# COMBINED BUTYL CYANOACRYLATE (HISTOACRYL) INJECTION AND BAND LIGATION IN THE MANAGEMENT OF BLEEDING GASTRIC VARICES: A NEW OPTION

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#### **ABSTRACT**

Background: Bleeding gastric varices is a highly fatal condition in cirrhotic patients with portal hypertension. The role of endoscopy in its management is still controversial. However both sclerotherapy and band ligation have been proven to be effective in management of bleeding gastric varices. This study was performed to describe the combined use of band ligation plus histoacryl injection for the management of gastric varices.

Methods: Combined technique, band ligation plus histoacryl injection, was performed in 42 patients with gastric varices: 8 patients had type 1 gastroesophageal varices, 20 had type2, 12 had isolated gastric varices type1 and 2 had isolated gastric varices type 2. The etiology of portal hy-

pertension was shistosomiasis in 15, post-hepatitic cirrhosis in 5 and mixed cirrhosis in 22 patients. The Child-Pugh classification was grade A in 10, B in 22, and C in 10 cases. Active variceal bleeding was present in all patients.

Results: Combined band ligation and histoacryl injection arrested acute bleeding in 37 patients (88.1%). Recurrent bleeding occurred in 7 (16.6%). Variceal obliteration was achieved in 35 patients (83.4%) at 4-6 months. The number of sessions needed for obliteration of varices was significantly less in patients with isolated gastric varices typel, when compared with those with type1 and type2 gastroesophageal varices. Eight patients died (19%), 4 due to recurrent bleeding, and 4 due to hepatic en-

cephalopathy.

Conclusion: Combined band ligation plus histoacryl injection technique, is a safe and effective method for controlling acute gastric variceal bleeding and for eradication of different types of gastric varices.

#### INTRODUCTION

Gastric varices (GV) is considered as a serious complication of portal hypertension in patients with liver cirrhosis. Although the risk of bleeding from GV is lower compared with esophageal varices (EV),1 the bleeding can be extremely severe and associated with a high mortality rate<sup>2</sup>. Due to their large size and extensive distribution, it is difficult to be eradicated by a single line of therapy. Endoscopic sclerotherapy of GV with cyanoacrylate glue was shown to be effective in controlling active bleeding from GV and-has gained popularity world wide<sup>3,4</sup>. However, controversies concerning its long-term efficacy and safety still exist. The rate of recurrent bleeding<sup>5,6</sup> and episodic complications as systemic embolization have been the main issues7. Endoscopic variceal band ligation has been shown to be an effective and safe method for the management of bleed-

ing esophageal varices 8,9. The development of multi band ligation technically easier to perform so that banding of GV can be accomplished with the endoscope retroflexed in the stomach 10. However, the application of ligation in the treatment of gastric varices has rarely been reported. 11,12 Therefore, there is a need to evaluate alternative treatment in an effort to improve the success of endoscopic therapy for GV. The present study is a trial to evaluate the efficacy and safety of histoacryl injection combined with band ligation for the treatment of different types of gastric varices.

#### PATIENTS AND METHODS

From July 2001 to December 2002, fourty two patients with bleeding gastric varices (proved endoscopically) presenting with hematemesis and/ or melena were included in this study. The etiology of liver cirrhosis was based on clinical examination, laboratory findings and ultrasonography which was post-bilharzial fibrosis in 15 patients (35.8%), post-hepatitic in 5 patients (11.9%) and mixed cirrhosis in 22 patients (52.3%). The definition of gastric variceal bleeding included 1) active spurting or oozing of blood from gastric varices during en-

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doscopy, 2) a clot or blackish ulcer was seen on a gastric varix. The exclusion criteria were 1) undetermined origin of bleeding from esophageal or gastric varices, 2) presence of deep jaundice, 3) hepatic encephalopathy, or hepatorenal syndrome, 4) association of hepatocellular carcinoma, uremia, cerebral vascular accident or coronary heart disease, 5) prior history of shunt operation or prior treatment of gastric varices by sclerotherapy.

Resuscitation was begun immediately after admission and included intravenous fluids, coagulant agents, fresh blood and frozen plasma transfusion, octreotide infusion (25  $\mu$ /hr) and lactulose enemas . Informed consent was obtained from all patients. The study protocol was approved by ethical committee of our institution.

The diagnosis of gastric varices was made on the basis of the criteria described by Sarin et al.<sup>3</sup> Varices were classified according to the location of the varix in the stomach and its relation to esophageal varices as follows: GOV1; the gastroesophageal varices that extending down the lesser curve by 2-5cm distal to the cardia; GOV2, varices extending along

the greater curve into the fundus; isolated fundic varices with absent esophageal varices (IGVI) and IGV2; ectopic varices at other sites in the stomach or duodenum.

Protocol: The plan of our work is to start by band ligation of the different types of gastric varices, then followed by histoacryl injection in the larger one or at the point of bleeding in the same sitting (combined technique). GV ligation was done by Saeed-Six Shooter Multi-Band Ligator (Wilson Cook, Winston-Salem, N.C). Endoscopy was performed under intravenous diazepam sedation using a Pentax videoendoscope (EG 3440, Pentax, Tokyo, Japan). During the initial examination, the endoscopic findings were recorded, then the endoscopy was removed, fitted with the Multi-Band Ligator device, and then reintroduced and reteroflexed inside the stomach if needed. The GV were ligated by punch method, where the tip of the ligator was approached to the periphery of the target varix and punching was done several times with firing of band rings, the centre of the large gastric varix, was clear not banded, where the head and thread of the band device was removed and then the injector needle (Olympus

NM- IK) was applied to it for injection of histoacryl. We use histoacryl (B-Braun, Melsungen, AG, Germany) 0.5mL mixed with 1.5mL Lipiodol ultra-fluide (Guerbet, Bios Cedex, France) for injection at the centre of the varix till cessation of bleeding or ballooning was achieved, usually not more than 2mL of histoacryl was used. Omperazole (20mg) twice daily was given orally for 2weeks after endoscopy to promote healing of the anticipated ulcers at the sites of ligation. Endoscopy was performed one week later and then every 2 weeks till completes eradication of the varices was achieved. The follow-up period ranged from 4 to 6 months. The efficacy was measured in terms of the ability to complete the procedure, control active bleeding and eradicate the varices. The types and number of complications, as well as deaths, were recorded.

The difference among different types of GV patients, as regard the demographic data was assessed with parametric one-way analysis of variance (ANOVA) techniques. Non - parametric methods, especially Kruskal-Wallis analysis and rank data, were used in the comparison between groups as in table 2 and 3.

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#### RESULTS

Atotal of 42 patients with bleeding GV were included in this study. They were 32 male and 10 female, aged 23 to 76 years. Patients were classified according to gastroesophageal varices as follows: 8 had GOV1, 20 had GOV2, 12 had IGV1 and 2 had IGV2. The demographic data of the patients in the different groups were comparable (Table 1). There is no significant difference between them as regard age, gender, etiology of cirrhosis, severity of liver disease, laboratory finding, number of blood units transfused per patient and the associated esophageal varices.

#### Gastroesophageal varices type 1:

They were 8 patients, 5 male and 3 female with mean age 48±1.2 years. All underwent band ligation for esophageal varices and combined band and histoacryl injection for GV. All had controlled bleeding at first endoscopy (100%) table 2. The number of band rings needed per patient was 6.2±3.1 and the dose of histoacryl was 1.0±0.7. After a follow-up period (4-6 months), one patient rebleeded (12.5%) and was treated by band ligation. Two patients died from liver cell failure and encephalopathy (death rate 25%). The number of patients

achieved complete obliteration was 7 (87.5%) after a number of sessions  $3.1\pm0.7$  and the time required was  $3.7\pm0.6$  weeks (Table 3).

Gastroesophageal varices type 2 : A total of 20 patients with GOV2 (17 male, 3 female; mean age 52±1.1) underwent combined technique. Active bleeding was successfully controlled at the initial endoscopy in 16 patients (80%) table 2. The number of band rings needed per patient was 8.1±2.4 and the dose of histoacryl was 2.1±1.0. Recurrent bleeding occurred in 3 patients at third and fourth days, two of them was treated by another session of band ligation and the third patient was referred to surgery (Child-B). After a follow -up period (4-6 months), 4 patients rebleeded (20%), 2 of whom died as a result of bleeding (10%), and the other two patients, passed conservative due to mild bleeding. Also a third patient died due to liver cell failure and encephalopathy (Table 3). The number of patients achieved complete obliteration was 16 (80%) after number of sessions 3.6 t 1.7 and the time required was 4.0±0.76 weeks (Table 3).

Isolated gastric varices type 1 : A total of 12 patients with IGVI (8

male, 4 female; mean age 54 ±2.1) underwent combined technique. Active bleeding was successfully controlled at initial endoscopy in 11 patients (91.7%) table 2. The number of band ligation rings needed per patient was 6.1 ± 1.1 and the dose of histoacryl was 2.0 ±1.3 (Table 2). Recurrent bleeding developed in 2 patients and passed conservative, need another endoscopy. After a follow-up period (4-6 moths), two patients rebleeded (16.6%), one died as a result of bleeding (8.3%) and the other died as a result of hepatic encephalopathy (8.3%). Another patient died as a result of advanced liver cell failure without rebleeding (Table 3). The number of patients achieved complete variceal obliteration was 10 (83.4%) after a number of sessions 2.7±0.7 and the time required was 3.3±0.7 weeks (Table 3).

Isolated gastric varices type 2:

They were two male patients with mean age 61±0.7, underwent combined technique where initial endoscopy was successfully controlled the bleeding (100%) after 8.3±2.1 number of band rings and 1.1±1.7 dose of histoacryl. No rebleeding episodes, either after initial endoscopy or in the follow-up

period. All patients achieved complete variceal obliteration after a number of sessions 4.1 ±0.2 and time required 4.1±1.1 weeks.

The view of the combined technique:

The technique of band ligation hand by hand with histoacryl injection wa completed in all patients and could be performed even during active bleeding, which was controlled in 37 of 42 patients (88.1%) (Table 2). Band release was always possible in the retroflexed position, but it was sometimes difficult to visualize the bleeding source during active bleeding, but effective suction, washing and repositioning the patients, together with bolus injection of octreotide (300ug) at the time of endoscopy, were often effective in providing good

visualization to complete the procedure. During the histoacryl injection, endoscopy was not removed from the patient, but just to remove the head and thread of the band device from the endoscopy, while it still introduced in the patient, and then apply the injector needle (gauge 20). The view of the varix was clearly seen during injection, while it ballooning.

#### Complications:

Multiple ulcerations at the sites of band ligation were seen in all patients but they were superficial, need 20mg omperazole twice daily for two weeks, where they were completely healed. Mild fever was occurred in the first 24 hours, but it was transient and resolved spontaneously. No major complications as embolization, deep ulcers or perforation.

Table (1): Basic patients characteristics.

= 8 3 ± 1.2 3 (37.5%) (50%) (12.5%)	N= 20 52 ± 1.1 17/3 11 (55%) 6 (30%) 3 (15%)	N= 12 54 ± 2.1 8/4 7 (58.3%) 4 (33.3%) 1 (8.4%)	N= 2 61 ± 0.7 2/0 1 (50%) 1 (50%)	NS NS
(37.5%) (50%)	17/3 11 (55%) 6 (30%)	54 ± 2.1 8/4 7 (58.3%) 4 (33.3%)	61 ± 0.7 2/0 1 (50%)	NS
(37.5%) (50%)	11 (55%) 6 (30%)	7 (58.3%) 4 (33.3%)	1 (50%)	
(50%)	6 (30%)	4 (33.3%)		NS
			0 (0%)	NS NS
(25%) (50%) (12.5)	7 (35%) 4 (50%) 1 (15%)	1 (8.3%) 7 (58.3%) 4 (33.4%)	0 (0%) 1 (50%) 1 (50%)	NS NS NS
$0 \pm 1.1$ $1 \pm 0.9$ $\pm 5.1$ $0 \pm 2.1$	$3.2 \pm 1.2$ $1.9 \pm 1.3$ $50 \pm 2.1$ $9.3 \pm 1.1$	$3.1 \pm 0.7$ $2.0 \pm 1.1$ $53 \pm 2.1$ $7.4 \pm 2.1$	$3.3 \pm 0.9$ $1.9 \pm 1.7$ $49 \pm 4.1$ $8.0 \pm 3.1$	NS NS NS
$2 \pm 0.1$	$1.6 \pm 0.6$	2.0 ± 0.2	$2.1 \pm 1.3$	NS
(75%)	7 (35%)	0 (0%)	0 (0%)	NS
	15 (75%) 1 (5%) 3 (15%)	6 (50%) 0 (0%) 1 (8.3%)	1 (50%) 0 (0%) 0 (0%)	NS NS NS NS
	(75%) (87.5%) (0%) (12.5%) (37.5%)	(87.5%) 15 (75%) (0%) 1 (5%) (12.5%) 3 (15%)	(87.5%) 15 (75%) 6 (50%) (0%) 1 (5%) 0 (0%) (12.5%) 3 (15%) 1 (8.3%)	(87.5%) 15 (75%) 6 (50%) 1 (50%) (0%) 1 (5%) 0 (0%) 0 (0%) (12.5%) 3 (15%) 1 (8.3%) 0 (0%)

Table (2): Outcome of combined treatment of GV:

	GOV1 N=8	GOV2 N= 20	IGV1 N= 12	IGV2 N= 2
Primary hemostasis Control of bleeding No of band rings / patient (mean ± SD) Dose of histoacryl / patient at 1 <sup>st</sup> session (mean± SD)	8/8 (100%) 16.2 ± 3.1 1.0 ± 0.7	$16/20(80\%) \\ 8.1 \pm 2.4 \\ 2.1 \pm 1.0$	11/12 (91.7%) 6.1 ± 1.1 2.0 ± 1.3	2/2 (100%) 8.3 ± 2.1 1.1 ± 1.7

Subsequent treatment	1			
No of band rings till complete obliteration / patient (mean± SD)	$11.0 \pm 2.1$	$17 \pm 3.1$	14 ± 1.1	$12 \pm 2.0$
Total dose of histoacryl injection / patient (mean ± SD)	$2.1 \pm 0.3$	$3.6 \pm 0.7$	3.1 ± 1.1	$1.6 \pm 1.1$
Patients achieved GV obliteration	8 (100%)	16 (80%)	10 (83.4%)	2 (100%)
Associated esophageal varices needed treatment	4 (50%)	7 (35%)	0 (0%)	0 (0%)
Complications			The second	
Band ligation ulcer	3 (37.5%)	6 (30%)	3 (25%)	1 (50%)
Post-injection ulcer	1 (12.5%)	3 (15%)	1 (8.3%)	0 (0%)
Bactermia	2 (25%)	2 (10%)	1 (8.3%)	0 (0%)

Table (3): Outcome of combined treatment of GV after 4-6 months follow-up:

	GOV1	GOV2	IGV1	IGV2
	N= 8	N = 20	N= 12	N= 2
Recurrent bleeding. Patients achieved complete obliteration	1 (12.5%)	4 (20%)	2 (16.6%)	0 (0%)
No	7 (87.5%)	16 (80%)	10 (83.4%)	2 (100%)
No of sessions	$3.1 \pm 0.7$	$3.6 \pm 1.7$	$2.7 \pm 0.7$	$4.1 \pm 0.2$
Time of obliteration (weeks) Mortality	$3.7 \pm 0.6$	$4.0 \pm 0.76$	$3.3 \pm 0.7$	4.1 ± 1.1
Due to recurrent bleeding 4/42	1(12.5%)	2 (10%)	1 (8.3%)	0 (0%)
due to liver failure and encephalopathy 4/42	1 (12.5%)	1 (5%)	2 (16.6%)	0 (0%)

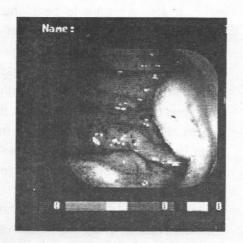


Fig 1: Patient with isolated gastric varix type1 and severe hypertensive gastropathy.



Fig 2: The same patient after band ligation (punch method).

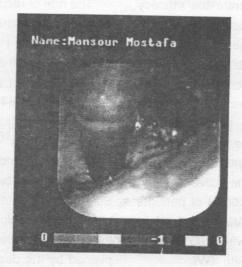


Fig 3: Histoacryl injection after band ligation (Combined technique).

#### DISCUSSION

is generally accepted that bleeding from gastric varices is usually more severe than from esophageal varices 1,14. In recent years the number of patients presenting with gastric variceal bleeding have been increasing, this could be ascribed to an increasing awareness or late complication of successful management of esophageal varices 1,15. Hence, the search for a more effective method to reduce rebleeding and to enhance survival rate is urgently needed. Preliminary trials have shown that both endoscopic obturation using histoacryl12,16 and gastric variceal ligation 11 are promising tools in the management of bleeding gastric varices. Our aim in this study to demonstrate the efficacy and safety of the use of both techniques, the band ligation and histoacryl injection combined together at the same time in controlling acute bleeding from different types of gastric varices. Active gastric variceal bleeding could be controlled in (88.1%) of all patients .According to the type of varices the active bleeding was controlled in (100%) of patients with GOVI and IGV2 compared to (80%) in those with GOV2 and (91.7%) in patients with IGVI.

This high success rate for initial control of gastric variceal bleeding is much higher than that achieved using histoacryl alone 12,17 or sclerotherapy18. It also appears to be higher than that achieved in a study by Shiha<sup>11</sup> using gastric varices band ligation alone, where acute bleeding was controlled in 75% of patients with GOVI and 80% of those with GOV2. It is also higher than that achieved in Sarin 19 study who used intra variceal and perivariceal absolute alcohol in which the success rate was 67%. While in Gin Ho12 study (2001), he compared histoacryl injection alone vs band ligation in controlling acute gastric variceal bleeding the result was 87%, 45% respectively.

The rate of recurrent bleeding after combined technique of gastric varices in this study was (16.6%) which is significantly lower than that reported by Gin Ho<sup>12</sup>, which was 31% in histoacryl group and 54% in band ligation group. And also lower than study reported by Huang<sup>16</sup>, who used histoacryl only for gastric varices, where the rate of recurrent bleeding was 23.3%. But nearly equal to the result obtained by Shiha <sup>11</sup>, which was 18.5%. This lower rate of rebleeding could be explained by the demonstrated efficacy

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of band ligation in the control of acute bleeding together with histoacryl plug, that obturate the centre of large varix, arresting blood flow, giving more chance to collapse the lumen and hence to obliterate the varix. Also, one of the interesting views of this combined technique that the histoacryl casts remained in the variceal channel for a long time (up to 1 year) with minimal ulceration, and once cast extrusion occurs, bleeding became minimal or unnoticed due to obliteration of the lumen of the varix by band ligation, arresting the blood flow. The etiology of portal hypertension in this study was mainly schistosomal and mixed (schistosomal + hepatitic), with relatively good survival rate in our series (81%). Complete variceal obliteration was achieved in 83.4% of cases after4-6 months follow-up period, with mean number of sessions 3.37 ±0.82 and mean time needed 3.8±0.8 weeks. Patients with IGV2 and GOVI shows complete variceal obliteration after the follow-up period while 80% in patients with GOV2 and 83.4% in patients with IGVI achieved obliteration only. Also eradication of IGVI required significantly fewer sessions of combined technique compared with IGV2, GOV2 and GOVI respectively this agrees with the result obtained by

Shiha et al 11.

The complications were mild and transient with no major adverse effects as embolization, deep ulcers or perforation. This disagrees with the result of Gin Ho <sup>12</sup>, who found 8% bleeding ulcers in band ligation group and 6% huge ulcers in histoacryl group and 28 cases in each group developed bacteremia. This may be explained by the use of omeprazole just after the technique and small dose of histoacryl injection.

Mortality rate was 19% in all types patients (8patients), 4 patients died due to recurrent bleeding, mainly in GOV2 group, and 4 patients died due to liver cell failure and encephalopathy, mainly in IGVI group.

In conclusion, our trial showed that endoscopic band ligation plus histoacryl injection in the same sitting is a new technique that was found to be effective and safe for control of active gastric variceal bleeding and for eradication of different types of gastric varices. It is of rare complications both acutely and long term and may be exceptionally useful when surgery is contraindicated. Longer follow-up is required and more number of pa-

tients to study the recurrence rate and survival of patients undergoing combined technique therapy.

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### علاج دوالى المعدة النازفة باشتراك حقن مادة البيتيل سيانو أكيرلات مع الربط الحلقى : اقتراح جديد

## د.أيمن نسيم محمد منيسى أستاذ مساعد الباطنة العامة - كلية طب المنصورة\*\*

المقدمة: يعتبر النزيف الحاد من دوالى المعدة في مرضى تليف الكبد المصابين بارتفاع ضغط الوريد البابى عملية شديدة الخطورة وقد تؤدى إلى الوفاة. ودور العلاج التنظيرى في القضاء على هذه الدوالى مازال تحت البحث وتحتاج إلى رؤية أخرى وعدد من الأبحاث لاثبات فاعليته.

ومع ذلك فبعض الأبحاث أثبتت فاعلية العلاج باستخدام الربط الحلقى لدوالى المعدة على وحدة أو استعمال عملية الحقن التصلبى سواء كان هذا بمادة السيانو اكبرلات أو الكحول النقى. ونحاول فى هذه الدراسة إثبات فاعلية وجدوى استخدام لتحاد عملية الحقن للدوالى بمادة السيانو اكبرلات مع عملية الربط الحلقى للدوالى فى آن واحد لعلاج النزيف.

مادة البحث :- يشمل هذا البحث ٤٢ مريضاً مصابين بتليف الكبد ونزيف من دوالى المعدة وقد قسموا وفقاً لاسباب التليف إلى : ١٥ مريضاً بسبب بهاريسى، ٥ مرضى بسبب فيروسى و ٢٢ مريضاً باشتراك السببين معاً. وقسم المرض وفقاً لننتيجة المنظار إلى : ٨ مرضى نتج النزيف من دوالى مرئ معدى. ٢٠ مريضاً ناتج من دوالى معدة أولى ومريضان من دوالى معدة نوع ثانى.

نتائج البحث : تم وقف نزیف دوالی معدة فی ۲۷ مریضاً (۱ر۸۸٪) وتکرر النزیف فی ۷ حالات (۲ر۲۰٪) و تم ضمور دوالی المعدة تماماً فی ۷ر۸۵٪ من المرضی فی فترة متابعة من ٤ إلی ٦ شهور وکانت أحسن النتائج فی مرضی دوالی المعدة المنفصلة نوع أولی و توفی ٨ مرضی أثناء فترة المتابعة.

ومن ذلك نستخلص : أن عملية إتحاد حقن مادة السيانو اكبرلات مع الربط الحلقي طريقة آمنة ومجدية تماماً في وقف نزيف دوالي المعدة وأيضاً التخلص من هذه الدوالي.

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