Results of Three Methods of Therapy for Massive Gastroduodenal Hemorrhage *

A Statistically Valid Comparison

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ALTHOUGH the management of upper gastro-intestinal bleeding is a frequently recurring problem, there is very little evidence in the literature upon which one may base conclusions as to which of the various methods of management is most satisfactory. There is a lack of objective criteria in reporting, of uniformity of patients, facilities, and personnel with which to establish comparisons. The deficiencies in objective criteria are principally related to a lack of definition of what is an "acute bleeder" and what is a "massive bleeder." Other factors which are involved in comparing results are variations in the nutrition and general health of the patients, differences in availability of adequate supplies and equipment, changes in the status of knowledge of physiology and surgery, and variations in the personnel concerned with the care of patients.

With these facets of the problem in mind, the present study was undertaken to compare three established methods of management of massive upper gastro-intestinal hemorrhage. The studies of Stewart [6, 7] are unique in the establishment of uniformity with regard to the definitions of "massive" and "acute" and we have adopted his definitions to standardize our selection of cases. Therefore, all of the patients included in our study have been selected according to Stewart's criteria and have had an acute bleeding episode within seven days of admission to the hospital, and all have bled sufficiently to reduce their total circulating red blood cell mass to less than 60 per cent of normal or their red cell count to less than 2.5 million per cu. mm.

Other factors, such as advances in knowledge of surgical care, variations in hospital clientele, and variations in ability and enthusiasm of attending personnel have been equalized insofar as possible by applying the methods of therapy under study on a basis of random selection, by caring for all patients in the same wards over the same period of time and by the same personnel.

Although review of our cases and review of the reports of others indicate that the majority of these cases are bleeding from peptic ulcers, this is a factor which is difficult to evaluate during the acute emergency. Emergency upper gastro-intestinal x-ray examination has been used to aid in the diagnosis, but the method has not proved to be of value in our hands because of fear of palpation of the abdomen, presence of blood clots in the stomach, and limited facilities.

The three types of therapy selected for study are 1) non-operative regimen, 2) immediately operative regimen, and 3) selectively operative regimen.

The non-operative regimen used has been

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that of Andresen,[1] a regimen which is based upon the concept that hypovolemia and hypotension prevent the clot from being dislodged from the bleeding vessel, that a quiet stomach assists in keeping the clot in place, and that low gastric acidity prevents the clot from being digested. Therefore, strict bed rest, reassurance, and frequent feedings of an antacid milk-gelatin mixture are the basis of the treatment. Blood is administered only for severe hypotension and evidences of anoxemia.

The immediately operative regimen is that proposed by Stewart *et al.*,[6, 7] based upon the concepts that gross gastroduodenal bleeding (from peptic ulcer) is a dangerous complication of the responsible underlying disease, that it is difficult to determine when bleeding has ceased or when it will recur, that the longer anoxemia from acute hemorrhage goes uncorrected the graver is the prognosis, that the diagnosis of gross bleeding can usually be made with reasonable accuracy, and that surgical arrest of such bleeding is feasible. Therefore, under this regimen the patient is immediately transfused and brought to the operating room as soon as the blood pressure and pulse are normal or it is determined that further improvement cannot reasonably be expected to occur preoperatively. Only patients who are moribund from associated diseases are excluded from operation.

The selectively operative regimen is based upon the concept that certain patients are more likely to die of hemorrhage than others. On the basis of the assumption that people with degenerative arterial disease are less likely to cease bleeding and are more likely to suffer complications of hypovolemia and anoxemia, all patients over 50 years of age and all patients who show clinical evidence of arteriosclerosis are operated upon as soon as it is possible to transfuse them and to restore their blood pressure and pulse to near normal levels. In this selectively operative regimen, patients who have a history of previous massive upper gastro-intestinal hemorrhage are also operated upon immediately because of the increased risk of repeated massive hemorrhage. Patients under 50 years of age and without arteriosclerosis or history of previous hemorrhage are treated according to the criteria of Hoerr, Dunphy, and Gray [3] in that if a predetermined amount of blood transfusion does not restore the blood pressure and pulse to normal and sustain them, operation is performed.

Method of Study

The protocol followed for the course of this study is as follows:

Patients who clearly are massive bleeders and patients who appear even possibly to be massive bleeders will be admitted to the same ward of the hospital for study and, if proved to be bleeding massively from the stomach or duodenum, for therapy; they 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 then ten minutes. Following admission to the "Study Group," studies on liver function will be performed to eliminate varices of the esophagus as the source of the hemorrhage, 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 admit patients to the "Study Group":

1. History in the seven days before admission of vomiting of blood or coffee-

ground material, or of pasage of tarry stools or unchanged blood by rectum.

2. An estimate by the Medical or the Surgical resident on Admissions on the University Service, whichever sees the patient first, that the patient has lost more than one-half liter of blood during the preceding seven days.

3. Absence of immediately obvious evidence or history of cirrhosis of the liver with esophageal varices or of blood dyscrasia.

4. Absence of any evidence of previous drainage operation on the stomach, or previous resection of the stomach.

A history of chronic bleeding or of acute bleeding for more than seven days does not eliminate patients from the group, provided factors 1, 2, 3, and 4 apply.

Admission to Therapy Group. Following admission to the "Study Group," either the RBC must be below 2.5 million, or the total circulating red blood cell mass must be below 60 per cent of normal (18 ml. per Kg. of 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 excretion.

Assignment to Type of Therapy. Designation of the type of therapy to be provided to any individual patient in the study must be truly random to achieve statistically sound conclusions. The type of therapy, therefore, will be determined on the basis of the last two digits of the hospital number. If the last two digits—as a single number—when divided by three: (a) come out even, then the Andresen regimen will be used, (b) come out with one left over, then the Stewart regimen will be used, (c) come out with two left over, then the Selectively Operative regimen will be used.

* RBC mass determined by RIHSA plasma volume and hematocrit.

Details of Method of Therapy to be Evaluated.

1. The non-operative regimen: Bed rest, gelatin-milk mixture every two hours, and mild sedation. Transfusion only for air hunger and evidences of cerebral or myocardial hypoxemia or for blood pressure below 80 mm. of mercury systolic, and then in 250 cc. amounts only. These patients will be followed and supervised by the medical consultant.

2. The immediately operative regimen: 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 felt that a further improvement will not occur preoperatively. Preoperative preparation should not require more than 12 hours.

3. The selectively operative regimen: Selection will be based upon several factors:

a) 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.

b) Arteriosclerosis: All patients who exhibit severe arteriosclerotic changes in eye grounds, films of the aorta, or peripheral arteries, will be operated upon as soon as properly evaluated and prepared (within 12 hours).

c) Previous massive hemorrhage: Patients who have a history of previous hemorrhage from the stomach or duodenum sufficient to cause clinical shock will be operated upon immediately (within 12 hours).

d) Failure of transfusion to combat shock: These patients will be evaluated and transfused with 1,500 ml. of whole blood 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 performed. If 1,500 ml. of blood is sufficient to restore the blood pressure and pulse to normal range, transfusion will be continued and, if more than 500 ml. of blood is required every eight hours to maintain normal blood pressure and pulse, operation will be done.

Patients re-admitted with massive upper gastro-intestinal hemorrhage who have once been in Therapy Group I (Andresen regimen) will be treated again in that group.

The operation to be performed in all cases in which operative therapy is selected is 75 per cent gastric resection with short loop, retrocolic Hofmeister-Polya gastrojejunostomy.

Findings

Between March 1, 1953, and April 1, 1958, 239 patients with upper gastro-intestinal bleeding were presented to us and admitted to the Study Group. One hundred and thirty patients were found to have met all the criteria for admission to the Therapy Group and to have been handled strictly by one of the three methods outlined above. The reasons for exclusion of study patients from the Therapy Group are listed in Table 1. The majority of the exclusions were made because of loss of circulating red blood cell mass of less than 40 per cent of estimated normal. Of the patients accepted into the Therapy Group for evaluation of methods, 58 were in the nonoperative sub-group, 37 in the immediate operative sub-group, and 35 were in the selective operative sub-group.

TABLE 1. *Reason for Exclusion from Therapy Group*

Insufficient blood loss	57
BSP elevated	12
Failure to follow protocol	9
Refusal of operation	6
Previous gastric surgery	5
Liver disease	5
Chronic hemorrhage	3
Neither blood nor acid	3
Previous transfusion	3
Gastritis from drugs	2
Questionable diagnosis	3
Intolerance to transfusion	1

TABLE 2. *Mortality of Therapy Groups*

Sub-Group	No. of Pts.	Deaths	Mortality
1. Nonoperative	58	8	14%
2. Immediate operation	37	5	14%*
3. Selective operation	35	5	14%
Total	130	18	14%

* 11 per cent mortality in patients who actually came to operation. (One died before operation could be done.)

The mortality of each sub-group was 14 per cent (Table 2). The causes of death in each Therapy sub-group are listed in Tables 3, 4, and 5. It is to be noted that one patient (R. T.) in the nonoperative sub-group was considered a failure of the nonoperative therapy after four episodes of massive hemorrhage, and operated upon on the tenth hospital day during one of these episodes. This patient expired on the 62nd postoperative day following a complicated course involving two subsequent laparotomies for recurrent bleeding from the previously excluded duodenal ulcer and progressive weight loss despite a high caloric, high protein diet which he took very well for the last month of his course. In sub-group 2, one patient (M. P.) died preoperative from cardiac failure but is considered in the mortality for this sub-group to give a true picture of the results from this method of management. There were 36 patients in sub-group 2 who were treated by immediate gastrectomy with four deaths, a mortality of 11 per cent in the group of patients subjected to operation. One patient in sub-group 3 (D. B.), age 53, was operated upon as an emergency and found to have a gastric lesion which was inter-

preted by the surgeon to be carcinoma. Because the condition of the adjacent gastric and duodenal tissue appeared to be too edematous and friable to permit safe gastrectomy, resection was not performed. This patient developed acute gastric dilation, vomited, and expired from aspiration of gastric contents on the fifth postoperative day. She is considered to represent a failure of therapy by the selective operative method.

The sources of bleeding in the Therapy Group are listed in Table 6. The sources of bleeding in the Study patients excluded from the Therapy Group are found in Table 7. The source of bleeding in each of the sub-groups in Table 6 are essentially the same, duodenal and gastric ulcers accounting for the majority of demonstrable lesions. A significant number of patients who had gastro-intestinal x-ray examinations did not have any lesion demonstrable. There were no x-ray examinations in the group 2 patients since these patients had all been subjected to gastrectomy on the day of admission. The sources of bleeding in the Study patients excluded from the Therapy Group are found to be largely gastro-duodenal lesions as well. Although an attempt was made to exclude patients with esophageal varices from the Therapy Group, one patient did not have this lesion demonstrated until after he had been successfully treated by the nonoperative regimen for the acute bleeding episode. This patient had a definite history of duodenal ulcer and was included in the Therapy Group on this basis.

TABLE 3. *Causes of Death*
Patients in Therapy Sub-Group 1

Patient	Age	Causes of Death
O. N.	62	Ca. of stomach, exsanguination, 1st day
I. H.	84	Exsanguination, 2nd day
H. B.	69	Transfused for air hunger, died during transfusion, 2nd day
S. B.	86	Congestive failure, 1st day
M. D.	77	Exsanguination on 20th day—17 transfusions (for anginal pain)
J. H.	72	Coronary occlusion at 4 weeks
B. K.	75	Perforated gastric ulcer, bronchopneumonia, 5th day
R. T.*	42	Chronic peritonitis, malnutrition on 62nd day following gastrectomy for repeated massive hemorrhage

* Considered a failure of the nonoperative therapy after four episodes of massive bleeding and shock, and gastrectomized on 10th day of hospitalization.

TABLE 4. *Causes of Death*
Patients in Therapy Sub-Group 2

Patient	Age	Causes of Death
J. P.	81	Perforation of duodenal stump, 3rd day
J. C.	50	Pulmonary embolus, 15th day
J. D.	54	Postoperative shock, 2nd day
S. W.	58	Myocardial infarction, 1st day
M. P.	85	Died preoperatively of cardiac failure

In an attempt to evaluate the risk of the three methods of therapy as fairly as possible, mortality rates in the three groups have been calculated with consideration of all patients with acute hemorrhage, a total circulating red blood cell mass less than 60 per cent of normal, no liver disease, and no previous gastric operation. Table 8 indicates the mortality of each sub-group, including all of these patients. This table includes the patients in the Therapy Group plus the patients who were excluded for various reasons which are listed in Tables 9, 10, and 11.

Those patients excluded from consideration of the results of the non-operative therapy were excluded by reason of having been previously transfused or transfused in amounts of blood greater than 250 cc. increments. These patients were then not considered proper for evaluation of the method of therapy as described by Andresen.

The single death listed in Table 10 (the sub-group which would have been treated by immediate operation) is a patient in

whom gastric carcinoma was diagnosed by emergency G. I. series. It was, therefore, decided not to perform an emergency gastrectomy. This patient died of cerebral vascular accident on the day of admission to the hospital.

The patients who expired after having been excluded from the selectively operative sub-group (Table 11) were excluded because they were not adequately transfused as required by this method of therapy. M. R., a 30-year-old male, received only 500 ml. of blood during the day of the patient's hospitalization. After receiving 500 ml. of blood slowly because there was no additional blood of this patient's type available in the blood bank, the patient developed extreme respiratory difficulty, cyanosis, and restlessness. He expired some hours later without recovering from these symptoms. Autopsy revealed that the patient had esophageal varices, chronic passive congestion and mild portal cirrhosis of the liver, bilateral hydrothorax, pulmonary edema, and beginning bronchopneumonia. There was no blood in the gastro-intestinal tract except in the colon. C. N., age 62, was not treated by immediate operation because there was insufficient blood available for transfusion. This patient died on his eighth hospital day from a perforated duodenal ulcer which apparently occurred on the sixth hospital day when it was overlooked in the concentration of attention to mild congestive failure and pneumonia.

The mean ages of the patients are shown in Table 12. It is noted that the age of each group is about the same, but that the ages of the patients who expired are considerably higher than the mean age. The mortality over the age of 50 is shown in Table 13.

TABLE 5. *Causes of Death*
Patients in Therapy Sub-Group 3

Patient	Age	Causes of Death
A. W.	82	Cardiac failure, 1st day
P. S.	81	Cardiac failure, 3rd day
R. P.	63	Fecal fistula, peritonitis, 31st day
Y. A.	63	Wound dehiscence, atelectasis, pneumonia, 7th day
D. B.	53	Gastric dilation and aspiration, 5th day

TABLE 6. *Sources of Bleeding—Therapy Group*

	Group 1	Group 2	Group 3	Total
Duodenal ulcer	19	21	17	57
Gastric ulcer	5	10	7	22
Gastric cancer	2	2	1	5
Gastritis	1	2	2	5
Hiatus hernia	4	—	—	4
No lesion at operation	1	1	—	2
Esophageal varices	1	—	—	1
Leiomyosarcoma, jejunum	1	—	—	1
No lesion by x-ray	14	—	5	19
Undetermined	10	1	3	14

TABLE 7. *Sources of Bleeding*
Study Patients Excluded from Therapy Group

Duodenal ulcer	40
Gastric ulcer	11
Gastritis	8
Gastric cancer	4
Hiatus hernia	3
Liver disease, varices	3
Duodenal diverticulum	2
Prolapsed antral mucosa	1
Undetermined	24
No lesion found on x-ray	11
No lesion found at operation	2
Total	109

TABLE 8. *All Patients with Acute Hemorrhage, RBC Mass Below 60%, No Liver Disease, and No Previous Gastric Operation* *

Sub-Group	No. of Pts.	Deaths	Mortality
1. Nonoperative	62	11	18% (14%)
2. Immediate operation	47	6	13% (14%)
3. Selective operation	44	7	16% (14%)
Total	153	24	16%

( ) = Therapy Group.

* This table includes the patients in the Therapy Group plus the patients who were excluded for various reasons which are listed in Tables 9, 10, and 11.

It is noted that the risk of operation in these elderly patients is probably no higher and may be slightly less than the risk of not operating upon these patients. The single death in the Therapy Groups under the age of 50 occurred in the patient aged 42 who was treated by the nonoperative regimen until that therapy was considered a failure.

The mortality of patients admitted with symptoms or signs of shock is listed for each group in Table 14. It is seen that there is no statistically significant difference in mortality among the three modes of therapy.

Comment

After our search of the surgical literature had failed to reveal any controlled observations on the comparison of the various methods of treating massive upper gastrointestinal hemorrhage, this study was undertaken to compare three well-established methods of handling these patients. Using the criteria of Stewart for massiveness and acuteness of hemorrhage, these three methods of therapy have been evaluated simultaneously, being careful to randomize among the three methods of therapy on a statistically valid basis. Our results indicate that the surgical therapy of patients who have bled acutely and have lost at least 40 per cent of the calculated normal total circulating red cell mass offers of salvage rate not significantly different from medical therapy for the bleeding episode. This is in contradistinction to the reports of Andresen and Meulengracht,[4] who have indicated that medical therapy results in a mortality rate of about 2 per cent. The latter figures, however, were calculated on the basis of paients who were not selected according to the criteria of Stewart.

Our experience in 239 patients indicates that the selection of patients for therapy of massive bleeding on the basis of a loss of 40 per cent of the calculated normal total circulating red cell mass is an extremely useful one. No patient in our series who had lost less than 40 per cent of his normal total circulating red blood cell mass had died of gastro-duodenal bleeding. It might be suggested, therefore, that mortality figures based upon groups of patients which include those who have lost less than 40 per cent of their normal red cell mass are less significant than those based on the criteria of Stewart.

While the majority of patients in the nonoperative therapy group died of exsanguination, the majority of those in the operative groups died of postoperative complications. However, the mortality from operation in sub-group II was 11 per cent. Also, it must be realized that the patients who were treated nonoperatively may be subjected to the same risk over again from

TABLE 9. *Sub-Group 1*

Excluded Cases with Acute Hemorrhage, RBC Mass Below 60%, No Liver Disease, and No Previous Operation

Patient	Reason Not Included	Result
S. B.	Previously transfused	Exsanguinated
I. S.	Previously transfused	Exsanguinated
C. B.	Previously transfused	Exsanguinated
J. L.	Over-transfused	Recovered

TABLE 10. *Sub-Group 2—Immediate Operation Excluded Cases with Acute Hemorrhage, RBC Mass Below 60%, No Liver Disease, and No Previous Operation*

Patient	Reason Not Included	Result
J. D.	Operation delayed	Recovered
W. B.	? upper gastro-intestinal bleeding	Recovered
J. C.	No gastric blood or acid	Recovered
E. T.	Misdiagnosis	Recovered
J. B.	Diagnosed carcinoma	Died, CVA
S. K.	Refused operation	Recovered
E. S.	Exploratory laparotomy only	Recovered
N. L.	Refused operation	Recovered
S. S.	Taken Butazolidine	Recovered
H. B.	Taken Clinitest tablets	Recovered

a subsequent episode of massive hemorrhage. The patients who have had gastrectomies appear to us less likely to experience this risk thereafter.

The operation used in all these cases was 75 per cent subtotal gastrectomy with a short loop Hofmeister-Polya retrocolic gastrojejunostomy. It may be that the use of different types of surgical therapy in selected cases would lower the operative mortality in these elderly patients. Perhaps the application of vagotomy in patients who are bleeding from gastritis, as suggested by Mixter and Hinton,[5] would reduce the postoperative complications in this group. Also, the use of segmental resection of the stomach plus pyloroplasty, as suggested by Wangensteen,[8] may make the operation in bleeding duodenal ulcer less formidable and result in a lower risk in this group. We have retained the original operative procedure in the interest of minimizing the number of variables in the study.

Early experience in this study indicated that the bromsulphalein test for liver function is an unreliable index of the presence of liver disease in bleeding patients. We found several patients with elevated BSP's while they were in hypovolemia whose BSP's returned to normal after the blood volume had been restored. Therefore, we no longer use the BSP as an index per se of the presence of cirrohsis of the liver and presumptive diagnosis of bleeding esophageal varices, but we use the test only as corroborative evidence. On the basis of the knowledge that patients with esophageal varices have a higher incidence of gastric and duodenal ulcers than the average population,[2] the patients with cirrhosis are not excluded from the Therapy Group without careful evaluation.

TABLE 11. *Sub-Group 3—Selective Operation Excluded Cases with Acute Hemorrhage, RBC Mass Below 60%, No Liver Disease, and No Previous Operation*

Patient	Reason Not Included	Result
M. R.	Inadequate transfusion	Died (cardiac ?)
C. N.	No blood	Died (perforated ulcer)
E. W.	Operation delayed	Recovered
A. L.	Cardiac failure	Recovered
I. R.	Operation delayed	Recovered
J. F.	Refused operation	Recovered
U. S.	Refused operation	Recovered
H. H.	Refused operation	Recovered
N. O'S.	Refused operation	Recovered

TABLE 12. *Average Age of Patients*

	Sub-Group 1	Sub-Group 2	Sub-Group 3
Study Group	54	55	56
Alive	51	53	56
Dead	68	70	61
Therapy Group	54	56	54
Alive	51	54	51
Dead	71	69	61

We previously used the absence of both free acid and blood in the gastric aspirate as a basis for exclusion of the diagnosis of bleeding duodenal ulcer. We have had two patients with duodenal ulcer and one with gastric ulcer who had no free acid or blood in the gastric aspirate. Other patients with gastritis and duodenitis have also had no free acid.

Examination of our experience with the nonoperative regimen in elderly patients indicates that the risk of nonoperative management in selected patients may not be as high as we had presumed when the protocol for this study was designed. Therefore, it appears that application of the method of selection described by Hoerr, Dunphy, and Gray to elderly patients may be preferable, and we are revising our evaluation of methods accordingly.

Conclusions

1. Management of 130 patients suffering from massive upper gastro-intestinal bleed-

ing has been divided into nonoperative, immediately operative, and selectively operative regimens by statistically valid means.

2. The mortality rate has been 14 per cent in each of the groups of patients who have been properly handled according to the various therapy regimens.

3. Although the operative therapy for a single episode of massive upper gastrointestinal bleeding was in this study identical to that of nonoperative therapy, the patient mortality may be lower in the operative group because these patients are usually no longer subject to further episodes of massive bleeding.

4. The mortality in the group of patients subjected to immediate operation was 11 per cent.

5. No patient who lost less than 40 per cent of the calculated normal total circulating red blood cell mass died of exsanguinating hemorrhage.

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TABLE 13. *Mortality According to Age Therapy Groups*

Over Age	No Operation*		Immediate Operation**	
50	(7/35)	20%	(9/46)	20%
60	(7/22)	32%	(7/34)	21%
70	(5/11)	45%	(5/15)	33%
80	(2/3)	66%	(3/5)	60%

One death under age 50 (in "No Operation" group).

* Sub-Group 1.

** Sub-Groups 2 and 3 (all of the patients in these two groups over age 50 were treated by immediate operation).

TABLE 14. *Mortality of Patients Admitted in Shock Therapy Groups*

Sub-Group	Living	Dead	Mortality
1. Nonoperative	24	5	17%
2. Immediate operation	19	3	14%
3. Selective operation	18	4	18%

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