

Evaluation of Different Modalities for Prevention of Esophageal Varices Recurrence

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Abstract: Introduction: Esophageal varices are present in 30% of patients with compensated cirrhosis and up to 60% of those with decompensated cirrhosis, Band ligation is the method of choice although injection therapy still has a role in acute bleeding. However varices frequently recur after endoscopic variceal ligation. In view of the unacceptable high rate of recurrence associated with this technique, the availability of other supplemental consolidation therapies is desired. **Aim of work:** To evaluate and compare different therapeutic approaches used as consolidation therapy including argon plasma coagulator, injection sclerotherapy and B-blockade for their efficacy in prevention of variceal recurrence, recurrent bleeding and complications after eradication by band ligation. **Subjects and methods:** This study was conducted on 60 patients presented with 1st attack of upper GIT bleeding, after history taking and physical examination, band ligation of varices was done till obliteration where the patients were classified into 3 groups; group I (20 patients) received argon plasma; group II (20 patients) received paravariceal sclerotherapy with ethanolamine and group III (20 patients) received propranolol. All patients were followed up for 1 year with endoscopy performed every 3 months to check for variceal recurrence. **Results:** Argon plasma coagulation had the least recurrence rate as compared to other groups ($P < 0.001$) with no significant difference between them as regards time of recurrence or recurrent bleeding ($P > 0.05$). there was no significant difference between Child's A and B class regarding recurrence. The recurrence was statistically related to P.V diameter in groups I&III ($P=0.003$ & 0.008), and number of setting in group I ($P=0.02$). No significant increase in PHG occurred with argon plasma in comparison with other groups ($P=0.03$). Retro-sternal pain and dysphagia significantly occurred in groups I&II; fever significantly occurred in group I while exertional dyspnea occurred in group III. **Conclusion:** Argon plasma coagulation is a safe and effective consolidation therapy following band ligation in prevention of variceal recurrence, recurrent bleeding in comparison with paravariceal sclerotherapy with ethanolamine oleate and use of beta blockers therapy, but is relatively expensive method.

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Key Words: Argon plasma coagulation, paravariceal sclerotherapy, esophageal varices, beta blockers.

1. Introduction

Esophageal variceal ligation (EVL) has been used widely use as a simple and effective method for treating esophageal varices [1]. EVL became the preferred technique for the endoscopic treatment of esophageal varices when it was proven in several randomized trials to be as effective as endoscopic variceal sclerotherapy but with fewer serious adverse events [2]. EVL is more effective than propranolol for the primary prevention of variceal bleeding [3]. Because band ligation does not cause thrombosis of the feeding veins, it may help to suppress capillary proliferation and invasion by perforating veins by inducing fibrosis of the distal esophageal mucosa to prevent recurrence [4]. However, in view of an unacceptably high rate of recurrence (or rebleeding) associated with this technique, the availability of supplemental consolidation therapy of some other kind was hoped for [3–6]. Attempts have been made to use various methods for this particular therapeutic purpose, centering on endoscopic injection sclerotherapy (EIS). Argon plasma coagulation

(APC) is a noncontact thermal coagulation method in which high-frequency current is applied to the target tissue through an argon plasma jet [4]. A distinctive characteristic of APC that it produces safe and effective shallow coagulation over extensive areas. Although use of APC after EVL appears promising, still needed are larger prospective trials, risk-benefit and cost-effectiveness analysis and comparisons with standard medical therapy (beta-blockers or nitrates) [7]. Adopting APC among the other unestablished means and procedures of consolidation therapy; it was tested for its clinical usefulness and safety.

Aim of Work

To evaluate and compare different therapeutic modalities used as consolidation therapy including argon plasma coagulation, paravariceal injection sclerotherapy and B-blockade for their efficacy in prevention of variceal recurrence, recurrent bleeding and complications after eradication by band ligation.

2. Subject and Methods

This prospective study was done from July 2009 to April 2010, We selected patients with portal hypertension who presented with 1st attack of upper GIT bleeding from esophageal varices. 60 eligible patients were included in the study in our hospital. Liver cirrhosis was diagnosed on the basis of clinical, biochemical and or ultrasonographic evidence. For all the patients, history taking and physical examination was obtained, liver function tests, C.B.C. and markers for hepatitis B and C viruses and antibilharzial antibody in serum were performed. The severity of the liver disease was classified according to Child-Pugh score. Written informed consent was obtained from the patients.

EVL was performed after the midazolam application (5-10 mg). An endoscope (fibro optic Olympus single channel CLK-4) was introduced, and the ligation was carried out using multiband ligator shooter, as many bands as possible were placed in the lower 2–5 cm of the esophagus on variceal columns. The varices were treated in multiple sessions until eradication.

Following variceal eradication our patients were classified into 3 groups:

Group (I): 20 patients received argon plasma coagulation: as additional consolidation therapy for the removal of the mucosa lining. APC performed on the entire circumference of the lower esophagus, from esophago-gastric junction to proximal segment about 5 cm, APC therapy was initiated within 30 days of variceal eradication and continued at 15- day intervals in two settings where the esophageal

circumference was divided approximately into 2 halves; each half had been treated at different setting. Procedures were performed with therapeutic endoscopes (fibro-optic Olympus single channel or CLK-4 Pentax EPM 3500 double channel or Olympus extra CLV 160 double channel), with an argon gas cylinder, gas flow meter; coupled with a high-frequency generator (TEKNO Germany ABC TOM 201), and flexible 2.3-mm diameter axial probes (BOWA Germany 425/257) Argon gas flow was set at 1-2 L/min and generator at 60 W. patients were treated with omeprazole (20 mg per day) to promote healing of the coagulated tissue.

Group (II): 20 patients were subjected to induction of fibrosis of distal esophageal mucosa by paravariceal injection sclerotherapy with ethanolamine oleate of about 0.5-1 cm in each side of the esophagus in one setting.

Group (III): 20 patients were given non selective B- blocker and were followed with aim of reduction of pulse rate about 25% of basal rate or to reach 55/min. the doses ranges from 20-60 mg/day in two divided doses.

All patients were followed for up to 1 year with upper GIT endoscopy performed every 3 month for detection of variceal recurrence, recurrent bleeding and complications.

3. Results:

Results are shown in the following tables (Table 1 to Table 10):

Table (1): patients' characteristics in study groups:

	Group (I)		Group (II)		Group (III)		F	P	Sig.
Age(years)									
Mean ±SD	46.1±9.3		46.9±5.6		46.7±6.8		0.05	0.9	
range	25-61		35-60		30-60				
Child score									
Mean ±SD	7.65±1.7		7±1.7		6.75±1.5		0.15	0.85	
range	5-9		5-9		5-9				
	N	%	N	%	N	%	X ²	P	Non Sig.
Sex									
Male	17	85	15	75	15	75	0.79	0.67	
female	3	15	5	25	5	25			
Aetiology									
HCV	14	70	17	85	16	80	2.26	0.68	
BIL.	3	15	2	10	2	10			
HCV&BIL	3	15	1	5	1	5			
HBV	0	0	0	0	1	5			

Table (2): comparison between different study groups as regarding No. of bands consumed, No. of settings needed for variceal eradication and eradication duration:

	Group I	Group II	Group III	F	P	Sig.
No of bands						
Mean \pm SD	11.05 \pm 2.7	9.1 \pm 2.3	11.4 \pm 6.8	1.54	0.22	Non sig.
Range	6-16	6-13	5-28			
No of settings						
Mean \pm SD	3.5 \pm 1.05	2.7 \pm 0.7	3.6 \pm 1.9	2.3	0.10	Non sig.
Range	2-5	2-4	2-8			
Eradication Duration (days)						
Mean \pm SD	53.5 \pm 15.1	43.1 \pm 13.8	60.3 \pm 44.8	1.85	0.16	Non sig.
Range	30-75	30-81	14-165			

Table (3): Comparison between different modalities (argon plasma group (I), paravariceal sclerotherapy (II) and B.blockers (III) regarding recurrence of esophageal varices, time of recurrence and recurrent bleeding:

	Group I		Group II		Group III		X ²	P	Sig.
	N	%	N	%	N	%			
Recurrence	3	15	16	84.2	12	63.2	19.83	<0.001	Sig.
Recurrent bleeding	1	5	1	5	3	15	3.75	0.15	Non sig.
							F	p	
Recurrence time (month)									
Mean \pm SD	7 \pm 1.7		6.25 \pm 3.6		6.3 \pm 3.57		0.05	0.9	Non sig.
Range	6-9		1-12		1-12				

Table (4): LSD ratio of recurrence of esophageal varices of the 3 groups:

	I	II
III	<0.001	Non sig.
II	<0.001	

Table (5): Relation between recurrences of esophageal varices and other parameters in group I:

	No recurrence	recurrence	t	P	Sig.		
Age(year)							
Mean \pm SD	45.1 \pm 8.9	52 \pm 10.8	1.19	0.24	Non sig.		
Range	25-60	40-61					
	N	%	N	%	X ²	P	Sig.
Sex							
Males	14	82.4	3	100	0.01	0.93	Non sig.
Females	3	17.6	0	0			
O.V grade							
II	3	17.6	0	0	4.31	0.36	Non sig.
II-III	6	35.2	0	0			
III	6	35.2	2	66.7			
III-IV	1	5.8	1	33.3			
IV	1	5.8	0	0			
PVdiameter (mm)							
Mean \pm SD	14.9 \pm 0.8	16.7 \pm 0.57					
Range	13-16	16-17	3.37	0.003			Sig.
Eradication duration (day)							
Mean \pm SD	50.5 \pm 14.2	70 \pm 8.6	1.4	0.17			Non sig.
Range	30-75	60-75					
No of bands							
Mean \pm SD	10.7 \pm 2.89	13 \pm 2	1.3	0.19			Non sig.
Range	6-16	11-15					

No of setting							
Mean ±SD	3.2±1.0		4.6±0.5		2.4	0.02	Sig.
Range	2-5		4-5				
PHG after band	N	%	N	%			
I	7	41.1	3	100			
I-II	0	0	0	0			
II	8	47	0	0	3.35	0.17	Non sig.
II-III	2	11.9	0	0			
III	0	0	0	0			
Child class	N	%	N	%			
Child A	9	52.9	1	33.3	0.0	1.0	Non sig.
Child B	8	47.1	2	66.7			

Table (6): Relation between recurrences of esophageal varices and other parameters in group II:

	No recurrence		recurrence		t	P	Sig.
Age (years)							
Mean ±SD	43.3±7.6		47.1±5.1		1.08	0.29	Non sig.
Range	35-50		40-60				
	N	%	N	%	X²	P	Sig.
Sex							
Males	3	100	12	75	0.04	0.83	Non sig.
Females	0	0	4	25			
O.V grade							
II	1	33.3	5	29.4			
II-III	0	0	1	5.8	0.39	0.94	Non sig.
III	2	66.7	10	58.8			
III-IV	0	0	1	5.8			
IV	0	0	0	0			
PV diameter (mm)							
Mean ±SD	15.1±0.76		15.2±0.1.2		0.06	0.095	Non sig.
Range	14.5-16		12-17				
Eradication duration(day)							
Mean ±SD	52.6±12.7		42.1±13.7		1.22	0.23	Non sig.
Range	38-60		30-81				
No of bands							
Mean ±SD	9.3±2.8		9.2±2.3		0.09	0.92	Non sig.
Range	6-11		6-13				
No of setting							
Mean ±SD	3.1±0.57		2.6±0.61		1.43	0.16	Non sig.
Range	3-4		2-4				
PHG after band	N	%	N	%			
I	2	66.6	15	88.2			
I-II	0	0	0	0	6.16	0.04	Sig.
II	0	0	2	11.8			
II-III	0	0	0	0			
III	1	33.3	0	0			
Child class	N	%	N	%			
Child's A	2	66.7	8	50	0.01	0.9	Non sig.
Child's B	1	33.3	8	50			

Table (7): relation between recurrences of esophageal varices and other parameters in group III:

	No recurrence		recurrence		T	P	Sig.
Age(years)							
Mean ±SD	46.2±7.4		46.9±7.1		0.18	0.85	Non sig.
Range	40-60		30-58				
	N	%	N	%	X ²	P	Sig.
Sex							
Males	5	71.4	9	75	0.14	0.71	Non sig.
Females	2	28.6	3	25			
O.V grade							
II	2	28.5	4	33.3	7.54	0.1	Non sig.
II-III	3	43	0	5.8			
III	2	28.5	4	33.3			
III-IV	0	0	3	25			
IV	0	0	1	8.4			
PV diameter (mm)							
Mean ±SD	14.9±0.6		16±0.79		2.98	0.008	Sig.
Range	14-16		15-17				
Eradication duration (days)							
Mean ±SD	50.8±51.6		68.3±42.5		0.80	0.43	Non sig.
Range	14-165		30-150				
Bands No.							
Mean ±SD	9.14±6.3		12.9±7.2		1.14	0.26	Non sig.
Range	5-15		5-28				
Setting No.							
Mean ±SD	3.1±1.8		4±2		0.89	0.38	Non sig.
Range	2-4		2-8				
PHG band after	N	%	N	%			
I	4	57.1	10	83.4	1.37	0.5	Non sig.
I-II	0	0	1	8.3			
II	3	42.9	0	0			
II-III	0	0	1	8.3			
III	0	0	0	0			
Child class	N	%	N	%			
Child's A	5	71.4	5	41.7	0.6	0.43	Non sig.
Child's B	2	28.6	7	58.3			

Table (8): Effects of different modalities (argon plasma coagulation, paravariceal sclerotherapy and B blockade) on PHG

	Group I		Group II		Group III		X ²	P	Sig.
	N	%	N	%	N	%	7	0.03	sig.
No increase or improved	17	85	9	45	12	63.1			
Increase	3	15	11	55	7	36.9			

Table (9): LSD ratio between groups regarding effect on PHG:

	I	II
III	0.23(non sig.)	Non sig.(0.25)
II	0.008(sig.)	

Table (10): Comparison between group I (argon plasma) & group II (paravariceal sclerotherapy) & group III (B.B) regarding complications:

	Group I N=20		Group II N=20		Group III N=20		X ²	P
	N	%	N	%	N	%		
Ulcer	0	0	0	0	0	0	0	1
Retrosternal pain	12	60	16	80	0	0	14.8	0.0005 sig.
Dysphagia	9	45	7	35	0	0	8.37	0.015 Sig.
Bleeding	0	0	0	0	0	0	0	1
Fever	14	70	0	0	0	0	28	<0.001 sig.
Stricture	0	0	0	0	0	0	0.0	1
Death during study	0	0	1	5	2	10	2	0.36
Recurrent bleeding	1	5	1	5	3	15	1.6	0.44
Exertional dyspnoea	0	0	0	0	4	20	8	0.018 sig.
Fatigue	0	0	0	0	2	10	4	0.13

4. Discussion

Currently, there are two mainstream therapeutic approaches to the endoscopic treatment of esophageal varices: EIS and EVL. Since the introduction of intravariceal injection sclerotherapy using 5% ethanolamine oleate, EIS has been the preferred modality. Its usefulness has been acknowledged because of the reliable therapeutic outcome, and based on evaluation of hemodynamics by endoscopic varicealography during sclerotherapy [8]. On the other hand, the clinical application of EVL had spread rapidly since it was first described by **Stiegmann** [1] mostly due to its efficacy, convenience and safety and the technique had become the treatment of choice for esophageal varices [9]. However, it has a higher rate of esophageal varices recurrence as compared with EIS [10].

Our three groups of patients were matched and quietly similar regarding their ages, gender, etiology of liver cirrhosis and their Child's score.

Comparing the results of the 3 groups as regards the incidence of variceal recurrence during follow up period, we found that argon plasma group had a significant low recurrence rate (15%) when compared to paravariceal sclerotherapy with ethanolamine oleate (84.2%) or B.B (63.2%). This was quietly similar to the results of **Nakamura et al.**, [9] who recorded a recurrence rate of 25.8%, after ligation plus APC. **Furukawa et al.**, [11] recorded 9% recurrence rate after the initial obliteration by EVL and APC. Also **Fouad, et al.**, [12] compared endoscopic band ligation plus argon plasma coagulation with scleroligation in prevention of variceal recurrence, they recorded a recurrence rate of 4%. However **Cipolletta et al.**, [4] recorded no recurrence of varices or variceal hemorrhage in the argon plasma

coagulation group in a mean follow up period of 16 months.

One patient (5%) had recurrent bleeding in argon plasma group during one year follow up period, this was similar to **Nakamura et al.**, [9] recurrent bleeding was observed after 6 months in one patient (3.3%) in the combined group (argon plasma and band ligation), compared to two more patients (6.7%) in the ligation group, also **Fouad, et al.**, [12] reported recurrent bleeding in one of the 2 recurrent patients (2%). However **Cipolletta et al.**, [4] reported that no variceal hemorrhage in the argon plasma coagulation group, whereas bleeding recurred in ligation group and that may be due to absence of variceal recurrence in the time of his study.

Shigenaga, et al., [13] studied recurrence of esophageal varices after mucosa-fibrosing therapy with APC compared with paravariceal injection sclerotherapy using 1% polidocanol recurrence rate was 6.7%.

Variceal mean free time of recurrence in APC group was higher than the other 2 groups (about 7±1.7 month), however in **Furukawa et al.**, [11] variceal recurrence was after 3 months and in **Shigenaga, et al.**, [13] variceal recurrence occurred after 15 month.

In APC group no significant relation to recurrence was found as regards age, sex, grade of O.V. the degree of PHG following EVL, mean duration of variceal eradication or the number of bands used. No significant difference between the recurrent and non recurrent cases regarding number and percentage of Child's class A or B patients. However P.V. diameter was significantly higher in recurrent cases, also the number of settings used was significantly higher in recurrent group.

Leonardo et al., [14] made analysis of factors that may increase the risk of variceal recurrence after eradication and found that only presence of gastric varices was related to the recurrence which was not present in any patient in our study.

Regarding the APC effect on worsening of PHG, we found significantly that argon plasma didn't increase the degree of PHG in comparison to other groups, This was in agreement with **Cipolletta, et al.**, [4].

Regarding complications of argon plasma coagulation about 70% of the cases had transient fever that was alleviated rapidly with antipyretics; this was in agreement with **Cipolletta, et al.**, [4] and **Nakamura et al.**, [9].

Dysphagia occurred in about 45% of patients which was nearly similar to **Cipolletta, et al.**, [4] and **Furukawa et al.**, [11] ; Transient retro-sternal pain or heart burn was developed in 60% of our patients which was in agreement with **Furukawa et al.**, [11] and **Cipolletta et al.**, [4]. This can be explained by that all these minor complications are actually "sequelae" when any thermal treatment method used in the esophagus and are therefore to some degree unavoidable.

Stricture didn't develop in any patient in our study; this was in agreement with **Cipolletta et al.**, [4] and **Fouad et al.**, [12].

No peri-operative bleeding, ulceration or death developed in our patients, this was in agreement with **Nakamura et al.**, [9]. However in **Fouad et al.**, [12] one case of ulcer and bleeding was reported but this may be explained by the larger number of patients studied (50 patient) compared to (20 patient) in our study and (30 patients) in **Nakamura et al.**, [9].

The 2nd group was complicated with a very high rate of variceal recurrence (84.2%) and this was in agreement with **Reveille et al.**, [15] Perivariceal sclerotherapy has long been the most widely used technique to achieve mucosal fibrosis [16]; **Laine et al.**, [17] and **Saeed et al.**, [8] founded that ligation combined with low-volume sclerotherapy is not better than ligation alone, and is therefore not recommended. These results were not in accordance with **Leonardo et al.**, [14].

The results of this study were not in agreement with **Shigenaga et al.**, [13] they found that 1- and 2-year cumulative recurrence free rates in 1% PD group were (76.9% and 87.9%; $P = 0.62$), not significantly lower than the Argon group (84% and 93.3%). Our high rate of recurrence may be explained by that different sclerosent substance (ethanolamine oleate) used in this study, also In **Shigenaga et al.**, [13] study in the initial sessions, EIS was performed and immediately after the EIS procedure, EVL was also performed for esophageal varices (EIS/EVL therapy).

However (8.8%) in the 1% PD group developed stricture of the esophagus, while no patient developed stricture in our study.

Only one patient in our study (5%) experienced rebleeding compared to 8.3% in the study of **Leonardo et al.**, [14] despite higher rate of recurrence in our patients, this can be explained with that controversy exists as to whether variceal recurrence is associated with an increased risk of recurrent bleeding, In multivariate analysis; the recurrence of varices was an independent predictor of recurrent bleeding [18]. Another explanation that our primary end point of the study was mainly the recurrence of the varices where we didn't complete the follow up duration (12 month) in patients with recurrent varices to detect recurrent bleeding.

Gin et al., [19] reported that the recurrence rate was 14% and recurrent bleeding was 8.4%.

Our different results may be explained by that different sclerosent agent was used and a study found that tetradecyl sulfate obliterated varices in a shorter period than ethanolamine oleate did indicating more powerful effect [20]. Also larger volumes and more settings were performed in their study compared to smaller volume and one setting used in our study.

The mean time for variceal recurrence in **Leonardo et al.**, [14] study was better than our study (9.5 month VS 6.25 month) this can be explained with larger volume of ethanolamine oleate injected and higher number of sessions used in **Leonardo et al.**, [14] study.

In our study we did analysis of the factors that may predispose to variceal recurrence following paravariceal sclerotherapy and we found that: no significant differences between recurrent and non recurrent cases were found, as regards age, sex, grade of O.V, the mean duration of variceal eradication, the number of bands used, Child's class, P.V. diameter or the number of sessions indicating that these factors had no relation to variceal recurrence; and this was in accordance to **Leonardo et al.**, [14] study, however in our study we found significant difference in number and percentage of PHG between recurrent and non recurrent cases and this may be due to larger number of recurrent cases (17) when compared to non recurrent (3).

Despite more good results in **Leonardo et al.**, [14] study however, **Furukawa et al.**, [11] reported that with consolidation therapies in conventional use, primarily those combined with EIS, complications as esophageal stricture and, mediastinitis, have been virtually inevitable and disastrous.

PHG increased during treatment with paravariceal sclerotherapy in about 55% in our study, this can be explained partially by the effect of sclerotherapy but it may be due to the natural course

of portal hypertension in these patients specially that they stopped the use of B.B during the treatment period and this may be the most acceptable explanation as there was improvement in PHG in group III in about 63.1% during B.B therapy despite this didn't reach a significance when compared to group II.

Regarding the use of B.B. therapy in group III; we found that there was a recurrence rate of 63.2% and mean time of recurrence was 6.3 ± 3.57 month with a range of 1-12 month, despite these results were better than group II, no statistical significance was reached and argon plasma group remained to have a more significant effect in reduction of variceal recurrence than B.B therapy (P value < 0.001). Recurrent bleeding occurred in 15% of our patients and death occurs in 10% due to bleeding.

Lo *et al.*, [21] found that recurrent variceal bleeding was encountered in 27% of the B.B. group and 19% of the control group. Their study concluded that the use of B.B. after variceal obliteration by sclerotherapy can neither prevent oesophagogastric variceal recurrence nor prevent further rebleeding.

However the recurrence rate with the use of B.B should be better evaluated by assessment of the response to B.B therapy by measurement of hepatic venous pressure gradient (HVPG) than clinical assessment before final conclusion is given. The respond to B. B. therapy is defined by a reduction in HVPG to 12 mm Hg or lower to at least 20% of the baseline value is more accurate [22]. However, HVPG measurement is not commonly used to determine whether patients are responding to B.B. therapy [23]. Also the compliance of the patients while taking the full dose of B.B. therapy 2ry to complications should be taken in consideration as exertional dyspnea and fatigue occurred in 20% & 10% of our patients respectively. Lastly No significant relation of variceal recurrence to specific etiology also as regards age, sex, grade of O.V, the mean duration of variceal eradication, the number of bands used, Child's class, P.V. diameter or the number of sessions.

Conclusion

We can conclude from this study that argon plasma coagulation is a safe and effective consolidation therapy following EVL (which is safe and had a rapid rate of variceal eradication) in prevention of variceal recurrence, recurrent bleeding and the risk of death in comparison with paravariceal sclerotherapy with ethanolamine oleate and use of B.B therapy, but is expensive technique.

Recommendation

Argon plasma should be used as a consolidation therapy following EVL to prevent variceal recurrence. Increasing the number of sessions of argon plasma may decrease the recurrence rate. Paravariceal sclerotherapy with ethanolamine oleate is not recommended as a consolidation therapy as it carries a high recurrence rate.

Effectiveness of B.B therapy in prevention of variceal recurrence may be better evaluated by measurement of HVPG than clinical assessment before final conclusion is reached.

More studies are needed for evaluation of less expensive methods for prevention of variceal recurrence as sandwich like method or scleroligation. More studies are also needed for evaluation of combined argon plasma coagulation and B.B therapy in prevention of variceal recurrence.

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