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[General Infirmary at Leeds and Gastric Follow-up Clinic, York Hospitals; and St. James' Hospital, Leeds, England]

This study reports the late results of three types of operations randomly allocated to duodenal ulcer patients-vagotomy and gastroenterostomy, vagotomy and antrectomy, and subtotal gastrectomy. Though the overall results were not greatly dissimilar, each of the procedures had its respective advantages and disadvantages. [The SCI® indicates that this paper has been cited in over 290 publications.

> I.C. Goligher Nuffield Hospital Horsforth Leeds LS18 4HP **England**

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For over 50 years a highly controversial issue in surgery has been the choice of operation for duodenal ulcer, especially since the introduction of vagotomy in the latter 1940s. Unfortunately, the vast majority of the papers published on the subject have been grossly partisan, merely reflecting the enthusiasm felt by their authors for the type of operation they favoured, often with selective references to the less satisfactory features of rival procedures recorded elsewhere in the literature. From such unbalanced material, a fair judgement on the relative merits of different methods was clearly impossible. What was needed for this purpose was an objective exposition of the results of various operations performed by the same group of surgeons on strictly comparable series of patients—a requirement that could only be met by a properly controlled prospective clinical trial, with random allocation of cases to the different procedures being evaluated.

But recognition of the desirability of such a trial was one thing and setting it up quite

another, especially at a time when surgical opinion was far from being attuned to the concept of making therapeutic decisions on doubtful issues by spinning a cord or plucking a card. However, the plain fact was that the selection of the form of operation for duodenal ulcer in many hospitals had already become something of a lottery, for, depending on the particular surgical service to which the family physician happened to refer his patient, he might have a subtotal gastrectomy, a vagotomy and drainage operation, or a vagotomy and antrectomy, according to the whim of the surgical chief concerned, Fortunately, when this point was emphasized to our surgical colleagues, most of them accepted that randomization would be better done by them than by the general practitioner. Each agreed to perform any one of the three operations indicated by the randomizing process and also to allow the follow-up assessments to be made by an independent panel of observers. This panel was kept in ignorance of the type of operation performed in each case until they had recorded their verdict.

The Leeds/York trial, thus inaugurated in 1958, certainly provided much better information about the relative efficacy of several popular operations for duodenal ulcer than had previously been available. Perhaps its main achievement, however, was to help foster the use of controlled clinical trials in the investigation of a variety of surgical problems. Some have related to peptic ulcer 1,2 but because of the sharp decline in the frequency of elective surgery for this condition, trials on this theme have become increasingly difficult to organize. Far more have been concerned with issues such as the choice of technique for bowel anastomosis,3 the relative merits of different antibiotics,4 and the value of supplementary radiotherapy or chemotherapy after cancer operations.5

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