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Emergency Surgical Treatment for Bleeding Duodenal Ulcer: Oversewing plus Vagotomy versus Gastric Resection, a Controlled Randomized Trial

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The best surgical procedure to treat bleeding bulbar peptic ulcer is unknown. The rates of postoperative bleeding recurrence, duodenal leakage, and mortality were compared in patients undergoing oversewing plus vagotomy (O+V) or gastric resection (GR) with ulcer excision. Of 202 patients undergoing emergency surgery for massive, persistent, or recurrent bleeding from bulbar peptic ulcer, 120 patients were enrolled in a prospective randomized trial. Fifty-nine were assigned to O+V and 61 to GR. One patient in each group was excluded after randomization. The two groups were well matched with respect to clinical and prognostic factors. The rate of postoperative bleeding recurrence was 17% after O+V and 3% after GR ($p < 0.05$). The duodenal leak rate was higher after GR than after O+V (13% vs. 3%) ($p < 0.10$) but was not different when the morbidity of reoperations for bleeding recurrence after O+V was considered on an "intention to treat" basis (12% vs. 13%). Overall postoperative mortality was similar: 22% (O+V) versus 23% (GR). Sixteen deaths were unrelated to the surgical procedure itself. Of 82 nonrandomized patients, 10 were not analyzed. In the 72 other nonrandomized patients, bleeding recurrence, duodenal leakage, and postoperative mortality rates were consistent with the results of the controlled trial, as they were 29% (O+V 32%; GR 0.7%), 16% (O+V 0.7%; GR 26%) and 27% (O+V 18%; GR 33.3%), respectively. We conclude that GR with ulcer excision is the procedure of choice for the emergency surgical treatment of bleeding duodenal ulcer because postoperative bleeding recurrence is lower, and the overall rates of mortality and duodenal leakage are the same as with O+V.

Despite increasing use of H₂-receptor antagonists, overall admission rates for bleeding duodenal ulcers remain unchanged and have even increased among the elderly [1, 2]. Bleeding duodenal ulcer is a significant cause of hospital death, with an overall mortality of 5% to 10% [3-8]. There is little doubt that despite adequate medical and endoscopic treatment, some patients still require surgical intervention to control bleeding duodenal ulcer.

Several retrospective studies have stated that oversewing the ulcer plus vagotomy and drainage was better than gastric resection with excision of the ulcer [9-14]. Other studies, however, showed that the mortality and morbidity of both operations were similar [15-18] or were in favor of gastric resection [19, 20]. To determine the most appropriate emergency surgical treatment (satisfactory short-term morbidity and mortality) for bleeding peptic duodenal ulcer, we compared these two methods in a controlled randomized clinical trial. To our knowledge, results of such a trial have not yet been published.

Patients and Methods

Patients

From January 1, 1978 to January 1, 1988 (10 years), 202 consecutive patients (136 men, 66 women; mean age 62.4 years, range 18-96) met the entry criteria for the study. Patients of both sexes, over 18 years of age, were eligible. Patients under 18 years of age or who had previously undergone surgical treatment for gastroduodenal disease were not included. The study was conducted by two French associations for surgical research that included 22 public and private surgical centers. Although all centers finished the study in 1988, some did not begin at the same time.

The diagnosis was established when a bulbar duodenal ulcer was believed to be the site of bleeding on endoscopic examination. Patients with a duodenal ulcer without endoscopic signs of active or recent bleeding, with gastric or postbulbar duodenal ulcers, or with acute gastroduodenal ulcerations were not included.

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Patients were included in this trial when they had one of the following types of hemorrhage: (1) massive hemorrhage (presence of clinical shock on admission requiring permanent, high-rate transfusion to stabilize blood pressure); (2) persistent hemorrhage (continued blood requirements exceeding 6 units in 4 days); (3) recurrent hemorrhage (new hemorrhage occurring during the first week with a subsequent fall of blood pressure of 40 mmHg or more, hematocrit less than 30%, or both). Melena alone was regarded as being insufficient evidence of recurrent hemorrhage.

Clinical and Laboratory Risk Factors

The following data were determined for each patient: prior use of ulcerogenic (steroid or nonsteroid) antiinflammatory drugs or anticoagulant therapy, cirrhosis of the liver, lowest preoperative red blood cell (RBC) count, preoperative transfusion requirements, and the delay from admission to surgery.

Treatment

Two surgical techniques were compared: (1) Oversewing of the ulcer plus truncal vagotomy (O+V) and drainage (Heineke-Mikulicz pyloroplasty or gastroenterostomy). Selective or proximal gastric vagotomy was allowed in this group. Ligation of the gastroduodenal and right gastroepiploic arteries [14] was performed whenever possible. (2) Gastric resection of the distal two-thirds of the stomach (GR) with complete excision of the anterior ulcer and the margins of posterior ulcer, leaving the bottom of the ulcer. Anastomosis or duodenal stump closure was always performed distal to the ulcer. Truncal vagotomy plus antrectomy was allowed in this group. The type of gastrointestinal reconstruction—Billroth I (BI) gastroduodenostomy or Billroth II (BII) gastrojejunostomy—was also randomized in 14 of the 22 surgical centers. Partial gastrectomy without excision of the ulcer was prohibited because of a high risk of bleeding recurrence. Surgeons were at liberty to choose between the hand-sewn or stapled techniques for gastric and duodenal stump closure because it has not yet been shown that one technique was better than another. All patients were operated on by senior residents or staff surgeons.

Randomization

Patients were randomly assigned to one of the treatment arms after the diagnosis had been confirmed at operation, bleeding had been arrested through an antropylootomy, and the feasibility of performing both operations was established. Randomization was performed in the operating room by unfolding the right upper corner of previously sequentially bound questionnaires hiding the particular treatment allocated to each patient, as generated with random number tables, according to the recommendations of the Cancer Research Campaign Working Party [21]. Randomization was stratified according to three criteria: sex, age (less than, more than, or equal to 60 years), and the presence or absence of liver cirrhosis; it was balanced every four patients, so that patient matching could be attained more easily in each center for each stratum. Allocation to GR BI or GR BII, when randomized, was determined in the same man-

ner. The research protocol was approved by the ethical committee of one of the participating centers.

Endpoint Criteria

The major endpoint of the study was the rate of postoperative bleeding recurrence, defined as rebleeding (diagnosed by fibroscopic investigation, reoperation, or both and requiring at least 1 unit of blood) that occurred during the same hospital admission or during the first month after discharge. This endpoint was chosen because the principal goal of treatment was to arrest the hemorrhage and because rebleeding after surgery is associated with high mortality [22]. Subsidiary criteria included (1) the rate of duodenal leak (defined as the leakage of gastroduodenostomy in BI, the duodenal stump closure, or of gastrojejunostomy in BII) and diagnosed by clinical discharge, gastrointestinal imaging [fistulograms, sodium diatrizoate x-ray study, computed tomography (CT) scan], reoperation or postmortem examination; (2) postoperative mortality (defined as death occurring during the same hospital stay); and (3) the duration of postoperative hospital stay. Postmortem examination was performed routinely to determine the cause of death.

Number of Patients

As regards the above defined population of patients, a retrospective study in the participating surgical centers prior to this trial had shown that, in this setting, three-fourths of the surgeons routinely used O+V, and one-fourth routinely used GR; among the latter, three-fourths preferred BII reconstruction. In that retrospective study, both the bleeding recurrence and the postoperative mortality rates were found to be approximately 25%. Likewise, a survey of the literature had shown that the bleeding recurrence rate ranged from 4% to 28% [10, 15, 18, 19]. Considering a 5% α and β risk in one-tailed analysis, and in order to detect a decrease in the bleeding recurrence rate from 25% to 5%, it was necessary to analyze the results after 60 patients had been enrolled in each group [23]. Groups were compared using Student's *t*-test for means and the χ^2 test with Yate's correction or Fisher's exact solution, as appropriate, for the evaluation of qualitative variables.

Results

Randomized, Unrandomized, and Withdrawn Patients

Of 202 consecutive patients, 33 were not included because the operating surgeons did not participate in the study. Of the 169 patients operated on by participating surgeons, 49 were not randomized: 32 because of organizational problems in some centers at the beginning of the study and 17 because they were considered as poor operative risks. The latter group underwent operation, however, because of the severity of hemorrhage; and the surgeon preferred to perform the operation with which he had the most experience. Of 120 patients who were randomized (71%), 58 had O+V, 60 had GR, and 2 were withdrawn because they did not have the originally assigned operation. One patient, randomized to O+V, had vagotomy plus antrectomy with BI reconstruction; he left the hospital in good health 9 days after operation. The other patient, randomized to GR, had O+V; he

Table 1. Operations performed in randomized patients.

Randomization and operation performed	No.
Oversewing + vagotomy	59
Truncal vagotomy	54
Selective vagotomy	3
Hyperselective vagotomy	1
Antrectomy Billroth I + vagotomy	1 ^a
Gastrectomy	61
Gastrectomy ^b Billroth I	18
Antrectomy Billroth I + vagotomy	6
Gastrectomy ^b Billroth II	20
Antrectomy Billroth II + vagotomy	16
Oversewing + vagotomy	1 ^a

^aPatients not included in final analysis.
^bResection of distal two-thirds of the stomach.

Table 2. Patient characteristics: comparability of groups.

Patient characteristics	Vagotomy + oversewing	Gastrectomy
Total no. of patients ^a	58	60
Sex ratio (M/F)	41/17	37/23
Mean (range) age (years)	62 (21-85)	60 (18-85)
Prior ulcerogenic drugs (no. patients)	23	21
Prior anticoagulant therapy (no. patients)	7	3
Lowest RBC count (mean ± SD) (10 ⁶ /ml)	2.7 ± 0.9	2.7 ± 0.8
Amount of blood transfused (mean ± SD) (units)	7.2 ± 4.4	7.1 ± 4.2
>Three units of blood transfused (no. patients)	45	48
Massive hemorrhage (no. patients)	18	18
Persistent hemorrhage (no. patients)	14	22
Recurrent hemorrhage (no. patients)	26	20
Mean (range) delay to surgery (hours)	57 (1-360)	64 (1-408)
Liver cirrhosis (no. patients)	5	7
Posterior duodenal wall ulcer (no. patients)	41	43
Mean (range) hospital stay ^b (days)	22 (6-90)	19 (6-86)

^aOne patient was withdrawn in each group because the randomly allocated operation was not performed.
^bPostoperative deaths excluded.

died of bleeding recurrence and associated leak of the pyloroplasty. Details of procedures are reported in Table 1. In the GR group, 22 patients had truncal vagotomy plus antrectomy. A BI reconstruction was performed in 24 patients and a BII reconstruction in 36.

Randomized Group

Comparability of Groups. The O+V and GR patient groups did not differ significantly by any of the characteristics listed in Table 2.

Postoperative Bleeding Recurrence. Bleeding recurrence occurred more frequently after O+V (17%) than after GR (3%) ($p < 0.05$) (Table 3). The 10 episodes of bleeding recurrence in the

Table 3. Postoperative complications.

Parameter	Oversewing + vagotomy		Gastric resection
No. of patients	58		60
Bleeding recurrences	10	*	2
Duodenal leaks	2	**	8
Deaths	13		14
Reoperations	8		1
For bleeding recurrences	6		0
For duodenal leaks	2		1
Deaths after reoperation	4		1

* $p < 0.05$; ** $p < 0.10$.

Table 4. Postoperative complications according to whether artery ligation was performed and the type of gastrointestinal reconstruction.

Complication	Oversewing + vagotomy		Gastric resection	
	Artery ligation	No artery ligation	BI	BII
No. of patients	8	50	24	36
Bleeding recurrence	0	10	1	1
Duodenal leaks	0	2	0	8
Deaths	1	12	5	9

BI: Billroth I; BII: Billroth II.
^a $p < 0.05$.

O+V group originated from the ulcer itself: four were treated conservatively with two deaths, whereas six patients had reoperation converting O+V to GR BII, with two deaths. In the GR group, two patients rebled: one from the mechanical suture of the gastric stump after GR BI, and the other from the duodenal stump after GR BII. Both patients recovered with conservative management.

Ligation of the gastroduodenal and right gastroepiploic arteries in the population treated by O+V lowered the rate of bleeding recurrence, as no bleeding recurrence was noted in 8 patients with arterial ligation versus 10 bleeding recurrences in 50 patients without arterial ligation (Table 4).

Duodenal Leakage. Duodenal leaks occurred more frequently after GR (13%) than after O+V (3%) ($p < 0.1$) (Table 3). Six additional GR BII were performed for bleeding recurrence after O+V, with five postoperative duodenal leaks. Therefore, when the results were analyzed on an "intention to treat" basis (i.e., including leaks after reoperation following failure of O+V), the duodenal leak rate was similar for O+V (7/58) and GR (8/60).

Duodenal leaks were less frequent after BI than after BII in patients randomized for reconstruction: No duodenal leaks occurred in the 13 patients with BI, and four duodenal leaks occurred in 16 patients with BII reconstruction (difference not statistically significant). In patients undergoing GR (Table 4), no leaks occurred in the 24 patients with BI, whereas 8 occurred in the 36 with BII reconstruction ($p < 0.05$). The duodenal leak rate was similar for BI (1/29) and O+V (5/115).

Deaths. Of the 118 patients (23%) included in the trial, 27 died during the postoperative period (Tables 3, 4, 5). There was no

Table 5. Pathologic conditions associated with intraoperative and postoperative death.

Condition	Oversewing + vagotomy (n = 58)	Gastrectomy (n = 60)
No. of deaths	13	14
Intraoperative cardiac arrest	2	0
Recurrence of bleeding from ulcer	4	0
Duodenal leak	4 ^a	4
Liver cirrhosis with portal hypertension	1	2
Associated terminal malignancy	0	1
Pulmonary complications (infection, inhalation, embolism)	3	3
Cardiac failure	2	4
Cerebrovascular stroke	1	0
Necrotizing enterocolitis	0	1
Septicemia	2	2
Renal failure with anuria	0	2
Unknown	1	0

Four patients had three pathologic conditions and four had two conditions.

^aTwo leaks occurred after reoperation (BII) for recurrence of bleeding.

significant difference in mortality between the two surgical procedures.

The main pathologic entities associated with postoperative death are listed in Table 5. Eight of 13 deaths in the O+V group and 4 of 14 deaths in the GR group were associated with postoperative recurrence of hemorrhage, duodenal leak, or both, as four patients died with recurrence of bleeding in O+V and none in GR; four in each group died with duodenal leak.

Prognostic Factors. Four factors were significantly associated with the risk of postoperative death (Table 6): age over 50 (76% of patients) and age over 60 (63%), massive hemorrhage, preoperative transfusions exceeding 3 units of blood, and site of the ulcer on the posterior duodenal wall. However, none of these same factors, not even cirrhosis (Table 6), significantly influenced the postoperative bleeding recurrence rate.

Mean Duration of Postoperative Hospital Stay. Not counting postoperative deaths, the mean duration of hospital stay was longer after vagotomy than after gastrectomy, but this difference did not reach statistical significance (Table 2).

Center Effect. There were no significant differences between centers concerning selection of patients and results.

Unrandomized Group

Of the 82 unrandomized patients, 57 had O+V, 15 had GR, and 10 were excluded from further comparison because they underwent procedures shown to be ineffective [22] and not allowed in the trial: Six patients had oversewing alone with six bleeding recurrences, one duodenal leak, and four deaths; and four patients had gastrectomy without ulcer excision, with three recurrent rebleeding episodes, three duodenal leaks, and three deaths.

Compared with the randomized group, the unrandomized group was significantly different with respect to four preoperative items: higher blood requirements, more frequent massive hemorrhage, less frequent recurrent hemorrhage, and shorter delay to surgery.

Table 6. Factors related to postoperative death.

Factor	Patients (no.)	Deaths (no.)
No. of patients	118 (100%)	27
Sex		
Male	78 (66%)	18
Female	40 (34%)	9
Age >50 years	90 (76%)	* 26
Age >60 years	74 (63%)	* 23
>Three units of blood preoperatively	93 (79%)	** 25
Massive hemorrhage	36 (31%)	* 14
Persistent hemorrhage	36 (31%)	7
Recurrent hemorrhage	46 (38%)	6
Presence of liver cirrhosis	12 (10%)	4
Posterior duodenal wall ulcer	84 (71%)	** 24

*p < 0.02; **p < 0.05.

The results of the unrandomized group confirmed those of the randomized trial: There were fewer postoperative bleeding recurrences after GR (1/15) than after O+V (18/57), fewer postoperative bleeding recurrences with O+V after arterial ligation (1/12) than after no arterial ligation (17/45), and fewer duodenal leaks after O+V (3/57) than after GR (4/15). The mortality rate was 21% (15/72), similar to that in the randomized group (27/118).

Discussion

Gastric resection with ulcer excision procures better definitive control of bleeding from bulbar duodenal ulcer than oversewing plus vagotomy. Gastroduodenal reconstruction is preferable to gastrojejunostomy because of the high rate of duodenal leak after the latter. When the gastroduodenal and gastroepiploic arteries are easily accessible to ligation, O+V is an attractive alternative. However, postoperative mortality after O+V or after GR for the emergency surgical treatment of bleeding duodenal ulcers is not different (Table 3).

The incidence of postoperative bleeding recurrence after O+V was 17% (Table 3), similar to that reported in 1990 by Hunt and McIntyre [18]. Although ligation of gastroduodenal and gastroepiploic arteries was not randomized, the absence of rebleeding in the randomized O+V group when this procedure was used is noteworthy (Table 4). In Weinberg's original report [14], this additional procedure was not used routinely but as a further precaution against recurrence of bleeding; it should be attempted only if these arteries are easily accessible. Other authors [15, 16] have assumed that this procedure should be added to O+V, but neither the feasibility nor the efficacy of the technique was evaluated.

Duodenal leaks occurred more frequently after gastrectomy. However, when the morbidity of reoperations for bleeding recurrence after O+V was considered on an "intention to treat" basis, the duodenal fistula rate after O+V was not different from that after GR BII, underscoring the preference for Weinberg's operation or GR BI. Leakage of pyloroplasty occurred in 0% to 6% of patients treated by O+V for bleeding duodenal ulcers [10, 17, 19, 24]. The risk of duodenal leakage after GR BI performed for bleeding duodenal ulcer has not been evaluated before, even in Herrington's and Davidson's report, which strongly advocated this type of reconstruction [15].

Duodenal leaks have been reported to occur in 2% to 10% of patients treated with GR BII for bleeding duodenal ulcer [16, 17, 19, 25]. Roux-en-Y gastrojejunostomy [15] or catheter duodenostomy [16] have been proposed as methods to prevent duodenal stump problems after BII reconstruction. In our study, duodenal leaks occurred nearly exclusively after GR BII. Although surgeons tend to perform GR BII when the duodenal stump seems less suitable for anastomosis or because the ulcer is posterior, we decided to minimize this bias by randomization between the two types of reconstruction. However, in this subgroup of randomized reconstruction, all leaks occurred in the BII group.

In accordance with other authors [4, 26–29], we found that age over 60 years and even over 50 years [11, 20, 30], preoperative transfusion requirements of more than 3 units, and massive hemorrhage were significantly associated with increased postoperative mortality (Table 6). In the present study, 31% of patients had massive hemorrhage, 76% were over 50 years old, and 79% had more than 3 units of blood transfused. This high proportion of poor-risk patients might explain why the overall mortality of 23% observed in our trial lies in the upper limit of the 15% to 25% range reported in the literature [5, 9, 15, 16, 19, 31]. As these prognostic factors were equally distributed within the two randomized treatment arms (Table 2), however, our results are in contradiction with general teaching, which states that O+V carries a lower mortality rate than GR and should be reserved for poor-risk patients. In fact, as may be seen in Tables 5 and 6, several deaths were not directly related to the surgical procedure itself and seemed unavoidable, lending support to the observation that for a given risk of death, surgical intervention per se has probably little or no influence on mortality [26]. A lower postoperative mortality rate would be expected, however, providing that the procedure procuring more definitive control of bleeding with fewer postoperative complications is employed. The rates of postoperative bleeding recurrence and duodenal leak may therefore represent better judgment criteria than mortality itself for comparing the two surgical procedures.

A reduction in the incidence of bleeding recurrence or of the need for emergency surgery for upper gastrointestinal hemorrhage after endoscopic sclerosis has been demonstrated in three trials [32–34]. However, according to the availability of skilled endoscopists, there is no alternative to emergency surgical hemostasis in patients with massive hemorrhage, pyloric stenosis, or a deformed bulb with posterior duodenal ulcer [34].

As case selection, resource availability, and surgical skill play a major role in the evaluation of surgical procedures, the multicenter, nationwide character of this study, including patients from public or private practices [5], and the analysis of all the unrandomized patients strengthens our conclusions and is consistent with the wide diffusion of results.

Although the optimal timing for surgery remains controversial, it seems reasonable to expect a reduction in the otherwise high mortality rates by performing earlier GR BI or O+V with artery ligation, particularly in patients at risk [18] (over 60 years old, severe bleeding on admission, and ulcers inaccessible to endoscopic methods) before their prognosis worsens by further recurrence [28].

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Résumé

La meilleure technique chirurgicale pour traiter l'ulcère du bulbe hémorragique n'est pas connue avec certitude. On a comparé les fréquences de récurrence hémorragique, de lâchage du moignon duodénal et de mortalité chez des malades ayant une vagotomie avec suture de l'ulcère (VS) avec celles des patients ayant eu une gastrectomie avec excision de l'ulcère (GE). Parmi 202 malades ayant eu une chirurgie d'urgence pour ulcère du bulbe dont l'hémorragie était massive, persistante ou récidivante, 120 ont été tirés au sort dans le cadre d'une étude prospective randomisée. Cinquante-neuf malades ont eu une VS et 61, une GE. Les deux groupes étaient similaires en ce qui concerne les facteurs pronostiques et leurs caractéristiques cliniques. La fréquence de récurrence hémorragique a été de 17% après VS et de 3% après GE ($p < 0.05$). La fréquence de lâchage du moignon était plus élevée après VS (13% vs 3%) ($p < 0.01$) mais ne différait plus lorsque ces mêmes fréquences ont été calculées en incluant les malades qui ont eu une gastrectomie secondaire après échec de VS (12% vs 13%). La mortalité postopératoire globale était similaire dans les deux groupes: 22% (VS) vs 23% (GE). Seize des décès n'étaient pas en rapport avec l'acte chirurgical lui-même. Parmi 82 autres malades non randomisés, 10 dossiers n'ont pas été analysés. Des 72 malades restants, la fréquence de récurrence hémorragique, de lâchage du moignon duodénal et de mortalité postopératoire étaient compatibles avec les résultats de l'étude randomisée: 29% (VS: 32%; GE: 0.7%), 16% (VS: 0.7% vs GE: 26%) et 27% (VS: 18%; GE: 33.3%), respectivement. Nous concluons que, par rapport à la VS, la GE est le procédé de choix pour traiter l'ulcère duodénal hémorragique car la fréquence de récurrence hémorragique est plus basse mais la fréquence globale de mortalité et de lâchage du moignon sont similaires.

Resumen

No se sabe cual es el mejor procedimiento quirúrgico en el manejo de una úlcera duodenal bulbar sangrante. Las tasas de resangrado postoperatorio, de fuga de la sutura duodenal y de mortalidad fueron comparadas en pacientes sometidos a sutura + vagotomía (S+V) o a resección gástrica (RG) con resección de la úlcera. De 202 pacientes sometidos a cirugía de urgencia por hemorragia masiva, persistente o recurrente a partir de una úlcera péptica bulbar, 120 fueron incorporados en un ensayo clínico prospectivo y randomizado. Cincuenta y nueve fueron asignados a S+V y 61 a RG. Un paciente de cada grupo fue excluido luego de la randomización. Los dos grupos eran similares en cuanto a factores clínicos y de pronóstico. La tasa de sangrado recurrente postoperatorio fue 17% después de S+V y de 3% después de RG ($p < 0.05$). La tasa de fuga de la sutura duodenal fue mayor con la RG que con la S+V (13% vs. 3%) ($p < 0.10$), pero no hubo diferencia cuando la morbilidad de las reoperaciones por recurrencia del sangrado después de S+V fue considerada sobre la base de una "intención de trat-

amiento" (12% vs. 13%). La mortalidad postoperatoria global fue similar: 22% (S+V) vs. 23% (RG). Dieciseis muertes no estuvieron relacionadas con el procedimiento quirúrgico mismo. De 82 pacientes no randomizados, 10 no fueron analizados; en los otros 72 no randomizados, las tasas de sangrado recurrente, escape duodenal y mortalidad postoperatoria aparecieron consistentes con los resultados observados en el ensayo clínico controlado: 29% (S+V: 32%; RG: 0.7%), 16% (S+V: 0.7%; RG: 26%) y 27% (S+V: 18%; RG: 33.3%), respectivamente. Nuestra conclusión es que la RG con resección de la úlcera es el procedimiento de elección en el tratamiento quirúrgico de urgencia de la úlcera duodenal sangrante, en virtud de una menor tasa de recurrencia postoperatoria del sangrado al tiempo que las tasas de mortalidad y de fugas de la sutura duodenal son iguales a las de la S+V.

References

- Bardhan, K.D., Cust, G., Hinchliffe, R.F.C., Williamson, F.M., Lyon, C., Bose, K.: Changing pattern of admissions and operations for duodenal ulcer. *Br. J. Surg.* 76:230, 1989
- Gustavsson, S., Kelly, K.A., Melton, J., Zinsmeister, A.R.: Trends in peptic ulcer surgery: a population-based study in Rochester, Minnesota, 1956-1985. *Gastroenterology* 94:688, 1988
- Hunt, P.S.: Surgical management of bleeding chronic peptic ulcer: a ten year prospective study. *Ann. Surg.* 199:44, 1984
- Larson, G., Schmidt, T., Gott, J., Bond, S., O'Connor, C.A., Richardson, J.D.: Upper gastrointestinal bleeding: predictors of outcome. *Surgery* 100:765, 1986
- Madden, M.V., Griffith, G.H.: Management of upper gastrointestinal bleeding in a district general hospital. *J.R. Coll. Phys. Lond.* 20:212, 1986
- Morris, D.L., Hawker, P.C., Brearley, S., Simms, M., Dykes, P.W., Keighley, P.R.B.: Optimal timing of operation for bleeding peptic ulcer: prospective randomized trial. *B.M.J.* 288:1277, 1984
- Saperas, E., Pique, J.M., Perez Ayuso, R., Bordas, J.M., Teres, J., Pera, C.: Conservative management of bleeding duodenal ulcer without a visible vessel: prospective randomized trial. *Br. J. Surg.* 74:784, 1987
- Vellacott, K.D., Dronfield, M.W., Atkinson, M., Langman, M.J.S.: Comparison of surgical and medical management of bleeding ulcers. *B.M.J.* 284:548, 1982
- Darle, N.: Operative treatment in massive peptic ulcer bleeding. *Scand. J. Gastroenterol.* 20(Suppl. 110):109, 1985
- Boulos, P.B., Harris, J., Wyllie, J.H., Clark, C.G.: Conservative surgery in 100 patients with bleeding peptic ulcer. *Br. J. Surg.* 58:817, 1971
- Jensen, H.E., Amdrup, E.: Selective vagotomy and drainage in surgery for massive gastroduodenal bleeding. *Scand. J. Gastroenterol.* 4:667, 1969
- Hedenstedt, S., Lundquist, G.: Selective proximal vagotomy as an emergency and definitive operation for massive ulcerous bleeding. *Acta Chir. Scand.* 144:241, 1978
- Vogel, T.T.: Critical issues in gastroduodenal hemorrhage: the role of vagotomy and pyloroplasty. *Ann. Surg.* 176:144, 1972
- Weinberg, J.A.: Treatment of the massively bleeding duodenal ulcer by ligation, pyloroplasty and vagotomy. *Am. J. Surg.* 102:158, 1961
- Herrington, J.L., Davidson, J.: Bleeding gastroduodenal ulcers: choice of operations. *World J. Surg.* 11:304, 1987
- Welch, C.E., Rodkey, G.V., Von Ryll-Gryska, P.: A thousand operations for ulcer disease. *Ann. Surg.* 204:454, 1986
- Buckingham, J.M., Remine, W.H.: Results of emergency surgical management of hemorrhagic duodenal ulcer. *Mayo Clin. Proc.* 50:223, 1975
- Hunt, P.S., McIntyre, R.L.E.: Choice of emergency operative procedure for bleeding duodenal ulcer. *Br. J. Surg.* 77:1004, 1990
- Byrne, J.J., Guardione, V.A., Williams, L.F.: Massive gastrointestinal hemorrhage. *Am. J. Surg.* 120:312, 1970
- Cocks, J.R., Desmond, A.M., Swynnerton, B.F., Tanner, N.C.: Partial gastrectomy for haemorrhage. *Gut* 13:331, 1972
- Cancer Research Campaign Working Party: Trials and tribulations: thoughts on the organization of multicentre clinical studies. *B.M.J.* 281:918, 1980
- Poxon, V.A., Keighley, M.R.B., Dykes, P.W., Heppinstall, K., Jaderberg, M.: Comparison of minimal and conventional surgery in patients with bleeding peptic ulcer: a multicentre trial. *Br. J. Surg.* 78:1344, 1991
- Schwartz, D., Flamant, R., Lellouch, J.: *Clinical Trials*. London, Academic Press, 1980
- Clark, C.G., Fresini, A., Araujo, J.C.G., Moore, F., Boulos, P.B.: Truncal vagotomy and drainage: a comparison of elective and emergency operations. *Br. J. Surg.* 72:149, 1985
- Palumbo, L.T., Sharpe, W.S.: Distal antrectomy with vagotomy for duodenal ulcer: results in 611 cases. *Ann. Surg.* 182:610, 1975
- Clason, A.E., Macleod, D.A.D., Elton, R.A.: Clinical factors in the prediction of further haemorrhage or mortality in acute upper gastrointestinal haemorrhage. *Br. J. Surg.* 73:985, 1986
- Himal, H.S., Watson, W.W., Jones, C.W., Miller, L., Maclean, L.D.: The management of upper gastrointestinal hemorrhage: a multiparametric computer analysis. *Ann. Surg.* 79:489, 1974
- Branicki, F.J., Boey, J., Fok, P.J., et al.: Bleeding duodenal ulcer: a prospective evaluation of risk factors for rebleeding and death. *Ann. Surg.* 211:411, 1990
- Macleod, I.A., Mills, P.R.: Factors identifying the probability of further haemorrhage after acute upper gastrointestinal haemorrhage. *Br. J. Surg.* 69:256, 1982
- Antler, A.S., Pitchumoni, C.S., Thomas, E., Orangio, G., Scanlan, B.C.: Gastrointestinal bleeding in the elderly: morbidity, mortality and cause. *Am. J. Surg.* 142:271, 1981
- Bekada, H., Charikhi, M., Haicheur, R., Yanes, Y., Mentouri, B.: Bleeding peptic ulcer: ten-year experience. *Am. J. Surg.* 147:375, 1984
- Chung, S.C.S., Leung, J.W.C., Steele, R.J.C., Crofts, T.J., Li, A.K.C.: Endoscopic injection of adrenaline for actively bleeding ulcers: a randomized trial. *B.M.J.* 1296:1631, 1988
- Pascu, O., Draghici, A., Acalovchi, I.: The effects of endoscopic hemostasis with alcohol on the mortality rate of non variceal upper gastrointestinal hemorrhage: a randomized prospective study. *Endoscopy* 21:53, 1989
- Panes, J., Viver, J., Forne, M., Garcia-Olivares, E., Marco, C., Garau, J.: Controlled trial of endoscopic sclerosis in bleeding peptic ulcers. *Lancet* 2:1292, 1987