

AIM OF THE WORK

The aim of the study was to compare the role of the ERCP versus percutaneous approach in the management of distal CBD strictures

SUBJECTS

Patients

This study included forty patients with established diagnosis of distal CBD stricture either benign or malignant. They were recruited at Gastroenterology unit, Internal Medicine Department and Interventional Radiology section of radiology department of The Main University Hospital of Alexandria. They were classified randomly into 2 groups:

Group I: 20 patients with distal CBD stricture who will be managed by ERCP.

Group II: 20 patients with distal CBD stricture who will be managed by Trans-hepatic approach.

The two groups were matched according to age, sex and etiology either benign or malignant.

Inclusion criteria

- The target study population consisted of patients with biliary obstruction due to distal CBD stricture either benign or malignant. Who accepted the participation in the study
- Patients should have no role for surgery in their conditions

Exclusion criteria

Patients with the following were excluded from the study:

- Massive tumoral hepatic infiltration (multiple nodules in either lobes or diffuse infiltration).
- Had previous biliary drainage.
- Patients with proximal CBD stricture.
- Had refused study participation

An informed consent was obtained from every patient included in the study.

METHODS

The patients were subjected to the following:

- History taking
- Complete physical examination.
- Laboratory investigations:

Whole blood samples were collected from patients for:

1. Complete blood count (CBC).
2. Renal profile (serum creatinine level, blood urea level).
3. Liver profile (Serum aspartate and alanine aminotransferases (AST and ALT), serum albumin, serum bilirubin (total and direct), serum gamma glutamyl trans-peptidase, alkaline phosphatase and prothrombin time.
4. Radiological investigations: ultrasound abdomen, multiphasic CT abdomen and MRCP

Group I: patients with distal CBD stricture with endoscopic management.

Group II: patients with distal CBD stricture with trans-hepatic management.

Were followed up for 30 days for:

- Technical success rate.
- Therapeutic success rate.
- Major complication rate.
- Type of complications:
 - Bacterial infection.
 - Acute pancreatitis.
 - Bile-leak peritonitis.
 - Hemorrhage.
- 30-day mortality rate.
- Causes of death:
 - Bacterial infection.
 - Multiorganic failure.
 - Hemorrhage.
 - Disease progression .
 - Mean duration of hospital stay after procedure.
- Patients were followed up for 30 days for evaluating the technical success rate, therapeutic success rate, incidence of major complications and 30 day mortality rate and the mean hospital stay post procedure. Data were fed to the computer and analyzed using IBM SPSS software package version 20.0.(216) Qualitative data were described using number and percent. Quantitative data were described using range (minimum and maximum), mean, standard deviation and median.⁽²²⁹⁾

RESULTS

The study was carried out on 40 patients had obstructive jaundice presented to the Gastroenterology outpatient clinic and Department, Alexandria Main University Hospital

The patients were subdivided into two groups as follows:

Group I: 20 patients with obstructive jaundice due to distal CBD strictures who will undergo ERCP

Group II: 20 patients with obstructive jaundice due to distal CBD strictures who will undergo PTD

The different data was collected and tabulated as follows

1. Demographic and clinical characteristics of the patients included in the study

1. Gender

It was found that the majority of the patients were males ,but the differences between the two groups were insignificant ($p=0.749$), in group I, there were 55.0% males and 45.0% females, in group II the males represent 60.0% and females 40.0%.

Tables VII: Comparison between the two studied groups according to gender.

	Group I (ERCP) (n = 20)		Group II (PTD) (n = 20)		Test of sig.	p
	No.	%	No.	%		
Gender						
Male	11	55.0	12	60.0	$\chi^2=0.102$	0.749
Female	9	45.0	8	40.0		

t: Student t-test

*: Statistically significant at $p \leq 0.05$

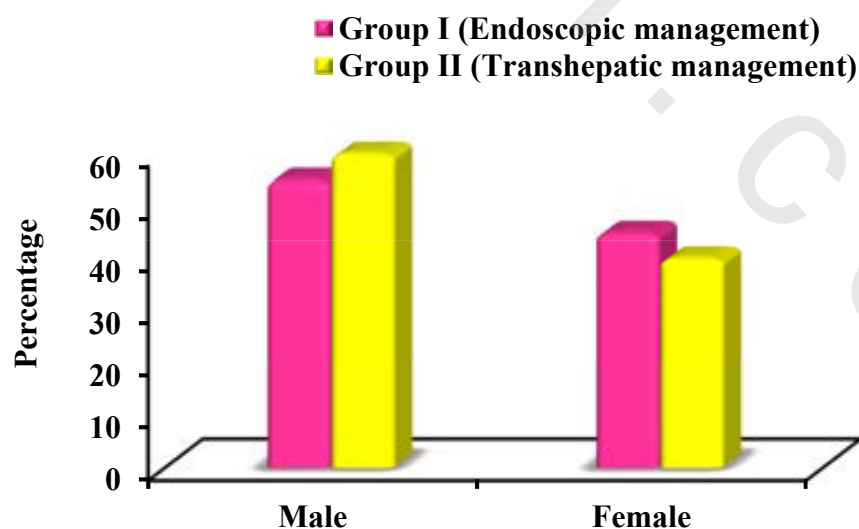


Figure (28): Percentage of male to female ratios between the two groups.

2. Age

The mean age in group I was 66.00 ± 9.5 years old, the mean in group II was 68.0 ± 9.2 years old. There was no significant relation ($p=0.081$) between the two groups regarding the age.

Tables VIII: Comparison between the two studied groups according to age.

	Group I (ERCP) (n = 20)		Group II (PTD) (n = 20)		Test of sig.	p
	No.	%	No.	%		
Age						
Mean $\pm$ SD.	66.0 ± 9.58		68.0 ± 9.2		$t= 1.967$	0.081

t: Student t-test

Z: Z for Mann Whitney test

*: Statistically significant at $p \leq 0.05$

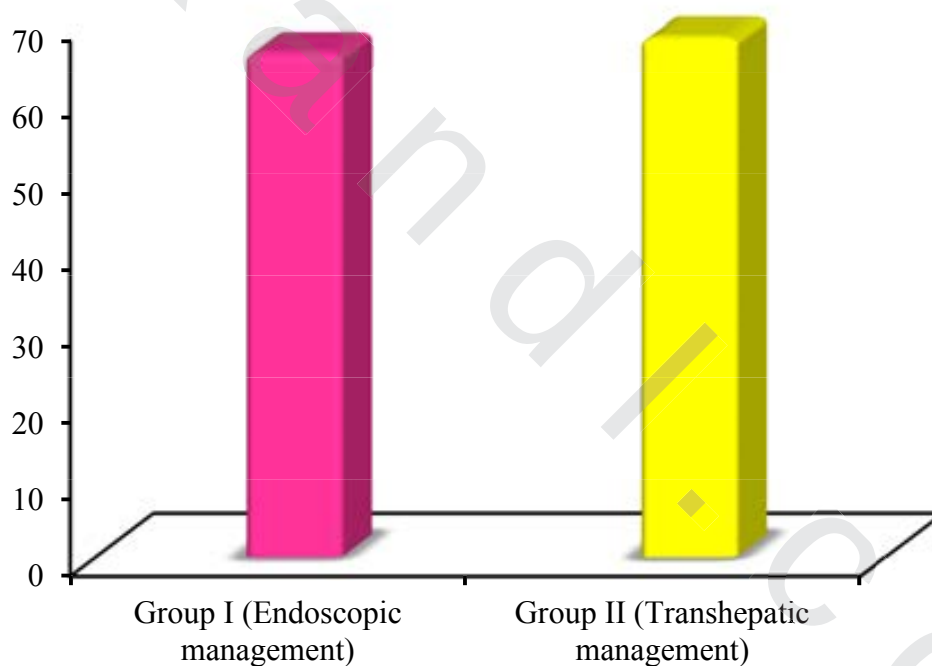


Figure (29): Mean age between the two groups.

3. Diagnosis

The patients were classified into benign and malignant according to clinical condition, laboratory investigation and radiological investigations, histological diagnosis whenever possible. in group I, there were 25% benign and 75% malignant, in group II, there were 25% benign and 75% malignant ,the relation between the two groups were insignificant "p= 0.519".

Tables IX: Comparison between the two studied groups according to diagnosis.

	Group I (ERCP) (n = 20)		Group II (PTD) (n = 20)		Test of sig.	p
	No.	%	No.	%		
Diagnosis						
Benign	5	25.0	5	25.0	$\chi^2 = 0.417$	0.519
Malignant	15	75.0	15	75.0		

t: Student t-test

Z: Z for Mann Whitney test

*: Statistically significant at $p \leq 0.05$

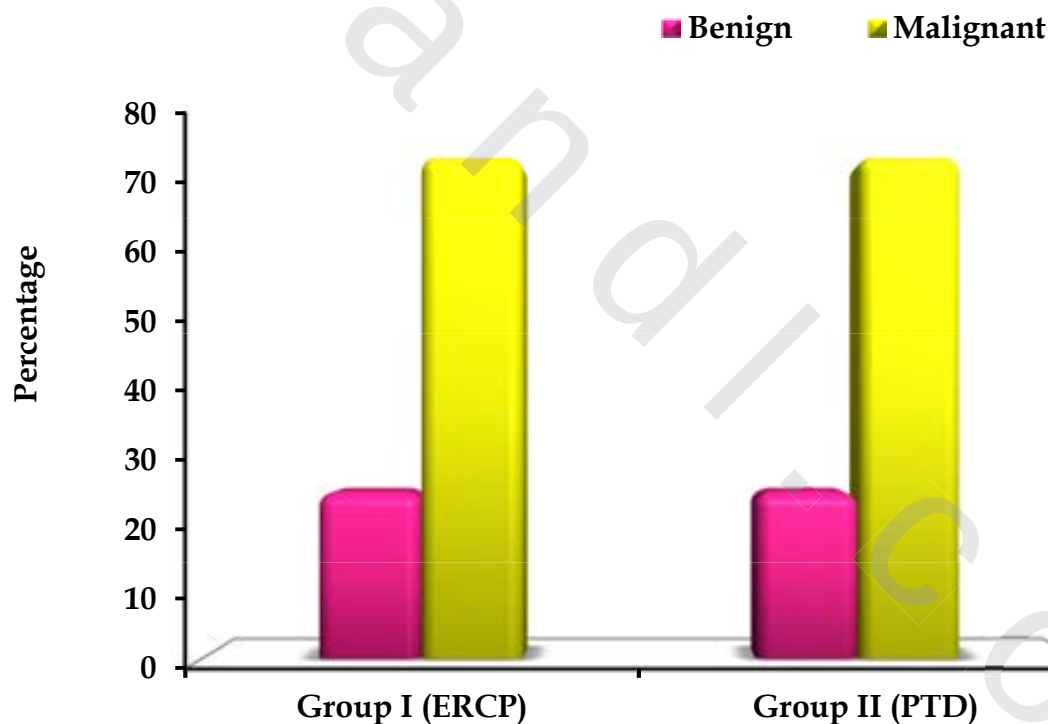


Figure (30): Comparison between two groups according to diagnosis.

2. Laboratory data of patients included in the study

1. Complete blood picture

The comparison between group I and group II was insignificant as regard hemoglobin ($p=0.065$), WBCs ($p=0.063$) and platelets ($p=0.504$).

It was found that mean hemoglobin concentration was 11.59 ± 1.34 in group I and was 9.97 ± 1.89 in group II while mean WBC count was 9.91 ± 3.74 in group I and was 8.37 ± 2.23 in group II while mean platelet count was 257.90 ± 101.49 in group I and was 276.85 ± 73.84 in group II

Tables X: Comparison between the two studied groups according to mean hemoglobin level.

	Group I (ERCP) (n = 20)	Group II (PTD) (n = 20)	Test of sig.	p
Hemoglobin				
Mean $\pm$ SD.	11.59 ± 1.34	9.97 ± 1.89	$t= 3.125$	0.065

t: Student t-test

Z: Z for Mann Whitney test

*: Statistically significant at $p \leq 0.05$

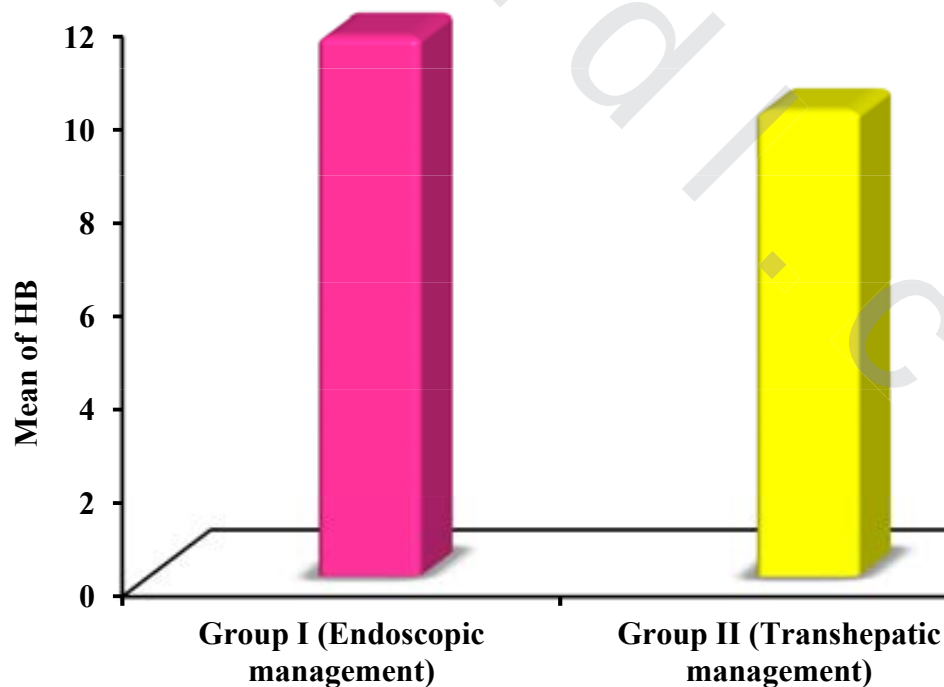


Figure (31): Mean of hemoglobin.

Tables XI: Comparison between the two studied groups according to mean platelets count.

	Group I (ERCP) (n = 20)	Group II (PTD) (n = 20)	Test of sig.	p
Platelets count				
Mean $\pm$ SD.	257.90 $\pm$ 101.49	276.85 $\pm$ 73.84	t= 0.675	0.504

t: Student t-test

Z: Z for Mann Whitney test

*: Statistically significant at $p \leq 0.05$

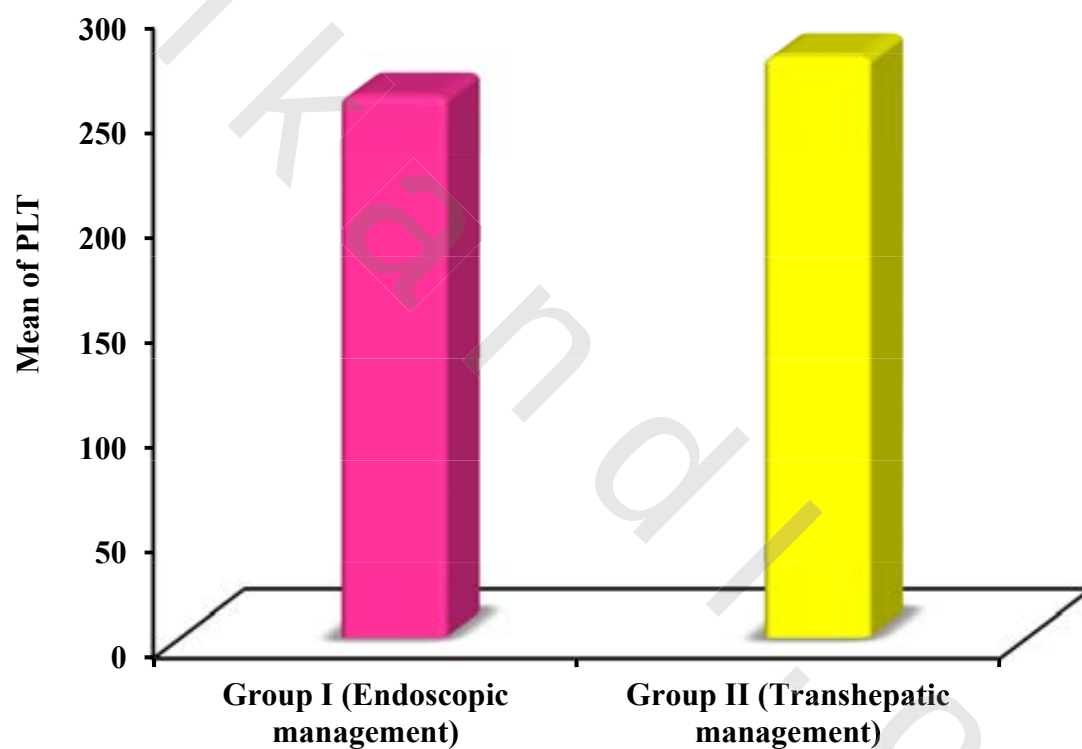


Figure (32): Mean of platelets count.

Tables XII: Comparison between the two studied groups according to white blood cell count.

	Group I (ERCP) (n = 20)	Group II (PTD) (n = 20)	Test of sig.	p
WBCs				
Mean $\pm$ SD.	9.91 $\pm$ 3.74	8.37 $\pm$ 2.23	Z= 1.858	0.063

t: Student t-test

Z: Z for Mann Whitney test

*: Statistically significant at $p \leq 0.05$

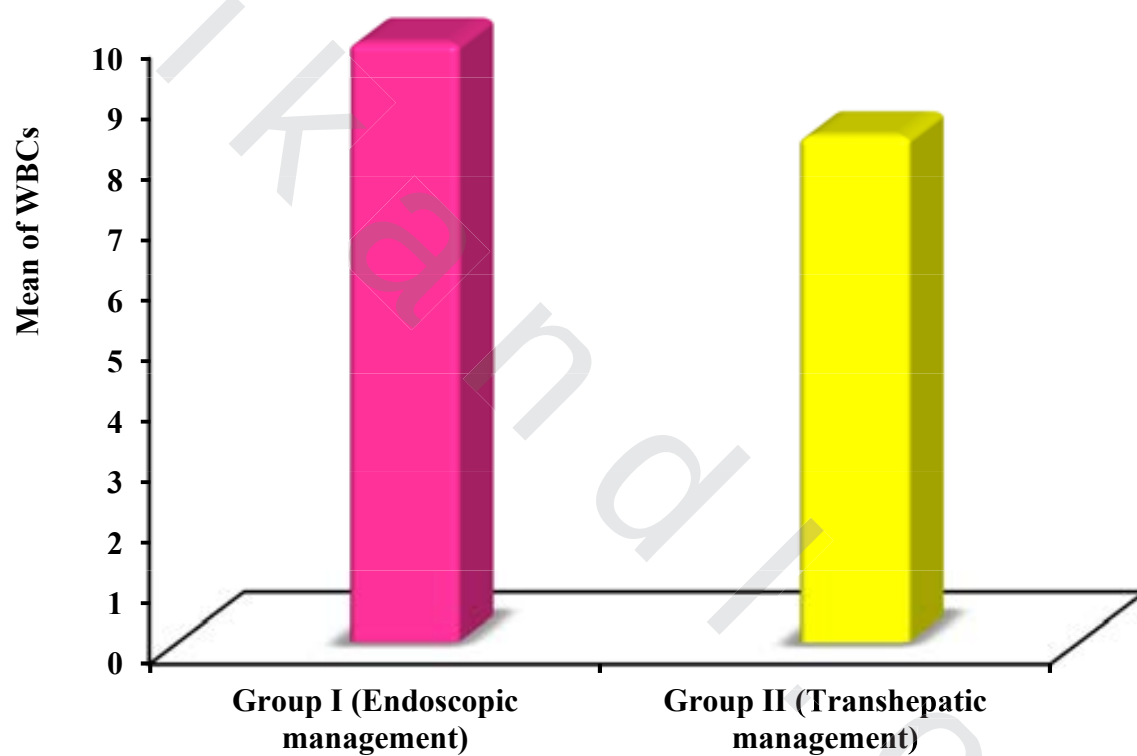


Figure (33): Mean of White blood cell count.

3. Liver functions test

The relation between group I and group II was statically insignificant as regard. AST (P=0.626), ALT (P=0.892), Albumin (P=0.711). Total bilirubin (P=0.559), direct bilirubin (p=0.644), GGT (p=0.903), ALP (P=0.163), Prothrombin time (p=0.939). It was found that mean serum AST was 83.40 ± 47.02 in group I while it was (83.10 ± 59.63) in group II. While mean serum ALT was (78.05 ± 36.71) in group I and it was (75.50 ± 66.43) in group II. Mean serum albumin was (2.87 ± 0.40) in group I while it was (2.88 ± 0.47) in group II. Mean total bilirubin level was (14.25 ± 5.70) in group I while it was (13.35 ± 5.26) in group II. Mean direct bilirubin level was (12.10 ± 5.99) in group I while it was (11.35 ± 5.264) in group II. Mean GGT level was (269.70 ± 145.14) in group I while it was (242.50 ± 69.27) in group II. Mean ALP level was (535.95 ± 109.16) in group I while it was (553.60 ± 152.59) in group II. Mean prothrombin activity in group I was (85.07 ± 13.63) while it was (85.35 ± 15.0) in group II.

Tables XIII: Comparison between the two studied groups according to mean serum AST.

	Group I (ERCP) (n = 20)	Group II (PTD) (n = 20)	Z	p
AST Mean $\pm$ SD.	83.40 ± 47.02	83.10 ± 59.63	0.487	0.626

t: Student t-test

Z: Z for Mann Whitney test

*: Statistically significant at $p \leq 0.05$

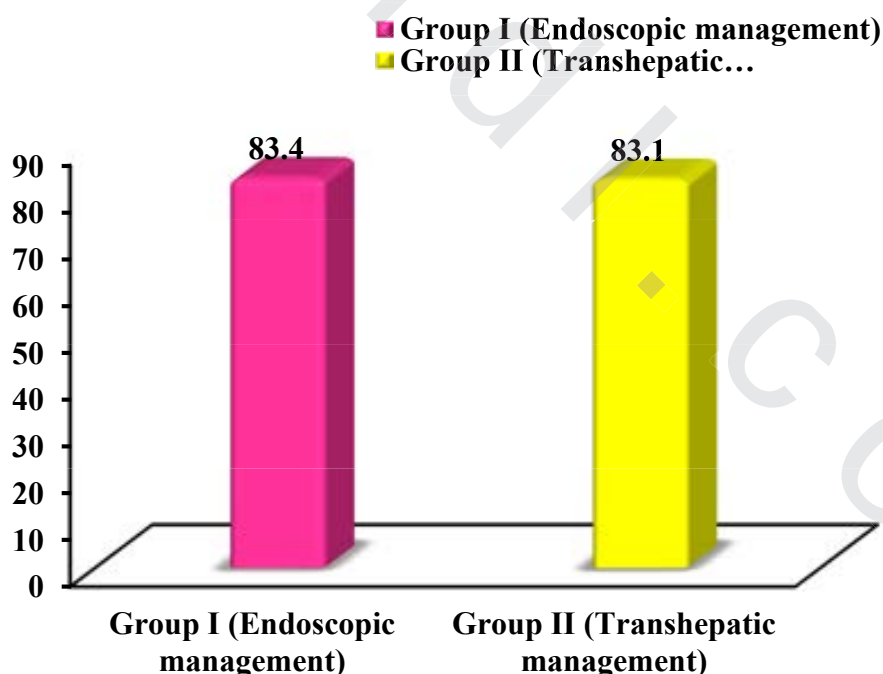


Figure (34): Mean of serum AST between the two groups.

Tables XIV: Comparison between the two studied groups according to mean serum ALT.

	Group I (ERCP) (n = 20)	Group II (PTD) (n = 20)	Z	p
ALT				
Mean $\pm$ SD.	78.05 $\pm$ 36.71	87.55 $\pm$ 66.43	0.135	0.892

t: Student t-test

Z: Z for Mann Whitney test

*: Statistically significant at $p \leq 0.05$

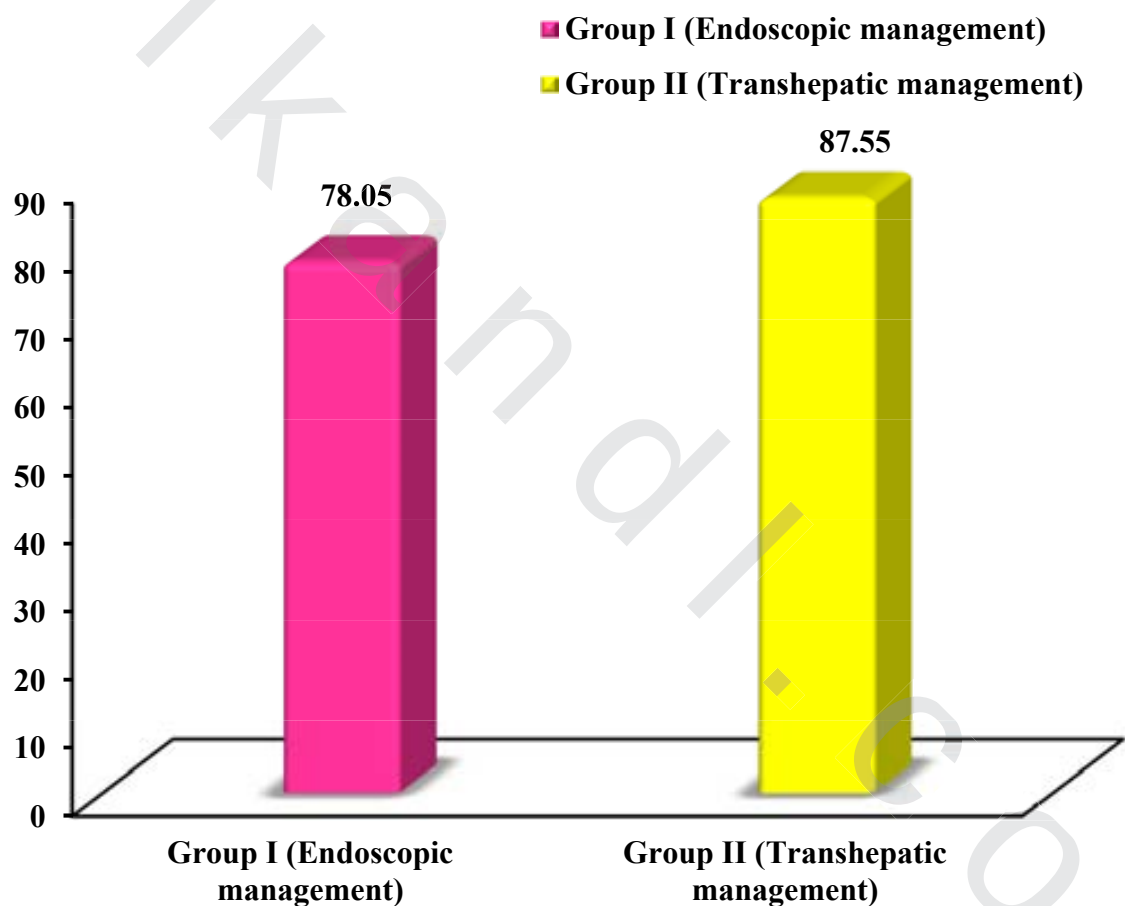


Figure (35): Mean of serum ALT between the two groups.

Tables XV: Comparison between the two studied groups according to mean serum albumin.

	Group I (ERCP) (n = 20)	Group II (PTD) (n = 20)	Z	p
Albumin				
Mean $\pm$ SD.	2.87 $\pm$ 0.40	2.88 $\pm$ 0.47	0.371	0.711

t: Student t-test

Z: Z for Mann Whitney test

*: Statistically significant at $p \leq 0.05$

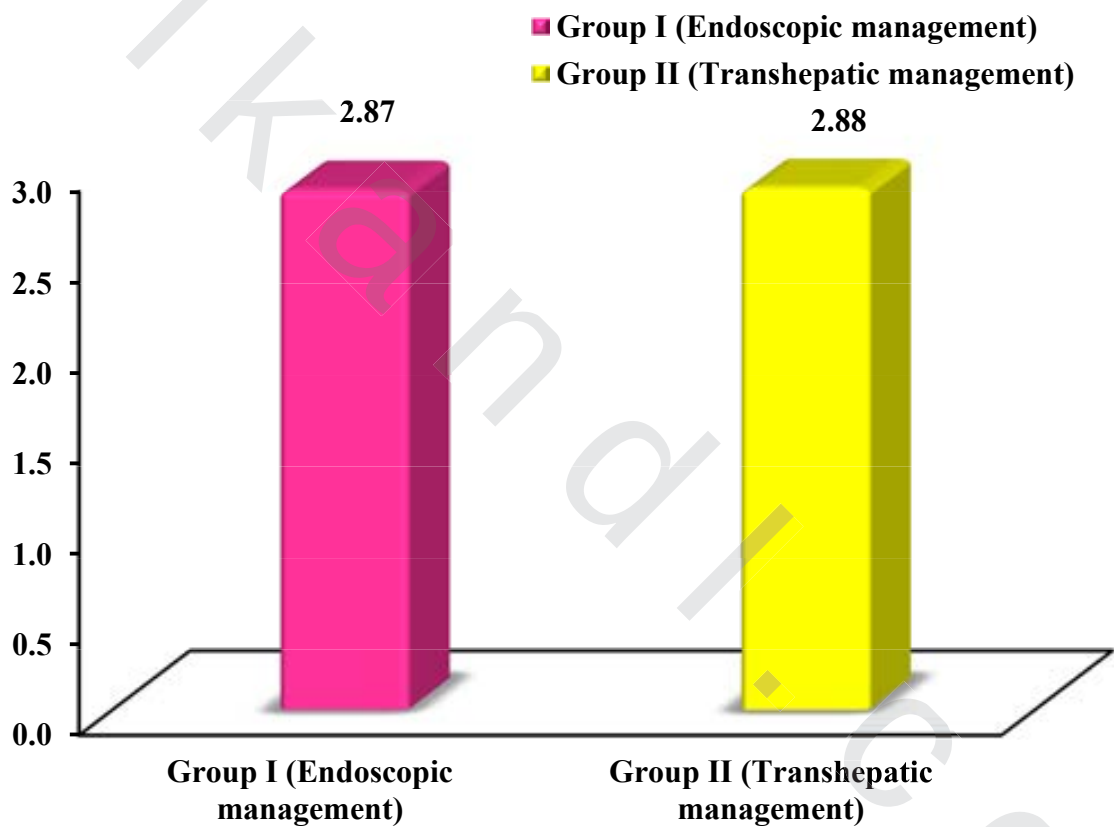


Figure (36): Mean of serum albumin between the two groups.

Tables XVI: Comparison between the two studied groups according to mean total serum bilirubin.

	Group I (ERCP) (n = 20)	Group II (PTD) (n = 20)	Z	p
Total Bilirubin				
Mean $\pm$ SD.	14.25 $\pm$ 5.98	13.35 $\pm$ 5.26	Z= 0.584	0.559

t: Student t-test

Z: Z for Mann Whitney test

*: Statistically significant at $p \leq 0.05$

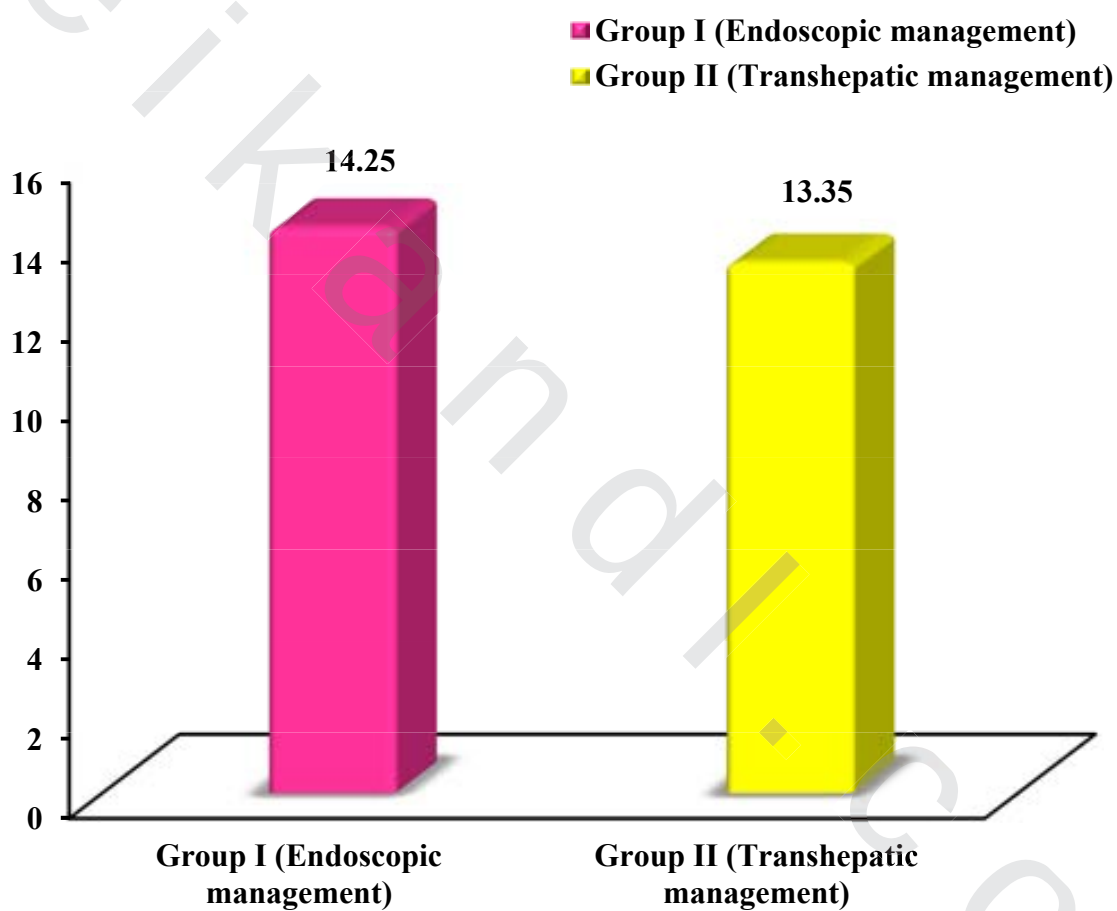


Figure (37): Mean total serum bilirubin of both groups.

Tables XVII: Comparison between the two studied groups according to mean direct serum bilirubin.

	Group I (ERCP) (n = 20)	Group II (PTD) (n = 20)	Z	p
Direct bilirubin				
Mean $\pm$ SD.	12.10 $\pm$ 5.99	11.35 $\pm$ 5.264	Z= 0.462	0.644

(t: Student t-test , Z: Z for Mann Whitney test ,statistically significant at $p < 0.05$)

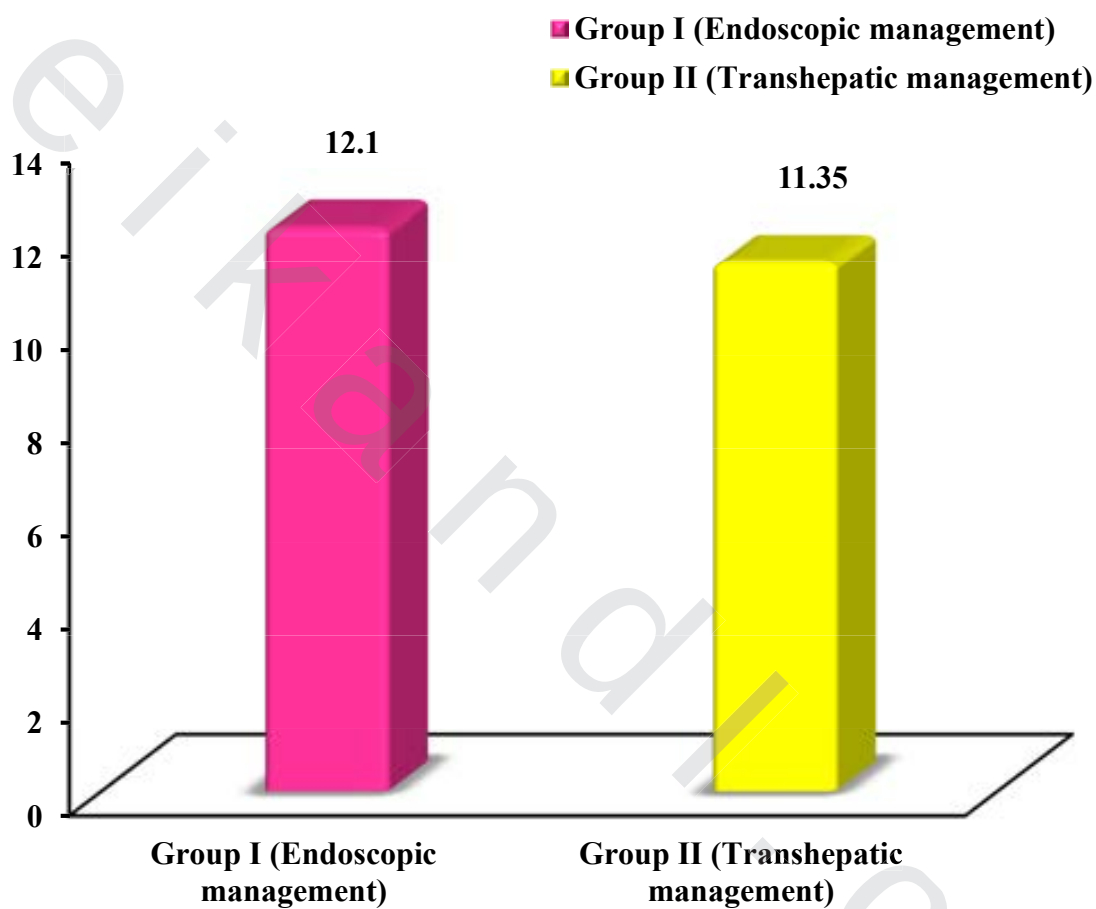


Figure (38): Mean total serum bilirubin of both groups.

Tables XVIII: Comparison between the two studied groups according to mean serum GGT.

	Group I (ERCP) (n = 20)	Group II (PTD) (n = 20)	Z	p
GGT				
Mean $\pm$ SD.	269.70 $\pm$ 145.14	242.50 $\pm$ 69.27	Z= 0.122	0.903

(t: Student t-test , Z: Z for Mann Whitney test ,statistically significant at $p < 0.05$)

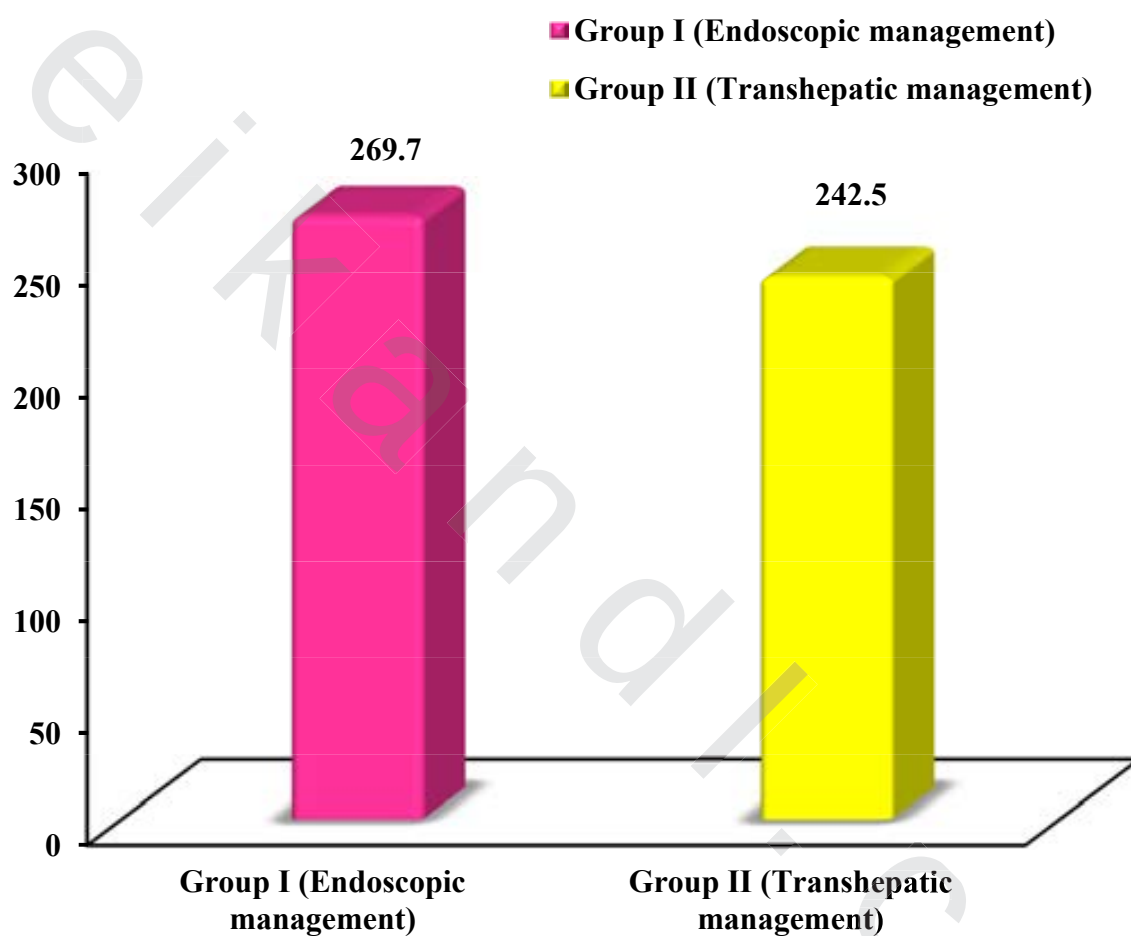


Figure (39): Mean serum GGT of the two groups.

Tables XIX: Comparison between the two studied groups according to mean serum ALP.

	Group I (ERCP) (n = 20)	Group II (PTD) (n = 20)	Z	p
ALP				
Mean $\pm$ SD.	535.95 $\pm$ 109.16	553.60 $\pm$ 152.59	Z= 1.393	0.163

(t: Student t-test , Z: Z for Mann Whitney test ,statistically significant at $p < 0.05$)

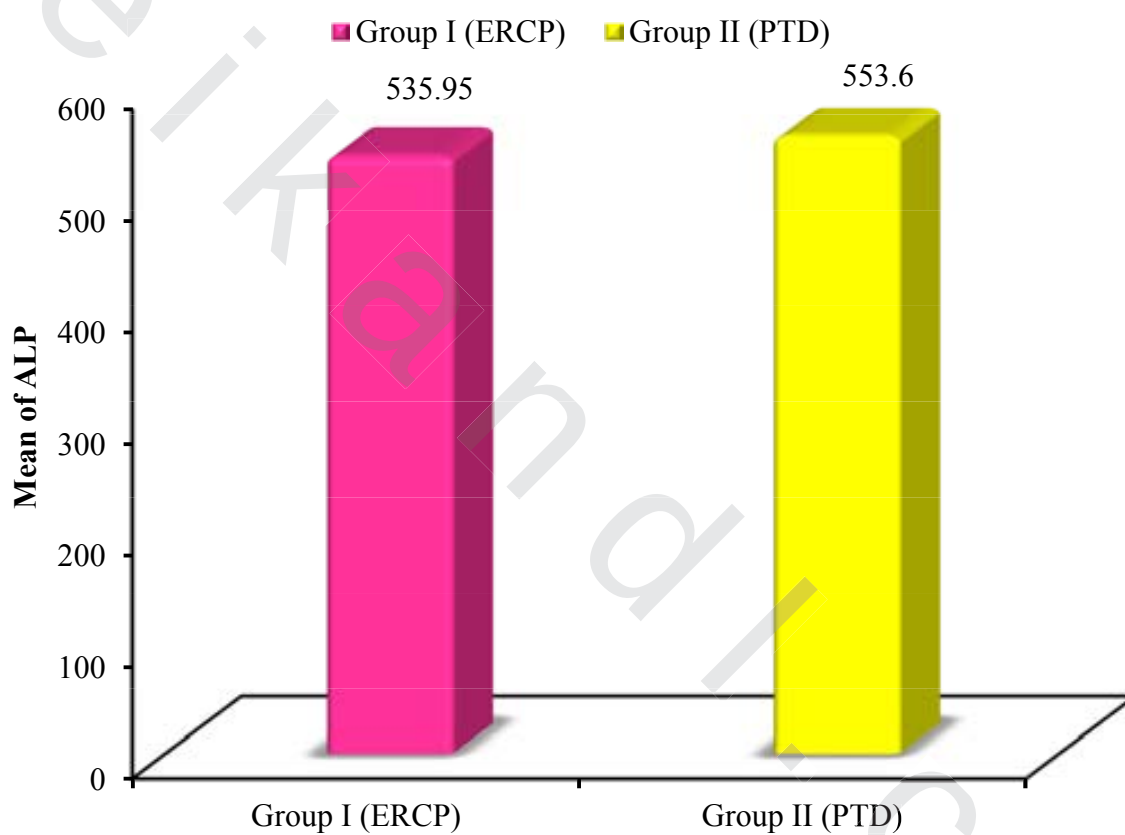


Figure (40): Mean serum ALP of the two groups.

Tables XX: Comparison between the two studied groups according to mean prothrombin activity.

	Group I (ERCP) (n = 20)	Group II (PTD) (n = 20)	Z	p
Prothrombin activity			t= 0.077	0.939
Mean $\pm$ SD.	85.70 $\pm$ 13.63	85.35 $\pm$ 15.0		

(t: Student t-test , Z: Z for Mann Whitney test ,statistically significant at $p < 0.05$)

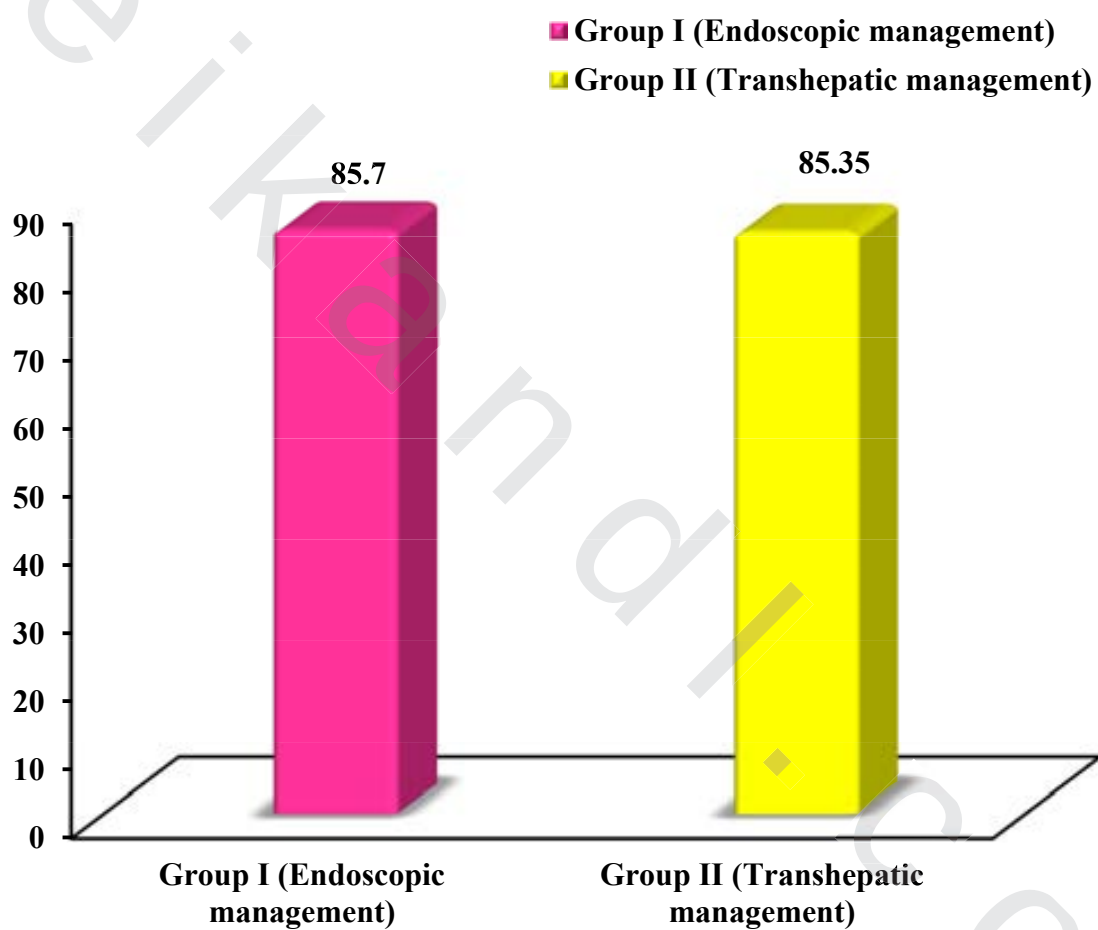


Figure (41): Mean prothrombin activity of the two groups.

4. Renal function tests

The relation between group I and group II was insignificant as regard blood urea ($p=0.011$) and serum creatinine ($p=0.107$)

It was found that mean blood urea in group I was (24.04 ± 14.99) and in group II was (38.07 ± 15.79), while mean serum creatinine in group I was (0.68 ± 0.48) and in group II was (0.80 ± 0.37)

Tables XXI: Comparison between the two studied groups according to mean serum creatinine.

	Group I (ERCP) (n = 20)	Group II (PTD) (n = 20)	Z	p
Creatinine				
Mean $\pm$ SD.	0.68 ± 0.48	0.80 ± 0.37	3.264	0.107

t: Student t-test

Z: Z for Mann Whitney test

*: Statistically significant at $p \leq 0.05$

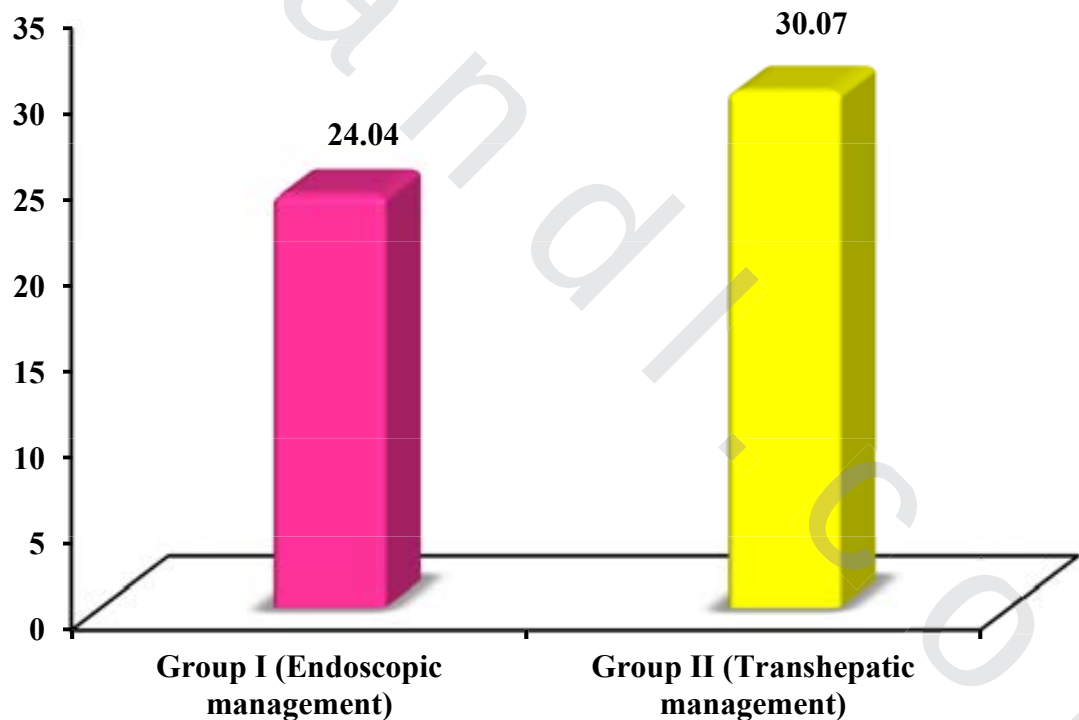


Figure (42): Mean serum creatinine in both groups.

Tables XXII: Comparison between the two studied groups according to mean blood Urea.

	Group I (ERCP) (n = 20)	Group II (PTD) (n = 20)	Z	p
Urea				
Mean $\pm$ SD.	24.04 $\pm$ 14.99	30.07 $\pm$ 15.79	3.264	0.011

t: Student t-test

Z: Z for Mann Whitney test

*: Statistically significant at $p \leq 0.05$

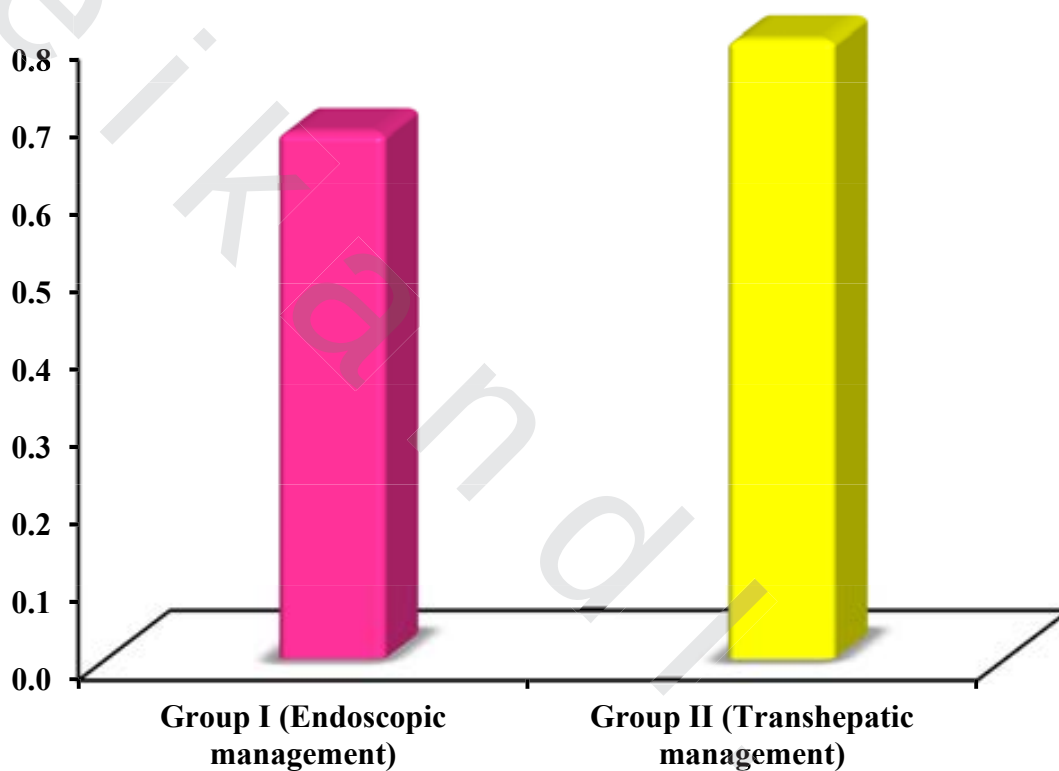


Figure (43): Mean blood urea in both groups.

5. Technical success rate and Therapeutic success rate

Technical success rate: Which was defined as successful cannulation of CBD and ensuring free drainage of bile either by stricture dilation or stent insertion by using ERCP or successful cannulation of CBD by trans-hepatic approach and successful insertion of stents.

Therapeutic success rate: Defined as if stricture dilatation and stent insertion resulted in fall of serum bilirubin greater than 20% of preprocedure value 15 days post procedure.

The relation between group I and group II was statistically insignificant as regard technical success rate ($p=0.723$), therapeutic success rate ($p=0.723$) however, it was found that 25% of group I was unsuccessful while 75% was successful. On the other hand 30% of group II was unsuccessful while 70% was successful.

In our study it was found that 75 % of group I was therapeutically successful while 25% of group I was therapeutically unsuccessful, on the other hand it was found that 70% of group II was therapeutically successful while 30 % of group II was therapeutically unsuccessful

With regard to the five patients in the endoscopic group in whom procedures failed, treatment was not attempted in two patients because of patient's refusal. In three other patients, there was successful cannulation but there were difficulties in stent insertion through the stricture even after dilation, those three patients were subsequently treated by percutaneous stent placement. In the 6 patients in the percutaneous who had failed procedures due to difficulties in stent insertion through the stricture even after dilation, four of the 6 patients were subsequently treated by means of endoscopic stent placement, and two received no further treatment.

Tables XXIII: Comparison between the two studied groups according to TSR and THSR and serum bilirubin (15 days post procedure).

	Group I (Endoscopic management) (n = 20)		Group II (Trans-hepatic management) (n = 20)		χ^2	p
	No.	%	No.	%		
Technical success rate						
Unsuccessful	5	25.0	6	30.0	0.125	0.723
Success	15	75.0	14	70.0		
Therapeutic success rate						
Unsuccessful	5	25.0	6	30.0	0.125	0.723
Success	15	75.0	14	70.0		
Total Bilirubin(15 days post procedure)						
Mean $\pm$ SD.	7.055 $\pm$ 5.98		10.425 $\pm$ 5.26		Z= 0.299	0.765

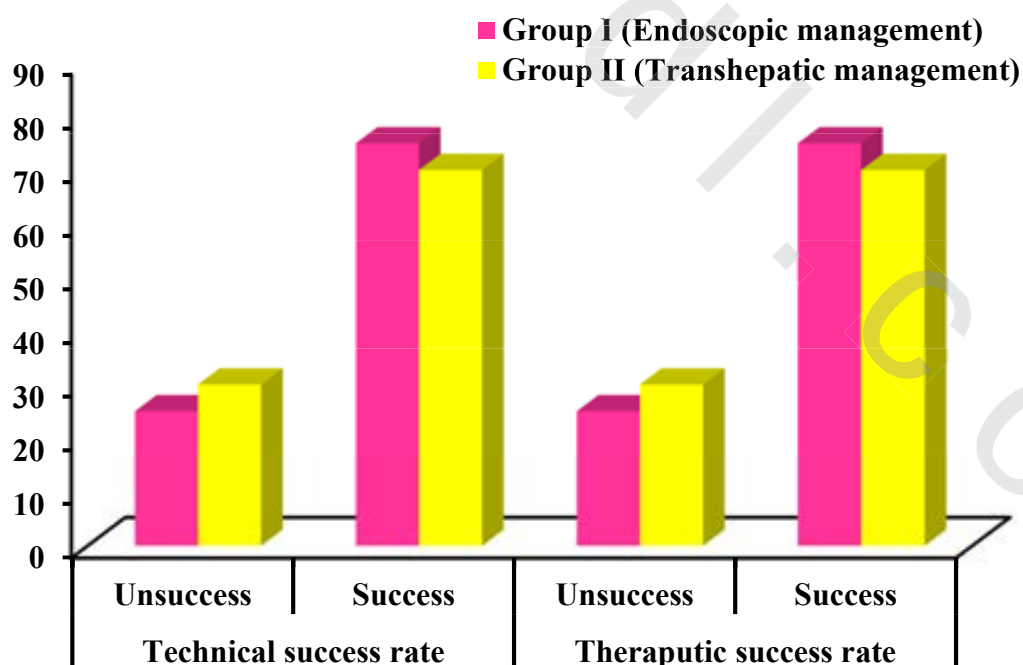


Figure (44): Comparison between the two studied groups according to TSR and THSR.

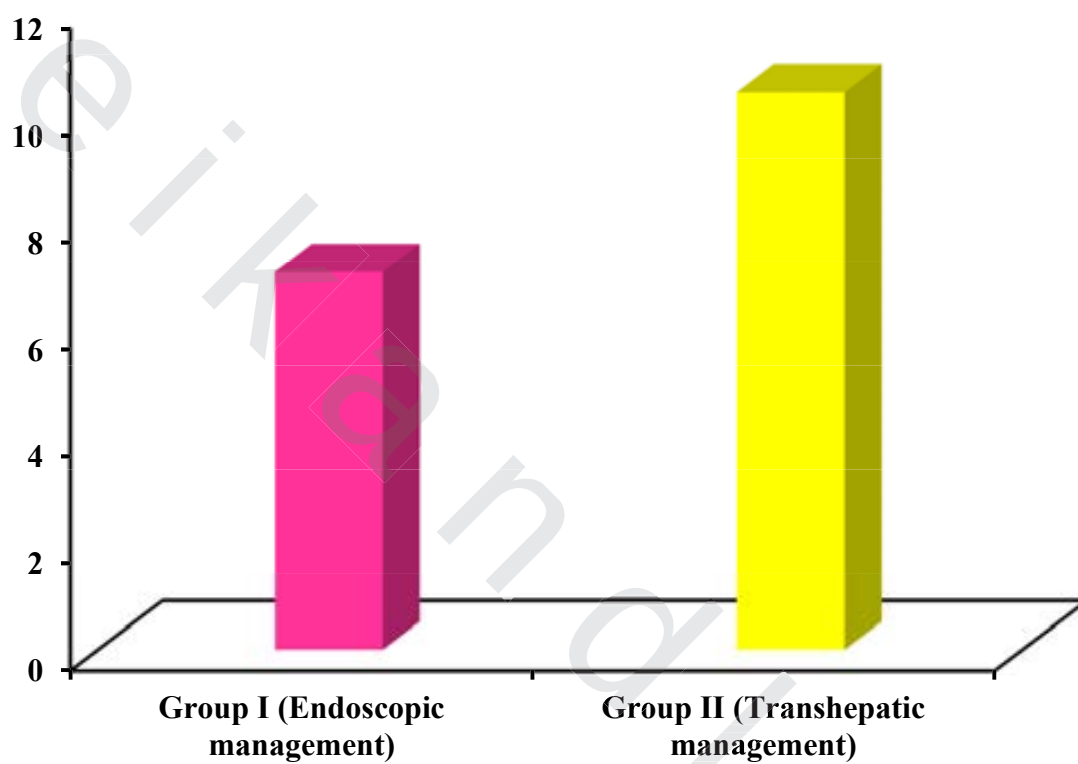


Figure (45): Comparison between the two studied groups as regard mean total serum bilirubin (15 days post procedure).

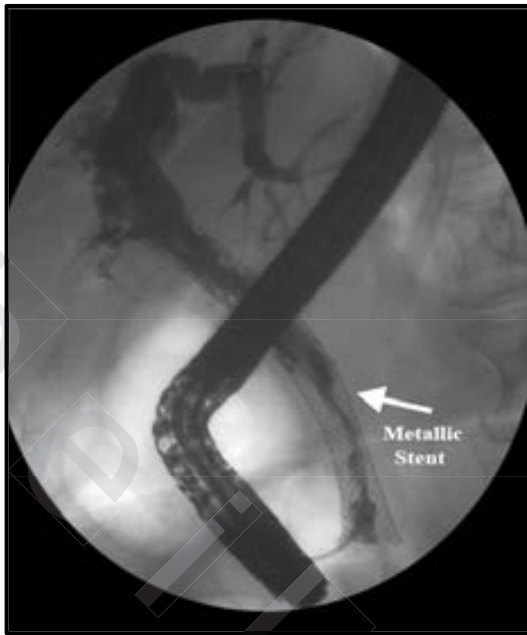


Figure (46): Case (1) inoperable cancer head pancreas managed by ERCP and metallic stent was inserted.



Figure(47): Case (2) Distal cholangiocarcinoma confirmed by CT and ERCP.



Figure (48): Case (3) Distal CBD stricture mostly benign diagnosed by ERCP.

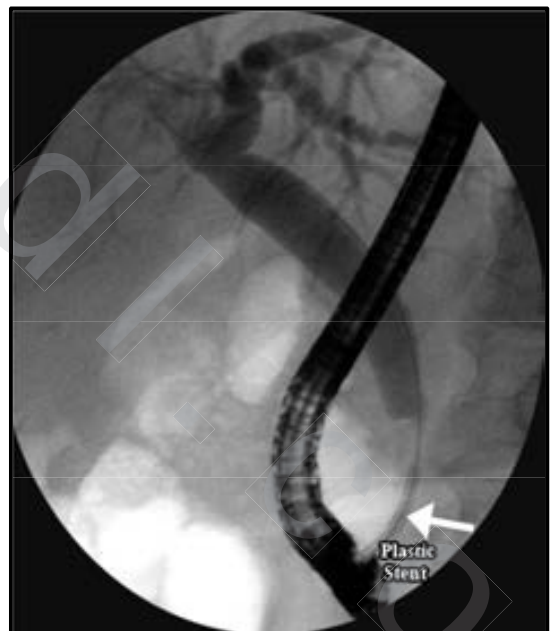


Figure (49): Case (3) Distal CBD stricture managed by plastic stent insertion by ERCP.



Figure (50): Case (1) PTC image of patient with Distal CBD stricture managed by plastic stent insertion.

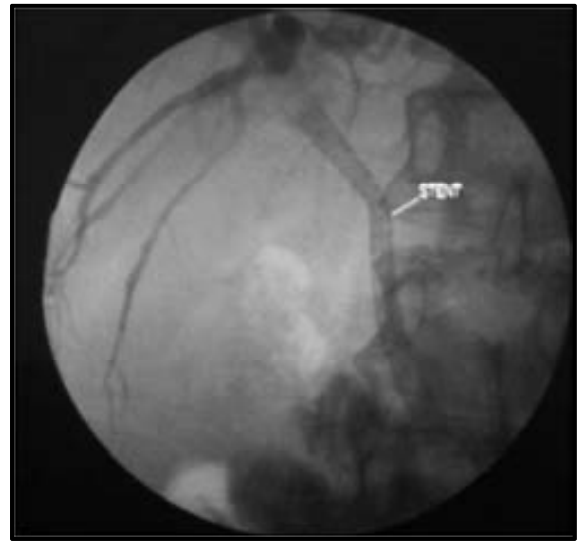


Figure (51): Case (2) PTC image of patient with Distal cholangiocarcinoma diagnosed by CT and managed by metallic stent insertion.



Figure (52): PTC image of patient with Distal CBD stricture due to Cancer pancreas diagnosed by CT.



Figure (53): PTC image of patient with CBD stricture managed by internal-external drain.

6. Comparison between the two studied groups according to complications and mortality

The relation between the two groups was statically insignificant as regard major complication rate ($p=0.519$) and 30 day mortality ($p=0.507$).

It was found that 15% of patients of group I developed cholangitis as compared to 30% of patients of group II, 10% of patients of group I developed pancreatitis as compared to none of group II, 10 % of patients of group II developed bile leak as compared to none of group I, percentage of hemorrhage as a complications was equal in both groups.

It was found that mortality was higher in patients of group II (40%) as compared to group I (30%) however the relation was not statistically significant.

Tables XXIV: Comparison between the two studied groups according to different parameters.

	Group I (Endoscopic management) (n = 20)		Group II (Trans-hepatic management) (n = 20)		χ^2	p
	No.	%	No.	%		
Major complication rate	6	30	8	40.0	0.107	0.519
Cholangitis	3	15.0	6	30.0	1.290	^{FE} p= 0.256
Pancreatitis	2	10.0	0	0.0	2.105	^{FE} p= 0.147
Bile leak peritonitis	0	0.0	2	10.0	2.105	^{FE} p= 0.147
Hemorrhage	1	10.0	1	10.0	0.0	^{FE} p= 1.000
30 Mortality	6	30.0	8	40.0	0.440	0.507

χ^2 : Chi square test

FE: Fisher Exact test; Student t-test

Z: Z for Mann Whitney test

*: Statistically significant at $p \leq 0.05$

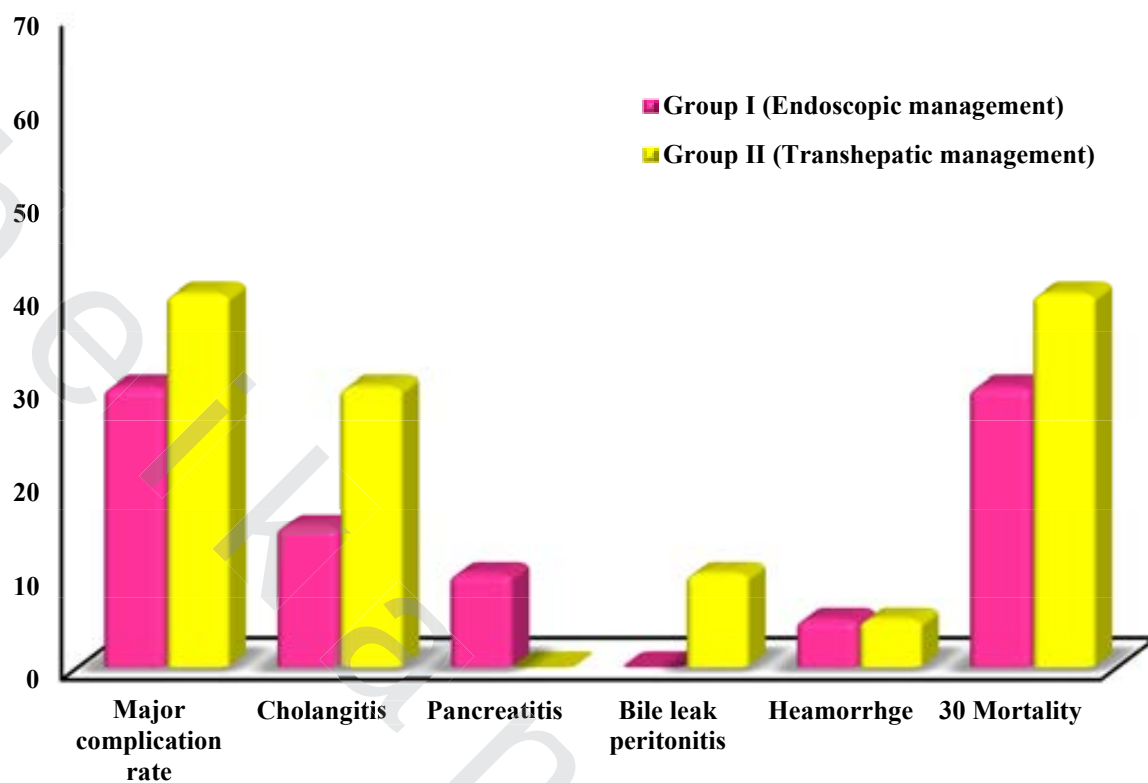


Figure (54): Comparison between the two groups as regard major complications and 30 day mortality.

7. Comparison between the two studied groups according to different causes of death

The relation between the two groups was statically insignificant as regard different causes of death that included cholangitis ($p=0.342$), Multiorgan failure ($p=0.457$), Hemorrhage ($p=1.000$), disease progression ($p=0.232$).

It was found that 10% of patients of group I died from bacterial infection as compared to 20% of patients of group II, 10% of patients of group I died from Multiorgan failure as compared to 25% of patients of group II. It was found that 10% of patients of group I died from disease progression as compared to 15% of patients of group II.

Tables XXV: Comparison between the two studied groups according to cause of death.

Cause of death	Group I (Endoscopic management) (n = 20)		Group II (Trans-hepatic management) (n = 20)		χ^2	^{FE} p
	No.	%	No.	%		
Cholangitis	2	10.0	4	20.0	2.057	0.342
Multiorgan failure	2	10.0	5	25.0	2.352	0.457
Hemorrhage	-	0	0	0.0	0.0	1.000
Disease progression	2	10.0	3	15.0	1.927	0.232

t: Student t-test

Z: Z for Mann Whitney test

*: Statistically significant at $p \leq 0.05$

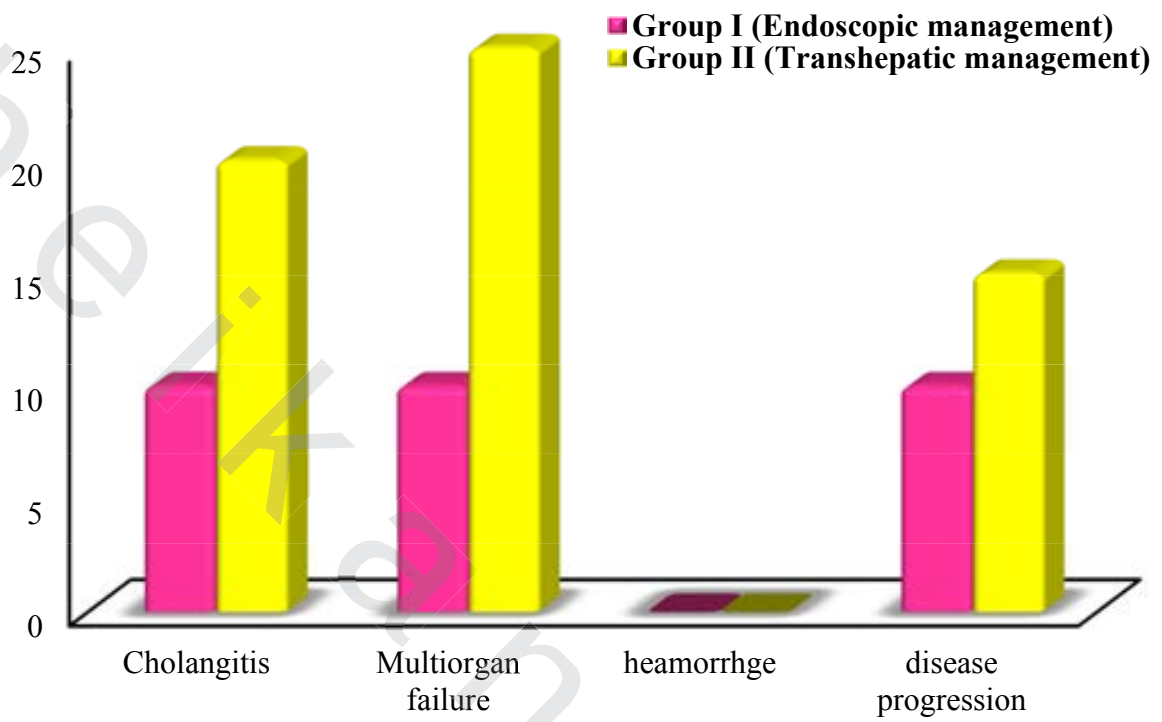


Figure (55): Comparison between the two groups as regard causes of death.

8. Comparison between the two studied groups according to mean hospital stay

The relation between the two groups showed statistical significance as regard mean hospital stay ($p=0.027$), it was showed that the mean hospital stay in group I was (7.35 ± 5.8) as compared to the mean hospital stay in group II which was (13.5 ± 10.8).

Tables XXVI: Comparison between the two studied groups according to mean hospital stay.

	Group I (ERCP) (n = 20)	Group II (PTD) (n = 20)	Z	p
Mean hospital stay				
Mean $\pm$ SD.	7.35 $\pm$ 5.8	13.5 $\pm$ 10.8	2.217*	0.0327*

χ^2 : Chi square test

t: Student t-test

*: Statistically significant at $p \leq 0.05$

Z: Z for Mann Whitney test*: Statistically significant at $p \leq 0.05$

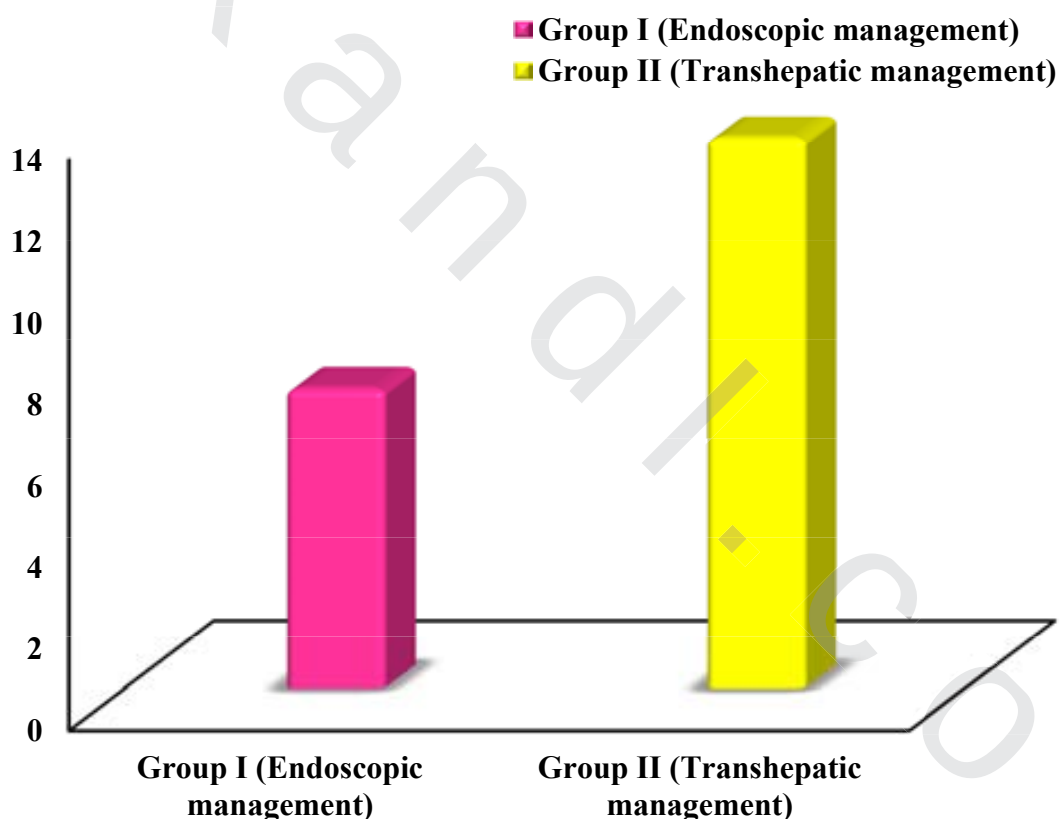


Figure (56): Comparison between the two studied groups according to mean hospital stay.