RESULTS

The results of this study is presented in tables (2) to (16) & figures (34) to (45)

Table (2): Comparison between group I (Indomethacin) and group II (Ibuprofen) as regards some quantitative data.

	No	Group I n =20	No	Group II n =20	t	P-value	Sign
GA(wks)	**20**	**30.7±2.5**	**20**	**30.4±1.7**	**0.44**	**> 0.05**	**NS**
BW(gm)	**20**	**1049±128**	**20**	**1146±260**	**1.4**	**> 0.05**	**NS**
HC(cm)	**20**	**27.3±0.8**	**20**	**27.6±0.9**	**0.41**	**> 0.05**	**NS**
Length(cm)	**20**	**38.2±1.3**	**20**	**39.3±1.4**	**2.11**	**> 0.05**	**NS**
Age of the mother (yr)	**20**	**26±3.3**	**20**	**26.8±3.4**	**0.75**	**> 0.05**	**NS**
Heart rate	**20**	**158.1±17.6**	**20**	**158.6±12.5**	**0.1**	**> 0.05**	**NS**
Respiratory rate	**20**	**65.9±9.1**	**20**	**64.3±9.8**	**0.29**	**> 0.05**	**NS**

GA: *gestational age,* ***BW:*** *body weight,* ***HC:*** *head circumference*

This table shows no statistically significant differences between two groups as regards gestational age, body weight, head circumference, length, age of the mother, heart rate and respiratory rate.

P-value

> 0.05: Non significant

< 0.05: Significant

< 0.01: High significant

< 0.001: High significant

Table (3): Comparison between group I (Indomethacin) and group II (Ibuprofen) as regards some qualitative data.

		Group I N=20 No %	Group II N=20 No %	Total No %	Z	P-value	Significance
Multiple pregnancy	Single	14 70%	13 65%	27 67.5%	0.34	> 0.05	NS
	Multiple	6 30%	7 35%	13 32.5%	0.28	> 0.05	NS
Sex	Female	12 60%	14 70%	26 65%	0.66	> 0.05	NS
	Male	8 40%	6 30%	14 35%	0.53	> 0.05	NS
Mode of delivery	CS	13 65%	12 60%	25 62.5%	0.2	> 0.05	NS
	Vaginal	7 35%	8 40%	15 37.5%	0.32	> 0.05	NS

CS: *cesarean section*

This table shows no statistically significant differences between group (I, II) as regards multiple pregnancy, sex and mode of delivery.

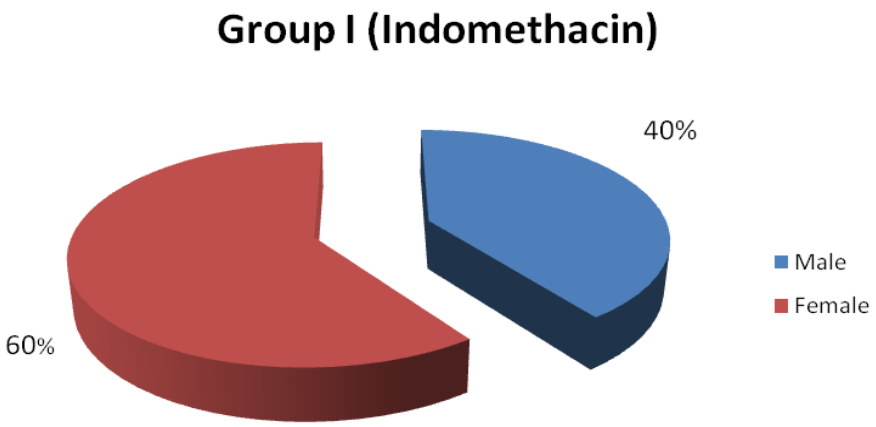

Figure (34): Sex distribution in group 1

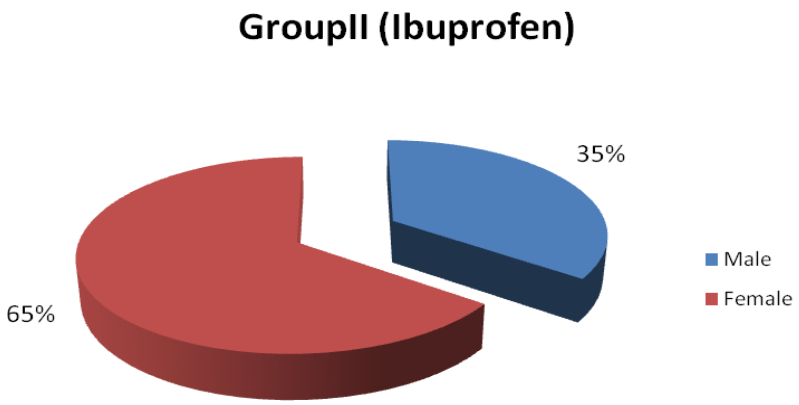

Figure (35): Sex distribution in group II

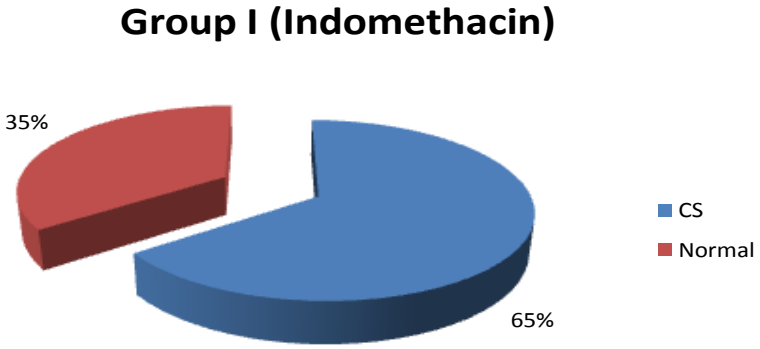

Figure (36): Mode of delivery in group I

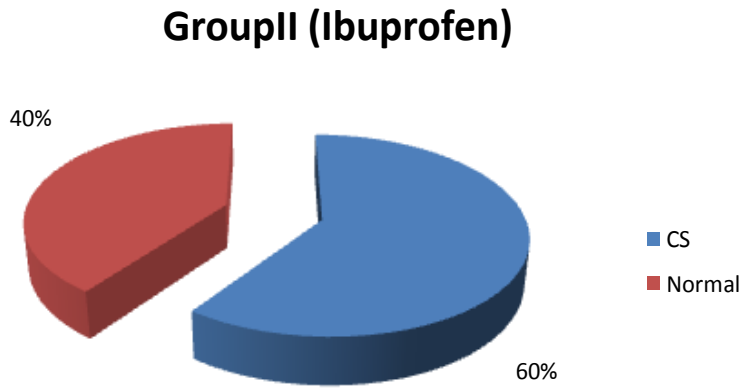

Figure (37): Mode of delivery in group II

Table (4): Comparison between group I (Indomethacin) and group II (Ibuprofen) as regards risk factors for prematurity.

		Group I N=20 No %	Group II N=20 No %	z	P-value	Significance
Maternal diabetes mellitus	No	17 85%	18 90%	0.45	> 0.05	NS
	Yes	3 15%	2 10%			
PROM	No	12 60%	14 70%	0.34	> 0.05	NS
	Yes	8 40%	6 30%			
Prenatal asphyxia	No	18 80%	19 95%	0.53	> 0.05	NS
	Yes	2 20%	1 5%			
Maternal hypertension or Preeclampsia	No	15 75%	17 85%	0.53	> 0.05	NS
	Yes	5 25%	3 15%			

PROM*: premature rupture of membrane*

This table shows no statistically significant difference between the two groups regarding risk factors for prematurity as "maternal diabetes, prenatal asphyxia, premature rupture of membranes, and pre-eclampsia".

Table (5): Comparison between group I (Indomethacin) and group II (Ibuprofen) as regards respiratory distress syndrome, respiratory aids and any medical problems.

		Group I N=20 No %	Group II N=20 No %	z	P-value	Significance
Respiratory distress syndrome	No	2 10%	3 15%	0.05	> 0.05	NS
	Yes	18 90%	17 85%			
Oxygen only	No	2 10%	1 5%	0.04	> 0.05	NS
	Yes	18 90%	19 95%			
NCPAP	No	10 50%	12 60%	0.47	> 0.05	NS
	Yes	10 50%	8 40%			
MV	No	10 50%	14 70%	1.01	> 0.05	NS
	Yes	10 50%	6 30%			
Other medical problems*	No	18 90%	18 90%	-	-	-
	Yes	2 10%	2 10%			

MV: mechanical ventilation, NCPAP: Nasal continuous positive airway pressure.
****Other medical problems: hypoglycemia, sepsis,…etc.***

This table shows no statistically significant differences between the two groups as regards respiratory distress syndrome, intermittent mandatory ventilation, nasal continuous positive airway pressure, oxygen supplementation and other medical problems.

Table (6): Comparison between group I (Indomethacin) and group II (Ibuprofen) as regards duration of respiratory aids in days.

Item	*Group I*	*Group II*	*t*	*P-value*	*significance*
IMV	**3.7±4.6**	**2.4±4.7**	**0.87**	**> 0.05**	**NS**
NCPAP	**1.4±2.2**	**0.85±1.2**	**0.98**	**> 0.05**	**NS**
Oxygen*	**1.65±2.1**	**1.05±1.4**	**1.06**	**> 0.05**	**NS**

**** Total duration of oxygen treatment***

This table shows no statistically significant differences between group I and group II as regards duration of respiratory aids**.**

Although there was no significant difference regarding MV in both groups, the first group received MV for longer duration 3.7±4.6 versus 2.4±4.7 in the 2nd group. Also the first group received NCPAP for longer duration 1.4±2.2 versus 0.85±1.2 in the 2nd group.

Table (7): Comparison between group I (Indomethacin) and group II (Ibuprofen) as regards clinical presentation of PDA and degree of shunting according to ECHO.

		Group I N=20 No %	Group II N=20 No %	z	P-value	significance
Murmur " Systolic or Continuous"	**Yes**	**20 100%**	**20 100%**	**-**	**-**	**-**
Tachycardia	**No**	**8 40%**	**9 45%**	**0.102**	**> 0.05**	**NS**
	Yes	**12 60%**	**11 55%**			
Hyperdynamic Precordium	**No**	**3 15%**	**2 10%**	**0.18**	**> 0.05**	**NS**
	Yes	**17 85%**	**18 90%**			
Cardiomegaly	**No**	**16 80%**	**17 85%**	**0.45**	**> 0.05**	**NS**
	Yes	**4 20%**	**3 15%**			
Degree of ductal shunt	**Mild**	**6 30%**	**5 25%**	**0.3**	**> 0.05**	**NS**
	Moderate	**13 65%**	**15 75%**	**0.38**	**> 0.05**	
	severe	**1 5%**	**0 0%**	**1.01**	**> 0.05**	
Pulmonary hypertension	**No**	**11 55%**	**15 75%**	**1.07**	**> 0.05**	**NS**
	Yes	**9 45%**	**5 25%**			
Desaturation or increase ventilatory support.	**No**	**5 25%**	**4 20%**	**0.28**	**> 0.05**	**NS**
	Yes	**15 75%**	**16 80%**			**NS**

This table shows no statistically significant differences between the two groups as regards systolic murmur, hyperdynamic precordium, tachycardia, cardiomegaly degree of ductal shunt and pulmonary hypertension. Ductal shunting could be suspected in small preterm infant with respiratory distress when there is deterioration of respiratory functions and /or increase ventilatory setting after day 3or 4 of life.

Table (8): Comparison between the two groups (I,II) as regard some echocardiographic findings

Item	Group 1	Group 2	T	P-value	significance
PDA size (cm)	**1.55±0.7**	**1.43±0.3**	**0.65**	**> 0.05**	**NS**
LA-AO ratio	**1.17±0.2**	**1.2±0.2**	**0.55**	**> 0.05**	**NS**
Pressure gradient (mm Hg)	**11.13±4.2**	**12.76±6.52**	**0.6**	**> 0.05**	**NS**

PDA: *patent ductus arteriosus,* ***LA-AO:*** *left atrium to aortic root*

This table shows no statistically significant difference between the two groups as regards patent ductus arteriosus size and left atrium to aortic root ratio.

NB. LA/AO ratio used as indicator for severity and degree of shunting as it detects the size of the left atrium which increases according to the severity of the shunting.

Pressure gradient across the ductus also is an indicator for size of the ductus as it increases with closure of the ductus and vice versa.

Table (9): Comparison between the two subgroups during 2-7 days of life of groups (I&II) as regards effect of treatment on the of PDA size.

Item		Before treatement	After treatment	z	P-value	Significance
GI a "Indomethacin" "2-7 days"	**Closed**	**0 0%**	**8 80%**	**3.65**	**<0.001**	**HS**
	open	**10 100%**	**2 20%**	**2.3**	**< 0.05**	**S**
GII a "Ibuprofen" "2-7 days"	**Closed**	**0 0%**	**8 80%**	**3.28**	**<0.001**	**HS**
	Open	**10 100%**	**2 20%**	**1.94**	**< 0.05**	**S**

This table shows high statistically significant difference between both subgroups (a) of both main groups before and after treatment, meaning that the Ibuprofen has the same efficacy of IV indomethacin during first 2-7 days of life.

NB. closed ductus means completely closure or restrictive ductus which can be detected as following:

Clinically: through improvement of symptoms and signs of PDA as "disappearance or decrease of tachypnea, tachycardia, pericardial pulsation and decrease ventilatory setting"

ECHO:

- Increase pressure gradient through the ductus.
- Appearance of systolic flow inspite of continous flow through the ductus.
- Decrease diameter of both ampullary and pulmonary ends of the ductus.
- Decrease left side diameter" left atrium and left ventricle".
- Decrease degree of mitral regurge murmur if it is present.

Table (10):Comparison between the two subgroups during 8-35 days of life of groups (I&II) as regards size of PDA before and after treatment.

Item		Before treatment	After treatment	z	P-value	Significance
GI b "Indomethacin" "8-35 days"	Closed	0 0%	7 70%	3.65	<0.001	HS
	open	10 100%	3 30%	2.3	< 0.05	S
GII b "Ibuprofen" "8-35 days"	Closed	0 0%	2 20%	1.49	> 0.05	NS
	Open	10 100%	8 80%	0.47	> 0.05	NS

This table shows high statistically significant in G I b before and after treatment, meaning that the Indomethacin retain its efficacy after 7 days of birth. While G II b shows no significant difference before and after treatment, meaning that the Ibuprofen has limited efficacy after 7 days of birth.

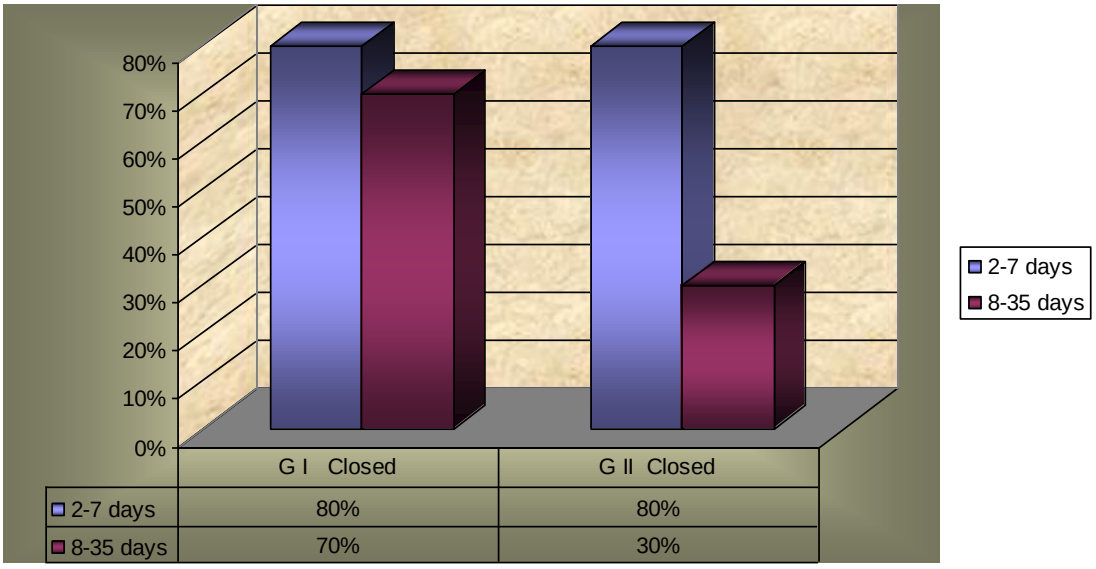

Figure (38): Effect of the treatment on closure of PDA during 2-7 days and 8-35 days.

Table (11): Comparison between urine output & laboratory values before treatment in group I (Indomethacin) and group II (Ibuprofen).

Item	Group I	Group II	t	P-value	significance
Urine output (cc/kg/hr)	**2.26±.696**	**2.120±.518**	**0.722**	**> 0.05**	**NS**
Hgb	**13.8±2.1**	**14.6±1.8**	**0.66**	**> 0.05**	**NS**
RBCs ($\times10^6/mm^3$)	**4.41±0.6**	**4.28±0.7**	**0.63**	**> 0.05**	**NS**
HCT	**44.3±8.2**	**42.2±6.1**	**0.92**	**> 0.05**	**NS**
Total leucocytic count ($\times10^3/mm^3$)	**7.93±3.032**	**8.17±4.795**	**0.185**	**> 0.05**	**NS**
Platelet count($\times10^3/mm^3$)	**194.3±32.092**	**172.3±55.816**	**1.147**	**> 0.05**	**NS**
Creatinine level (mg/dl)	**0.580±.176**	**0.472±.179**	**1.913**	**> 0.05**	**NS**
BUN (mg/dl)	**16.75±2.099**	**15.80±2. 567**	**1.281**	**> 0.05**	**NS**
Prothrombin time (sec)	**13.27±1.662**	**13.22±1.951**	**0.087**	**> 0.05**	**NS**
Partial thromboplastin time (sec)	**40.98±3.071**	**39.15±7.191**	**1.047**	**> 0.05**	**NS**
CRP	**2.4±4**	**4.2±7.8**	**0.91**	**> 0.05**	**NS**

BUN: *blood urea nitrogen* ***Hgb****: Haemoglobin* ***HCT****: Haematocrite*

This table shows no statistically significant differences between the two groups before treatment regarding urine output, haemoglobin, RBCs, haematocrite, total leucocytic count, platelet count, blood urea nitrogen, creatinine, prothrombin time , partial thromboplastin time, and CRP.

Table (12): Comparison between urine output & laboratory markers before and after treatment in Indomethacin group.

Item	Before treatment No = 20 Mean±SD	After treatment No = 20 Mean±SD	Paired t	P-value	significance
Urine output (ml /kg/hr)	2.260±0.696	1.400±0.565	7.931	< 0.001	HS
Hgb	13.8±2.1	13.96±2.2	0.2	> 0.05	NS
RBCs ($\times 10^6/mm^3$)	4.41±0.6	4.19±0.6	0.77	> 0.05	NS
HCT	44.3±8.2	40.9±7.9	1.12	> 0.05	NS
Total leucocytic count ($\times 10^3/mm^3$)	19.6±12.1	20.47±10.4	0.21	> 0.05	NS
Platelet count ($\times 10^3/mm^3$)	194.30±32.092	125.45±19.972	2.95	< 0.05	S
Creatinine level (mg/dl)	0.58±0.176	0.945±0.463	3.974	< 0.001	HS
BUN (mg /dl)	16.75±2.099	20.35±2.943	6.55	< 0.001	HS
Prothrombin time (sec)	13.27±1.662	15.44±2.383	1.85	> 0.05	NS
Partial thromboplastin time (sec)	40.98±3.071	45.98±3.071	1.65	> 0.05	NS
CRP	2.4±4	6.9±10.9	0.98	> 0.05	NS

BUN: Blood urea nitrogen

NB, after treatment means that results were obtained at 0-24 hours after administration of last dose.

This table shows no statistically significant differences in Indomethacin group after treatment regarding haemoglobin, RBCs, haematocrite, total leucocytic count, , PT, PTT and CRP " although there's no significant difference in CRP but it changed from negative "< 6" to the positive " > 6".

But there's significant difference in platelet count and urine output synchronized with increase in serum creatinine level and blood urea nitrogen.

Table (13): Comparison between urine output & laboratory values before and after treatment in Ibuprofen group.

Item	Before treatment No = 20 Mean±SD	After treatment No = 20 Mean±SD	Paired t	P-value	significance
Urine output (ml/kg/hr)	**2.120±0.517**	**1.915±0.563**	**2.04**	**> 0.05**	**NS**
Hgb	**14.6±1.8**	**13.7±1.9**	**0.9**	**> 0.05**	**NS**
RBCs ($\times10^6/mm^3$)	**4.28±0.7**	**4.37±0.6**	**0.32**	**> 0.05**	**NS**
HCT	**42.2±6.1**	**44.1±7.8**	**0.48**	**> 0.05**	**NS**
Total leucocytic count($\times10^3/mm^3$)	**16.6±7.6**	**18.24±10.4**	**0.42**	**> 0.05**	**NS**
Platelet count($\times10^3/mm^3$)	**172.3±55.816**	**168.1±39.754**	**1.122**	**> 0.05**	**NS**
Creatinine level (mg/dl)	**0.57±0.1**	**0.64±0.2**	**0.68**	**> 0.05**	**NS**
BUN (mg/dl)	**15.83±2.567**	**17.35±3.249**	**0.95**	**> 0.05**	**NS**
Prothrombin time (sec)	**13.22±1.951**	**14.43±2.843**	**1.01**	**> 0.05**	**NS**
Partial thromboplastin time (sec)	**39.15±7.191**	**40.98±3.071**	**0.92**	**> 0.05**	**NS**
CRP	**4.2±7.8**	**2.7±5.99**	**0.39**	**> 0.05**	**NS**

BUN: *Blood urea nitrogen*

This table shows no statistically significant differences in Ibuprofen group after treatment regarding urine output, haemoglobin, RBCs, haematocrite, total leucocytic count, platelet count, blood urea nitrogen, creatinine, prothrombin time , partial thromboplastin time, and CRP.

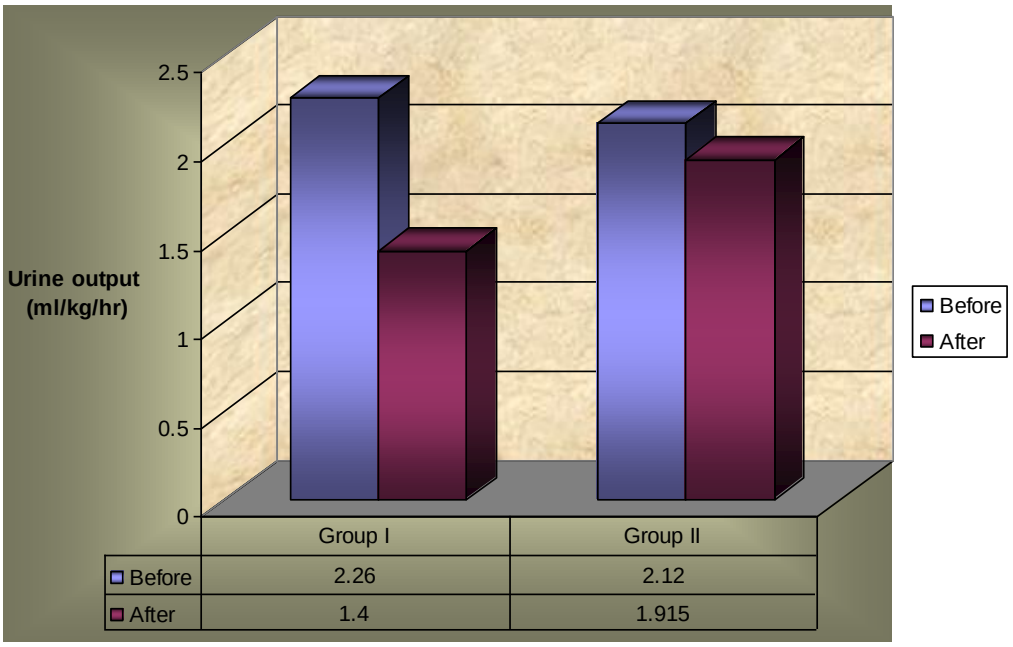

Figure (39): Urine output before and after treatment in both Indomethacin and Ibuprofen group

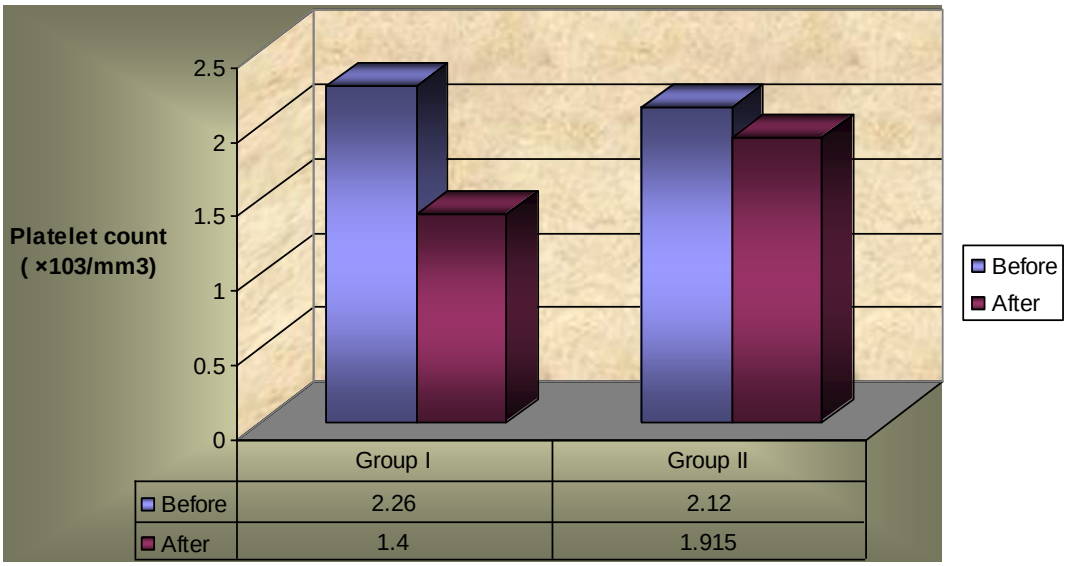

Figure (40): Platelet count before and after treatment in both iIndomethacin and Ibuprofen group

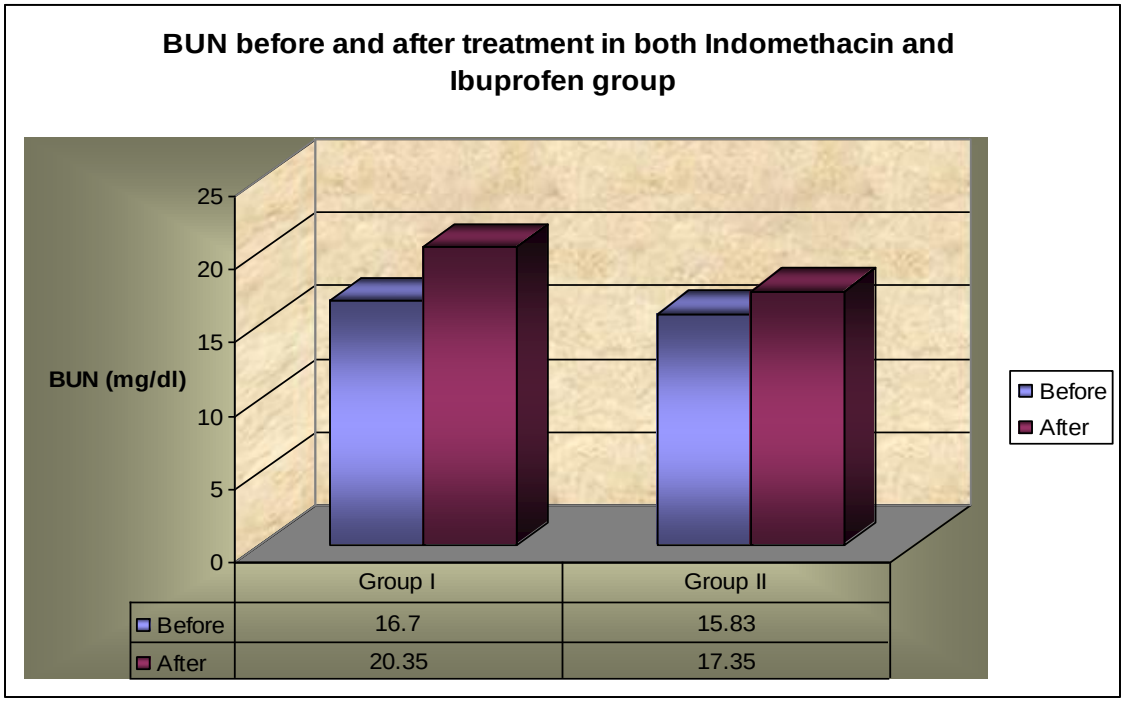

Figure (41) : BUN before and after treatment in both Indomethacin and Ibuprofen group.

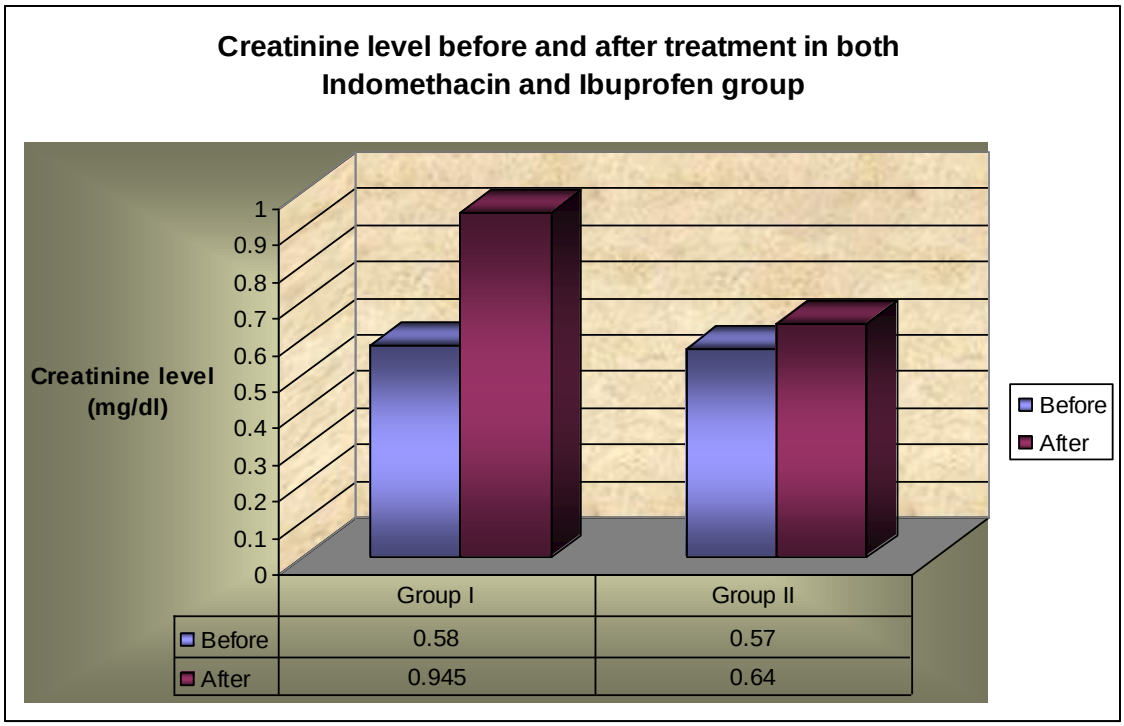

Figure (42) : Creatinine level before and after treatment in both Indomethacin and Ibuprofen group

Table (14): Comparison between group I (Indomethacin) and group II (Ibuprofen) after treatment

Item	Group I No = 20 Mean±SD	Group II No = 20 Mean±SD	t	P-value	significance
Urine output (ml/kg/hr)	1.40±.566	1.915±.563	2.885	< 0.01	HS
Hgb	13.96±2.2	13.7±1.9	0.31	> 0.05	NS
RBCs ($\times 10^6/mm^3$)	4.19±0.6	4.37±0.6	0.95	> 0.05	NS
HCT	40.9±7.9	44.1±7.8	1.29	> 0.05	NS
Total leucocytic count ($\times 10^3/mm^3$)	20.47±10.4	18.24±10.4	1.01	> 0.05	NS
Platelet count ($\times 10^3/mm^3$)	125.45±19.972	168.1±39.754	2.9	< 0.05	S
Creatinine level (mg/dl)	0.945±.463	0.64±0.2	2.96	< 0.05	S
BUN (mg/dl)	20.35±2.943	17.35±3.249	3.01	< 0.05	S
Prothrombin time (sec)	15.43±2.383	14.43±2.843	0.004	> 0.05	NS
Partial thromboplastin time (sec)	45.98±3.071	40.98±3.071	0.38	> 0.05	NS
CRP	6.9±10.9	2.7±5.99	1.03	> 0.05	NS

BUN: *blood urea nitrogen*

This table shows no statistically significant differences between the two groups after treatment regarding haemoglobin, RBCs, haematocrite, total leucocytic count, prothrombin time and partial thromboplastin time, and CRP.

But there's high significant difference in urine output with significant difference in creatinine level and blood urea nitrogen.

Also there's significant difference in platelet count which decreases in Indomethacin group more than Ibuprofen group.

Table (15): Comparison between group I (Indomethacin) and group II (Ibuprofen) regarding early complications (within 7 days)

		Group I N=20 No %	Group II N=20 No %	z	P-value	significance
Necrotizing enterocolitis	No	18 90%	20 100%	1.13	> 0.05	NS
	Yes	2 10%	0 0%			
GIT bleeding	No	17 85%	19 95%	1.9	< 0.05	S
	Yes	3 15%	1 5%			
Bowel perforation	No	18 90%	20 100%	1.01	> 0.05	NS
	Yes	2 10 %	0 0 %			
Intracranial Hemorrhage	No	18 90%	20 100%	2.11	< 0.05	S
	Yes	2 10%	0 0 %			
*Oliguria	No	16 80%	19 95%	1.89	< 0.05	S
	Yes	4 20%	1 5%			

GIT: gastrointestinal tract ***Oliguria: urine output <1 cc/kg/hr**

This table shows statistically significant increased frequency of gastrointestinal bleeding, intracranial hemorrhage and oliguria in group I when compared to group II.

Other early complications show no statistically significant difference between the two groups.

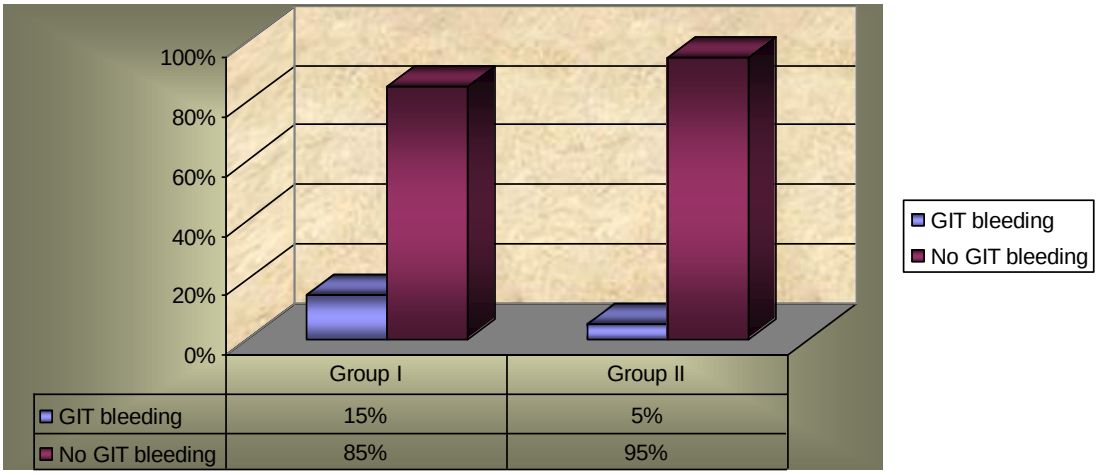

Figure (43) : GIT bleeding after treatment in both groups

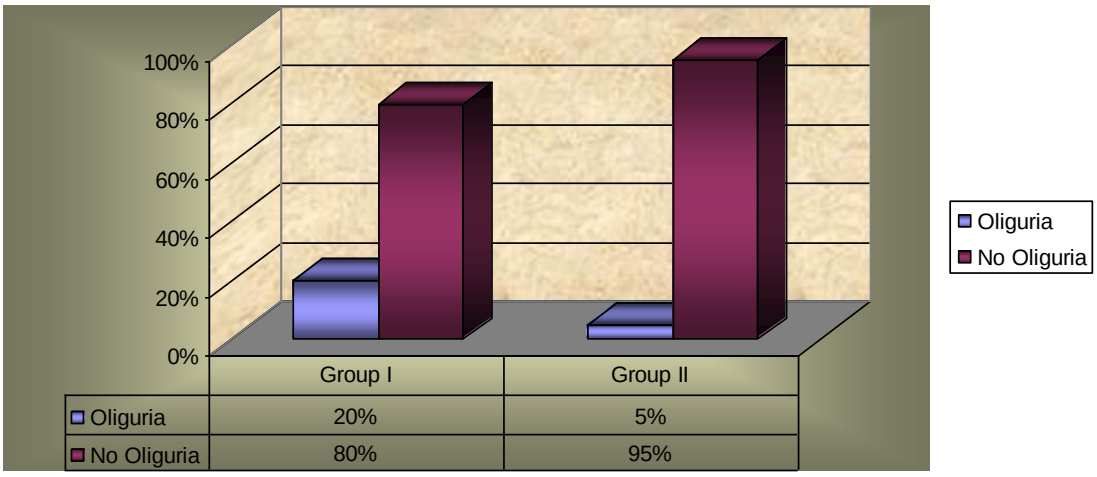

Figure (44) : Oliguria after treatment in both groups.

Table (16): Comparison between the two groups regarding late complications (from the 8th day to 2 months).

		Group I N=20 No %	Group II N=20 No %	X^2	P-value	significance
Bronchopulmonary dysplasia	No	16 0%	16 80%	0.00	> 0.05	NS
	Yes	4 20%	4 20%			
Mortality	live	14 70%	15 75%	0.102	> 0.05	NS
	dead	6 30%	5 25%			

This table shows non-significant statistical difference between the two groups as regards late outcome (8 days to 60 days) as bronchopulmonary dysplasia and the mortality rate.

Causes of death in group (1):

- 3 patients died due to complications of neonatal sepsis.
- 1 patient died due to pneumothorax as a complication of mechanical ventilation.
- 1 patient died due to hypoxic ischemic encephalopathy and intraventricular hemorrhage grade IV.
- 1 patient died due to heart failure.

Causes of death in group (II):

- 3 patients died due to complications of neonatal sepsis.
- 1 patient died due to pneumothorax as a complication of mechanical ventilation.
- 1 patient died due pulmonary hemorrhage.

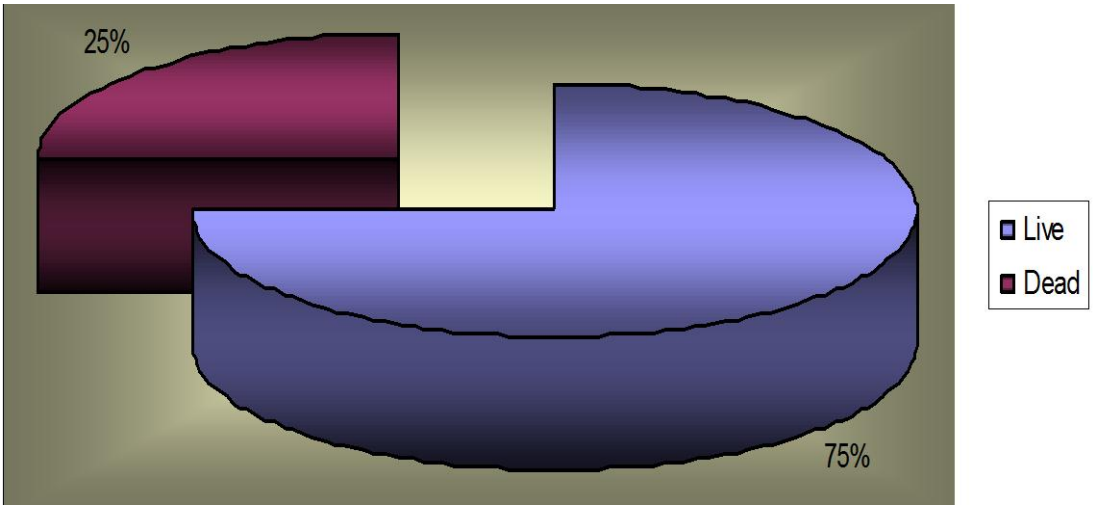

Figure (45): Mortality among Ibuprofen group

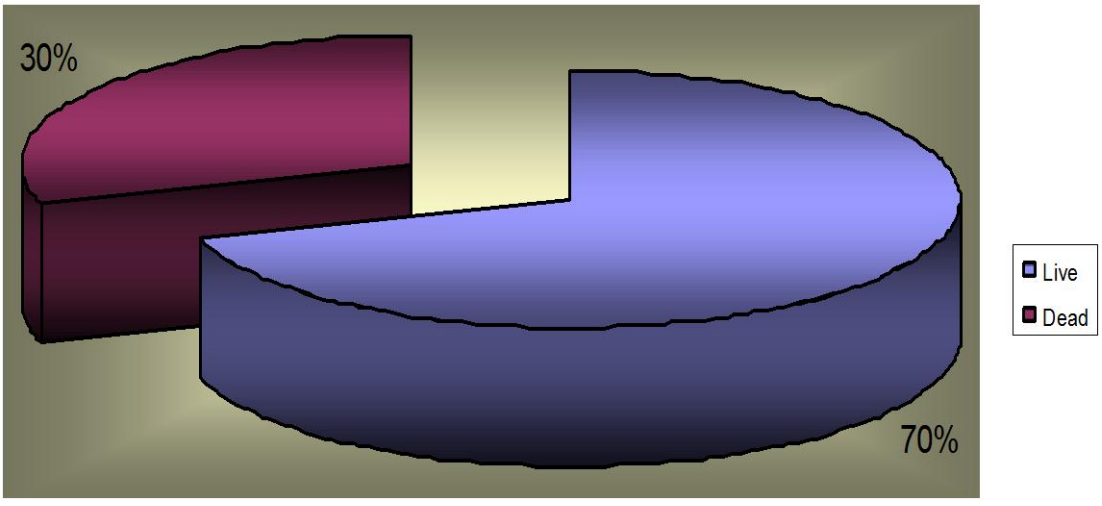

Figure (46): Mortality among Indomethacin group