# Compare Between Endoscopic Variceal Band Ligation and Injection Sclerotherapy Treatment Among Acute Variceal Bleeding Patients MSI Bleeding Center, Khartoum State, Sudan, 2018

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**ABSTRACT:** *This study was carried out in MSI bleeding center, Ibn Sina teaching hospital in Khartoum State, Sudan, with in the period from June to October 2018. The Objectives: Of this study to compare between endoscopic variceal band ligation and injection sclerotherapy treatment among acute variceal bleeding patients. The study also aimed to assess the outcome of the treatment in term of the occurrence of post treatment re-bleeding within the first and sixth weeks after the treatment, and to assess if the type of the treatment used is associated with a difference in the outcome (occurrence of re-bleeding). The study covered all patients diagnosed with acute variceal bleeding attend the study area with in the study time period. 100 cases have been selected. A questionnaire used to collect data, which was computed and statistically analyzed by using SPSS version 25.0. The result of study found that participants were 83% male and 17 females, age of 40 – 60 years old (51%) followed by age group 20 to 40 years (25%) and 24% for the age group of more than 60 years old. 44% of the study group were from Aljazeera state, followed by Khartoum state which was 32% of the study group, and 23% from other states. 32% of participants were diagnosed by liver cirrhosis, while 67% of the study group diagnosed by schistosomiasis. 51% had EVL, and 49% had EIS. 4% of patients who had EVL, experienced rebleeding within six weeks, while 8% of the of patients who had EIS experienced rebleeding (4% within one week and 4% within six weeks). Mortality was not associated with type of treatment of acute variceal bleeding.The study Conclude that the recurrent bleeding was more associated with EIS than EVL, treatment by EVL is more effective than EIS in the matter of timing of rebleeding.*

**KEY WORD:** compare, treatment, EVL, EIS, bleeding center

## INTRODUCTION

Acute variceal bleeding is a fatal complication in patients with liver cirrhosis. In patients with decompensated liver cirrhosis accompanied by ascites or hepatic encephalopathy, acute variceal bleeding is associated with a high mortality rate [1]. Nearly 50% of patients with newly diagnosed liver cirrhosis have accompanying varices; every year, new varices are developing or the preexisting varices worsen in 7% of patients, and first bleeding occurs in 12% of patients each year [2].

The risk factors for variceal bleeding include the size of the varix, a red color sign on the surface of the varix, and the degree of deterioration of liver function. Alcohol consumption is also a risk factor for variceal bleeding. Studies on patients with large varices showing the red color sign and with a grade higher than F2, the accumulated bleeding rate after 2 years was higher at 57% in patients who continued to drink compared with 35% in patients who were abstinent [2]. The 6-week mortality rate due to variceal bleeding is 15% to 20%, and in patients with severe decompensated liver cirrhosis of higher than Child-Turcotte-Pugh grade C, the mortality rate increases up to 30%. Therefore, in patients with acute variceal bleeding, timely endoscopic hemostasis and prevention of rebleeding is most important [3].

Endoscopic Variceal Band Ligation (EVL) is performed by placing the head of the endoscope with a rubber band ligation device over the varix to be ligated, suctioning the varix into the device, and tying the varix by discharging the rubber band. For actively bleeding varices, it is better to perform prophylactic ligation on the varices within 5 to 10 mm to 5 cm from the esophagogastric junction [3]. Previous accessories for endoscopic ligation allowed only one ligation to be performed at a time. Consequently, in case an attempt at ligation failed the first time owing to the lack of a clear visual field because of bleeding, it was difficult to perform successive ligations, and the endoscope had to be removed each time a ligation was attempted; thus, an overtube was used, which increased the risk of esophageal rupture [3].

Endoscopic Injection Sclerotherapy (EIS) is performed by injecting a sclerosant into the varix, and treatment is completed by inducing thrombosis of the varix. With this method, complete obliteration of the varix is most important to prevent recurrence. Various sclerosing agents such as 5% ethanolamine oleate (mainly used, injected in ravenously) or sodium morrhuate are used [4]. As 5% ethanolamine oleate has a strong hemolytic effect and may cause hemoglobinuria or renal failure when systemically injected in large doses, the dose to be used per treatment should be within 0.4 mL/kg [5].

Throughout this context, this study is aim to compare between variceal band ligation and injection sclerotherapy treatment among acute variceal bleeding patients, IbnSina Teaching Hospital, Khartoum State, Sudan, 2018.

## General Objective

1- To compare between endoscopic variceal band ligation and injection sclerotherapy treatment among acute variceal bleeding patients MSI bleeding center, Khartoum State, Sudan, 2018.

## Specific objectives

1.      To describe general characteristic of the patients in term of gender, age, socioeconomic level etc.
2.      To determine the final diagnosis of the patient that presented with variceal bleeding.
3.      To determine the endoscopic treatment given to the patients (either variceal band ligation or sclerotherapy) and the frequency of administration.
4.      To assess the outcome of the treatment in term of the occurrence of post treatment re-bleeding within the first and sixth weeks after the treatment.
5.      To assess if the type of the treatment used is associated with a difference in the outcome (occurrence of re-bleeding).

## Problem Statement

Variceal bleeding is a devastating complication of portal hypertension. The 6-wk mortality in patients with liver cirrhosis is between 17%-28% and the risk of re-bleeding after acute variceal haemorrhage (AVH) is highest within the first 6wk with a peak in the first 5 d. [16]

Gastroesophagealvarices are present in about 50% of all patients with cirrhosis and a predictor of their presence is the severity of liver disease. Cumulative incidence of varices over 10 years is 44.

## Justification and Rational

There is no available of published research work that aim to compare between endoscopic variceal band ligation and injection sclerotherapy treatment among acute variceal bleeding patients, MSI bleeding center, Khartoum State, Sudan, with in the last few years. Also, this study may help to offer valuable rationalized information for variety of beneficiaries such as the patients themselves and their families regarding cost effective and by availing effective evidence-based treatment solutions that needed to be applied.

## MATERIALS AND METHODS

**Study design.** Descriptive hospital based cross-sectional study.
**Study area.**The study will be conducted in MSI bleeding center, Ibn-Sina teaching hospital that located in Khartoum state, Sudan.  It is considered one of main reference Gasto Intestinal teaching hospital in Sudan. This hospital had laboratory, X ray department, blood bank, pharmacy, PICU, Renal unit, surgical operation compound, referred clinic, private rooms, and medical director office. Totally, it has buildings that

contain not less than 10 wards for long admissions. Teaching and training opportunity offered for medical students, house officers and registrars. The hospital provided services basically for Khartoum area residency, and also for the general population from all over the country.

**Study duration.**
The study will be conducted with in the period from June to October 2018. The detailed schedule of different steps of the study shown on the coming parts of this document.

**Study Population.**
This study will cover all patients diagnosed with acute variceal bleeding attend the study area with in the study time period and who fulfill the following criteria:

**Inclusion Criteria**
- Diagnosed with variceal bleeding AND
- Treated with at least one of the following procedures:
o Endoscopic variceal band ligation OR
o Endoscopic Injection sclerotherapy
- Accept to participate in the study - AND
- Recruited from the study area within time period

**Exclusion Criteria**
- Patients not having variceal bleeding.

**Sample size and technique**
**Sample size.** Since this is a cross sectional study with simple random sampling methods, with known estimated number of populations, the size of the study can be determined through the following formula: [18]
**n=N/ (1 + N (e)$^2$)**
- Where n is the sample size and N is the population size.
- Estimated population size = expected number of cases variceal bleeding during the data collection period = 100 cases seen in MSI bleeding center per month $\times$ 2 months = 200 cases per month (duration of data collection)
- So, the calculated sample size can be adjusted through the following:
- n = 200/ (1+ 200 $\times$ 0.05 $\times$ 0.05)) = 130 study participants in the minimum throughout study period.
- The information about estimated number of patients is obtained from the patients' record in MSI bleeding center.

**Sample technique.** Simple random sampling method will be applied to recruit the study participants since the population is homogeneous with available sampling frame.

**Data collection tools and methods**

The data was collected though the comprehensive structural close ended questionnaire. It will cover all personal and medical factors, treatment used, and the overall outcome data for all study participants recruited under the study.

**Statistical analysts:**

- Data will be entered, cleaned, and analyzed using SPSS version 25.0

- Descriptive statistics in term of frequency tables with percentages and graphs. Means and standard deviations will be presented with relevant graphical representation for quantitative data.

- Bi-variable analysis to determine the associations between the main outcome variable (occurrence of re-bleeding) and the other relevant factors (type of treatment) with Chi square test (for categorical variables) and t- test (quantitative variables) statistical tests.

- The relation between quantitative variable will be assessed by Pearson correlation coefficients.

- P value of 0.05 or less is considered statistically significant.

**Ethical considerations**

- Written ethical clearance and approval for conducting this research will be obtained from Sudan Medical Specialization Board Ethical Committee.

- Written permission will be obtained from the Administrative authority of Ibn-Sina teaching hospital.

- Study data/information will be used for the research purposes only. The privacy issues will be intentionally considered.

- The participation Is voluntary. Any participants have his own right to stop at any stage.

**RESULTS AND DISCUSSION**

The current study showed that participants were 83% male and 17 females, most of the study group were in age of 40 – 60 years old (51%) followed by age group 20 to 40 years (25%) and 24% for the age group of more than 60 years old. 44% of the study group were from Aljazeera state, followed by Khartoum state which was 32% of the study group, and 23% from other states. The reason for high segments of the study group from Khartoum and Aljazira state may the large population in these two states, and availability of transport and short distance to MSI Bleeding Center. 54% of the study group had health insurance while 46% of them had no health insurance.
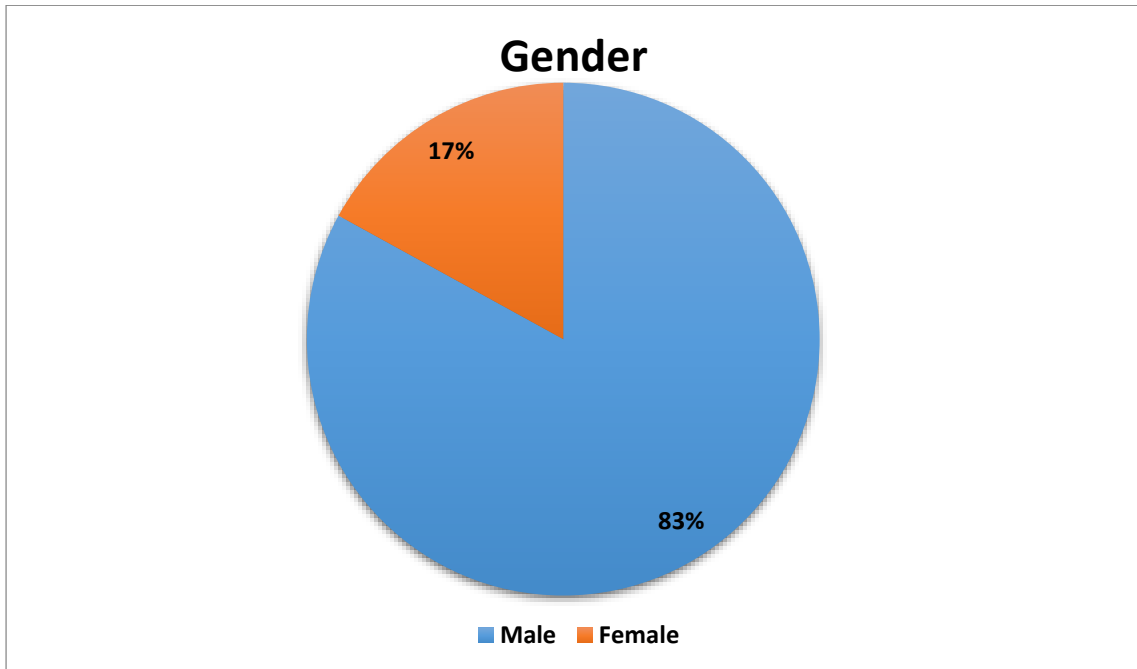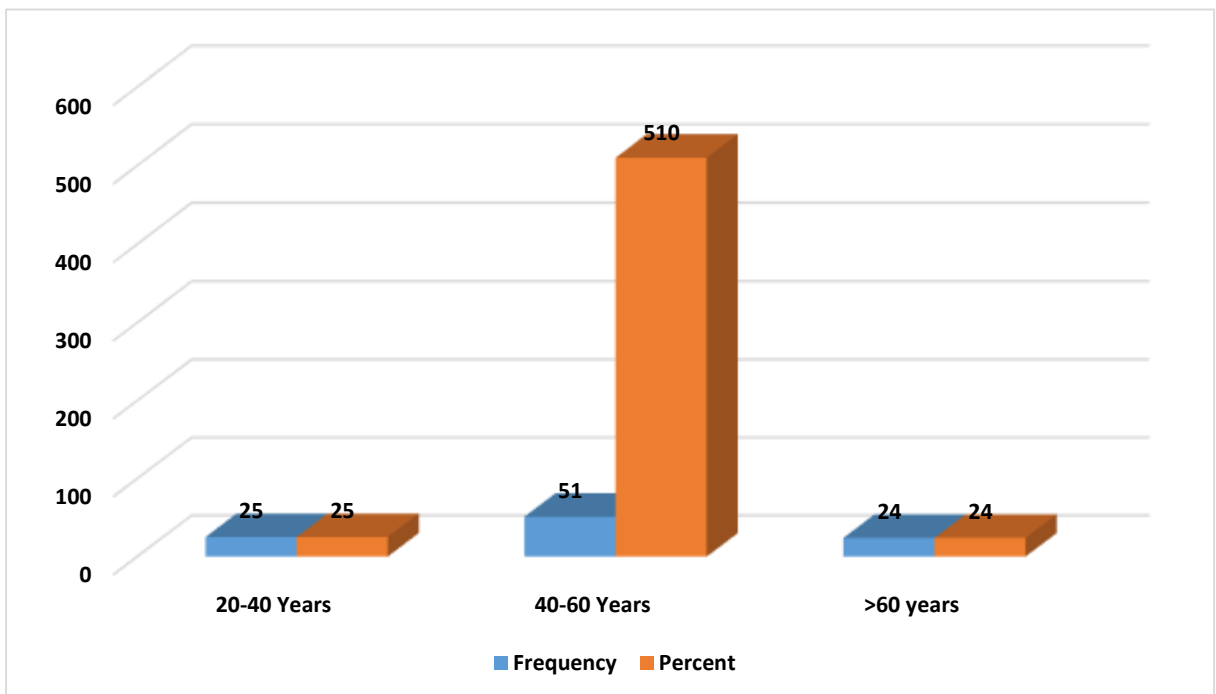
Figure (1) Gender distribution among study group



Figure (2) Ages distribution among study group

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Table (1) Residence of participants in the study group

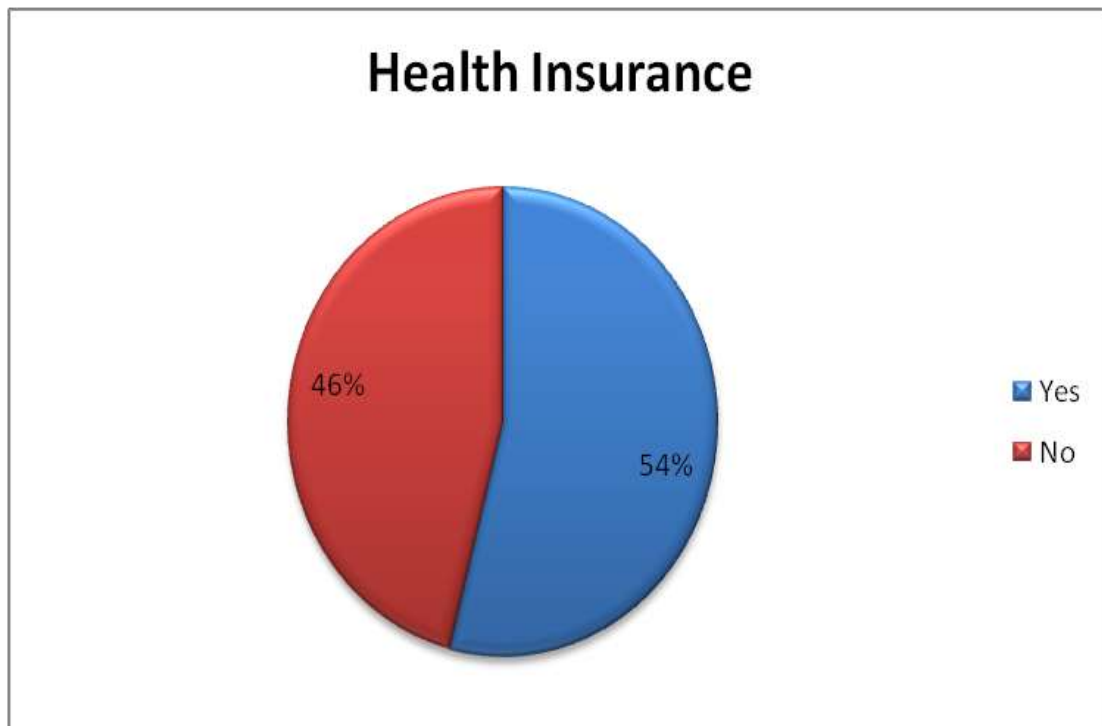| Residence | Frequency | Percent |
|---|---|---|
| Khartoum State | 32 | 32.0 |
| Aljazera State | 44 | 44.0 |
| White Nile State | 11 | 11.0 |
| Red sae State | 2 | 2.0 |
| Sinnar | 2 | 2.0 |
| Blue Nile | 2 | 2.0 |
| South of Darfour | 1 | 1.0 |
| Northan stae | 3 | 3.0 |
| Kassla | 1 | 1.0 |
| North of Krdofan | 1 | 1.0 |
| Nahr Alneel | 1 | 1.0 |
| **Total** | **100** | **100.0** |



Figure (3) Health Insurance of participants in the study group

The current study found that 32% of participants were diagnosed by liver cirrhosis, while 67% of the study group diagnosed by schistosomiasis. This result was in agreement with the findings of (Gasim, et al, 2018) who stated Sudan is a country endemic with schistosomiasis that schistosomiasis, AVH in the majority of cases is

caused by portal hypertension due to schistosomal periportal fibrosis (PPF), while cirrhosis is less common.

The study group in the current study were treated by both endoschopic variceal band ligation (EVL (51%) and endoscopic injection sclera-therapy (EIS) (49%), this results may indicate that half of patients may were not eligible to have EVL treatment, (Kim, et al, 2014) argued that EIS does not show better treatment results than EVL and results in higher fatality and complication rates, it is not recommended as the first-line therapy for the endoscopic treatment of esophageal varices, and may be tried only in case EVL fails or if it is impossible to perform EVL.
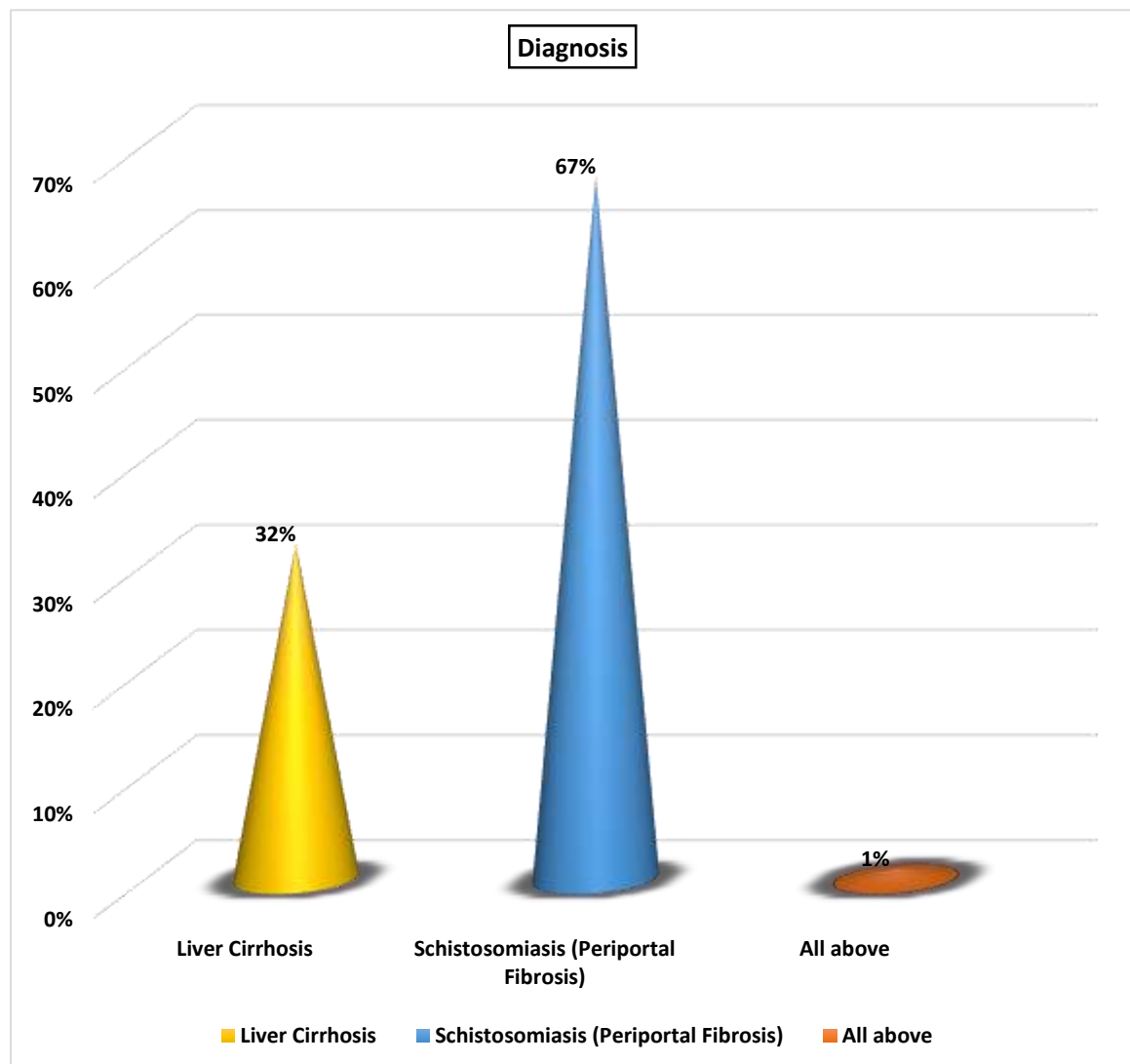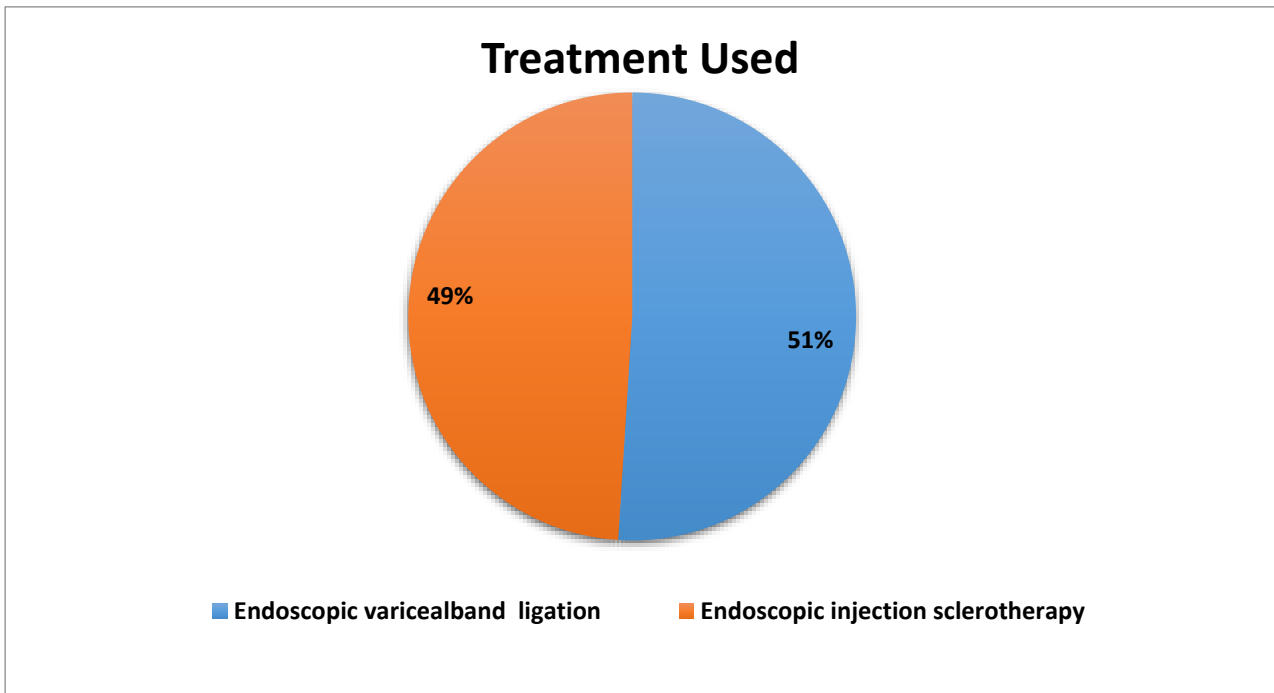
Figure (5) Treatment Used among study group

The current study showed that 4% of patients who had EVL, have exposed to recurrent bleeding, while 4 cases, while 8% of patients who had EIS have exposed to recurrent bleeding. This result indicated that recurrent bleeding is more associated with EIS than EVL treatment. This result was in agreement with the finding of (Slosberg, et al, 2010) who found that EVL is  more effective in the control of acute bleeding but achieves obliteration of varices in fewer treatment sessions with presumably less cost, results in a lower rebleeding rate, has fewer complications, and is associated with reduced mortality.
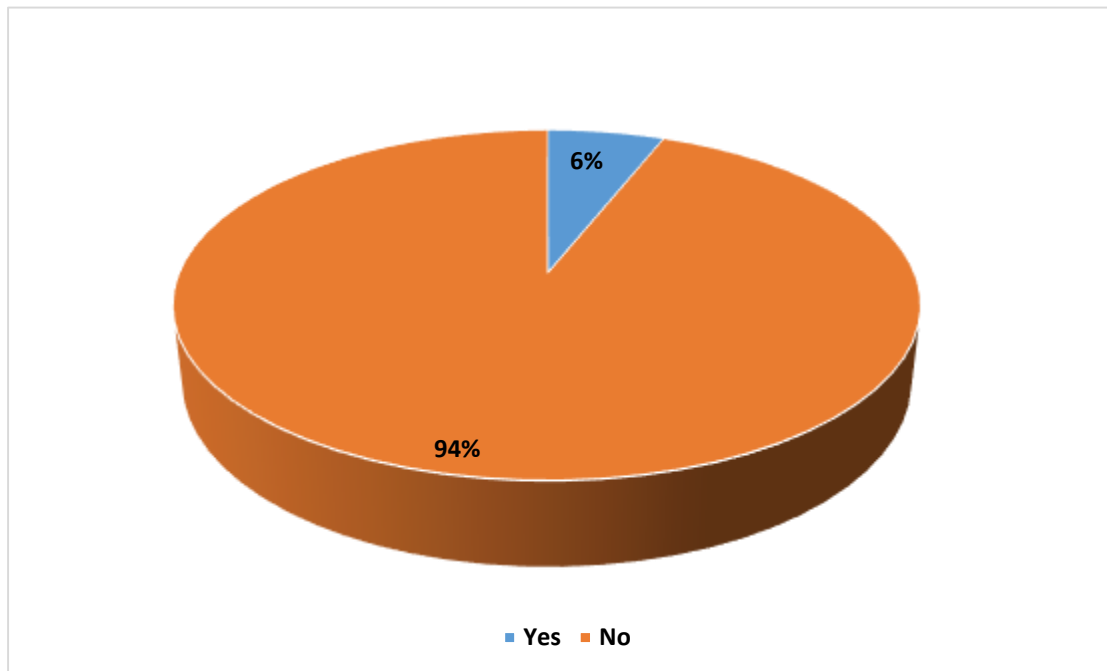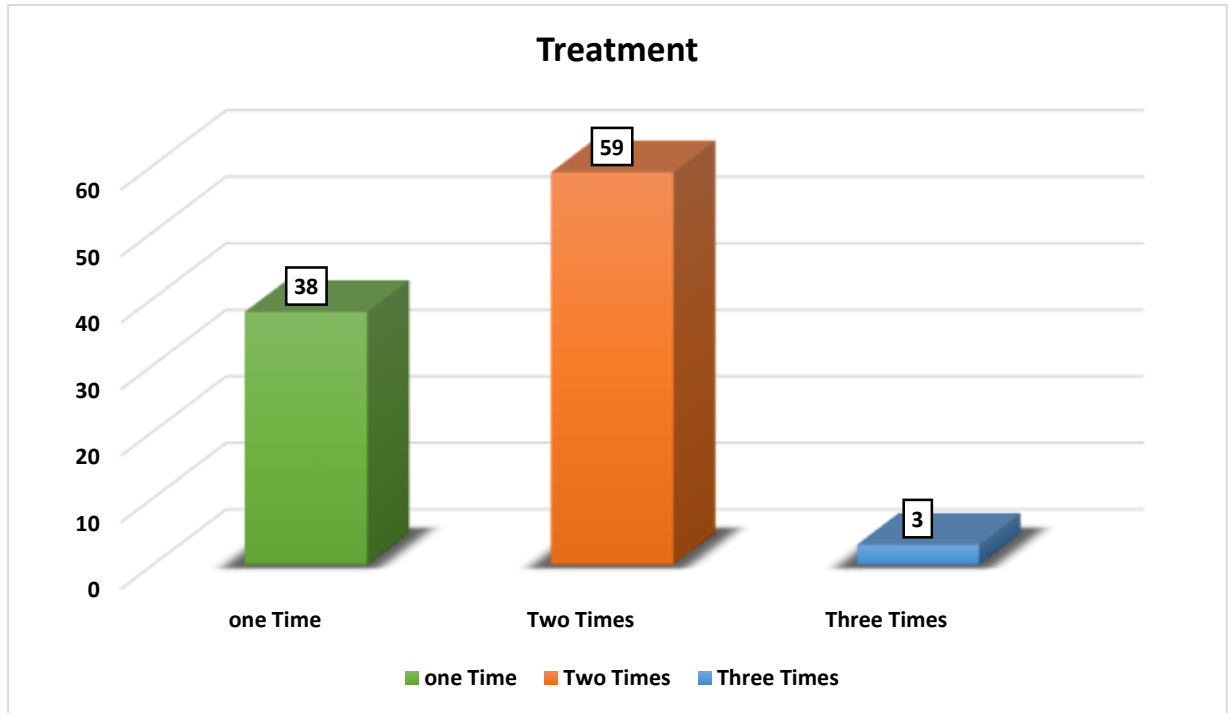
**Figure (7)** Recurrent Bleeding among participants in the study group.

Timing of rebleeding after treatment was different in the current participants, result showed that all cases of rebleeding (4%) among patients who had EVL, happened with in six weeks, while half of cases with rebleeding among patients who had EIS, happened within one week and half of them happened within six weeks. This result indicated that EVL is more effective in the matter of timing of rebleeding. This result is reinforced by the finding of (World J, et al, 2015) who stated that The rebleeding rate in actively bleeding varices patients in the EVL group was significantly lower than that in the EIS group.

Mortality was not associated with type of treatment of acute variceal bleeding in the current study, 8% dead cases was reported for both type of treatment among the study group in the current study, which were less than the rate stated by (Augustin, et al, 2011) who reported that he 6-week mortality rate due to variceal bleeding is 15% to 20%.
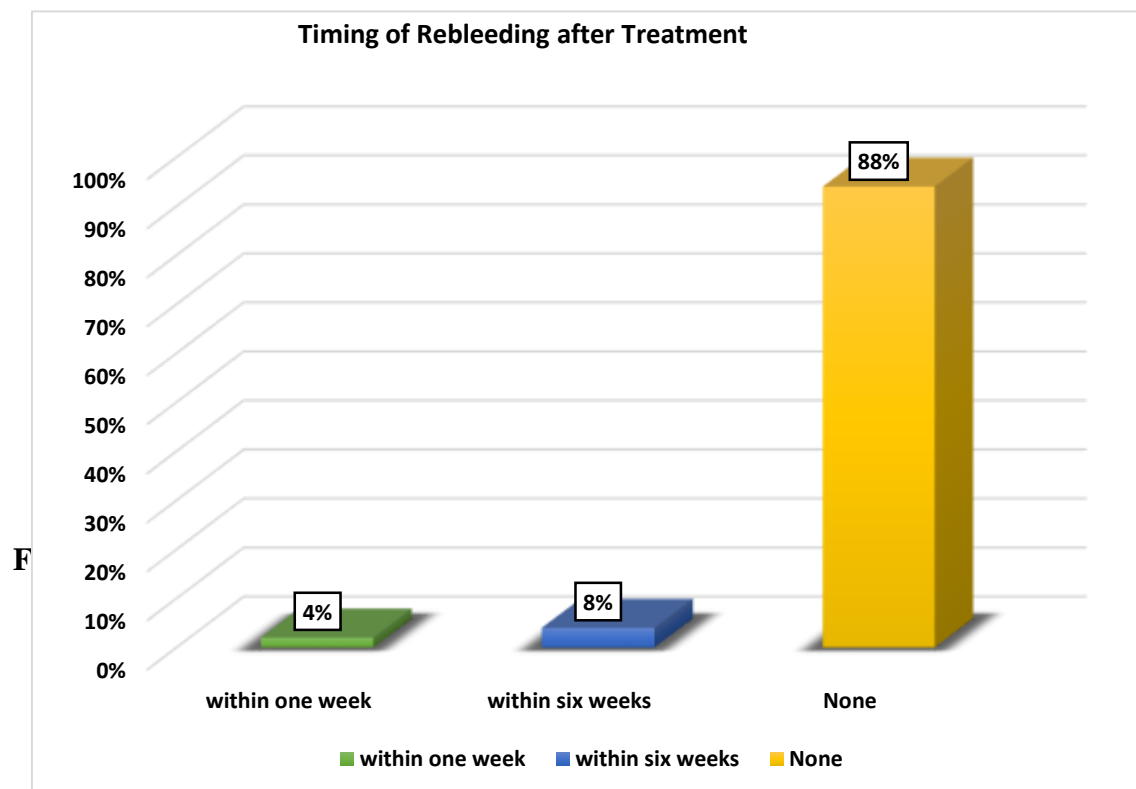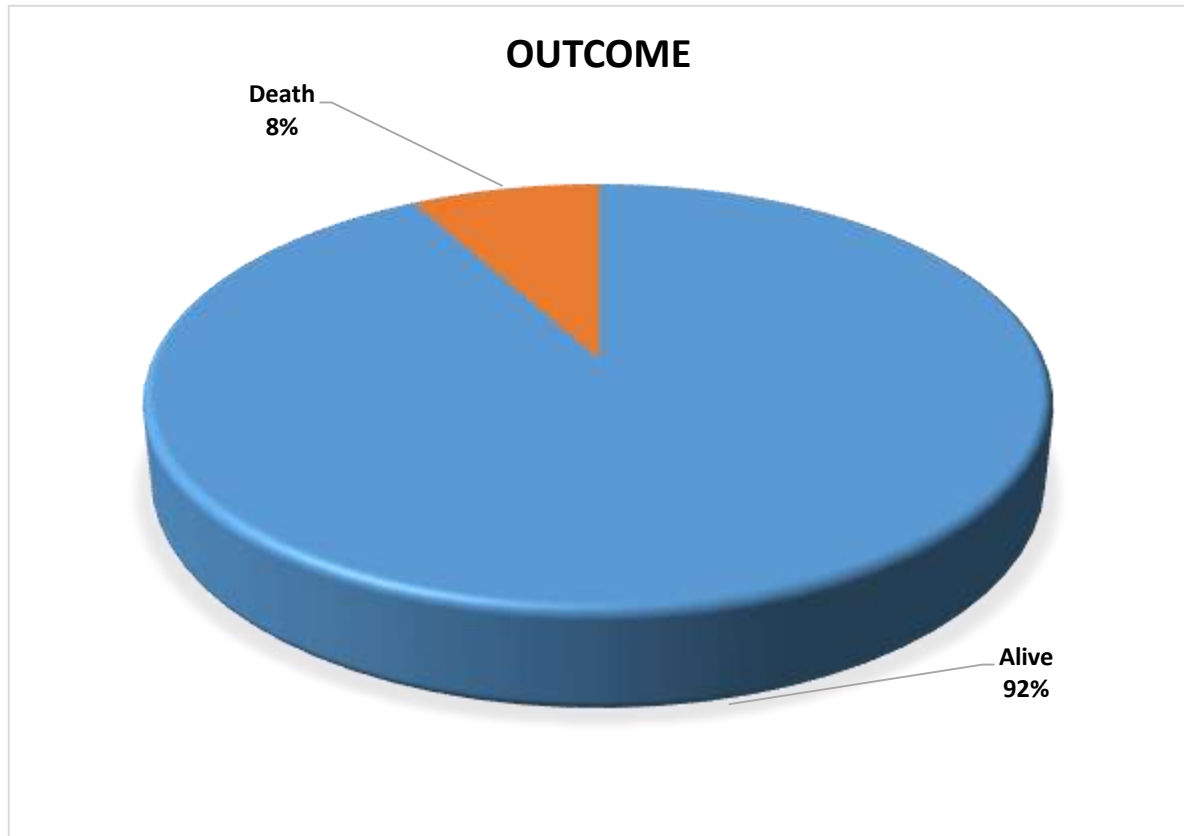
**Figure (9)** Mortality among study group

**Correlation between esophageal varices grades and treatment used:**
The study in dictating the positive and very week correlation between esophageal varices grades and treatment used as shown in table (2).

**Correlation between timing of recurrent bleeding after treatment used and treatment used:**
Also the result found the positive and medium correlation between the timing of recurrent bleeding after treatment used and treatment used as shown in table (3).

**Correlation between mortality and the treatment used**
The result revealed that the positive and strong correlation between mortality and the treatment used as shown in table (4)
Table (2) Correlation between esophageal varices grades and treatment used

| Treatment Used | Esophageal Finding | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| | Esophageal Varices Grade 1 | Esophageal Varices Grade 2 | Esophageal Varices Grade 3 | Esophageal Varices Grade 4 | Esophageal Varices Grade 5 | Total |
| Endoscopic varicealband ligation | 0 | 14 | 21 | 15 | 1 | 51 |
| Endoscopic injection sclerotherapy | 2 | 20 | 10 | 14 | 3 | 49 |
| Total | 2 | 34 | 31 | 29 | 4 | 100 |
| PV=.093 | | | | | | |

Table (3) the timing of recurrent bleeding after treatment used

| Treatment Used | The Timing of Rebleeding after Treatment | | | Total |
| --- | --- | --- | --- | --- |
| | within one week | within six weeks | None | |
| Endoscopic varicealband ligation | 0 | 2 | 49 | 51 |
| Endoscopic injection sclerotherapy | 2 | 2 | 45 | 49 |
| Total | 2 | 4 | 94 | 100 |
| PV=.345 | | | | |

Table (4) Correlation between mortality and the treatment used

| Treatment Used | Outcome | | |
| --- | --- | --- | --- |
| | Alive | Death | Total |
| Endoscopic varicealb and ligation | 47 | 4 | 51 |
| Endoscopic injection sclerotherapy | 45 | 4 | 49 |
| Total | 93 | 8 | 100 |
| PV=.736 | | | |

## CONCLUSION

**The study concluded the following:**
1. 32% of participants were diagnosed by liver cirrhosis, while 67% of the study group diagnosed by schistosomiasis.
2. Type of treatment was equally distributed among the study group, 51% had EVL, and 49% had EIS.
3. 4% of patients who had EVL, experienced rebleeding within six weeks, while 8% of the of patients who had EIS experienced rebleeding (4% within one week and 4% within six weeks).
4. Mortality was not associated with type of treatment of acute variceal bleeding.

## RECOMMENDATIONS

**The study recommended the following:**
1. EVL should be the first-line therapy for the endoscopic treatment of esophageal varices, and EIS may be tried only in case EVL fails or if it is impossible to perform EVL.
2. Perform a study about a combined therapeutic method of EVL and EIS inn comparison with EIS alone.

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