Statistically Valid Ten-Year Comparative Evaluation of Three Methods of Management of Massive Gastroduodenal Hemorrhage *

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ALTHOUCH no method of management for massive gastroduodenal hemorrhage is universally accepted, majority opinion is expressed by F. Avery Jones: ⁵ "The ideal professional combination is a keen physician and a somewhat reluctant surgeon."

After the establishment of a full-time surgical faculty to the State University of New York and to Kings County Hospital in 1951, massive gastroduodenal hemorrhage represented one of the most serious professional problems. The Departments of Medicine and Surgery, in a joint study, evaluated three widely accepted forms of therapy:

1. The method of A. F. R. Andresen ^{1, 2} and later adopted with slight modifications by Meulengracht.⁷ This consists of free feeding of a liquid formula, substantial sedation and stringent avoidance of transfusion and operation.

2. The method of J. D. Stewart,¹¹ consisting of rapid transfusion and prompt gastrectomy.

3. The method of Hoerr, Dunphy and Gray,⁴ according to which operation was reserved for patients who failed to retain stable vital signs during transfusion at a maximum arbitrary rate of one unit per 8-hour period.

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The study included all ward patients of the University Division of Kings County Hospital from Mar. 1, 1953 to Dec. 31, 1963 and, after 1959, the entire Kings County Hospital. Our definition of massive bleeding is that of J. D. Stewart, namely acute blood loss sufficient to reduce the circulating red blood cell mass to a level below 18 ml./Kg. body weight (60% of estimated normal). A condensation of the protocol employed best clarifies the methods of procedure.

Methods

Patients who either clearly or possibly are massive bleeders will be admitted to one surgical ward of the hospital for study and, if proved to be bleeding massively from the stomach or duodenum, for therapy; all such patients will be evaluated by the same personnel.

To expedite management and thereby increase the safety of the patients, they will first be assigned to a Study Group on the basis of observations which can be made in less than 10 minutes. Following admission to the Study Group, studies on liver function will be performed to eliminate varices of the esophagus as the source of bleeding, and blood volume and other studies will be done to establish the massive nature of the blood loss and the likelihood of peptic ulceration as the source, following which those who qualify will be admitted to the Therapy Group. Members of the Study Group found not to be admissible to the Therapy Group will be transferred to the Medical Service or handled in another appropriate manner.

The following factors must jointly be present to permit admission of patients to the Study Group:

^{*} Presented before the American Surgical Association, May 12-14, 1965, Philadelphia, Pa.

1. History in the 48 hours before admission of vomiting blood or coffee-ground material, or passage of tarry stools or unchanged blood by rectum.

2. An estimate by the medical or surgical resident on Admissions, whoever sees the patient first, that the patient has lost more than $\frac{1}{2}$ L. of blood during the preceding 48 hours.

3. Absence of immediately obvious evidence of cirrhosis of the liver with esophageal varices, or of blood dyscrasias.

4. Absence of evidence of previous operation on the stomach. A history of chronic bleeding or of acute bleeding for more than 48 hours does not eliminate patients from the Study Group provided factors 1, 2, 3 and 4 apply.

Admission to Therapy Group. Following admission to the Study Group, either the red blood cell count must be below 2.5 million/mm.³ or the total circulating red blood cell mass must be below 18 ml./Kg. body weight for admission to the Therapy Group. The studies done in the Study Group will be hemoglobin, bleeding and clotting times, hematocrit, blood volume and bromsulphalein[®] (sulphobromophthalein sodium) excretion.[•]

Assignment to Pattern of Therapy. Designation of the pattern of therapy to be provided to any individual patient in the study must be truly random to achieve statistically sound conclusions. (In the first few months patients were alternated; then a formula for decision based on the digits of the assigned hospital number was employed, and for the final 8 years a random sampling technic using randomized cards in sealed envelopes was employed). The patient's randomly selected therapy pattern must be recorded on his chart and in the record book of the Gastroduodenal Hemorrhage Study.

Details of Patterns of Therapy to be Evaluated

Pattern I. The Nonoperative Pattern: Bed rest, gelatin-milk mixture every 2 hours and mild barbiturate sedation.² Transfusion only for air hunger and evidences of cerebral or myocardial hypoxemia or for systolic blood pressure below 80 mm. of Hg and then in 250 ml. amounts only. These patients will be followed and supervised by the medical consultant.

Pattern II. The Immediately Operative Pattern: Three-quarter gastrectomy will be undertaken in every patient in this group as soon as the patient is completely evaluated and proper preoperative preparation accomplished. Transfusion should be expedited and continued until blood pressure and pulse are normal or until it is believed that a further improvement will not occur preoperatively. Preoperative preparation should not require more than 12 hours.

Pattern III. The Selectively Operative Pattern: Conservative management is the basis, but selection of operative therapy will be based upon two factors:

1. Age. All patients 50 years of age or older will have subtotal gastrectomy as soon as they are properly evaluated and optimally prepared. Preparation should not require more than 12 hours.

2. Failure of transfusion to combat shock. These patients will be evaluated and transfused with 1,500 ml. of whole blood, if needed, as soon as possible. If this amount of blood transfusion does not bring the patient out of shock, transfusion will be continued at a sufficient rate to restore normal blood pressure and pulse rate, if possible, and operation will be performed. If 1,500 ml. of blood is sufficient to restore blood pressure and pulse to normal range, transfusion will be continued but, if more than 500 ml. is required in any 8-hour period to maintain normal blood pressure and pulse, gastrectomy will be performed at once.

N.B. Patients readmitted with massive gastroduodenal bleeding who have once been in Therapy Pattern I will be treated again in that pattern. (Only two patients presented again; each of them was in the Therapy Group on the first admission but did not qualify on the second admission because of insufficient blood loss.)

The operative procedure to be performed in all cases in which operation is selected is 75% gastrectomy with short loop, retrocolic Hofmeister-Polya anastomosis. All such gastrectomies will be performed by designated members of the attending staff and will be done, whether or not a gastric or duodenal lesion is recognized, unless a lesion elsewhere explains the hemorrhage or the stomach is deemed unresectable because of neoplasia.

Two major changes in the protocol were made during this study:

1. After June 15, 1958 the patients in Pattern III 50 years of age and older were treated conservatively unless rate of needed blood replacement dictated operation.

2. After June 30, 1961, because of our medical colleagues' disillusionment with the Andresen nonoperative pattern, no patient was admitted to Pattern I. All were as-

[•] These determinations were performed by a technician during the 40-hour work week and by members of the house staff on call for this purpose at other times—but not on call for any other aspect of the gastroduodenal bleeding study.

Pattern of Therapy	Through June 30, 1961*	After June 30, 1961	Totals
I Non-operative	121		121
II Immediate oper.	78	55	133
III Selective oper.	91	58	149
With operation	39	10	49
Without operation	52	48	100
Excluded	209	29	238
			641

TABLE 1. Total Experience—Gastroduodenal Hemorrhage Study (March 1, 1953-December 31, 1963)

* 23 patients refused operation; they would have been included in Category II and III (15 and 8, respectively).

signed in random manner to Patterns II and III.

Results

The total cumulative experience is shown in Table 1. The inequality of the populations of the three Patterns of Therapy is due in part to refusal of 23 patients to consent to operation—patients who otherwise would have fallen into operative patterns; they were then excluded from the study. The populations would otherwise have been 121, 93 and 99, respectively, up to June 30, 1961. (Statistical analysis suggests that this distribution can readily be found by chance alone; p > 0.05).

Slightly more than one third of the patients admitted to the Study Group were

TABLE 2. Reasons for Exclusion fromTherapy Group

Reason	Number
Insufficient blood loss	104
Failure to follow protocol	34
Patient refused operation	23
Elevated BSP	20
Clinical liver disease	19
Questionable diagnosis	8
Prior gastric surgery	7
Chronic hemorrhage	7
Prior transfusion	4
Lower tract bleeding	3
Neither blood nor acid	3
Gastritis from drugs	2
Obstruction or perforation	2
Patient terminal	2
	238

excluded from assignment to the Therapy Group. The bases for exclusion from the Therapy Group are shown in Table 2. Nearly half the 238 exclusions were based upon inadequate blood loss. Stewart's definition of massive hemmorrhage as one which causes loss of 40% of the circulating red blood cell mass proved highly reliable, since only one patient died of exsanguination after exclusion from the study on the basis of insufficient blood loss.

Initially we were primarily concerned with bleeding from peptic ulcerations and sought to exclude other sources by eliminating patients lacking both blood and HCl from the gastric aspirate. Many patients were found to have major hemorrhage from duodenal ulcers who had no blood in the stomach, and several were found who had no acid. Two patients had absence of both and yet proved to have peptic ulcer disease. This reason for exclusion was therefore abandoned.

As shown in Table 3, among those cases excluded from the Therapy Group, peptic ulcers were the sources of bleeding in most of the diagnosed cases. The 61 undetermined cases include patients who left the hospital against advice, patients who died without autopsy and patients for whom studies were not pursued.

Table 4 presents the sources of bleeding in the patients admitted to the Therapy Group and treated according to protocol. The types of lesions resemble those of the Volume 162 Number 4

excluded group except for a higher fraction of documented peptic ulcers (236 of 403 cases). In the few instances of combined hiatal hernia and duodenal ulcer, the cases are listed under the heading of duodenal ulcer.

High gastric ulcers were found at operation which would have required total gastrectomy for removal; all were handled by three-quarter gastrectomy according to protocol, occasionally with addition of a hemostatic suture through the base of the ulcer. There was no problem with postoperative bleeding in these five patients, but two died in the early postoperative period.

The differences in mortality rates among the three patterns of management are not statistically significant (Table 5). There were also no statistically significant differences in the mortalities among the three patterns of treatment in patients under 50 years of age (Table 6).

Striking elevations of mortality with advancing age were apparent in all three patterns of therapy (Table 7). Our experience with patients above 50 years of age who fell into Pattern III is of particular interest.

TABLE 3	. Source	of .	Bleedin	g—Cases	Excluded
	f rom	T/	herapy (Group	

Reason	Number
Duodenal ulcer	70
Gastric ulcer	20
Esophageal varices	12
Hiatal hernia	10
Gastritis (erosions)	10
Gastric cancer	7
Lesion in colon	3
Duodenal diverticulum	2
Prolapsed antral mucosa	1
Marginal ulcer	1
Esophageal cancer	1
Gastric leiomyoma	1
Duodenitis, second portion	1
Mesenteric thrombosis	1
Negative x-ray findings	32
Negative operative findings	5
Undetermined	61
	
	238

As noted above, our protocol changed on June 15, 1958, and after that date all older patients in this Pattern were treated by the Hoerr-Dunphy method and not arbitrarily subjected to immediate gastrectomy as done prior to that date. No alteration in mortality rate resulted from this change;

Source	I Non- Oper.	II Immed. Oper.	III Select. Oper.	Tota
Duodenal ulcer	35	68	61	164
Gastric ulcer	14	28	25	67
Gastritis (erosions)	1	8	4	13
Hiatal hernia	7	0	6	13
Gastric cancer	3	4	3	10
Esophageal varices	1	0	1	2
Duodenal + gastric ulcers	2	3	0	5
Leiomyosarcoma stomach	0	1	1	2
Leiomyosarcoma jejunum	1	0	0	1
Gastric polyp	1	0	0	1
Gastric varices	0	1	0	1
Prolapsed antral mucosa	0	0	1	1
Polyarteritis small intestine	0	1	0	1
Multiple carcinoid tumors of intestine	0	1	0	1
No lesion at operation	1	16	0	17
No lesion by x-ray	29	0	31	60
Undetermined	26	2	16	44
				403

TABLE 4. Source of Bleeding-Cases in Therapy Group

Pattern of Therapy	No. of Patients	Deaths	Mortality Rate
I (Non-operative)	121	24	19.8%
II (Immediate oper.)	133	22	16.5%
III (Selective oper.) With operation Without operation	149 49 100	21 13 8	14.1% 26.5% 8%

TABLE 5. Mortality by Treatment Pattern

 X^2 (2 degrees of freedom) = 1.72.

p <0.5>0.3 I vs. II or I vs. III.

five deaths occurred among 22 patients (22.7%) in the earlier period, and 15 deaths occurred among 68 patients (22.0%) in the later period. This mortality for patients over 50 years of age is the least of the three major patterns under evaluation, but the differences from the rates in Patterns I and II (29% and 26.2%, respectively) are not statistically significant.

The single death in a patient younger than 40 years occurred under Pattern I; this might have been preventable, although his course was complicated by acute cholecystitis with sepsis and by coronary artery disease.

One hundred forty-six patients presented either with classical signs of hemorrhagic shock or with signs of impending shock (syncope, weakness, thirst, tachycardia). There was no positive relationship between these symptoms and signs and the magnitude of blood loss as measured by isotope dilution technic, and we believe that the patients presenting with signs of shock had been bleeding more rapidly than those who did not show these signs. The elegance of Stewart's definition of massive hemorrhage as that in which more than 40% of the circulating red blood cell mass has been lost is indicated in Table 8 in which the increase in mortality occasioned by shock is not statistically significant in any of the three patterns of therapy. There is also no significant difference in the mortality rates among the three patterns. In contrast, of all the 104 patients excluded from the Therapy Group because of inadequate blood loss, to satisfy Stewart's criteria, only one died of exsanguination.[•]

Our initial purpose was to compare the results of three patterns of therapy for pa-

[•] This was an 83-year-old woman admitted from a nursing home with hematemesis and melena. After exclusion from the Therapy Group because of a circulating red blood cell mass of 21.3 ml./Kg., she was treated nonoperatively and stopped bleeding. Five days later she bled massively, aspirated and died.

	\mathbf{U}_{1}	Under Age 50				Over Age 50				Total			
		Mo	orta	lity			Morta	lity			M	orta	lity
Pattern	No.	N	Jo.	%		No.	No.	%		No.		No.	%
I (Non-operative)	49		3	6.1		72	21	29		121		24	19.8
II (Immediate oper.)	49		0	0		84	22	26.2		133		22	16.5
III (Selective oper.) With operation	59 7	1	1	1.7	42	90	20 12	22.2	49	149	13	21	14.2
Without operation	52	0			48		8		100		8		

TABLE 6. Effect of Age and Treatment on Mortality

	Ι ((Non-oper.) II		II (In	nmed. Op	er.)	III (Select. Oper.)			
		Mortality			Mortality		lity		Mortality	
Age Group No.	No.	No.	%	No.	No.	<i>c</i> %	No.	No.	%	
10-19	1	0	0	0	0	0	2	0	0	
20-29	10	0	0	13	0	0	12	0	0	
30-39	12	1	8	13	0	0	14	0	0	
40-49	22	2	9	21	0	0	29	1	3	
50-59	24	3	12.5	19	3	16	21	3	14	
60-69	29	9	31	32	3	9.5	40	8	20	
70-79	15	6	40	28	10	39	24	3	12.5	
80-89	8	3	37.5	7	4	57	6	5	83	
90–99	0	0		0	0	—	1	1	100	
	121	24		133	20		149	21		

TABLE 7. Mortality by Age

tients with massive hemorrhage from peptic ulcers. It is apparent from Table 4 that only 58.5% of our patients had peptic ulcers, although another 20 to 30% probably did. The results of management of patients with proved ulcer disease are shown in Table 9. The mortality in proved ulcer disease (30/236 or 12.7%) is less than our overall rate of 16.6% and is statistically significantly less than that from bleeding not proved to be due to ulcer disease (37/167 or 22.1%) (p < 0.05). The mortality rates in proved ulcer disease with massive hemorrhage are remarkably similar among the three patterns of therapy.

There were no significant differences in the ages of patients in the different patterns of management—either among survivors or among those lost. The median age among fatalities in each pattern was significantly greater than that among survivors (Table 10). Tables 11–13 list the causes of death. Exsanguination was the most common cause in the nonoperative Pattern I. Most of the deaths in the gastrectomized patients were directly related to operative or postoperative complications. As many patients survived duodenal stump blowout and abdominal wound disruption as were lost. Three deaths followed desperate operations upon patients who had failed to cease to bleed under nonoperative therapy. These were related to duodenal stump blowout, homologous serum jaundice and cachexia with chronic peritonitis.

Thirty of 238 patients (12.6%) excluded from the Therapy Group, for reasons listed in Table 2, died. More than half these patients had cirrhosis and varices and had been excluded because of high bromsulphalein retentions.

TABLE 8. Effect of Impending or Overt Shock on Mortality

Pattern of Therapy	Sh	ock Patien	ts	Non-shock Patients			
		Mor	tality		Mortality		
	No.	No.	%	No.	No.	%	
I (Non-oper.)	45	11	24.4	76	13	17	
II (Immed. oper.)	55	10	18.2	78	12	15.4	
III (Select. oper.)	46	9	19.5	103	12	11.7	

	Duodenal Ulcer		Gastric Ulcer		Duod. & Gastric Ulcers		Total	
Pattern of Therapy	No.	Deaths	No.	Deaths	No.	Deaths	No.	Deaths
I (Non-oper.)	35	3	14	2	2	2	51	7 (13.7)
II (Immed. oper.)	68	9	28	3	3	1	99	13 (13.0)
III (Select. oper.)	61	5	25	5	0	0	86	10 (11.6)
	164	 17 (10.3%)	67		5		263	30 (12.7)

TABLE 9. Mortality in Patients with Proved Ulcer Disease

Discussion

A preliminary report of this study was presented before the American Surgical Association in 1958. The mortality rates among the three Patterns of Therapy differed from those of the present report; all three were identical (14%). The slight differences between overall mortality then (14%) and now (16.8%) are not significant. Welch, Allen and Donaldson ¹⁶ also noted an increasing mortality rate during their study at Massachusetts General Hospital and attributed this to an increasing average age. We have been unable to fine such an explanation for the slight increase in our own experience.

It has been argued ³ that studies such as this are "to be deplored" and should be supplanted by studies in which "medical skill" rather than random sampling should determine the pattern of therapy. Judgment in the absence of objective facts is no different today than when John Hunter urged Edward Jenner to try vaccination rather than judge it without data at the end of the 18th century. In regard to mortality in massive gastroduodenal hemorrhage at Kings County Hospital, our data for the

TABLE 10. Age of Patients (Median)

Pattern of Therapy	Living (years)	Died (vears)
I (Non-oper.)	53	65
II (Immed. oper.)	55	72
III (Select. oper.)	53	68

period prior to this study are inadequate for several reasons, including the absence of determinations of circulating red blood cell mass, but the operative-emergency mortality was about 40 per cent. During this study period the mortality has decreased immensely, even though it has failed to establish an advantage of one pattern of management over the others.

Despite determined efforts to gain longterm data nearly half of the patients have been lost to follow up within the first year. Our results, therefore, present only the survival or death of patients during that admission made for massive hemorrhage. We know that several of the patients who were treated nonoperatively and ceased to bleed died following gastrectomy on subsequent admissions—a hazard not faced by patients treated by gastrectomy on the initial admission. No statistically significant difference has been found in mortality between the nonoperative and operative patterns. Nevertheless the likelihood is about

TABLE 11. Causes of Death-Pattern I

	Exsanguination	11
	Mycardial infarction	4
No	Aspiration	2
operation	Perforated ulcer	1
121 patients	Congestive failure	1
•	Cachexia	1
	Fatal associated disease*	1
Operation	Surgical deaths after desperate	
5 patients	gastrectomy	3

* Cirrhosis with marked electrolyte imbalance.

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two of three that the higher mortality in the nonoperative Pattern I is due to factors other than sampling errors. Fatalities among patients dismissed after cessation of bleeding on nonoperative therapy indicate that the p value of the long-range advantage of operative over nonoperative therapy is almost certainly less than 0.3, *i.e.*, there is more than a two-to-one chance that operation is safer in massive gastroduodenal hemorrhage.

The evaluation of Andresen's nonoperative pattern of therapy was undertaken with reservation, yet all who observed these patients closely and objectively were impressed by the satisfactory courses of most of them. As a result, the factors involved in spontaneous control of hemorrhage have been the subject of experimental laboratory studies.^{9, 10} Bleeding from the severed saphenous artery of the dog produces shock but rarely exsanguination. Under control conditions the mean blood loss in four experiments was 323 ml., and bleeding was stopped in 28 minutes (Fig. 1). With transfusion of predrawn autologous blood to replace volume-for-volume that lost from the saphenous artery, the blood loss in a series of experiments was over 1.5 L., more than the estimated total blood volume, and bleeding continued $2\frac{1}{2}$ hours and stopped only after exhaustion of autologous blood for transfusion. With vasopressors

TABLE	12.	Causes	of	Death-I	Pattern	II
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	Surgical complications*					
	Postoperative shock					
	Myocardial infarction	3				
	Sepsis Pulmonary complications					
Operation						
129 patients	Massive pulmonary embolus	1				
-	Cerebrovascular accident	1				
	Serious associated disease	1				
	Unexplained postoperative death	1				
	Overtransfusion	1				
No operation Death before operation could						
4 patients be done		4				

* Duodenal stump blowout (2), anastomotic bleeder (1).

Operation 49 patients	Surgical complications* Sepsis Postoperative congestive heart failure Pulmonary complications Anesthetic complication Postoperative shock Unexplained postoperative death	4 2 2 1 1 1
No operation 100 patients	Myocardial infarction Congestive heart failure Convulsions and coma Exsanguination** Pyelonephritis	4 1 1 1 1

TABLE 13. Causes of Death—Pattern III

* Fecal fistula, wound dehiscence, anastomotic leak, evisceration—one each.

** Died in operating room prior to operation.

the loss and duration of bleeding were also increased. Preliminary withdrawal of blood before section of the artery reduced blood loss from such section to 8 per cent and duration to less than half of control levels. On demonstration that bleeding is closely associated with blood pressure, a vasodilator (trimethaphen camphorsulfonate) was employed to drop the blood pressure and, as Figure 1 indicates, resulted in further curtailment of blood loss. Finally, vasodilator hypotension with replacement of blood volume to normal not only minimized volume and duration of bleeding. but at systolic pressures of 70 mm. Hg was associated with an excellent urine flow if appropriate infusions of amine buffer were employed. Essentially similar findings have been observed in bleeding of venous origin, whether from the systemic or portal systems.5

Subsequent to these and other laboratory findings, clinical trials have indicated the utility of temporary control of blood loss by utilization of vasodilator-facilitated normovolemic hypotension until the source of hemorrhage could be exposed and controlled surgically. One rapidly massive hemorrhage from a gastric ulcer has been handled thus with temporary success, only to end in death from septicemia secondary to an emergency venesection. Massive post-

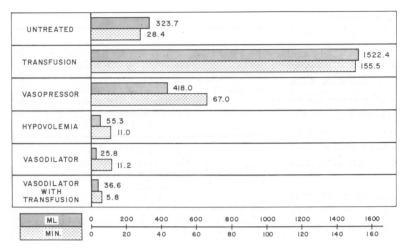


FIG. 1. Sums of minutely weighed blood loss and duration of bleeding. Each bar is the mean of 4 experiments. (From Chiu, C. J., G. W. Shaftan and C. Dennis: Surgical Forum 15: 3, 1964. Reprinted with permission of the publishers.)

traumatic retroperitoneal hemorrhage has been handled by normovolemic hypotension alone, with recovery. Three other patients with massive hemorrhage—one from a presumed stress ulcer complicating colic perforation and peritonitis, one from a terminal cancer of the colon and one from esophageal varices—all were controlled although the patients died of their primary diseases. We believe that such patterns of management may represent the treatment of choice for massive gastroduodenal hemorrhage.

We have not attempted to determine the source of bleeding by emergency radiographic or endoscopic studies. As Table 4 indicates, in only the 4 per cent of missed diagnoses could such studies have altered our therapy, but we believe that we would have raised our mortality by this margin had such studies been undertaken. A good clinical history and physical examination, good evidence of upper tract bleeding and a bromsulphalein excretion test have permitted us to exclude all but three patients with serious liver disease and all but ten of those with gastric cancers. All others we believe to have been handled appropriately by the methods of this study. Our experience concurs with Wangensteen's ¹² thesis that massive gastroduodenal hemorrhage in the absence of discoverable discrete lesions

in most safely handled by blind gastrectomy.

Seventeen patients in Pattern II and five patients in Pattern III were found at operation to have no gross lesion in the stomach or duodenum. All were treated by "blind" gastrectomy, and three patients died in the early postoperative period. In none of the 22 patients was recurrent or persistent bleeding detected.

During the course of this study, several new technics have been proposed to treat ulcer bleeding—among them gastric cooling ^{13, 14} and vagotomy with pyloroplasty.¹⁵ Each has been tried in desultory fashion on patients excluded from the Therapy Group; a few patients have responded favorably, but we have not evaluated these technics. Gastrectomy continues to be our standard operation, primarily to afford the basis for a statistical study, but the consistent efficacy of this procedure has been documented.

Read, Huebl and Thal ⁸ also compare two methods of management in an immediately operative group and a selectively operative group. One criterion for inclusion of patients in their study is that the patients be "fit for operation." In order to compare results we screened our cases to exclude all "unfit for operation." The findings are shown in Table 14. No difference exists be-

	Present Series		Not Fit for Operation			Fit for Operation			
	Мо		tality	<u>.</u>	Mortality			Mortality	
Pattern of Therapy	No.	No.	%	No.	No.	%	No.	No.	%
I (Non-oper.)	121	24	19.8	8	4	50	113	20	17.7
II (Immed. oper.)	133	22	16.5	9	8	89	125	14	11.3
III (Select. oper.)	149	21	14.1	6	5	83	143	16	11.2

TABLE 14. Evaluation of Data Using Read's⁸ Criteria

tween mortality rates in immediately operative and selectively operative patterns in terms of the associated hospital admission, but about two thirds of the latter group may have to encounter gastrectomy or repeated hemorrhage on subsequent admission. In considering those patients "fit for operation," the nonoperative Pattern I therapy is less effective than patterns employing surgical intervention but not to a significantly significant level (p > 0.05). As Table 14 suggests, the rigid nonoperative pattern may prove least hazardous for those patients described as "unfit for operation."

Summary

A 10-year study at Kings County Hospital included 403 cases of massive gastroduodenal hemorrhage, defined as blood loss sufficient to reduce the circulating red blood cell mass to less than 18 ml./Kg. body weight. Review of the effect of impending or overt shock on mortality in these patients confirms the excellence of Stewart's definition of "massive." Excluding those with cirrhosis and varices, only one patient with a higher red cell mass on admission died of exsanguination.

Comparison of mortality rates shows no difference between those treated by the selectively operative pattern of Hoerr, Dunphy, and Gray and those treated by the immediately operative pattern of Stewart. The mortality with the nonoperative pattern of Andresen was higher, but not statistically significantly so. The overall mortality was 16.8%. If consideration is focussed on patients with proved peptic ulcer disease, the mortality rates in the three patterns of therapy are statistically identical.

Among patients with massive gastroduodenal hemorrhage, the mortality rate is statistically significantly lower if proved ulcer is the source than if other basis of bleeding is responsible. This is true even though bleeding from esophageal varices is excluded.

A vigorous clinical trial of the principle of "buying time" by induction of normovolemic hypotension as a component of preoperative preparation is strongly indicated by laboratory and preliminary clinical observations.

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