gastroenterostomy in the rejected patients. However, as a rule, the differences between the various operations are not statistically significant except at two years, when vagotomy and antrectomy is significantly better than vagotomy and gastroenterostomy either in rejected patients ($P < 0.02$) or in the trial ($P < 0.05$), and subtotal gastrectomy is significantly better than vagotomy and gastroenterostomy in reject cases ($P < 0.05$) but not better than this operation in the trial ($P > 0.1$).

The second point brought out by Fig. 2 is the progressive deterioration in the overall results of all types of operation with the passage of time. Thus the percentage of combined Visick I and II cases after subtotal gastrectomy drops from 84% at one year to 76% at six years, that after vagotomy and antrectomy from 80% at one year to 77% at five years (with a rise again to 80% at six years), that after vagotomy and gastroenterostomy in the trial from 81% at one year to 72% at six years, and that after the same operation in reject cases from 72% at one year to 68% at six years.

Findings in Female Patients

Unfortunately the number of women patients in our records is relatively small, only 127 in all. Of these 77 were entered in the trial and no fewer than 50 were rejected, the reason for the high rejection rate being that several of the surgeons were unhappy about the known results of gastrectomy in female patients and were very ready to find reasons for excluding women from a trial which might end up in them having this operation. There were no operative deaths, seven patients died subsequently of intercurrent disease, and nine patients could not be traced at the five- to eight-year follow-up, which left 69 patients in the trial and 42 rejected patients available for assessment at this period. Obviously the number of cases in the trial is too small to allow of subdivision into groups corresponding to the three operations and statistical analysis. But virtually all the rejected patients were treated by vagotomy and gastroenterostomy; combining these cases with those in the trial submitted to this operation gives us a series of 66 women having vagotomy and gastroenterostomy. It seemed to us that it might be useful to compare the results in this series with the results in the corresponding series of 215 male patients (made up of 96 rejected cases and 119 cases in the trial) having vagotomy and gastroenterostomy. Admittedly the relative composition of these two series in terms of accepted and rejected cases is not quite similar, but they probably give us some indication of the differences in the overall clinical results of vagotomy and gastroenterostomy for duodenal ulcer in the two sexes.

Table XIV provides a comparison of the incidence of symptoms due to disturbances of alimentary function in men and women at the time of the latest follow-up five to eight years after this operation. Though the majority of the symptoms were more common in female patients, in regard to four only was the difference statistically significant—namely, bile regurgitation, nausea, epigastric fullness after meals, and food vomiting.

The overall incidence of recurrent ulcer (excluding very dubious ulcer) at the latest follow-up in the 215 male patients was 11 or 5%. In the 66 female patients followed between five

TABLE XIV.—Comparison of Incidence of Postgastric Operation Syndromes Five to Eight Years After Vagotomy and Gastroenterostomy in Male and Female Patients

Symptom	Males (% of 215 Cases)	Females (% of 66 Cases)	P
Bile vomiting	13.7	35.4	< 0.001*
Nausea	15.7	38.5	< 0.001*
Epigastric fullness	39.0	56.9	< 0.001*
Early dumping	16.2	16.9	> 0.95
Late dumping	5.7	1.6	> 0.2
Flatulence	18.7	25.8	> 0.3
Heartburn	18.3	23.8	> 0.5
Reflux	6.7	11.1	> 0.3
Food vomiting	4.3	15.6	< 0.01*
Dysphagia	1.1	4.2	

* Statistically significant.

and eight years there were six recurrent ulcers, an incidence of 9%.

As regards Visick grading the relative scores in the two sexes at the time of the latest follow-up, five to eight years after vagotomy and gastroenterostomy, are recorded in Table XV. It will be noted that the number of category IV cases among the women is a good deal higher than in men, while the proportion of combined category I and II cases in women is some 13% lower than in men. If the relative proportions of the top two categories in women and men respectively are examined at varying times from one to six years after operation (Fig. 3), it is seen that this disparity is persistent, but at no stage is the difference statistically significant.

TABLE XV.—Comparison of Percentage of Visick Grading in All Male and Female Patients at Latest Follow-up Five to Eight Years After Vagotomy and Gastroenterostomy

Category	Males (% of 215 Patients)	Female (% of 66 Patients)
I	45	28
II	26	30
III	15	20
IV	14	22
	71	58

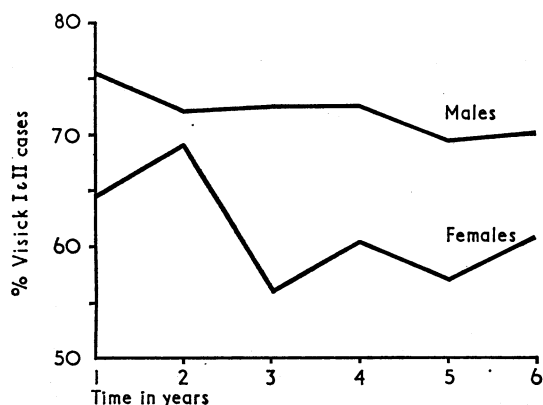


FIG. 3.—Comparison of proportion of combined Visick I and II results after all vagotomy and gastroenterostomy operations in men and women respectively.

Discussion

Our findings, like those of Cox (1968) in a recent study, certainly afford no grounds for dogmatic assertion of the superiority of any one operative method, for the differences observed in the overall clinical results of the three operations (Table VIII) fail to achieve statistical significance. But, so far as they go, they slightly favour vagotomy and antrectomy and subtotal gastrectomy, which seem to offer better protection against recurrent ulceration and marginally better Visick gradings than vagotomy and gastroenterostomy, the latter being only partly rectified by the outcome of further surgery in unsatisfactory cases.

However, two other considerations ought to be taken into account when contemplating these results in regard to the choice of routine operation for duodenal ulcer. The first is that subtotal gastrectomy and vagotomy and antrectomy appear to be followed by more malabsorption and metabolic ill-effects than is vagotomy and gastroenterostomy. These are shown to some extent in our own trial by the greater loss of weight (Table V) after these two operations, and have been demonstrated more impressively by other workers such as Cox, Hutchison, and Wardrop (1968) and Cox and Pulvertaft (1968).

The second important consideration is that of operative mortality. As already stated, we had no immediate deaths after any of the three operations in our trial (Table I), but from the way cases were selected for the trial to exclude some of those likely to give rise to technical difficulties and dangers during the conduct of a gastrectomy it would be unfair to assume that

we have obtained a full measure of the intrinsic hazards of gastric resection, if applied as the routine elective procedure. Indeed we are only too well aware from our own considerable past experience of gastrectomy as the standard surgical procedure for duodenal ulcer how difficult it is to get the operative mortality down to as low as 1 or 2%. By contrast there are now on record many large series of cases treated routinely by vagotomy and gastroenterostomy with a mortality of less than 0.5%. We have no doubt that one operative death outweighs at least four or five unsatisfactory results in surviving patients.

On these latter two scores it may be doubted whether subtotal gastrectomy or vagotomy and antrectomy (which involves exactly the same operative hazards as does ordinary gastrectomy) can be justified as the routine procedure for *all* cases of duodenal ulcer coming to elective surgical treatment, despite their good showing in our trial. But, as our experience in this trial has shown, if some of the technically more difficult cases are relegated to vagotomy and a drainage procedure, and if a reasonably high standard of surgical skill is available, the remainder can probably be handled by subtotal gastrectomy or vagotomy and antrectomy with negligible operative mortality and very good or excellent clinical results in the great majority of patients.

Those surgeons who favour vagotomy and a drainage procedure for the elective surgical treatment of duodenal ulcer will claim that its inherent safety under all circumstances compensates for the higher proportion of symptomatic failures after its use, and will argue that some of the unsatisfactory long-term results can be converted to satisfactory ones by further operation. This is certainly a reasonable argument, but unfortunately reoperations of this kind are not always as successful as might be hoped. Thus in our group of 13 category IV cases after vagotomy and gastroenterostomy in the trial (Table IX) there were five who were considered worthy of further operation, but the resulting symptomatic improvement was sufficient to justify upgrading in only one of these patients. The outcome of reoperations in the 16 category IV cases after vagotomy and gastroenterostomy in rejected patients (Table X) was much more impressive, for of the 10 cases submitted to such further operations no fewer than seven were considered subsequently to be suitable for upgrading. But it must be emphasized that some of the bad results after vagotomy and antrectomy (Table XI) and subtotal gastrectomy (Table XII) have also been improved by surgical reintervention. If the overall functional assessments after the three operations in the trial and after vagotomy and gastroenterostomy in rejected cases are recalculated to include any improvements secured by reoperations (Table XIII), it is seen that the patients treated by the two resection procedures continue to enjoy superior results.

It has already been demonstrated by one of us (Pulvertaft, 1964) that the overall results of ordinary Polya gastrectomy for duodenal ulcer deteriorate with the passage of time. It is interesting but disappointing to find that a similar deterioration in results occurs after vagotomy and gastroenterostomy and vagotomy and antrectomy (Fig. 2).

It is well known that subtotal gastrectomy is apt to be followed by poorer results in women than in men; but our trial indicates that the results of vagotomy and gastroenterostomy are also worse in women than in men (Tables XIV and XV, Fig. 3).

Summary

A controlled trial of vagotomy and gastroenterostomy, vagotomy and antrectomy, and subtotal gastrectomy in the elective treatment of duodenal ulcer has been running since 1959. It included 452 patients of both sexes. Particular attention has been directed to the 375 men, of whom all survived their operation, but 18 died subsequent to discharge from hospital of intercurrent conditions and 15 were lost to follow-up. The 342 traced male cases have been reviewed

annually, and this paper describes the latest results obtained on them at follow-up five to eight years after operation:

(1) Most "postgastric operation syndromes" occurred with roughly equal frequency after all three operations, but early dumping was marginally more common and severe after subtotal gastrectomy; however, it very seldom assumed crippling proportions. Diarrhoea was certainly more frequent after the two vagotomy operations than after gastrectomy, but most of it was very slight and occurred episodically, so that it was only rarely a source of disability.

(2) A comparison between the postoperative weight of patients and the optimal weight of individuals of the same age and height, as calculated from life assurance tables, showed a distinctly greater reduction of weight after gastrectomy and vagotomy and antrectomy than after vagotomy and gastroenterostomy.

(3) Recurrent ulceration was diagnosed in 7 to 10% of patients after vagotomy and gastroenterostomy and in 2 to 5 or 6% of patients after vagotomy and antrectomy or subtotal gastrectomy.

(4) Overall assessment of the quality of the results (Visick grading) after the three operations showed vagotomy and antrectomy and subtotal gastrectomy to be slightly superior to vagotomy and gastroenterostomy, but the difference was statistically insignificant. The results of all operations tended to deteriorate gradually with the passage of time.

The results in female patients were analysed only in those who had had vagotomy and gastroenterostomy. A comparison of the outcome of this operation in women and men, revealed

that the results were distinctly poorer in the former, with a higher incidence of most postgastric operation symptoms and of recurrent ulceration than in men.

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Clinical Comparison of Vagotomy and Pyloroplasty with Other Forms of Elective Surgery for Duodenal Ulcer*

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When the controlled trial of elective surgery for duodenal ulcer in Leeds and York (Goligher *et al.*, 1968) closed for admission of new cases in 1962, in accordance with current trends vagotomy and pyloroplasty became the operation of choice for this condition in the University Department of Surgery at the General Infirmary, Leeds, and in the Surgical Department of the York hospitals. Some 90% of our duodenal ulcer patients coming to elective operation now have this operation, the remaining 10% being treated instead by vagotomy and gastroenterostomy because of anticipated technical difficulties from oedema or scarring of the first part of the duodenum if a pyloroplasty were attempted. Up till 1965 only total truncal vagotomy was employed in conjunction with either of these forms of gastric drainage, but in the past two years selective vagotomy has been under trial in Leeds, though not in York.

In this article we wish to report on the immediate outcome and results at two years after operation in a series of 175 men

with duodenal ulcer treated by elective truncal vagotomy and Heineke-Mikulicz pyloroplasty (see Fig.) in accordance with this policy in York and Leeds between January 1963 and July 1965.

Findings

Operative Mortality.—There were two deaths in the immediate postoperative period, both due to acute cardiac failure, one complicating bronchopneumonia. In neither instance could the fatal outcome be attributed to any technical failure of the operation.

Subsequent Deaths.—Four patients died after discharge from hospital, one from bronchial carcinoma, one as a result of a road accident, and two from causes not clearly ascertained but not obviously connected with the original ulcer or the operation undertaken for its cure.

Cases Failing to Attend for Review at Two Years.—Eleven patients have been lost to follow-up or did not attend for their annual review two years after operation, and were therefore not available for inclusion in this survey of the results at that particular time.

Cases Reviewed at Two Years.—The remaining 158 patients have been interviewed and examined two years after operation. The clinical results obtained in these cases are analysed and

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