# Cyanoacrylate glue for gastroesophageal varices: a single centre experience from North India

Maniri GARG<sup>1</sup>, Tarana GUPTA<sup>2</sup> and Sandeep GOYAL<sup>3</sup>

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ABSTRACT - Background - In natural history of cirrhosis, variceal bleeding is one of the earliest decompensations to happen, and, if adequately managed, survival is improved. Gastric varices have challenges in management due to their location, size and propensity to bleed. The N-butyl 2-cyanoacrylate (NBC) glue application has emerged as definitive therapy in bleeding gastric varices. Here we present our experience with use of NBC in management of gastric and difficult cases of esophageal varices. Methods - A total of 75 patients underwent NBC glue application for varices which included 69 patients with gastric varices and six patients with esophageal varices. All the procedures were done with flexible endoscope and sclerotherapy needle after due precautionary measures. Results – Hemostasis was varices in all patients after endotherapy. The average quantity of glue used was 2.75±0.95 mL. Complete obliteration with single session of NBC application was achieved in 55 patients. Re-bleeding occurred in five patients within 5 days of index event. 20 patients had in-hospital mortality but none was related to gastrointestinal bleeding. 6-week all-cause mortality was 26 (35%). Conclusion - Glue therapy with NBC is a life saving therapy in patients with bleeding gastric varices and esophageal varices not amenable to endoscopic variceal ligation or sclerotherapy.

Keywords - N butyl 2- cyanoacrylate; gastric varices; esophageal varices; signs of recent hemorrhage.

#### INTRODUCTION

Acute variceal bleed is most dreadful complication associated with portal hypertension and accounts for approximately 20% mortality at 6 weeks<sup>(1)</sup>. Gastric variceal bleed (GVB) accounts for approximately 20% of all variceal bleeding but are more severe and carries a higher mortality<sup>(2)</sup>. The management of gastric varices is different from the esophageal varices and the tissue glue therapy has been advocated. However, the glue therapy is challenging in clinical practice and carries an inherent risk of spillage of glue on operator/assistant, endoscope channels blockage, endoscope lens damage, profuse bleeding from puncture site and potential risk of embolisation into systemic vessels<sup>(3)</sup>. Moreover, it needs expertise to use glue therapy, failing which the outcome can be catastrophic.

Our hospital is a tertiary care centre in North India providing facilities for the gastrointestinal bleeding cases, and tissue glue therapy has been used for control of variceal bleed (gastric and esophageal) for last 5 years. With this data, we are presenting our experiences of tissue glue use, N-butyl 2-cyanoacrylate (NBC) in patients of variceal bleed with respect to outcomes and complications.

#### **METHODS**

#### Patients and study design population

This is a retrospective study in which all patients admitted in Emergency Department of Medicine with upper gastrointestinal bleed (UGIB) were screened during June 2017 - June 2021 at Post Graduate Institute of Medical Sciences, Rohtak, Haryana

(India). All patients undergoing glue therapy for gastric varices were included into the study. Gastric varices were classified as given by Sarin et al.<sup>(4)</sup> Esophageal varices were classified as small (<5 mm) and large (>5 mm) in size with presence or absence of red color signs (red wale marks or red spots)<sup>(5)</sup>. The written, informed consent was taken before each procedure. A checklist was cleared for all UGIB patients before endoscopy which included systolic blood pressure >90 mmHg, mean arterial pressure >65 mmHg, haemoglobin >7 gm/dL, arterial saturation >94%. Patients with higher grades of hepatic encephalopathy, hemodynamic instability were taken for endoscopy after securing airway in intensive care settings. Demographic and clinical data were recorded from available medical records including the etiology of the portal hypertension, comorbidities and medications used. Endoscopic reports and data regarding the volume, number and sessions of NBC injections were retrieved from the available records.

#### Technique of glue application

We used NBC in all cases. All the procedures were done by the authors themselves (SG, TG) with the help of gastroscope (OLYMPUS GIF-H 190, Tokyo, Japan or KARL STORZ 13821 PKSK/NKSK, Tuttlingen, Germany) and sclerotherapy needles (21/23 G, 230 cm). The tissue glue, NBC, is a watery liquid that transforms into a solid state when added to a physiological medium containing hydroxyl ions, such as blood<sup>(6)</sup>. Upon injection into a varix, the glue polymerizes instantaneously and hardens; thereby obturating the lumen of the varix, with resultant rapid haemostasis. Over time, the glue cast is extruded into the lumen.

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Disclosure of funding: no funding received <sup>1</sup> MD Medicine. Associate Professor, Department of Medicine, Pt. B. D. Sharma PGIMS, Rohtak, Haryana. <sup>2</sup> MD Medicine, DM Hepatology, Senior Professor, Department of Medicine, Pt. B. D. Sharma PGIMS, Rohtak, Haryana. 3 Medicine, DM Gastroenterology. Professor, Department of Medicine, Pt. B. D. Sharma PGIMS, Rohtak, Haryana. Corresponding author: Sandeep Goyal. E-mail: sandeepgoyal20000@gmail.com

There are no standardised techniques for performing glue injection into the gastric varices. A mixture of glue with lipiodol/ distilled water/dextrose for application have been used in literature<sup>(3,6-8)</sup>. In our cases, the needle was flushed with 5% dextrose with no air drying of needle and then the glue (in mL) was injected based on the approximate size of gastric varices and thereafter the needle was flushed with 0.8–1.5 mL of 5% dextrose again to deliver the remaining glue into the gastric varices. We named this technique as 'Sandwich technique' for glue application. The needle was then withdrawn into sheath immediately with application of firm pressure to injection site with sheath for 10–15 seconds. In case of sheath getting stuck into injection site, we applied the 'push scope inside' technique (in retroverted state) rather than forcefully pulling the sheath from the injection site.

### Safety measures

The operators and technicians took all protection gears (gloves, caps, gowns face shields/Goggles) in order to avoid any injury due to spillage of glue. The help of suction was kept at minimum during entire procedure. Both light guide lens and objective lens were thoroughly cleaned with acetone after each procedure.

#### **Outcome measures**

Primary outcomes were 6-week mortality due to bleed related events and procedure-related complications. Procedural complications included intra-procedural bleeding, hypotension, allergic reaction, systemic embolic events.

Secondary outcomes were post procedure blood transfusion requirements, duration of hospital stay, need of salvage therapy (balloon tamponade, transjugular intrahepatic portosystemic shunt, surgery), rebleeding and 6-week all-cause mortality. The rebleeding was defined as either hemoglobin drop >3 gm/dL or requirement of >2 packed red blood cell transfusions or systolic blood pressure drop <90 mmHg due to bleeding during hospital stay with in 5 days.

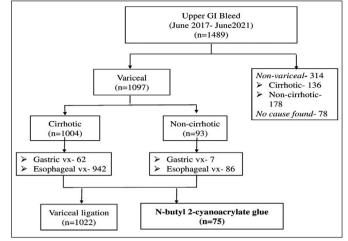
#### Statistics

All the data were filled in Microsoft excel sheets. Means  $\pm$  standard deviation and ranges were used to summarise data for continuous variables, whereas percentages were used for categorical variables.

#### RESULTS

#### **Demographic characteristics**

Out of total 1489 patients of UGIB, 1097 had varices related bleed and 314 had non-variceal bleed. In 1097 patients with varices related bleed, 1022 underwent variceal ligation and 75 had NBC glue application done (FIGURE 1). Among 75 patients with NBC done, the mean age was 50.4±14 years with male predominance (M:F- 2.4:1). Among the causes of UGIB patients undergoing glue therapy, cirrhosis was present in 68 (90.6%), non-cirrhotic portal fibrosis (NCPF) in 4 (5.4%), extrahepatic portal venous obstruction (EHPVO) in 2 (2.7%) and splenic vein thrombosis a as (complication of acute pancreatitis) in 1(1.3%) patient. Out of 68 as a patients of cirrhosis, etiology was alcohol in 37, chronic hepatitis C (CHC) in 10, non-alcoholic steatohepatitis (NASH) in four, chronic hepatitis B (CHB) in five, autoimmune hepatitis in three patients and co-infection of CHB and CHC in one patient. Seven patients were labelled with cryptogenic cirrhosis as no cause of cirrhosis was found (TABLE 1).



# FIGURE 1. Distribution of varices and endotherapy in patients of upper GI bleed.

Upper GI bleeding: upper gastrointestinal bleeding.

TABLE 1.	Clinical	and	demograp	ohic	profile	of	patients	(n=75).

Variable		Number of patients; n (%)	
Age (years)		50.4±14	
Males (n)		53	
	Liver cirrhosis	68 (90.6%)	
Variceal bleed	NCPF	4 (5.4%)	
distribution (n=75)	EHPVO	2 (2.7%)	
	Splenic vein thrombosis	1 (1.3%)	
Etiology of cirrhosis	Alcohol/CHC/NASH/ CHB/		
(n=68)	Cryptogenic/ AIH/ CHB+CHC	37/10/4/5/8/3/1	
Gastric varices (n=69)	GOV1/GOV2/ IGV1/IGV2	21/37/10/1	
Esophageal varices (n=66)	Small/Large	42/24	
Approxiate volume of bleed (mL)		154±80	
Bleeding episodes (n)		2.3 (1-6)	
Baseline Hb (gm/dL)		5.7 (3.2–11)	
MAP (mm of Hg)		70±16	
S bilirubin (mg/dL)		8.7 (1-32)	
INR		1.6±0.5	
Serum creatinine (mg/dL)		$1.4 \pm 0.8$	
CTP		8.5 (5-15)	
MELD		17 (11–34)	

NCPF: non-cirrhotic portal fibrosis; EHPVO: extra hepatic portal vein obstruction; CHC: chronic hepatitis C; NASH: non-alcoholic steatohepatitis; CHB: chronic hepatitis B; Hb: haemoglobin; MAP: mean arterial pressure; INR: international normalized ratio; CTP: Child--Turcotte Pugh Score; MELD: Model for end stage liver disease; GOV: gastroesophageal varices; IGV: isolated gastric varix. The data is presented as mean ±SD/range or percentage (%) only.

#### **Distribution of varices**

Out of 75 patients, 69 had gastric varices which included GOV1 in 21, GOV2 in 37, IGV1 in 10, IGV2 in one patient. Esophageal varices were present in 66 patients, of which 24 had large and 42 had small varices (TABLE 1). PHG was present in 70 (93.3%) whereas 5 (6.7%) patients had no endoscopic evidence of PHG as defined by McCormack et al.<sup>(9)</sup>.

#### Endotherapy

Out of total 75 patients, 57 (76%) underwent alone NBC glue therapy whereas 18 (24%) underwent combined endoscopic variceal ligation (EVL) and cyanoacrylate glue application (TABLE 2). No patient was subjected to EVL prior to glue therapy. Overall 55 patients required one, 17 needed two and three needed three sessions of glue endotherapy to achieve complete obliteration of varices. The successive sessions were planned after 2 weeks of initial therapy. Overall the average quantity of glue required was  $2.75 \pm 0.95$  mL (TABLE 2).

TABLE 2. Endotherapy used in patients (n=75).

Endotherapy		N (%)
Conservation	Gastric varices	51 (68)
Cyanoacrylate glue	Esophageal varices	6 (8)
EVL and cyanoacrylate glue both		18 (24)
Session of glue (n)	1	55 (73.3)
	2	17 (22.7)
	3	3 (4)
Volume of cyanoacrylate (mL)		2.75 <u>+</u> 0.95

EVL: endoscopic variceal ligation. The data is presented as mean ±SD/range or percentage (%) only.

# High risk signs requiring glue therapy

Sign of recent hemorrhage (SRH) viz adherent clot or fibrin plug, depending on its location on esophageal variceal columns were taken as high risk factors which may require endotherapy with glue. All 21 patients with GOV1 had SRH and were deemed unfit for EVL therapy and underwent glue therapy successfully. 12 (16%) patients had SRH on esophageal variceal columns, however only 6 (8%) of these required glue therapy and rest were managed with EVL only.

#### **Primary outcomes**

Primary outcomes were achieved in all patients (TABLE 3). None of the patient had bleed related 6-weeks mortality. The he-

 TABLE 3. Primary and secondary outcomes after endoscopic glue application (n=75).

Outcomes	Variables	
Duine	6-week bleed related mortality	Nil
Primary	Post procedural complications	Nil
	PRBC requirement (Unit)	1.6±0.5
	Duration of hospital stay (days)	4.7 (3–8)
Secondary	Salvagetherapy (TIPS/balloon tamponade/surgery)	Nil
	Re-bleeding (within 5 days)	5

PRBC: packed red blood cell; TIPS: transjugular intrahepatic portosystemic shunt.

#### Secondary outcomes

Patients required mean  $1.6 \pm 0.5$  units of packed RBCs after endotherapy. The mean duration of hospital stay was 4.7 (3–8) days. No patient required salvage therapy. Re-bleeding occurred in five patients within 5 days of index event which was well controlled with repeat endotherapy (TABLE 3). 20 patients had in-hospital mortality but none was related to gastrointestinal bleeding. Out of these, 10 patients had septic shock, three had hepatorenal syndrome (HRS), four had persisting hepatic encephalopathy and three had respiratory failure. The 6-week all-cause mortality was 26 (35%).

#### DISCUSSION

This retrospective analysis highlights NBC glue application to be an effective therapy in achieving hemostasis in different grades of gastric varices as well as esophageal varices with SRH which are not amenable for variceal band ligation. There were no immediate post procedure complications with nil 6-week mortality due to bleed related events.

Gastric variceal (GV) bleeding is relatively uncommon compared to esophageal variceal bleeding but carries a potential life threat<sup>(10)</sup>. In comparison to espohageal varices which are common in diffuse portal hypertension, gastric varices are result of segmental portal hypertension especially left side of abdomen and are common in patients with splenic vein thrombosis. Unlike esophageal varices, which have a bleeding risk directly related to hepatic venous pressure gradient (HVPG), the gastric varices bleeding risk is related to varix size and wall tension. The therapies for management of gastric varices include use of beta blockers, tissue glue therapy, coil embolisation and transjugular intrahepatic portosystemic shunt (TIPS). Mishra et al. showed cyanoacrylate glue to be more effective than non-selective beta blocker in prevention of GV bleed (10% vs 38%) and bleed related mortality (0 vs 10%) in primary prophylaxis of GV bleeding<sup>(11)</sup>.

Glue therapy for variceal bleeding had been existent since 1986 and had been widely accepted for management of bleeding gastric varices. Endoscopic gastric variceal obturation with intravariceal injection of NBC has been endorsed by the gastroenterologists all over the world except only a few reports from USA where it is not approved for this indication. The success with the use of NBC had been phenomenal with median achievement of primary haemostasis being 95.2% (range 71-100%) while the median rate for complete variceal obliteration was 87% (range 51-100%) in one to three sessions among 32 case series of glue therapy<sup>(6)</sup>. In our study enrolling 75 patients, we had replication of these success rates with achievement of primary hemosatasis in all patients (100%). Majority of patients (55; 73.3%) had complete obliteration of varices and did not need another endotherapy session whereas only 20 (26.7%) patients underwent another session of therapy indicating a marked response with glue therapy. Our findings get strength from the previous studies stating a good obliteration rate of gastric varices with glue therapy<sup>(12-14)</sup>.

Variceal bleed due to underlying cirrhosis of liver was present in majority (90.7%) of patients (TABLE 1). The cirrhosis of liver was largely attributed to significant alcohol intake followed by CHC infection, NASH and CHB infection and causes of cirrhosis are in accordance with the previous studies from the western world and Indian data<sup>(15,16)</sup>. Males predominated as compared to females which is largely attributed to alcohol drinking habits.

In practice, GOV1 are usually managed with EVL banding just like esophageal varices<sup>(17)</sup>. However, we had 21 patients with GOV1 who underwent glue therapy due to SRH. In all of these patients, the EVL banding or sclerotherapy was deemed unsuitable due to size of variceal column and SRH being located below GE junction. There is scarce data of NBC use in esophageal varices, however we had six patients with esophageal varices not amenable to EVL banding/sclerotherapy due to either variceal column ulcers or SRH at difficult site and were successfully managed subsequently with glue therapy. Sayed et al. in a recent review highlighted the use of NBC in esophageal varices in difficult situations<sup>(18)</sup>.

The glue therapy had side effects with potential life threatening complications. Re-bleeding rates have ranged between 3.7% and 58%<sup>(19,20)</sup>. As a systemic complication, the incidence of embolism had been reported to be  $0-4.3\%^{(21,22)}$ . In our study, all the procedures went uneventfully with nil incidence of procedure/post procedure bleeding and no episodes of embolism. Rebleeding episode occurred in five patients within 5 days of procedure and was managed successfully with repeat session of endotherapy.

The repeat sessions of glue therapy for complete obliteration of gastric varices were needed in 20 patients. Eight patients had recurrence of bleed within 4 weeks and 12 patients underwent repeat sessions in view of incomplete obliteration of varix as assessed by gentle probing with sclerotherapy needle sheath on follow up endoscopy. We had in hospital mortality of 20 patients however none was related to gastrointestinal bleed secondary to endotherapy. Septic shock emerged as major cause of mortality in these patients. Though 6-week mortality was high upto 35% however none of the patients had demise due to uncontrolled gastrointestinal bleeding.

We have certain limitations with our study. First, only NBC was used for endotherapy in all patients so we cannot comment

on the efficacy of other tissue adhesives in variceal bleeding control. Second, we did not use lipoidol for glue application as with lipoidol large amount of glue can be applied in a single session. However, we needed repeat sessions in only 20 patients, thus magnitude of this limitation got minimised in this study. Additionally, lipoidol increases the cost of endotherapy with an increased risk of increased embolic phenomenon. Thirdly, we did not have facility for endoscopic ultrasound and coil embolization which is upcoming modality for these patients. However, we had no failure of endotherapy and our primary outcome was achieved in all patients. To add upon, NBC therapy also reduces cost of endotherapy in comparison to endoscopic ultrasound guided coil embolization/TIPS.

In conclusion, glue therapy with NBC is a life saving therapy in patients with bleeding gastric varices and esophageal varices not amenable to EVL or sclerotherapy. However, it needs expertise and the potential side effects should be kept in mind before contemplating the procedure.

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# Authors' contribution

Garg M: Concepts, definition of intellectual content, literature search, data acquisition, data analysis, statistical analysis, manuscript preparation, manuscript editing, manuscript review. Gupta T: Concepts, design, definition of intellectual content, literature search, clinical studies, data acquisition, manuscript editing, manuscript review. Sandeep Goyal S: Concepts, design, definition of intellectual content, literature search, clinical studies, data acquisition, statistical analysis manuscript preparation, manuscript editing, manuscript review.

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Manjri Garg: 0000-0002-4217-1583. Tarana Gupta: 0000-0003-3453-2040. Sandeep Goyal: 0000-0003-2890-9593.

Garg M, Gupta T, Goyal S. Cola de cianoacrilato para varizes gastroesofágicas: uma única experiência central no norte da Índia. Arq Gastroenterol. 2022;59(3):434-8.

RESUMO – Contexto – Na história natural da cirrose, o sangramento de varizes é uma das primeiras descompensações a acontecer e, se adequadamente controlada, a sobrevivência é melhorada. Varizes gástricas têm desafios na sua gestão devido à sua localização, tamanho e propensão a sangrar. A aplicação de cola N butil 2-cianoacrilato (NBC) surgiu como terapia definitiva em varizes gástricas sangrantes. Apresentamos nossa experiência com o uso da NBC na gestão de casos gástricos e difíceis de varizes esofágicas. Métodos – Um total de 75 pacientes foram submetidos à aplicação de cola NBC para varizes que incluiu 69 pacientes com varizes gástricas e seis pacientes com varizes de esôfago. Todos os procedimentos foram feitos com endoscópio flexível e agulha de escleroterapia após as devidas medidas de precaução. Resultados – A hemostasia foi alcançada em todos os pacientes após a endoterapia. A quantidade média de cola utilizada foi de 2,75+0,95 mL. A obliteração completa com sessão única de aplicação da NBC foi alcançada em 55 pacientes. O reexame ocorreu em cinco pacientes dentro de 5 dias após o evento de índice. 20 pacientes tiveram mortalidade hospitalar, mas nenhum foi relacionado com o sangramento gastrointestinal. A mortalidade após 6 semanas foi de 26 (35%). Conclusão – A terapia de cola com a NBC é uma terapia que salva vidas em pacientes com varizes gástricas hemorrágicas e varizes esofágicas não condizíveis à ligadura endoscópica ou escleroterapia.

Palavras-chave – N butil 2-cianoacrilato; varizes gástricas; varizes do esôfago; sinais de hemorragia recente.

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