PRIMARY PROPHYLAXIS IN PREVENTING 1ST BLEED IN OESOPHAGEAL VARICIES

Muhammad Iqbal*, Khursheed Utra, Adnan Qadir, Farooq Khattak, Javaid Iqbal Khattak

*Military Hospital Rawalpindi, Combined Military Hospital Rawalpindi

ABSTRACT

Objective: To study the efficacy of oesophageal band ligation versus use of β-blockers for primary prophylaxis of 1st variceal bleed in portal hypertension

Study Design: Randomized controlled trial

Place and duration of study: At department of Medicine and Gastroenterology, Combined Military hospital Rawalpindi, during June 2006 to June 2007

Patients and Methods: Sixty eight patients with portal hypertension were included in the study after screening endoscopy. All the patients were divided in two groups, A and B. Group A patients underwent oesophageal band ligation and patients in group B were given β-blockers for primary prophylaxis. Each group contained equal number of 34 patients to start with but in the very first week, 6 patients in group B could not tolerate β blockers. They were switched to group A treatment. These patients were followed up for next one year

Results: Group A patients who underwent band ligation had significantly reduced incidence of 1st variceal bleed(p value=0.020) as compared to group B who received β-blockers. As far as mortality is concerned there was no significant difference (p=0.067) was noted between the two groups.

Conclusion: The oesophageal band ligation is superior to β -blockers in preventing 1st oesophageal variceal bleed but no difference in mortality was noted whichever prophylaxis was used in this study.

Key words: Oesophageal varices, Rubber band ligation, Beta blockers prophylaxis

INTRODUCTION

Oesophageal varicies are the major but unpredictable complication of portal hypertension as a consequence to cirrhosis of liver[1]. Bleed from oesophageal varicies carries substantial mortality of 20% as described by D'Amico et al[2] and this figure goes up from 8 % to as high as 50%[3]. However, now with the advent of development of various modalities to control bleeding, the out-come in the scenario of Oesophageal bleed has certainly improved. Pauwels et al[4], demonstrated 50% decrease in mortality of hospitalized cirrhotic patients over the past 15 years. Similarly in an other study, the same trend about improvement in mortality of patients with oesophageal bleed was noted by Mccormik et al[5]. The mortality rate with oesophageal bleed in our own country tends to be around 8.7% as reported by Ismael et al[6], in their study, carried out at Agha khan university hospital. The concept of secondary prophylaxis for oesophageal bleed is now well established and both modalities of injection sclerotherapy or particularly oesophageal band ligation are a routine practice. However now, the concept of primary prophylaxis is assuming even more importance due to substantial mortality associated with variceal bleed. Thus prevention of 1st bleed in a patient with portal hypertension is of paramount importance. Undoubtedly in primary prophylaxis, non-selective β-blockers are well established modality but role of oesophageal variceal band ligation requires to be ascertained. This quasi experimental study is an attempt to compare the efficacy of band ligation against use of β-blockers for primary prophylaxis of 1st oesophageal bleed.

PATIENTS AND METHODS

Following the available guide lines of ASLD, all patients presenting at Combined Military Hospital Rawalpindi from June 2006 to June 2007 with clinical features of portal hypertension were offered screening

Correspondence: Brig Muhammad Iqbal, Advisor in Gastroenterology, Military Hospital Rawalpindi
Email: miqbalmed10@hotmail.com
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endoscopy for detection of oesophageal varicies. Out of all endoscoped patients, 68 patients were selected for study after strict criteria of inclusion and exclusion .Only patients having varicies of more than 5 mm size or/ and having red wale sign were included in the study . The criteria of exclusion was age more than 70 years, unwilling or unconvinced patients not readily giving consent for endoscopy, history of previous bleed or having co-morbid conditions like unstable ischaemic heart disease or known history of bronchial asthma. Similarly patients with smaller than 5 mm sized varicies were also excluded .Patients with gastric varicies were also not included in the study. The patients finally included in the study were randomly divided into 2 groups and were followed for one year.

In group A, oesophageal band ligation was done till complete obliteration of the varicies was achieved which required 3 to 5 sessions on the average .To reduce the cost of procedure, the barrel of Saeed multi band shooter was re-loaded with haemorroidal bands. EVS 160 EXERA videoscope was used.

Group B comprised patients who were given standard prophylaxis with non-selective β- blockers . In this group, 6 patients were unable to tolerate β-blockers due to bronchospasm, (4 patients) showed development of symptomatic hypotension along with bradycardia, (2 patients). They were switched to group A which ultimately comprised of 40 patients and reducing the number of group B to 28 patients.

Data was analyzed using SPSS version 15. Descriptive statistics had been used to describe the data. T-test was used to compare numeric variables between the two groups and Fisher Exact test was used to compare the categorical variables between the two groups. The P-value < 0.05 was considered as significant.

RESULT

The demographical data and possible aetiology is given in table-1. With respect to underlying aetiology and with reference to clinical condition of the patient as determined by Pugh-Child classification.(Table-1). The p value for each of these categories was not significant.

Out of total number of 40 patients in group A, one patient (2.5 %) died and 3 patients (7.5%) experienced oesophageal bleed whereas in group B out of the total of 28 patients, 4 patients (14.28 %) died and 8 patients (28.57%) experienced variceal bleed at the end of one year follow-up (Table-2).

The Fisher Exact test was applied to determine the p value which was 0.067 for mortality and hence no significant difference in mortality could be found but the p value for oesophageal bleed was 0.020 showing band ligation to be significantly superior to use of β-blockers in preventing 1st variceal bleed.

Table-1: Showing sub-classification according to gender and aetiology

Gender	**Group A**	**Group B**	**p-value**
Male	30	25	0.140
Female	10	3	
Aetiology			
Hepatitis C	38	28	0.229
Hepatitis B	2	NIL	
Pugh-Child classification	0	0	0.474
A	35	26	
B	5	2	
C			

Table-2: Showing results of two groups

Group	**Number of patients died**	**Number of patients who bled**
Group A n=40	1	3
Group B n=28	4	8
p-value	067	020

DISCUSSION

Oesophageal varicies are present in 30-40% of compensated cirrhosis and in up to 60% of de-compensated cirrhosis[7,8]. Annual incidence of variceal bleed is 5% to 20%[9]. The size of the varices does co-relate with the risk of bleed. Varicies having size more than 5 mm have 30% chance of bleeding in subsequent two years[10]. Most commonly, primary prophylaxis of oesophageal variceal bleed is done with β-

blockers[11]. Merkel et al[12], concluded that if the β-blockers, are started earlier when the varicies are even less than 5 mm in size, it proves more beneficial rather than starting the β-blockers late. The chances of 1st bleed were 12% at 5 years in case of earlier start than starting late with bigger sized varicies when the chances of 1st bleed rose to 22% at 5 years. However, the effect of β-blockers is not uniform and in at least 40% of patients the hepatic venous pressure gradient does not decrease even if the heart rate has gone down to required 25% of base line reading[13,14]. It is to be appreciated that decrease in heart rate is due to β- 1 blockade and decreased in portal hypertension which actually brings about the prophylactic effect for bleed of oesophageal varices is due to β- 2 effects. Hence, decrease in heart rate in itself offers no protection on its own.

Although Sclerotherapy as first line treatment had unacceptable mortality of 32.5% in sclerotherapy group than in sham therapy group[15], but band ligation versus β-blockers still requires to be assessed for primary prophylaxis. Band ligation was first reported by Van Stiegmann[16]. Band ligation was considered superior by Lay et al[17], in a prospective study in which they studied 176 patients with cirrhosis where band ligation was found to significantly reduce the cumulative bleeding rate i.e 19% in banding group vs 60 in non-treated group. Shepke et al[18] found no difference between banding and giving β-blocker. Similarly there are other studies which also show no clear difference between the two modalities[19]. Nevertheless, Psilopoulos et al[20], proved band ligation to be superior to β-blockers.

Present study also shows that oesophageal band ligation is superior to β-blockers in preventing the first bleed .The risk factor for the mortality related to first bleed are well known . Patch et al describes six factors to have independent prognostic value for death. They include moderate to severe ascites, need for ventilation, white blood cell count, platelet count, partial thromboplastin time along with creatinin levels[21]. However our study has come up with an additional risk factor for mortality. This factor relates to the distance of patient from the endoscopy centre. In our study, all the patients who died were brought to endoscopy centre from outside of main city and hence valuable time was lost on the way proving that such categories of patients must undergo band ligation at the very first instance rather than waiting for the bleed to occur or relying on β-blockers which are effective but certainly not uniformly reliable. This factor may be unique because it is relevant to our own circumstances due to lack of any developed health system. However, use of a patient tailored approach should be adopted. The β-blockers being cheap and effective, should be the logical first choice but when the side effects of these drugs preclude their use then obviously band ligation should be opted for[22].

CONCLUSION

It can be concluded from this study that oesophageal band ligation is superior to β -blockers in preventing 1st oesophageal variceal bleed but no difference in mortality. Whereas it may still require further studies to make a clear distinction between establishing the preferred method of treatment for primary prophylaxis of oesophageal variceal bleed but this study certainly points to the fact that any body who is away from a centre of endoscopy, β-blocker use cannot be depended upon for him. Such patient would be more safe if one should go for prompt endoscopy and an early band ligation.

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