

Modern Clinical and Epidemiological Features and New Technological Possibilities in the Treatment of Bleeding Gastroduodenal Ulcers

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Abstract

The aim of this research was to study the current clinical and epidemiological features of ulcerative gastroduodenal bleeding (GDB) and to evaluate the outcomes of using new technological approaches in patients with bleeding from acute (symptomatic) and chronic (peptic ulcer disease) gastroduodenal ulcers.

Methods and Results: The present study involved 221 patients with bleeding gastroduodenal ulcers. Depending on the source of bleeding, all patients were divided into 2 groups. Group 1 included 143 patients with acute symptomatic gastroduodenal ulcers; Group 2 consisted of 78 patients with peptic ulcer disease (PUD) complicated by bleeding. In the complex treatment of patients of all the studied groups, an individual approach was used that included the innovative technologies of endoscopic cytoprotective treatment of GDB, based on the combined use of traditional means of endoscopic hemostasis (EH) in combination with the use of endoscopic pneumoinsufflation of biologically active drainage sorbent of a new generation Aseptisorb-D and powdered hemostatic Zhelplastan. Our analysis showed that acute symptomatic gastroduodenal ulcers prevailed in the structure of GDB – 143(64.7%) patients; PUD complicated by bleeding was diagnosed in 78(35.3%) cases. To assess the type of ulcerative bleeding, the classification of J. Forrest (1974) was used. The use of new technological approaches, including cytoprotective treatment of bleeding defects with biologically active draining sorbents of a new generation in combination with local hemostatics in the complex therapy of patients with ulcerative GDB, has significantly improved the results of treatment, which is confirmed by high rates of final hemostasis (95.0%), indicators of the effectiveness of primary EH in type FIA-IB (93.1%) and prevention of recurrence of FIIA-IIB bleeding (92.5%), with a low frequency of repeated bleeding (4.07%), emergency surgeries (2.7%), and mortality (3.2%).

Conclusion: Currently, in the structure of ulcerative GDB, acute symptomatic gastroduodenal ulcers are the most common – 64.7%, and the share of PUD complicated by bleeding accounts for 35.3% of cases only. PUD and gastroduodenal ulcers complicated by bleeding have certain clinical and epidemiological features, which must be taken into account when treating these patients. Symptomatic gastroduodenal ulcers are more difficult to treat, which shows the need to develop new complex technologies for their treatment. (**International Journal of Biomedicine. 2021;11(4):428-434.**)

Key Words: bleeding gastroduodenal ulcers • endoscopic hemostasis • biologically active drainage sorbent

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Abbreviations

APC, argon-plasma coagulation; EH, endoscopic hemostasis; GDB, gastroduodenal bleeding; GDUs, gastroduodenal ulcers; PUD, peptic ulcer disease.

Introduction

The problem of treating patients with bleeding gastroduodenal ulcers (GDUs) is among the most difficult in modern urgent surgery. High mortality rates indicate an urgent need to improve modern technologies for the treatment of this pathology.⁽¹⁻⁶⁾

The etiological structure of GDUs, according to many studies, has undergone significant changes in recent decades. If in the 1990s, in the structure of GDB, the share of complicated peptic ulcer disease (PUD) of the stomach and duodenum accounted for up to 70.2% of cases, currently, their number does not exceed 30.6%. At the same time, however, acute symptomatic GDUs are becoming increasingly important in clinical practice.⁽⁷⁻¹⁰⁾

The treatment of patients with acute bleeding GDUs is a difficult task of modern gastric surgery. These patients often have severe co-morbid pathology, multiple lesions of the mucous-submucosal layer of the digestive tract, disorders of platelet and coagulation links of hemostasis against the background of taking antiplatelet drugs, anticoagulants, and other drugs.⁽¹¹⁻¹⁵⁾

Minimally invasive hemostasis technologies are becoming increasingly important in the treatment of patients with acute symptomatic GDUs. Various methods of endoscopic hemostasis (EH) have become widespread: argon-plasma coagulation (APC), laser coagulation, diathermocoagulation, injection hemostasis, clipping and combined techniques. But even when using combined methods of traditional endohemostasis, the frequency of recurrent bleeding reaches 10%-46%, which shows the need to use new technological capabilities in treating patients with ulcerative GDB.⁽¹⁶⁻²⁰⁾

The aim of this research was to study the current clinical and epidemiological features of ulcerative GDB and to evaluate the outcomes of using new technological approaches in patients with bleeding from acute (symptomatic) and chronic (PUD) GDUs.

Materials and Methods

A clinical study was conducted in the Voronezh City Specialized Center for the treatment of patients with gastrointestinal bleeding (Voronezh City Clinical Emergency Hospital №1) in 202-2021. The present study involved 221 patients with bleeding GDUs. Depending on the source of bleeding, all patients were divided into 2 groups. Group 1 included 143 patients with acute symptomatic GDUs; Group 2 consisted of 78 patients with PUD complicated by bleeding.

The clinical and epidemiological characteristics of the study groups are presented in Table 1.

Our analysis showed that acute symptomatic GDUs prevailed in the structure of GDB –143(64.7%) patients; PUD complicated by bleeding was diagnosed in 78(35.3%) cases. The structure of the general incidence of bleeding GDUs was dominated by persons of retirement age – 53.0% of patients. At the same time, the retirement age was typical for Group 1 (66.6%). However, there was an opposite picture among patients of Group 2: 71.7% of patients were of working age, and only 28.3% of retirement age.

Table 1.

Clinical and epidemiological characteristics of the study groups

Indicator	Group 1 (n=143)	Group 2 (n=78)	P-value	General group (n=221)
Social status of patients				
Employee	20(13.9%)	24(30.7%)	P=0.0028	44(19.9%)
Non-employee	28(19.5%)	32(41.0%)	P=0.0006	60(27.1%)
Pensioner	95(66.6%)	22(28.3%)	P=0.0000	117(53.0%)
Age and gender of patients				
Age (years)	69.0 (54.0;79.0)	51.0 (37.0;61.0)	P<0.001	62.0 (47.0;72.0)
Men	84(58.7%)	61(78.2%)	P=0.0036	145(65.6%)
Women	59(41.3%)	17(21.8%)	P=0.0036	76(34.4%)
Localization of the source of bleeding				
Duodenal ulcers	72(50.3%)	55(70.5%)	P=0.0038	127(57.5%)
Stomach ulcers	71(49.7%)	12(15.3%)	P=0.0000	83(37.5%)
Gastroentero-anastomosis-ulcers	-	11(14.2%)	-	11(5.0%)
Number of gastroduodenal ulcers				
One	119(83.2%)	71(91.0%)	P=0.1102	190(85.9%)
Two	12(8.4%)	7(9.0%)	P=0.8821	19(8.6%)
Multiple	12(8.4%)	-	-	12(5.5%)
Localization of stomach ulcers				
Body of the stomach	43(60.5%)	6(50.0%)	P=0.0001	49(59.0%)
Antrum	22(30.9%)	5(41.6%)	P=0.0516	27(32.5%)
Cardiac and fundus of the stomach	4(8.6%)	1(8.4%)	P=0.6587	5(8.5%)
Localization of duodenal ulcers				
Anterior wall	29(40.2%)	24(43.6%)	P=0.0809	53(41.7%)
Posterior wall	12(16.6%)	5(9.0%)	P=0.5974	17(13.4%)
Upper wall	24(33.3%)	20(36.3%)	P=0.1151	44(34.6%)
Lower wall	8(9.9%)	6(11.1%)	P=0.7471	14(10.3%)
Bleeding type ⁽²¹⁾				
Forrest IA	15(10.4%)	2(2.5%)	P=0.0346	17(7.7%)
Forrest IB	9(6.2%)	3(3.8%)	P=0.4428	12(5.4%)
Forrest IIA	11(7.6%)	8(10.2%)	P=0.5159	19(8.6%)
Forrest IIB	34(23.7%)	14(17.9%)	P=0.3154	48(21.7%)
Forrest IIC	64(44.7%)	40(51.2%)	P=0.3529	104(47.1%)
Forrest III	10(7.4%)	11(14.4%)	P=0.0850	22(9.5%)

Table 1.
Clinical and epidemiological characteristics of the study groups (continued)

	Group 1 (n=143)	Group 2 (n=78)	P-value	General group (n=221)
The degree of severity of blood loss ⁽²²⁾				
Mild	68(47.5%)	44(56.4%)	P=0.4444	112(50.7%)
Moderate	25(17.5%)	12(15.4%)		37(16.7%)
Severe	50(35.0%)	22(28.2%)		72(32.6%)
Helicobacter pylori test results				
Positive	16(11.1%)	32(41.0%)	P=0.0000	48(21.7%)
Negative	127(88.9%)	46(59.0%)		173(78.3%)

The average age of patients of Group 2 was 51.0(37.0;61.0) years, while in Group 1, the average age was significantly higher - 69.0(54.0;79.0) years ($P<0.001$).

The gender composition of patients was as follows: 78.2% men and 21.8% women in Group 2, 58.7% men and 41.3% women in Group 1.

Depending on the location of the source of bleeding, patients with bleeding GDUs were distributed as follows: bleeding ulcers of the duodenum – 57.5%, stomach ulcers and gastroenteroanastomosis – 37.5% and 5.0%, respectively. In Group 1, duodenal ulcers accounted for 50.3% of cases, and stomach ulcers for 49.7%. In Group 2, duodenal ulcers accounted for 70.5% of cases, stomach ulcers for 15.3%, and gastroenteroanastomosis ulcers for 14.2%. It should be noted that GDUs in 85.9% of cases were single; paired and multiple GDUs were found in 8.6% and 5.5% of cases, respectively.

When analyzing the localization of ulcerative defects, we found that for stomach ulcers, the most typical localization was the stomach body – 59.0% of cases; the antrum of the stomach – 32.5%; ulcers of the cardiac region and the fundus of the stomach were less common – 8.5% of cases. For duodenal ulcers, damage to the anterior and upper walls of the duodenum was the most frequent (41.7% and 34.6%, respectively), damage to the posterior and lower walls was less frequent (13.4% and 10.3%, respectively).

To assess the type of ulcerative bleeding, the classification of J. Forrest was used.⁽²¹⁾ The most frequent type of ulcerative bleeding was FIIC – 47.1% of cases. FIIB type was detected in 21.7% of patients, FIII in 9.5%, FIIA in 8.6%, FIA in 7.7%, and FIB was observed in only 5.4% of cases. It should be noted that in patients of Group 1, the type of bleeding FIA was statistically significantly more common than in patients of Group 2: 10.4% and 2.5%, respectively ($P=0.0346$).

According to the severity of blood loss,⁽²²⁾ the patients were distributed as follows: the most common were mild and severe degrees of blood loss – 50.7% and 32.6% of cases, respectively. A moderate degree of blood loss was observed in 16.7% of patients. At the same time, there were no statistically significant differences in the volume of blood loss between the study groups.

All patients were examined for the presence of *Helicobacter pylori*. Positive results of the examination were revealed in 21.7% of patients; the negative urease test was found in 78.3% of patients. At the same time, positive test results for *Helicobacter pylori* were detected in 41.0% of cases in Group 2 and only in 11.1% of cases in Group 1 ($P<0.0001$).

The structure of concomitant pathology in patients with ulcerative GDB is presented in Table 2. In the structure of concomitant pathology in patients with ulcerative hemorrhages, diseases of the cardiovascular system prevailed (66.0%). It should be noted that for patients of Group 1, compared with Group 2, diseases of the cardiovascular system were much more common. Also, in patients of Group 1 diabetes mellitus was more common than in Group 2 – 13.9% and 3.8%, respectively ($P=0.018$).

Table 2.
Structure of concomitant pathology

	Group 1 (n=143)	Group 2 (n=78)	P-value	General group (n=221)
Diseases of the cardiovascular system	108(75.5%)	38(48.7%)	P=0.0001	146(66.0%)
Respiratory system diseases	13(9.1%)	7(8.9%)	P=0.9748	20(9.04%)
Digestive system diseases	33(20.1%)	18(23.1%)	P=0.8671	51(23.1%)
Diseases of the musculoskeletal system	5(3.5%)	1(1.28%)	P=0.4278	6(2.7%)
Diseases of the urinary system	21(14.7%)	7(8.9%)	P=0.2225	28(12.7%)
Nervous system diseases	14(9.8%)	5(6.4%)	P=0.3916	19(8.6%)
Oncopathology	9(6.3%)	5(6.4%)	P=0.7989	14(6.3%)
Diabetes mellitus	20(13.9%)	3(3.8%)	P=0.0203	23(10.4%)
Ulcerative medications				
Anticoagulants	22(15.4%)	1(1.28%)	P=0.0013	23(10.4%)
Disaggregants	30(21.0%)	11(14.1%)	P=0.2089	41(18.6%)
NSAIDs	14(9.8%)	4(5.12%)	P=0.3061	18(8.1%)

Analyzing the effect of ulcerative medications on the development of ulcerative bleeding, it was found that 18.6% of patients, just before the development of the bleeding episode, took disaggregants, 10.4% of patients – anticoagulants and 8.1% – NSAIDs. It is important to note that anticoagulants were much more often taken by patients in Group 1 – in 15.4% of cases compared to 1.28% of cases in Group 2 ($P=0.001$).

In the complex treatment of patients of all the studied groups, an individual approach was used that included the innovative technologies of endoscopic cytoprotective

treatment of GDB, based on the combined use of traditional means of EH in combination with the use of endoscopic pneumoinsufflation of biologically active drainage sorbent of a new generation Aseptisorb-D and powdered hemostatic Zhelplastan (Patent RF № 2633588).⁽²³⁾

Thus, in patients with ongoing bleeding (FIA-FIB), bleeding was initially stopped by injection of a 5% solution of ϵ -aminocaproic acid at the source of bleeding, followed by APC. EH in the group always ended with endoscopic insufflations of powdered Zhelplastan in combination with Aseptisorb-D.

In patients with unstably stopped bleeding FIIA-FIIB, the method of endoscopic prevention of the resumption of hemorrhage was used by conducting APC of the thrombosed vessel with the type of bleeding FIIA; and with the type FIIB, the clot was washed from the ulcerative defect with subsequent coagulation of the source of hemorrhage. In order to increase the reliability of hemostasis and prevent recurrence of bleeding and endoscopic cytoprotective treatment, each case of therapeutic endoscopy always ended with pneumoinsufflation of Zhelplastan in combination with Aseptisorb-D.

In patients with bleeding type FIIC and FIII, endoscopic treatment was performed through combined insufflations of Zhelplastan and Aseptisorb-D in order to accelerate the processes of reparative regeneration and prevent possible resumption of bleeding.

In complex treatment, patients received modern drug therapy according to the standards of treatment of patients with ulcerative bleeding: antisecretory drugs – proton pump inhibitors (esomeprazole), general hemostatics with the inclusion of modern hemostatics (tranexamic acid, aminomethylbenzoic acid), infusion-transfusion and symptomatic therapy. The indication for surgical treatment in patients with ulcerative bleeding was continued bleeding with the impossibility or ineffectiveness of EH and recurrence of hemorrhage in hospital PUD inpatients, according to National Clinical Guidelines for the treatment of patients with ulcerative GDB.⁽²⁴⁾

The following indicators assessed the effectiveness of the treatment: reliability of primary hemostasis in type FIA-IB, effectiveness of endoscopic prevention of recurrent bleeding in types FIIA-IIIB and FIIC, frequency of bleeding recurrence, prevention of emergency operations, mortality rates.

Statistical analysis was performed using Microsoft Excel software package. For descriptive analysis, results are presented as median (Me) and interquartile range (IQR). Wilcoxon rank sum test was used to test for difference in medians. Group comparisons with respect to categorical variables are performed using chi-square tests with Yates correction or, alternatively, Fisher's exact test when expected cell counts were less than 5. A probability value of $P < 0.05$ was considered statistically significant.

The study was carried out in compliance with Ethical Principles for Medical Research Involving Human Subjects, Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013. The study

was approved by the Ethics Committee of Voronezh State Medical University named after N. N. Burdenko. Written informed consent was obtained from all participants.

Results and Discussion

All patients in the studied groups received personalized preventive technologies of cytoprotective treatment of GDUs complicated by bleeding with biologically active granular sorbent of a new generation Aseptisorb-D in combination with the hemostatic agent Zhelplastan, according to the developed technique. Studies have shown that immediately after pneumoinsufflation, Aseptisorb-D in combination with Zhelplastan formed a powerful layer of biologically active hydrogel on ulcerative defects, which protected the ulcerative defect, thrombosed vessel, and coagulation necrosis from the aggressive action of gastric and duodenal contents, showing local hemostatic and cytoprotective effects, preventing the resumption of bleeding and contributing to the favorable course of the reparative process in ulcerative defects.

At the same time, it was noted that in 24 patients of Group 1 with the FIA-FIB type of bleeding, primary EH was achieved in 23(95.8%) patients.

Clinical example. In a 47-year-old woman, against the background of uncontrolled Warfarin intake, continued bleeding from an acute ulcer of the duodenum was not stopped endoscopically. This patient was urgently operated on – a bleeding vessel in the ulcer was stitched. The postoperative period proceeded without complications, the patient was discharged for outpatient treatment on Day 13 after inpatient treatment.

There were no episodes of resumption of bleeding after successful primary EH in Group 1. In this group of patients, a 66-year-old man with the FIA type of bleeding died: His ongoing bleeding was stopped successfully and no repeated bleeding was noted during inpatient treatment, but the patient died from decompensation of concomitant pathology against the background of acute blood loss.

In Group 2, out of 5 patients with ongoing bleeding (FIA-FIB), primary EH was effective in 4 patients (80%). One patient was operated on “at the height of bleeding.” There were no relapses of bleeding or fatal outcomes in this group.

When analyzing the results of treatment of patients in Group 1 with unstable stopped bleeding (FIA-FIB), 3(6.67%) of 45 patients had repeated bleeding. All of these 3 patients had disorders of the blood coagulation system due to taking anticoagulants. In 2 patients, repeated bleeding was stopped endoscopically using the developed techniques in combination with complex hemostatic therapy, which made it possible to avoid surgical treatment. One patient was operated on due to the failure of repeated hemostasis and died of pneumonia in the postoperative period. Also in this group of patients, 2 more, aged 81 and 84, died from decompensation of concomitant diseases on the background of anemia.

In Group 2, hemorrhagic relapses were observed in 2(9.1%) of 22 patients with unstably stopped bleeding (FIA-FIB). Both patients were operated on; they underwent the

operation “stitching a bleeding vessel” in an ulcer. One patient died in the postoperative period.

In 64 patients of Group 1 with the FIIC type of bleeding, repeated bleeding was observed in 2(3.1%) patients. These patients also took disaggregants and anticoagulants. All of them underwent repeated EH, according to the developed technique, which was effective in both patients. There were no surgical interventions in this group, but one, a 40-year-old patient, died from decompensation of cardiovascular pathology on the background of anemia.

Of the 40 patients in Group 2 with the FIIC type of bleeding, repeated bleeding was observed in 2(5.0%) patients. One recurrent bleeding was stopped endoscopically, the second underwent surgical treatment – resection of the stomach. There were no fatal outcomes in this group of patients.

With type FIII bleeding in both groups of patients, there was no recurrence of bleeding, emergency operations, or deaths.

Considering the results of treatment of patients in Group 1, it should be noted that the resumption of bleeding from acute GDUs in all 5 patients occurred on 1.5(1.0;2.0) days, which was caused primarily by pronounced hypocoagulation on the basis of taking medications. All these patients underwent repeated EH. In 4(80.0%) out of 5 patients with repeated GDB, the use of the developed innovative technologies of EH made it possible to carry out final hemostasis and avoid surgery; in 1 patient with an acute ulcer of the posterior wall of the duodenum, repeated bleeding could not be stopped endoscopically, and the patient was operated on.

Summarizing the treatment of Group 1 patients with acute GDUs, we noted that in order to achieve final hemostasis in these patients, repeated therapeutic endoscopies, a large number of therapeutic manipulations are necessary, which reduces the effectiveness of the treatment and worsens the quality of life of patients. It is important to note that the cause of acute erosive and ulcerative GDB in most of these patients was taking antiplatelet drugs, which caused them to have disorders of the blood clotting system. The difficulty for the doctor was that most of the patients in this group had a high and very high risk of thromboembolic complications and needed to resume anticoagulant therapy after bleeding was stopped. The decision on the timing of the resumption of therapy with antiplatelet drugs was decided individually, taking into account the risk-benefit ratio in each case.

In addition, of the patients of Group 1 with acute symptomatic GDUs, 66.6% were of retirement age with severe concomitant pathology. The developing GDB in these patients led to decompensation of somatic pathology, which, along with the bleeding itself, posed a direct threat to the life and health of patients. In treating such patients, it is necessary to maximize all the possibilities of conservative therapy aimed at preventing the resumption of GDB and correcting decompensated somatic pathology.

In treating patients with acute GDB and decompensated concomitant pathology, we also used a multidisciplinary approach. All these patients were hospitalized in the intensive care unit, where a dynamic resuscitator constantly monitored them. In addition, a team of doctors of various

specialties was immediately involved in their treatment: therapists, cardiologists, neurologists, pulmonologists, clinical pharmacologists, etc. This approach allowed us to stabilize the condition of patients. However, despite the efforts made, 6(4.19%) patients of Group 1 died from decompensation of the underlying disease against the background of anemia.

In patients of Group 2 with gastric ulcer and duodenal ulcer, recurrence of ulcerative bleeding was observed on Day 4.0(2.5;6.0) of inpatient treatment. The cause of bleeding recurrence in 1 patient was an ulcer of the posterior wall of the duodenum penetrating into the head of the pancreas, and in 3 patients, the development of bleeding recurrence was due to the presence of erosive vessels in the ulcerative defect. All these patients were operated on “at the height of bleeding”; 1 patient died in the postoperative period.

The final results of the treatment of patients are presented in Table 3.

Table 3.

Comparative effectiveness of patient treatment

	Group 1 (n=143)	Group 2 (n=78)	P-value	General group (n=221)
The effectiveness of primary EH in FIA-IB	23(95.8% with respect to n=24)	4(80% with respect to n=5)	P=0.3202	27(93.1% with respect to n=29)
The effectiveness of endoscopic prevention of recurrent bleeding in FIIA-IIB	42(93.3% with respect to n=45)	20(90.9% with respect to n=22)	P=0.9999	62(92.5% with respect to n=67)
Overall re-bleeding rate	5(3.49%)	4(5.1%)	P=0.7235	9(4.07%)
Day of appearance of repeated bleeding	1.5(1.0;2.0)	4.0(2.5;6.0)	P=0.048	2.1(1.5;5.5)
Final hemostasis	137(95.8%)	73(93.5%)	P=0.5242	210(95.0%)
Emergency surgeries	2(1.4%)	4(5.12%)	P=0.1882	6(2.7%)
Suturing a bleeding vessel in an ulcer	2(1.4%)	3(3.8%)	P=0.3482	5(2.3%)
Stomach resection	-	1(25.0%)	-	1(16.7%)
Mortality	6(4.19%)	1(1.3%)	P=0.4258	7(3.2%)

The use of new technological approaches, including cytoprotective treatment of bleeding defects with biologically active draining sorbents of a new generation in combination with local hemostatics in the complex therapy of patients with ulcerative GDB, has significantly improved the results of treatment, which is confirmed by high rates of final hemostasis (95.0%), indicators of the effectiveness of primary EH in type FIA-IB (93.1%) and prevention of recurrence of FIIA-IIB bleeding (92.5%), with a low frequency of repeated bleeding (4.07%), emergency surgeries (2.7%), and mortality (3.2%).

Conclusion

Currently, in the structure of ulcerative gastroduodenal bleeding, acute symptomatic gastroduodenal ulcers are the most common – 64.7%, and the share of peptic ulcer disease complicated by bleeding accounts for 35.3% of cases only. Peptic ulcer disease and gastroduodenal ulcers complicated by bleeding have certain clinical and epidemiological features, which must be taken into account when treating these patients. The use of modern, new technological approaches based on the introduction of innovative endoscopic technologies with the use of biologically active draining sorbents and local hemostatic agents allowed us to improve the results of treatment, to ensure the possibility of final hemostasis in 95.0% of cases, to reduce the number of recurrent hemorrhages to 4.07% of cases and total mortality to 3.2%. Symptomatic gastroduodenal ulcers are more difficult to treat, which shows the need to develop new complex technologies for their treatment.

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Competing Interests

The authors declare that they have no competing interests.

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