RESULTS

Fourty high risk newborns were included in this study after admission to Neonatal Care Unit of Benha University Hospital. Cord blood samples were obtained from these infants within the first 6 hours after birth and a subsequent sample of venous blood was obtained 48 hours later. The following laboratory tests were conducted on the obtained blood samples:

- Blood Culture
- CRP
- CBC to calculate the sepsis score according to the hematological scoring system of ***Manroe et al. (1979).***
- IL-6

For the purpose of statistical analysis cases which showed a positive blood culture in either the cord blood (early samples) or venous blood (late samples) were considered as the septicemic group throughout the study.

Sepsis was diagnosed in (18) cases (45%) out of 40 high risk newborns.

Table (1), Figure (1) shows the sex distribution of the newborn infants under the study. They were 21 males (52.5%) and 19 females (47.5%).

The septic group was composed of 18 cases [9 males (50%) and 9 female (50%)] and the non septic group was composed of 22 cases [12 males (54.5%) and 10 females (45.5%)]. $X^2 = 0.541$ with P-value > 0.05

No statistically significant difference was observed between the septic and the non septic group as regards sex.

Table (2) shows the distribution of the studied groups according to the mode of delivery, 27 cases were delivered by vaginal delivery (67.5%) and 13 cases were delivered by Cesarean section (32.5%). In the septic group, 12 cases (66.6%) were delivered by NVD and 6 cases (33.4%) were delivered by C.S. In the non septic group, 15 cases (68.2%) were delivered by NVD and 7 cases (31.8%) were delivered by C.S. $X^2 = 0.732$ with P-value > 0.05.

No significant difference was observed between the septic and the non septic groups.

Table (3) shows the range, mean and standard deviation of body weight (Kgs) of newborn infants under study. In the septic group their birth weight ranged between 1.400 kg and 3.150 kg with mean of 2.250 ± 0.545 kg while, in the non septic group, it ranged between 1.800 kg and 3.600 kg with a mean value of 2.550 ± 0.602. The P-value was > 0.05.

No significant difference was observed between septic and non septic groups as regards body weight.

Table (4) shows the range, mean and standard deviation of gestational age (weeks) of newborn infants under study. In the septic group, their gestational age ranged between 28-37 weeks with a mean value of 34.0 ± 2.351 weeks. In non septic group their gestational age ranged between 32-40 weeks with a mean value of 36.5 ± 1.503 weeks. The p-value was < 0.05.

Statistical analysis showed significant increase of sepsis in premature infants as compared to full term infants.

Table (5), Figure (2) shows the distribution of clinical presentations among septicemic newborns. The most common clinical presentations of septicemic cases were poor feeding (95%), respiratory distress (83%), lethargy (72%) and hypothermia (66%). Less common were abdominal distention (50%), apnea (50%), jaundice (38%), seizures (33%), hepatomegaly (28%), bleeding tendency (28%), vomiting (22%), pallor (16%) and fever (11%).

Table (6), Figure (3) shows the organisms detected in the blood cultures of the cord blood (early samples) and the venous blood (late samples) of the septicemic group.

In cord blood samples only 3 cases showed a positive blood culture (16.6%) out of 18 cases which eventually proved to be septicemic. (GBS, E-coli and Staph aureus).

In the venous blood samples 18 cases showed positive blood culture. GBS was the most frequent causative organism (44.4%), followed by E-coli (27.7%), Staph aureus (16.6%) and Klebsiella (11.1%).

Table (7) shows the mean and standard deviation of hematological findings of the complete blood picture of cord blood (early samples) among the studied groups.

Statistical analysis, showed no significant difference between the values of HB%, RBCs count, platelet count, immature neutrophil count, immature/mature neutrophil count,

immature/ total neutrophil count between septicemic and non septicemic groups. P-value > 0.05.

Table (8) shows the mean and standard deviation of hematological findings of the complete blood picture of venous blood samples (late samples) among the studied groups. Statistical analysis showed a highly significant increase in the values of immature neutrophilic counts, immature/total neutrophil ratio and immature/ mature neutrophil ratio in the septic group compared to the non septic groups (P-value < 0.001).

There was a significant difference in HB%, RBCs count (P-value < 0.05) but, no significant difference in total leucocytic and neutrophilic counts between septic and non septic groups (P-value > 0.05). Platelet count was significantly lower in the septic than the non septic groups (P-value < 0.001).

Table (9) shows the range, mean and standard deviation of HSS in the cord blood (early samples) and the venous blood (late samples) among the studied groups. In the cord blood samples, the HSS of septic group were ranging between 0-2 and a mean of 1.0 ± 1.029 and in the non septic group it ranged between 0-2 and a mean of 0.778± 0.808 (P-value > 0.05).

No significant difference in the HSS was observed in the cord blood samples. In venous blood samples, the HSS of septic group ranged between 1-6 and a mean of 4.222 ± 1.437 while, in the non septic group, it ranged between 1-2, and a mean of 1.222 ± 0.732.

There was a highly significant difference between the septic and non septic groups in the venous blood (late samples) ($P < 0.001$).

Table (10) shows the diagnostic value of HSS as a screening test in comparison to blood culture as a definitive test. In cord blood (early sample) the HSS was negative in all septicemic cases so its sensitivity was zero. In venous blood (late sample) the HSS was positive in 13 cases out of 18 septicemic neonates and was negative in 22 cases out of 22 non septicemic newborns and its sensitivity was 72.2% and its specificity was 100% on late samples.

Table (11) shows the range, mean and standard deviations of serum CRP among the studied groups. In cord blood (early sample) CRP of the septic group ranged between 0-19.5 mg/l with a mean of 5.4 ± 3.28 mean while, the CRP of non septic group ranged between 0-6.5 mg/l with mean of 4.3 ± 2.74. P-value was > 0.05 (Not significant). In venous blood (late sample) CRP of septic group ranged between 6.5 - 52 mg/l with a mean of 24.45 ± 9.12 mean while CRP of the non-septic group ranged between 0 - 6.5 mg/l with a mean of 1.95 ± 3.14. P-value was < 0.001.

A highly significant difference was observed in the mean CRP level in the late (venous blood) sample.

Table (12) shows the diagnostic value of CRP as a screening test in comparison to the blood culture as a definitive test for neonatal sepsis.

In cord blood (early sample) CRP was positive in 4 cases out of 18 septicemic newborn and was false positive in 3 cases out 22 non-septicemic cases, therefore, its sensitivity was calculated to be 22.2% and its specificity was 86.4% in the early sample.

In the venous blood (late sample) CRP was positive in 12 cases out of 18 septicemic newborns and it was negative in 21 cases out of 22 non septicemic newborns. Therefore, its sensitivity was calculated to be 66.6% and specificity was 95.4% in the late sample.

Table (13) shows the range, mean and standard deviations of serum IL-6 among the studied groups.

In cord blood (early samples), there was a highly significant increase in the level of IL-6 in the septic cases as compared to the non septic cases (mean = 790.2 ± 176.9 pg/ml in septic group VS. 119.1 ± 71.4 pg/ml in non-septic group with P-value < 0.001).

In venous blood (late sample) there was a highly significant increase in the level of IL-6 in the septic group compared to the non septic groups (mean = 1474.04 ± 198.8 pg/ml in septic group compared to 301.1 ± 82.8 pg/ml in the non septic group with P-value < 0.001).

Table (14) shows the diagnostic value of IL-6 as a screening test in comparison to the blood culture as a definitive test.

In cord blood (early sample), IL-6 was positive (> 150 pg/ml) in 12 cases out of 18 septicemic newborns and 4 cases out of 22 non septicemic newborns. Therefore, its sensitivity was calculated to be 66.6% and its specificity was 81.8% on the early sample.

In venous blood (late samples) IL-6 was positive (> 500 pg/ml) in 17 cases out of 18 septicemic cases and negative in 20 cases out of 22 non septicemic newborns. Therefore, its sensitivity was calculated to be 94.4% and its specificity was 90.9% on late sample.

Table (15) shows the comparison between the mean values of IL-6 in both premature septicemic newborns (11) cases (61.1%) and full term septicemic newborns (7) cases (38.9%). In the preterm septic group the mean value of IL-6 was 2014.2 ± 176.9 VS. 1975.5 ±234.1 in the full term septic group with P-value >0.05. No significant difference was observed.

Table (16) shows the IL-6 and CRP response in relation to the type of infecting organisms. Blood cultures were positive in 18 cases (11 cases were gram positive and 7 cases were gram negative). As regards CRP values of cord blood samples, the mean value was 6.6 ± 2.9 in G+ ve group VS 5.3 ± 2.1 in G-ve group with P-value > 0.05). No significant difference was observed. Mean while the CRP values of venous blood samples (late sample) (the mean was 21.6 ± 8.1 in G +ve group VS 22.4 ± 7.1 in G -ve group with P-value > 0.05). No significant difference was observed.

As regards IL-6 values of venous blood (late sample its mean values were 1563.4 ± 292.6 in G +ve group and 1944.9 ±211.5 in G -ve group with P-value > 0.05). No significant different difference was observed.

Table (17) shows the correlation between the serum level of IL-6 of cord blood (1st sample) and other variables. (Sex, mode of delivery, weight, GA, CRP, HB%, RBCs count, Plat count, TPMN, I/T ratio, I/M ratio, HSS of cord blood). No significant correlation were observed (P-value > 0.05).

Table (18) shows the correlation between the serum level of IL-6 of venous blood (late sample) and other variables. (CRP, HB%, RBCs count, platelet count, TPMN, I/T ratio, I/M ratio, HSS). No significant correlations were observed (P - value > 0.05).

Table (19) shows the comparison between the diagnostic value of IL-6 to other studied parameters in detection of sepsis in cord blood samples of the septicemic cases.

IL-6 was positive in 12 cases (66.6%) out of 18 septicemic neonates. CRP were positive in 4 cases (22.2%) with P-value < 0.05.

Blood cultures was positive in 3 cases (16%) with P-value < 0.05. HSS was negative in all septicemic cases. There was a significant difference between sensitivity of IL-6 and sensitivity of either CRP, blood culture and HSS as test to detect sepsis in cord blood samples (P-value < 0.05).

Table (20) shows the comparison between the diagnostic value of IL-6 to other studied parameters (CRP, blood culture, HSS) in detection of sepsis in venous blood (late sample) of the septicemic cases.

IL-6 was positive in 17 cases (94.4%) out of 18 septicemic cases. CRP was positive in 16 cases (88.8%) with P-value > 0.05. Blood culture was positive in 18 cases 100% and HSS was positive in 17 cases (94.4%). Statistical analysis showed no significant difference between sensitivity of IL-6 and sensitivity of CRP, blood and HSS as a test to detect sepsis in the late (venous blood) samples.

Table (21) shows the comparison between the diagnostic value of IL-6 to other studied parameters in exclusion of sepsis in cord blood samples of the non septicemic cases there was no significant difference between specificity of IL-6 and specificity of CRP, blood culture and HSS as a test to exclude sepsis in cord blood samples (P -value > 0.05).

Table (22) shows the comparison between the diagnostic value of IL-6 to other studied parameters in exclusion of sepsis in venous blood samples of the non septicemic cases there was no significant difference between specificity of IL-6 and specificity of CRP, blood culture and HSS as a test to exclude sepsis in venous blood samples (P -value > 0.05).

Figure (4), (5) show the individual CRP levels in cord blood and venous blood (after 48 hours) in septic and non septic groups. CRP is positive above 6.5 mg/L.

Figure (6), (7) show the individual IL-6 level in cord blood and venous blood in septic and non septic groups. The cut off point of cord blood IL-6 for sepsis is 150 pg/ml and 500 pg/ml for venous blood IL-6 after 48 hours.

Table (1) : Sex distribution of newborn infants under study .

Sex / Studied groups	Male		Female	
	No.	%	No.	%
Septic newborns	9	50%	9	50%
Non septic newborns	12	54.5%	10	45.4%
Total	21	52.5%	19	47.5%

X^2 = **0.541** **P > 0.05**

Table (2): Distribution of the studied groups according to mode of delivery.

Mode of delivery / Studied groups	C.S		NVD	
	No.	%	No.	%
Septic newborns	6	33.3%	12	66.6%
Non septic newborns	7	31.8%	15	68.2%
Total	13	32.5%	27	67.5%

X^2 **= 0.541** **P > 0.05**

Table (3) : Range, mean and standard deviation of body weight (kgs) of newborn infants under study.

Studied Group / Weight in Kg.	Septic group (n = 18)	Non septic group (n = 22)
Range	1.400-3.150	1.800-3.600
X	2.250	2.55 O
± SD	± 0.545	± 0.602
t	1.674	
P	> 0.05	

Table (4) : Range, mean and standard deviation of gestiational age (weeks) of newborn infants under the study.

Studied Group / G.A (weeks)	Septic group (n = 18)	Non septic group (n = 22)
Range	28-37	32-40
X	34.0	36.5
± SD	± 2.351	± 1.503
t	2.413	
P	< 0.05	

Table (5) : The frequency distribution of clinical presentations among septicemic newborns.

Clinical Findings	Number of Cases	%
(1)Poor Feeding	17	95%
(2)Respiratory distress	15	83%
(3)Lethargy	14	72%
(4)Hypothermia	12	66%
(5)Abdominal distention	9	50%
(6)Apnea	9	50%
(7)Jaundice	7	38%
(8)Seizures	6	33%
(9)Hepatomegally	5	28%
(10)Bleeding tendency	5	28%
(11)Vomiting	4	22%
(12)Pallor	3	16%
(13)Fever	2	11%

Table (6) : Causative organisms among septicemic group .

Timing of blood culture	Organisms	No. of cases	% of cases	Total No.	Total %
Early sample	G B S	1	5.55		
Cord blood	Staph aureus	1	5.55	3	16.6%
	E-coli	1	5.55		
Late sample	G B S	8	44.4%		
Venous blood	Staph aureus	3	16.6%	18	100%
	E-coli	5	27.7%		
	Klebsiella	2	11.3%		

Table (7) : The hematological findings of CBC in cord blood (1st sample) among the studied groups.

Studied groups / variables	Septic group X ± SD.	Non Septic group X ± SD.	t	p
Hb %	18.372 ± 1.247	18.250 ± 1.103	0.324	> 0.05
R.B. Cs count.	6.144 ± 0.522	6.0556 ± 0.420	0.581	> 0.05
Palt . Count	221.0 ± 44.576	200.506 ± 54.705	1.306	> 0.05
W.B.C. Count	10.978 ± 7.164	11.467 ± 5.595	0.234	> 0.05
TPMN	4363.89 ± 1222.633	4334.61 ± 1516. 523	0.068	> 0.05
IPMN	663.556± 444.803	604.444 ±275.835	1.703	> 0.05
I/T	0.134 ± 0.042	0.105 ± 0.065	1.703	> 0.05
I/M	0.164 ± 0.077	0.123 ± 0.079	1.656	> 0.05

Table (8) : The hematological findings of CBC in venous blood samples (2nd Sample) among the studied groups.

Studied groups / Variables	Septic group X ± SD.	Non Septic group X ± SD.	t	p
Hb	16.324 ± 1.914	17.888 ± 1.019	3.124	< 0.05
R.B.Cs Count	5.371 ± 0.758	5.856 ± 0.381	2.471	< 0.05
Plat. Count	159.294 ± 32.372	214.529 ± 36.939	5.037	<0.001
W.B.C. Count	9.941 ± 7.930	13.089 ± 8.01	1.243	> 0.05
TPMN	4474.0 ± 2782.91	4447.44±1245.393	0.038	> 0.05
IPMN	1867.588±1410.806	642.056± 286.219	3.625	< 0.01
I/T	0.271 ± 0.062	0.137 ± 0.073	6.276	<0001
I/M	0.374 ± 0.108	0.141 ± 0.075	7.751	<0.001

Table (9) : Comparison of the results of the Hematological sepsis score (HSS) between the septic and non septic groups in both early and late samples.

Studied groups \ HSS		Range	Mean	SD	Test of significant	
					t	P
Cord blood samples	Septic group (n = 18)	0-2	1.0	± 1.03	0.74	> 0.05
	Non septic group (n = 22)	0-2	0.78	± 0.81		
Venous blood samples	Septic group (n = 18)	1-6	4.22	± 1.44	0.844	< 0.001
	Non septic group (n = 22)	1-2	1.22	± 0.73		

Table (10) : Diagnostic value of HSS as a screening test among the studied groups

HSS \ Studied group		Septicemic (n=18)	Non septicemic (n=22)	Sensitivity %	Specificity %
Cord blood samples	HSS+ve	0	0	0	100%
	HSS-ve	18	22		
Venous blood samples	HSS+ve	13	0	72.2%	100%
	HSS-ve	5	22		

Table (11) : Distribution of C. reactive protein (CRP) among the studied groups.

Studied groups \ HSS		Range	Mean	SD	Test of significant	
					t	P
Cord blood samples	Septic group (n = 18)	0 - 19.5	5.4	± 3.28	1.792	> 0.05
	Non septic group (n = 22)	0 - 6.5	4.3	± 2.74		
Venous blood samples	Septic group (n = 18)	6.5 - 52	24.45	± 9.12	6.541	< 0.001
	Non septic group (n = 22)	0 - 6.5	1.95	± 3.14		

Table (12) : Diagnostic value of CRP as a screening test among the studied groups.

Studied group / CRP		Septicemic (n=18)	Non septicemic (n=22)	Sensitivity %	Specificity %
Cord blood samples	CRP+ve	4	3	22.2%	86.4%
	CRP-ve	14	19		
Venous blood samples	CPR+ve	12	1	66.6 %	95.4%
	CPR-ve	6	21		

Table (13) : Comparison of levels of IL-6 between the septic and non-septic newborns in both early and late samples.

Studied groups \ HSS		Range	Mean	SD	Test of significant	
					t	P
Cord blood samples	Septic group (n = 18)	0-1800	790.2	±176.9	16.44	< 0.001
	Non septic group (n = 22)	0 - 650	119.1	± 71.4		
Venous blood samples	Septic group (n = 18)	350 - 2300	1474.4	±198.8	18.4	< 0.001
	Non septic group (n = 22)	0-650	301.1	± 82.8		

Table (14) : Diagnostic value of IL-6 as a screening test among the studied groups.

Studied group / IL-6		Septicemic (n=18)	Non septicemic (n=22)	Sensitivity %	Specificity %
Cord blood samples	IL-6+ve	12	4	66.6%	81.8%
	IL-6-ve	6	18		
Venous blood samples	IL-6+ve	17	2	94.4%	90.4%
	IL-6-ve	1	20		

N.B. : The cut-off points for positivity of IL-6 were :
IL-6 + ve in cord blood samples > 150 pg/ml
IL-6 +ve in venous blood samples > 500 pg/ml.
(Lehrnbecher et al., 1995).

Table (15) : Comparison between the mean values of IL-6 in both premature and fullterm neonates with neonatal sepsis.

IL-6 pg/ml / Studied groups	Number (n =18)	X	SD	Test of significant	
				t	P
Septicemic preterm group	11 (61.1%)	2014.2	±176.9	1.872	> 0.05
Septicemic full term group	7 (38.9%)	1975.5	±234.1		

: The IL-6 and CRP response in relation to the type of infecting organism .

ied parameter ire	CRP				I L-6			
	1St sample		2 nd sample		1St sample		2 nd sample	
	x	±SD	x	±SD	x	±SD	x	±SD
positive aph) (n=11)	6.6	±2.92	21.64	±8.10	280.3	±170.8	1563.4	±292.6
negative bsiella) (n=7)	5.3	±2.13	22.44	±7.10	277.5	±133.4	1944.9	±211.5
T	0.1068		0.0463		0.123		0.173	
P	> 0.05		> 0.05		> 0.05		> 0.05	

Table (17) : Correlation between serum level of IL - 6 in cord blood (1st sample) and other variables.

Cord blood IL-6 / Variables	r	p
Sex	0.04637	> 0.05
Mode of delivery	0.10681	> 0.05
Weight	0.12335	> 0.05
Gestional age	0.26314	> 0.05
CRP	0.36673	> 0.05
HB.%	0.21513	> 0.05
R.B.Cs Count	0.31446	> 0.05
Plat. Count	0.20776	> 0.05
W.B.C. Cont	0.10636	> 0.05
TPMN	0.21154	> 0.05
IPMN	0.11637	> 0.05
I/T	0.12435	> 0.05
I/M	0.23554	> 0.05
HSS	0.31739	> 0.05

Table (18) : Correlation between serum level of IL - 6 in venous blood (2nd sample) and other variables.

Venous blood IL-6 / Variables	r	p
CRP	0.31607	> 0.05
HB.%	0.03686	> 0.05
R.B.Cs Count	0.01807	> 0.05
Plat. Count	0.08304	> 0.05
W.B.C. Cont	0.16140	> 0.05
TPMN	0.21154	> 0.05
IPMN	0.03860	> 0.05
I/T	0.21325	> 0.05
I/M	0.21325	> 0.05
HSS	0.32718	> 0.05

Table (19) : Comparison of the diagnostic value of the studied parameters in detection of sepsis in the early samples of the studied cases .

Studied group / Investigation	*Sensitivity* NO	%	Z	P
IL - 6	12	66.6%		
CRP	4	22.2%	1.963	< 0.05
Blood Culture	3	16.6%	2.007	<0.05
HSS	0	0%	6.00	< 0.05

Table (20): Comparison of the diagnostic value of the studied parameters in detection of sepsis in the late samples of the studied cases.

Studied group / Investigation	*Sensitivity* NO	%	Z	P
IL - 6	17	94.4%		
CRP	12	66.6%	0.577	> 0.05
Blood Culture	18	100%	1.004	>0.05
HSS	13	72.2%	0.466	> 0.05

Table (21) : Comparison of the diagnostic value of the studied parameters in exclusion of sepsis in the early samples of the studied cases .

Studied group / Investigation	*Specificity* NO	%	Z	P
IL - 6	18	81.8%		
CRP	19	86.4%	0.372	> 0.05
Blood Culture	22	100%	1.682	> 0.05
HSS	22	100%	1.682	> 0.05

Table (22) : Comparison of the diagnostic value of the studied parameters in exclusion of sepsis in the late samples of the studied cases.

Studied group / Investigation	*Specificity* NO	%	Z	P
IL - 6	20	90.4%		
CRP	21	95.4%	0.271	> 0.05
Blood Culture	22	100%	0.411	> 0.05
HSS	22	100%	0.411	> 0.05

Fig. (1) : Sex distribution of newborn infants under study.

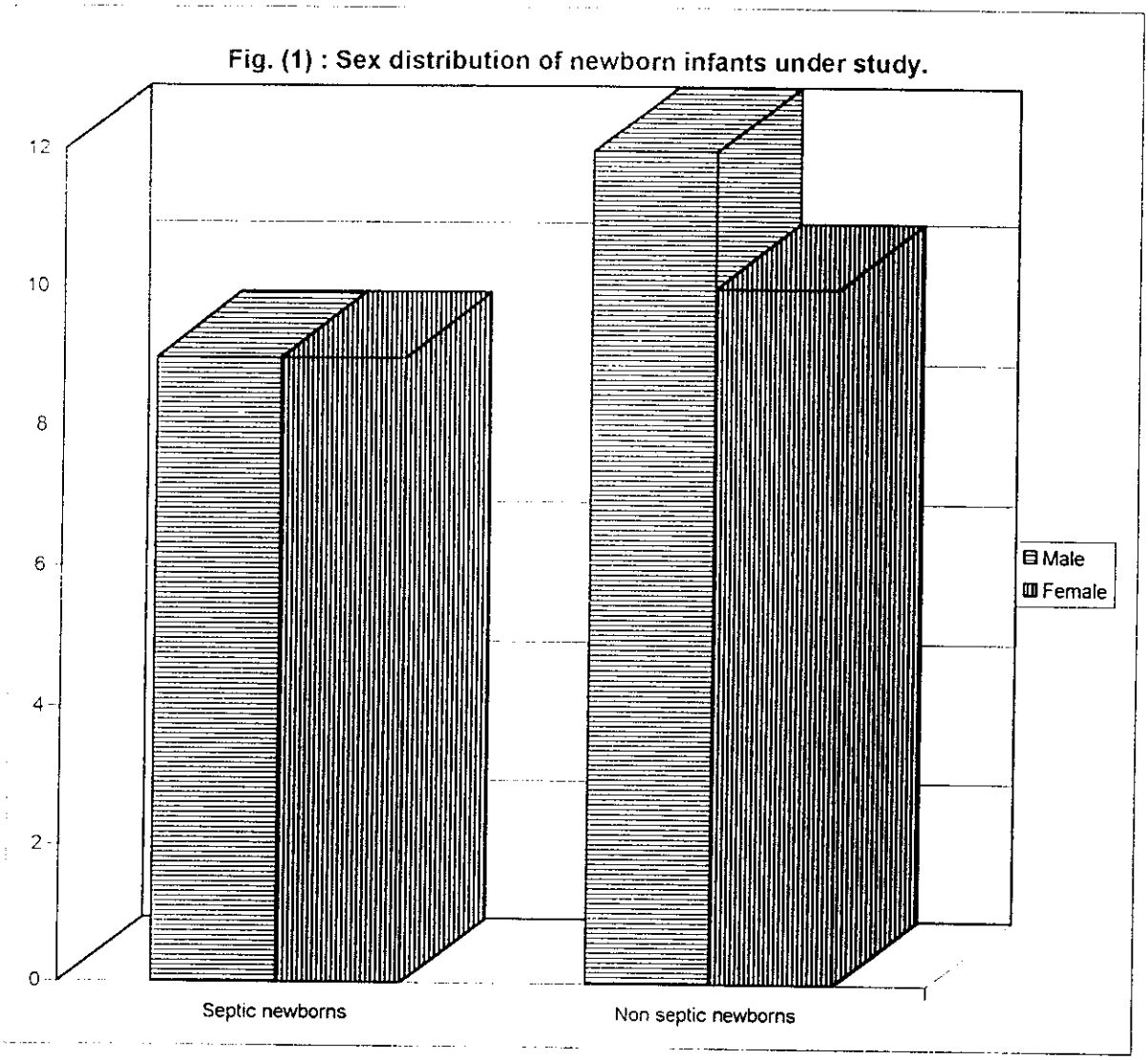
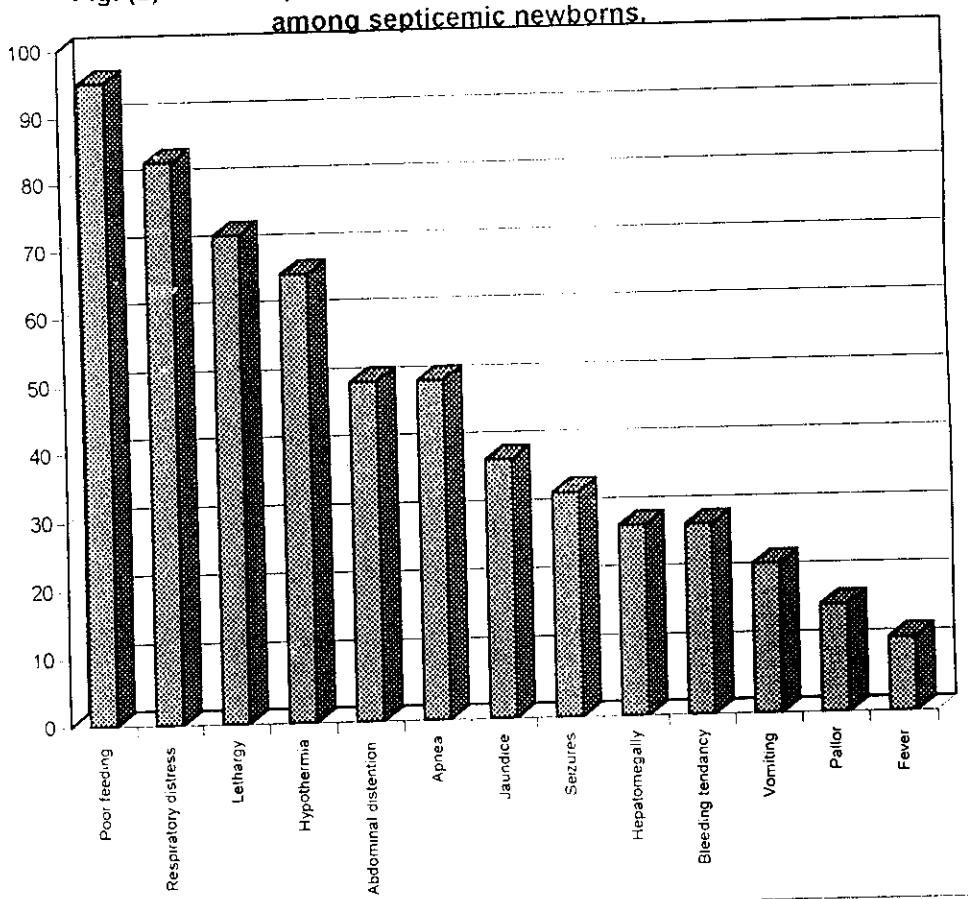


Fig. (2) : The frequency distribution of clinical presentations among septicemic newborns.



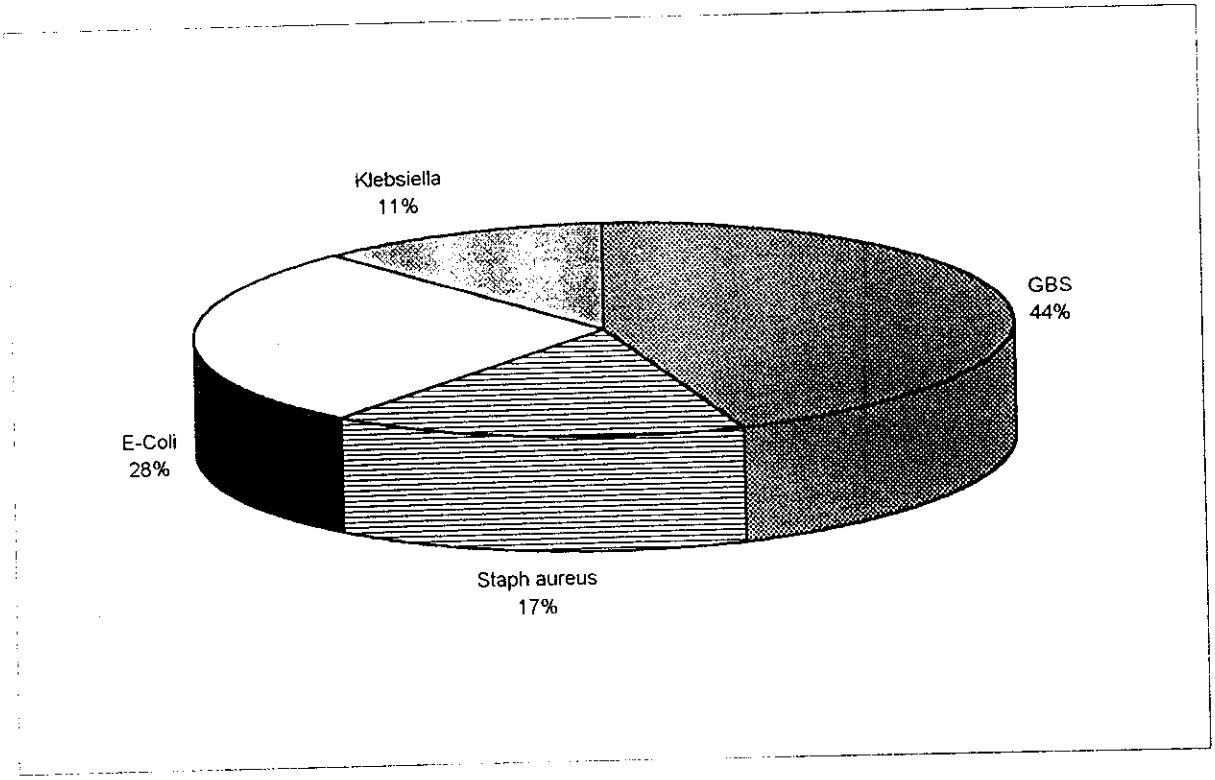


Fig. (3) : Causative organisms among septicemic group. (Venous blood samples)

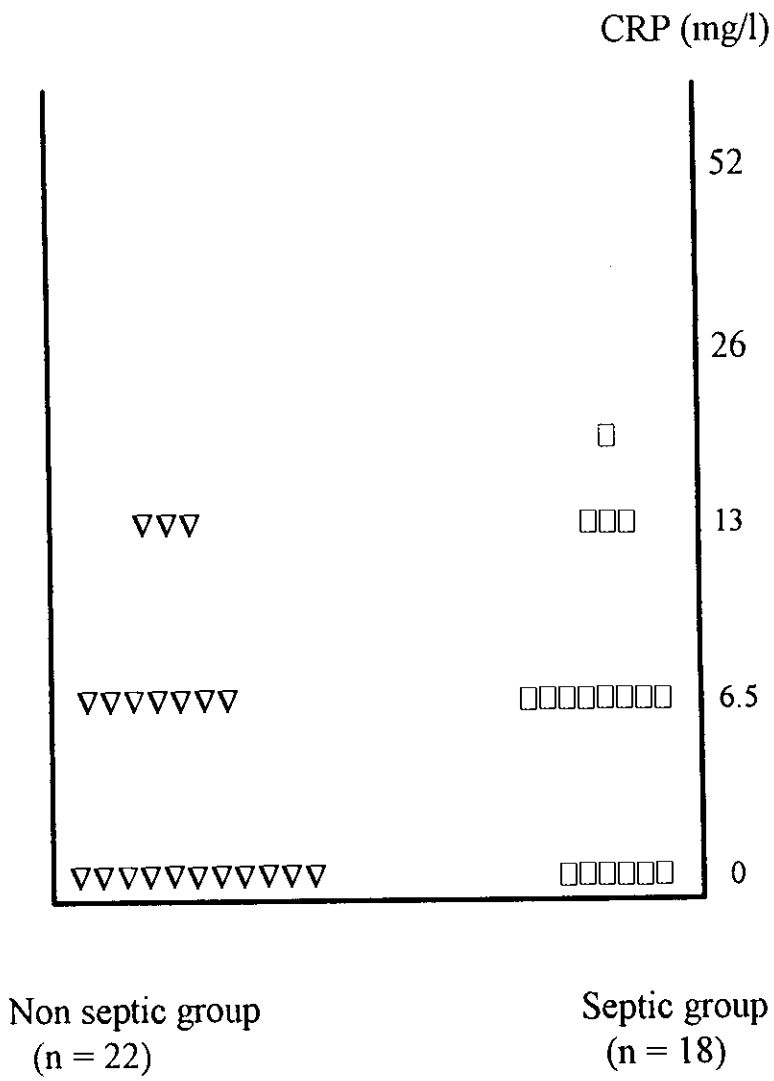


Figure (4) : Cord blood CRP levels in septic and non septic neonates
CRP is positive above 6.5 mg/L.

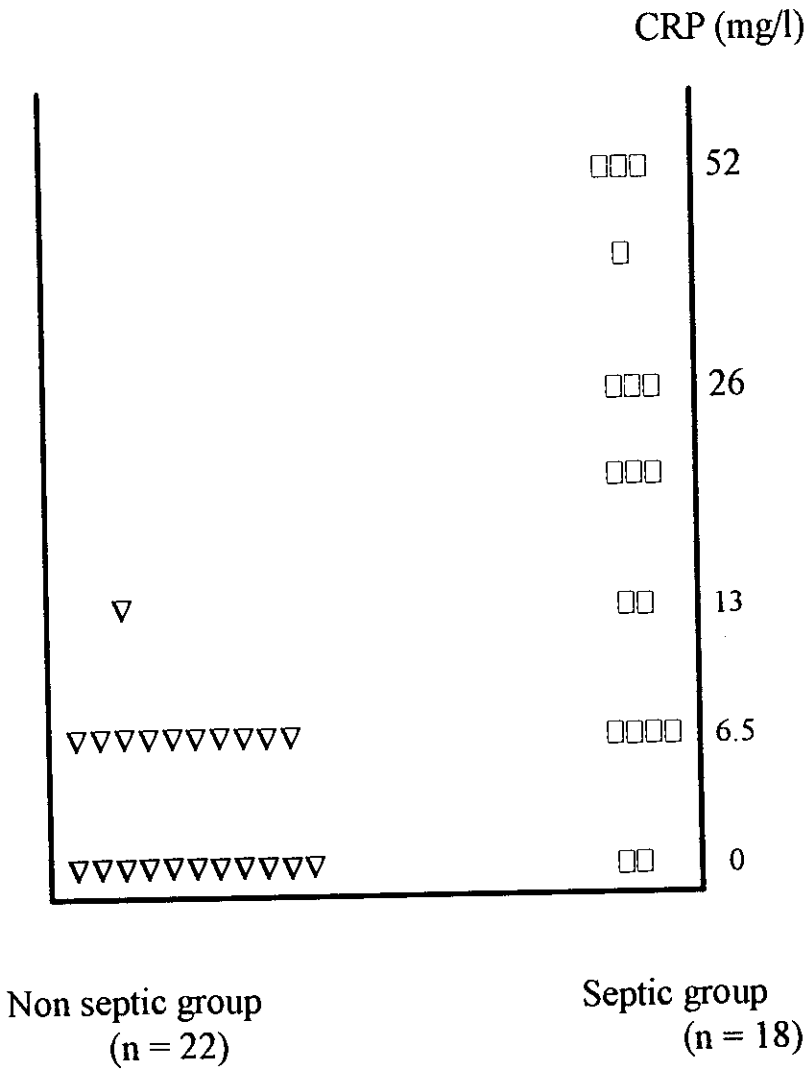


Figure (5) : Venous blood CRP levels in septic and non septic neonates after 48 hours.
CRP is positive above 6.5 mg/L.

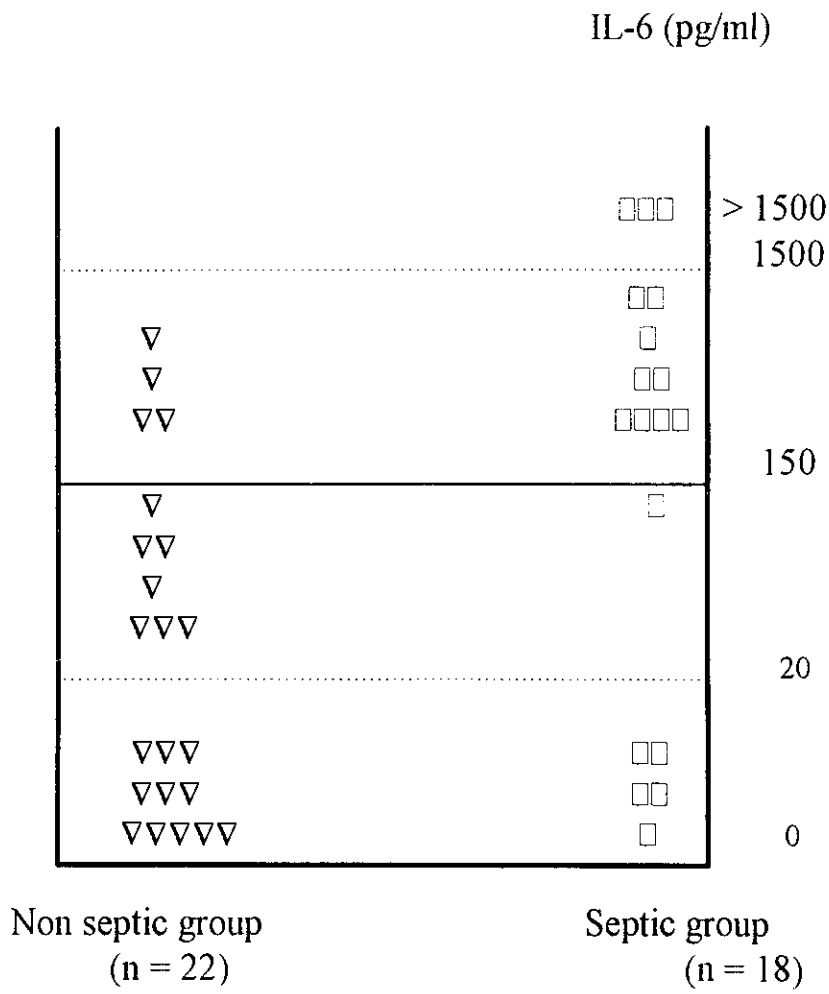


Figure (6) : Cord blood IL-6 levels in septic and non septic neonates. The cut off point for sepsis is 150 pg/ml. It is indicated by single solid line.

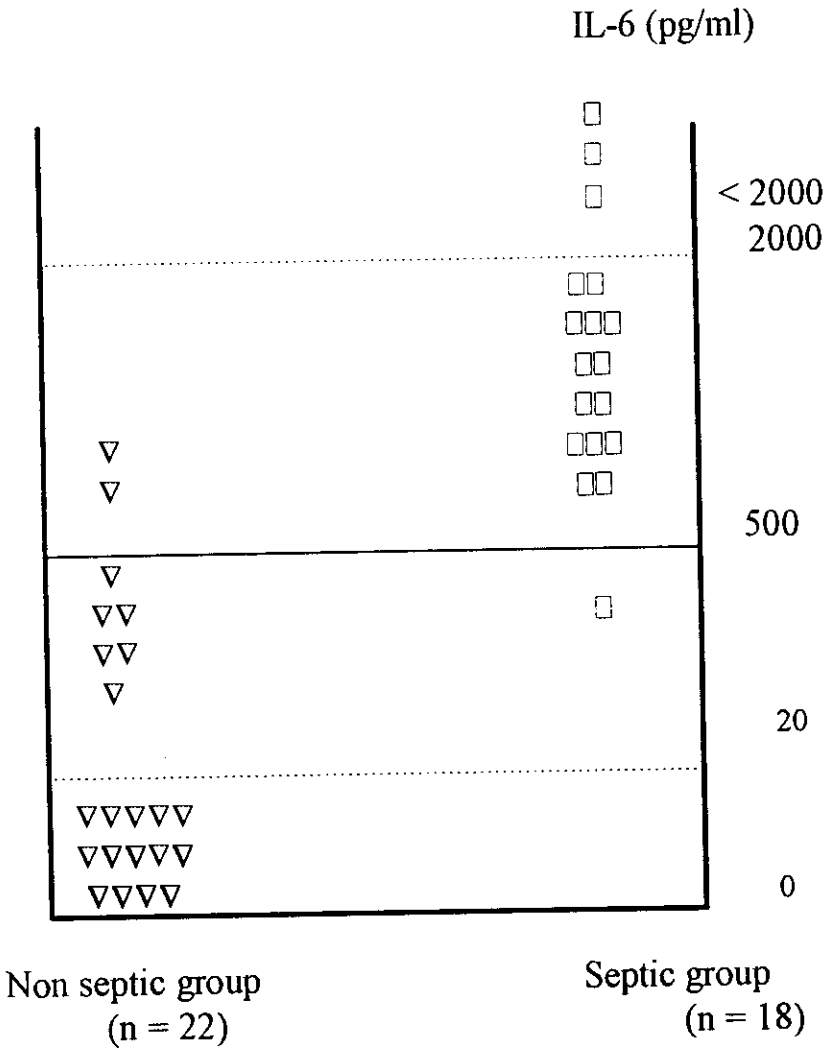


Figure (7) : Venous blood IL-6 levels in septic and non septic neonates after 48 hours.
The cut off point for sepsis is 500 pg/ml.