

PAPERS AND ORIGINALS

Proximal Gastric Vagotomy: Interim Results of a Randomized Controlled Trial

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British Medical Journal, 1975, 2, 301-303

Summary

In a randomized controlled trial 50 patients with duodenal ulcer treated by proximal gastric vagotomy (P.G.V.) without drainage were compared with 50 who underwent selective vagotomy and gastrojejunostomy. The clinical results were assessed in 99 patients one to four years after operation. Patients who had undergone P.G.V. had significantly less dumping, nausea, and bile vomiting and fared better in their overall clinical grading. The postoperative Visick grading of the 50 patients with P.G.V. was similar to that of 56 controls with no known gastrointestinal disease who had not undergone operation. The results obtained in the patients who had had P.G.V. without drainage were compared with those of a further group of 24 patients subjected to P.G.V. with gastrojejunostomy, and the better results obtained in the former group were thought to be due to elimination of the drainage procedure.

The average follow-up period of the trial was just over two years, but there were no indications that the recurrent ulceration rate after P.G.V. would be any higher than after other types of vagotomy and drainage.

Introduction

Though the results of orthodox truncal vagotomy and drainage for duodenal ulcer are generally satisfactory they are not always perfect. About one-third of all patients have some unwanted side effects—dumping, nausea, flatulence, bile vomiting, or episodic diarrhoea. In earlier controlled trials^{1 2} we found that

the incidence of diarrhoea was diminished by selective vagotomy. The type of drainage used made little difference to the results and about one-third of all patients had dumping and other minor symptoms.

In an attempt to eliminate these unwanted side effects proximal gastric vagotomy (P.G.V.; highly selective vagotomy or parietal cell vagotomy) without drainage has been introduced and enthusiastically reported by workers in Leeds³ and Denmark.⁴ They claim almost complete absence of dumping, diarrhoea, and recurrence of duodenal ulcer, though gastric ulcers may occur. Wastell *et al.*⁵ in an interim report of a controlled trial found two early recurrences of duodenal ulcer, and Kronborg and Madsen⁶ in a controlled trial found an alarming 22% of recurrences after P.G.V. though the clinical results in other respects were excellent.

In 1970 after a pilot study we started a controlled trial of P.G.V. without a drainage procedure against selective vagotomy and gastrojejunostomy (S.V. + G.J.), which our previous trials had led us to accept as the best orthodox procedure.

Design of Trial

One hundred patients coming to elective operation for duodenal ulcer entered the trial. After the abdomen was opened the feasibility of either operation was confirmed and other gross gastrointestinal disease such as gastric ulcer, hiatus hernia, or gall stones excluded. At this stage a nurse drew a card blindly from a box containing 50 indicating P.G.V. without drainage and 50 indicating S.V. + G.J. There was no escape clause. Most patients had preoperative acid studies with pentagastrin stimulation and postoperative insulin tests were carried out on about the ninth or 10th day when practicable, but elderly patients and those with a history of coronary artery disease were not tested. Follow-up was conducted by a doctor ignorant of which operation had been performed.

We used a simplification of the Visick grading to give a measure of the overall clinical result: grade 1 indicated absolutely no gastrointestinal symptoms of any kind—a perfect result; grade 2 indicated some symptoms but not serious ones (often they were not complained of spontaneously)—a qualified success; grade 3 indicated more severe symptoms causing some disability, but still better than preoperatively—a qualified failure; and grade 4 indicated recurrent ulceration or a need for reoperation for stoma malfunction, and all those who were not improved or were made worse by the operation were classed as grade 4—a total failure.

Two other groups were studied: 24 patients who underwent P.G.V.

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plus gastrojejunostomy were studied in the same way as the patients in this trial and similarly categorized, and a control group of 56 age- and sex-matched patients with no known gastrointestinal disease or operation were interviewed and given a clinical Visick grading. These were patients with hernias, varicose veins, benign breast lumps, minor injuries, and other irrelevant conditions.

The exact probability test for fourfold tables⁷ was used in determining the significance of differences between the results of P.G.V. and S.V.+G.J. A two-tailed probability was calculated in each case by summing the exact probabilities of the observed table and all the more extreme tables in either direction. The minimum level of significance accepted was $P=0.05$. The mean weight gains were compared using the t test.

OPERATIONS

In the S.V.+G.J. group the whole stomach was denervated but the pyloric nerve was not divided. The hepatic and coeliac nerves were carefully preserved. The gastrojejunostomy stoma was retrocolic and placed in the antrum as close to the pylorus as possible; the afferent loop was as short as possible, usually no more than 2 cm measured from the ligament of Treitz.

In P.G.V. the terminal branches of the anterior nerve of Latarjet were always seen and at least one major branch of the terminal leash was preserved. The point of division of the lesser omentum was measured by calipers from the pylorus upwards so that a 6-cm length of omentum, vessels, and nerves was always preserved. When measuring, care was taken not to overstretch the antrum.

When we started this trial we were worried lest there might be early gastric retention in some cases so in every case we introduced a double-lumen gastrostomy tube⁸ with one limb in the stomach and the second one in the duodenum or upper jejunum. The tubes were sutured in position with catgut and used for an insulin test about the ninth or 10th day, after which they were removed. Patients normally stayed in hospital for 10 days or until they could take a normal unrestricted diet.

Early in the trial many patients were rejected because of "pyloric" stenosis of varying degree. Towards the end of the trial we found that it was perfectly satisfactory to correct the stenosis by a duodenoplasty. The narrowing was usually one or more centimetres beyond the pyloric ring and could easily be corrected by a longitudinal incision, sutured transversely, without impinging on the pyloric ring itself. This procedure was used in four patients.

Results

The two groups were comparable with regard to age and sex. Further data are given in table I.

Recurrence and Reoperation.—Perhaps the most important factor to consider is the recurrence rate; we found one recurrent duodenal ulcer in the P.G.V. group, and one jejunal ulcer in the S.V.+G.J. group, both of which were confirmed at a second operation. One patient from the S.V.+G.J. group was suspected of recurrence but this had not been proved at the time of writing. One patient from the S.V.+G.J. group required reoperation for retrograde intussusception of his gastrojejunostomy and was thus regarded as a failure. This complication was also diagnosed in a second patient in the same group, who may need reoperation later.

TABLE I—Comparability of Groups

	No. of Patients		Mean Age (Years)	No. of Days in Hospital	Insulin Tests*		No. Followed Up 1-4 Years	
	Men	Women			Negative	Positive	By Interview	Postally
P.G.V.	41	9	41.7	11.8	45	2	47	3
S.V.+G.J.	40	10	42.3	12.7	44	2	48	1

*Results judged by Hollander's⁹ criteria.

Dumping.—There was a highly significant difference in the incidence of dumping ($P=0.0006$). In the S.V.+G.J. group there were 14 cases of mild dumping and four of moderate or severe dumping—an incidence of 37%, which was much the same as we found in our previous trials of selective vagotomy.^{1,2} In the P.G.V. group there were only four patients with mild symptoms—an incidence of 8%.

Diarrhoea.—This was defined as urgent diarrhoea with three or more watery motions in an attack. Almost all the episodic diarrhoea was linked with dumping, as we have found before. The only patient in whom diarrhoea caused much trouble came from the S.V.+G.J. group, though the other five patients in this group who had diarrhoea and two patients who underwent P.G.V. had quite mild and infrequent attacks.

Weight Gain.—Though some patients lost weight after operation there was an overall increase in each group, the mean increase, 4.2 kg, in the P.G.V. group being significantly greater than the 0.32 kg in the S.V.+G.J. group ($P<0.001$). Weight change is not an important or accurate index of clinical success.

Miscellaneous Symptoms.—Bile vomiting and nausea were significantly more common in the S.V.+G.J. group. Vomiting of food was not very common and occurred almost equally in each group. The incidence of heartburn and flatulence did not differ significantly (table II).

Overall Clinical Grading.—The Visick grading was based on a general assessment (table III). Any patient with any of the symptoms mentioned above, including the miscellaneous symptoms but excluding weight loss, was automatically eliminated from grade 1 even though he was entirely satisfied with the result. Likewise, any patient with reoperation or recurrence was automatically classified as grade 4 regardless of the success of his second operation. Significantly more of the patients with P.G.V. than those with S.V.+G.J. achieved Visick 1 grading (30 v. 16; $P=0.0087$). There were also significantly more failures (grades 3 and 4) in the S.V.+G.J. group (12 v. 2; $P=0.0038$). The reasons for these gradings are worth considering. In the P.G.V. group the one grade 4 was allotted for recurrent ulcer and the grade 3 for repeated and troublesome vomiting of food, but this did not need reoperation. In the S.V.+G.J. group two of the grade 4s were earned by proved or suspected recurrence and the third by retrograde intussusception. Grade 3 was allotted for retrograde intussusception (in one case), severe dumping (four cases), bile vomiting (four cases).

TABLE II—Numbers of Patients with Miscellaneous Symptoms

	No. of Patients	Nausea	Food Vomiting	Bile Vomiting	Heartburn	Flatulence
P.G.V.	50	5	5	1	7	9
S.V.+G.J.	49	14	5	7	8	16
P		0.0223	N.S.	0.0309	N.S.	N.S.
Controls	56	2	3	0	10	7

N.S. = Not significant.

TABLE III—Clinical Grading in Patients and Controls

	No. of Patients	Visick Grade			
		1	2	3	4
P.G.V. . . .	50	30	18	1	1
S.V.+G.J. . .	49	16	21	9	3
Controls . . .	56	43	13	0	0

Comparison with Controls.—The incidence of miscellaneous symptoms among the 56 normal controls was similar to that in the P.G.V. group (table II). Forty-three controls were Visick grade 1 and the remaining 13 grade 2. There was no statistically significant difference between the ratio of Visick 1 to other Visick grades in the P.G.V. group when compared with the controls.

Proximal Gastric Vagotomy with Gastrojejunostomy.—As it was impossible to say whether the differences in this trial were due to the gastrojejunostomy per se or vagal innervation or denervation of the antrum it seemed worthwhile to compare the patients who had undergone P.G.V. without drainage with 24 prospectively studied patients who underwent P.G.V. combined with gastrojejunostomy and who were followed for more than two years. Four of the 50 undrained patients had mild dumping, and among the 24 patients with gastrojejunostomy there were seven cases of dumping, three being moderate or severe ($P=0.0319$).

Discussion

Some surgeons have been so pleased with the results of truncal

vagotomy and drainage that they see no need to look for better results,¹⁰ but we agree with Amdrup *et al.*¹¹ that we should try to eliminate all tiresome side effects. The safety of P.G.V. has been shown by Johnston,¹² who studied 5257 cases drawn from 40 international centres and showed a mortality of only 0.3%. We had no deaths in either group in this trial and have not seen the lesser curve necrosis which has been described.

The key factor to be considered about any new operation for duodenal ulcer must be the recurrent ulcer rate, not just in the duodenum but also in the stomach. We have had just one proved recurrence in each group—a rate of 2%, which is quite acceptable. Kronborg and Madsen⁶ in a very similar trial had a rate of 22%, which is totally unacceptable. Why should there be this great difference? We believe that not all surgeons are doing the same operation. We have preserved the innervation to a measured 6 cm of the distal lesser curve, sometimes preserving only one of the terminal branches of the anterior nerve of Latarjet. Kronborg located the junction of the corpus and the antrum using a pH probe or by staining the mucosa with Congo red through a small gastrotomy. He found that the junction varied between 4 and 17 cm from the pylorus, with a mean of 8.6 cm. It seems, therefore, that he preserved more antral innervation than we have done, which may explain our different recurrence rates. Amdrup *et al.*¹¹ have recently reported two gastric ulcers and three suspected but unproved duodenal recurrences among 108 patients followed for a minimum of two and a maximum of four years.

The most striking result of our trial was the virtual elimination of dumping in the P.G.V. group, a result that we had expected since uncontrolled gastric emptying is prevented. Not surprisingly, episodic diarrhoea was also almost eliminated; most of the diarrhoea in both groups was linked to dumping, and we have previously found that this is the type of diarrhoea that is not eliminated when truncal is replaced by selective vagotomy. Our finding of retrograde intussusception in two patients was surprising but must be regarded as further evidence against drainage.

Nutritionally the patients who underwent P.G.V. seemed to fare better, but we have found that clinical status bears no relation to weight loss or gain (unpublished data).

Bile vomiting is related to regurgitation of duodenal content into the stomach, and this readily occurs after gastrojejunostomy or pyloroplasty but is rare after P.G.V. with an intact pylorus.

Two symptoms that we feared might occur in this study were flatulence and vomiting of food due to delay in gastric emptying. That this is not a problem in practice is indicated by our finding that these symptoms were no commoner after P.G.V. than in our control group of patients with no known gastrointestinal disorder. Though we had one patient with troublesome food vomiting we did not need to reoperate, and stasis did not prove a problem in this series. Amdrup *et al.*¹¹ reoperated for stasis in two of their 108 cases while Johnston¹² reported a reoperation rate of 0.6% on this account in his 5257 cases.

Our results in this trial must be compared with those of Kronborg and Madsen,⁶ who have reported the only other random controlled trial. The design of their trial was remarkably similar: 50 patients who underwent P.G.V. were compared with 50 undergoing selective vagotomy and pyloroplasty. Ninety-six patients were followed for one year. They found significantly less dumping, diarrhoea, and epigastric fullness in patients who had had P.G.V., and when the recurrent ulcers were excluded there were significantly better overall clinical results.

From our results we conclude that P.G.V. is a safe operation in which side effects are almost eliminated. There is a low recurrence rate in the first two years, but more time is needed to give a definite answer about the ultimate recurrence rate. As yet nothing indicates that it will prove to be any higher than that of other forms of vagotomy and drainage. Should it do so later little or no harm will have been done as we found no difference in the proportion of Visick I gradings between our P.G.V. patients and our controls. The technique is not difficult to learn, and P.G.V. without drainage should be more widely used in the treatment of duodenal ulcer.

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Psychosocial Effects of Disaster: Birth Rate in Aberfan

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British Medical Journal, 1975, **2**, 303-304

Summary

An increased birth rate occurred in Aberfan during the five years after the disaster there in 1966. It was not confined to the bereaved parents.

Introduction

On 21 October 1966, in the Welsh mining village of Aberfan

and its companion village Merthyr Vale, 116 children and 28 adults were killed when an avalanche of coal slurry engulfed the village primary school and several houses. Some of the psychological damage produced was reported by Lacey (summarized by Anthony¹). Using statistics now available from the Registrar of Births and Deaths we have plotted changes in the birth rate during the five years before and after the disaster.

Method

Birth rate is measured as births per 1000 population. Thus an increase may result from either a rise in the number of births or a fall in the population. The fall in the population of Aberfan due to the disaster would therefore be expected to be associated with a rise in the birth rate even if the number of births remained the same.

In attempting to find whether there was a rise in the birth rate attributable to an increase in births among those of reproductive age it was necessary to exclude from consideration the children who died

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