

RESULTS

The study start on september 1984 and continue until September 1987. At the end of the study 90 patients were randomly selected to sclerotherapy and 30 patients to medical treatment.

The age in sclerotherapy was from 18-65 years with a mean of 42.8 ± 12.3 years.

The male/female ratio in sclerotherapy was 18/1 and in medical treatment was 35/1.

The units number transfused before entering the study in sclerotherapy were 1-8 units with mean 3.41 ± 2.9 and in medical treatment were 1-4 units with mean 1.8 ± 2.1 . The

The results were matched according to the child's classification which was a simple scoring system for grading the severity of the liver functions which had a value in predicting the outcome of management:

Those patients whose score were good (Grade A)

Those patients whose score were moderate (Grade B)

Those patients whose score were poor (Grade C)

The grading of the liver functions according to the child's classification were: in the table before.

Both sclerotherapy and medical groups were matched in out study according to the child's as follow:

Clinical data of the patients in both groups in Table (1):

The sclerotherapy group:

Child A 40 patients (44.4%)

Child B 35 patients (38.9%)

Child C 15 patients (16.7%)

The Medical group:

Child A 15 patients (50%)

Child B 8 patients (26.7%)

Child C 7 patients (23.3%)

Sex ratio M/F:

In sclerotherapy 18/1

In Medical 35/1

The liver functions tests table (2):

In sclerotherapy group:

Total serum bilirubin was (0.5-2.8 mg%) with mean (1.4 ± 0.81)

Total serum protein was (5.5-8.1 gm%) with mean (6.5 ± 0.8)

Serum albumin was (2.8-3.9 grm%) with mean (3.5 ± 0.4)

SGOT was (16-71 IU/L) with mean (41 ± 11.8)

Alkalinephosphatase was (9-21 k.A.U.) with mean (14 ± 2.11)

Prothrombin time was (14-22 second) with mean (16 ± 3)

In Medical group:

Total serum bilirubin was (0.5-1.5 mg%) with mean (1.35±0.76)

Total serum protein was (5.1-7.8 grm%) with mean (6.3±0.7)

Serum albumin was (3-4.2 grm%) with mean (3.4±0.5)

SGOT was (14-75 I.U/L) with mean (43±12.3)

Serum alkaline phosphatase was (8-25 K.A.U) with mean (15±3.21)

Prothrombin time was (15-21 second) with mean (17±2.8)

Patients with obliterated varices: Table (3):

All our cases of injected varices were suffering from liver cirrhosis either Bilharzial or endemic in origin. The range of number of settings needed to obliterate varices were (3-20) with mean (5.1±2.2).

It was followed up for 1-36 months with mean (5.1±2.2) to be obliterated.

Rebleeding occurred (1-30 days) with mean (7 days). Recurrence of bleeding occurred with 12-18 months with mean (14±3.7).

Fate of varices in relation to the mean amount of sclerosant
Table (4)

- 37% of the cases were completely eradicated using 119.65 ml of sclerosant.
- 31% of the cases were almost eradicated using 91.21 ml of sclerosant.
- 22% of the cases were fibrosed using 81.11 ml of sclerosant.

Relation of the varices to the number of sessions:Table (5)

In 37% of the patients, the number of sessions needed for complete eradication of varices was 5.4.

In 31% of the patients the number of sessions needed for almost eradication of varices was 5.1.

In 22% of the patients the number of sessions needed for fibrosis was 4.8.

Complications according to the method of injection using ethanolamine in both types table (6)

In intravariceal injection: 40 cases

Early bleeding 3 cases (7.5%)

Pain 30 cases (75%)

Pyrexia 26 cases (65%)

Mucosal ulceration 2 cases (5%)

Bleeding related death 2 cases (5%)

No perforation and no symptomatic stricture.

In paravariceal injection: 30 cases

Early bleeding 2 cases (6.7%)

Pain 25 cases (83%)

Pyrexia 20 cases (66%)

Mucosal ulceration 6 cases (20%)

Bleeding related death 1 case (3.3%)

No perforation and no symptomatic stricture.

Complications of sclerotherapy according to the type of sclerosant : table (7)

Among 90 patients allocated for sclerotherapy they were divided into 2 groups:

The first group 70 patients injected by ethanolamine.

The second group 20 patients injected by sclerovin

* The first group (70 patients injected by ethanolamine:

Early bleeding 5 cases (7.1%)

Pain 55 cases (78.5%)

Pyrexia 46 cases (65.7%)

Mucosal ulceration 8 cases (11.4%)

Bleeding related death 3 cases (4.1%)

No perforation & No symptomatic stricture.

The second group (20 patients) injected by sclerovin:

Early bleeding 12 cases (60%)

Pain 8 cases (40%)

Pyrexia 7 cases (35%)

Mucosal ulceration 2 cases (10%)

Bleeding related death one case (5%)

No perforation & no symptomatic stricture.

The survival percentage in sclerotherapy and medical groups: $P < 0.01$: table (8)

In sclerotherapy group:

In the interval of the first three months it was 96.7% survival

In the interval from 3rd to 6th month it was 95.7% survival.

In the interval from 6th to 9th month it was 94.4% survival.

In the interval from 9th to 12th month it was 94.4% survival.

In the interval from 12th to 15th month it was 94.4% survival.

In the interval from 15th to 18th month it was 94.4% survival.

In the interval from 18th to 21th month it was 94.4% survival

In the interval from 21th to 24th month it was 93.3% survival.

In the interval from 24th to 27th month it was 92.2% survival.

In the interval from 27th to 30th month it was 91.1% survival.

In the interval from 30th to 33th month it was 91.1% survival.

In the interval from 33th to 36th month it was 91.1 survival.

In medical group:

In the first three months it was 86.7% survival.

In the interval from 3rd to 6th month it was 83.4% survival.

In the interval from 6th to 9th month it was 76.7% survival.

In the interval from 9th to 12th month it was 76.7% survival.

In the interval from 12th to 15th month it was 73.3% survival.

In the interval from 15th to 18th month it was 73.3% survival.

In the interval from 18th to 21th month it was 70% survival.

In the interval from 21th to 24th month it was 70% survival.

In the interval from 24th to 27th month it was 70% survival

In the interval from 27th to 30th month it was 66.7% survival.

In the interval from 30th to 33th month it was 66.7% survival.
In the interval from 33th to 36th month it was 66.7% survival.

i.e. there is a significant difference in survival rates
in both groups at all intervals.

The mortality percentage in sclerotherapy and medical group;

table (9)

In sclerotherapy:

In the first month 3 cases 3.3%

During the entire observation 5 cases 5.6%

The total cases were 8 cases 8.9%.

In medical treatment:

In the first month 10 cases 33.3%

During the entire observation 15 cases 50%

The total cases were 25 cases 83.3%.

The outpatient clinic sclerotherapy:

During 12 months period of the study a number of 30 patients received 117 settings of injections in the clinic units. Each patients had a mean of 3.5 ± 2.3 settings. During each setting every injection was performed with 5.2 ± 2.1 ml of the sclerosant.

Only chest pain in 20 cases & dysphagia related to the pain in 9 cases were observed as complications.

No rebleeding in any case was observed after each injection.

No death and no other major complication was observed in this group of patients.

Table 1: Clinical data of the patients allocated to
medical treatment & sclerotherapy.

	Medical = 30	Sclerotherapy = 90
Age/year \pm S.D.	42.8 \pm 12.3	42.3 \pm 11.5
Sex ratio male/female	35/1	18/1
Child's classification:		
Grade A	15 (50%)	40 (44.4%)
Grade B	8 (26.7%)	35 (38.9%)
Grade C	7 (23.3%)	15 (16.7%)
Median number of	1-4	1-8
prerandomization units transfused.	Mean (1.8 \pm 2.1)	Mean (3.41 \pm 2.9)

Table 2: Laboratory data of patients with variceal haemorrhage allocated to medical treatment and sclerotherapy.

	Medical treatment	Sclerotherapy
	Number of patients =30	Number of patients=90
Total Bilirubin (Mg%)	0.5-2.5 Mean (1.35±0.76)	0.5-2.8 Mean (1.4±0.81)
Total serum protein (gm%)	5.1-7.8 Mean (6.3±0.7)	5.5-8.1 Mean (6.5±0.8)
Albumin (gram%)	3 - 4.2 Mean (3.4±0.5)	2.8-3.9 Mean (3.5±0.4)
SGOT IU/L	14-75 Mean (43±12.3)	16-71 Mean (41±11.8)
Serum alkaline phosphatase (K.A.U)	8 -25 Mean (15±3.21)	9 -21 Mean (14±2.11)
Prothrombine time (Second)	15-21 Mean (17±2.8)	14-22 Mean (16±2.9)
P>0.5 Non significant		

Table 3: Patients with obliterated varices

Chronic liver disease secondary to cirrhosis	Number of session to obliterate	Months followed after obliteration	Days to rebleed	Months to recurrence of bleeding
	3-20	1-36	1-30	12-18
	Mean(5.1±22)	Mean(5.1±22)	Mean(7)	Mean (14±37)

Table 4: Relation of the fate of the varices to the mean amount of sclerosant in ml.

Group	Mean amount	No cases
Eradicated	119.65 ml	(37%)
Almost eradicated	91.21 ml	(31%)
Fibrosed	81.11 ml	(22 %)

Table 5: Relation of the fate of the varices to the number of sessions.

Group	Mean sessions	Number of cases
Eradicated	5.4	37%
Almost eradicated	5.1	31%
Fibrosed	4.8	22%

Table 6: Comparison between complication of intrav. & perivariceal injection

	Intravariceal (40)	Perivariceal(30)
Early bleeding	3(7.5%)	2(6.7%)
Pain	30(75%)	25(83%)
Pyrexia	26(65%)	22(66%)
Mucosal ulceration	2(5%)	6 (20%)
Perforation	-	-
Symptomatic stricture	-	-
Bleeding related death.	2(5%)	1 (3.3%)

Table 7: Frequency of complication of sclerotherapy according to the type of sclerosant using ethanolamine & sclerovein.

	Ethanolamine	Sclerovein
	Number of patients = 70	Number of patients = 20
Early bleeding	5(7.1%)	12(60%)
Pain	55(78.5%)	8(40%)
Pyrexia	46(65.7%)	7(35%)
mucosal ulceration	8(11.4%)	2(10%)
Perforation	-	-
Symptomatic stricture	-	-
Bleeding related death	3.(4.1%)	1(5%)

Table 8: Survival percentage in sclerotherapy & medical treatment.

Interval in month	Sclerotherapy 90 % survival	Medical treatment 30 % survival	P
0-3	96.7%	86.7%	<0.01
3-6	95.7%	83.4%	<0.01
6-9	94.4%	76.7%	<0.01
9-12	94.4%	76.7%	<0.01
12-15	94.4%	73.3%	<0.01
15-18	94.4%	73.3%	<0.01
18-21	94.4%	70%	<0.01
21-24	93.3%	70%	<0.01
24-27	92.2%	70%	<0.01
27-30	91.1%	66.7%	<0.01
30-33	91.1%	66.7%	<0.01
33-36	91.1%	66.7%	<0.01

Table 9: Mortality among patients allocated to sclerotherapy and medical treatment groups during the first month and the entire observation period.

	First month		Entire observation		Total mortality	
	Number	Percentage	Number	percentage	Number	percentage
Sclerotherapy No =90 patients	3	3.3%	5	5.6%	8	8.9%
Medical treatment No=30 patients	10	33.3%	15	50%	25	83.3%