RESULTS

One hundred and fifteen couples were enrolled in this clinical study. Sixty cases in group 1(IUI only) and fifty five in group 2 (lidocaine+IUI). The demographic variation in the clinical data, type of infertility, hormonal variation and ultrasonic criteria were evaluated between both groups, between pregnant and non-pregnant cases and finally between pregnant cases in both groups.

Table 5: Clinical data in group 1 (IUI only) and group 2 (lidocaine+IUI):

Study cases	Group 1 n=60 $\bar{x}$±SD	Group 2 n=55 $\bar{x}$±SD	t	p
Age	25.5±4	25.9±3	0.61	>0.05
weight	78.3±9.8	74.8±10.1	1.88	>0.05
height	1.68±0.09	1.65±0.09	1.78	>0.05
BMI	27.6±2.5	27.7±3.1	0.19	>0.05
Duration of infertility	3±1.7	3.2±1.4	0.69	>0.05

As demonstrated, the variation in age, weight, height, BMI and duration of infertility between both groups were non-significant.

Table 6: Comparing the type of infertility& previous trials in group 1 (IUI only) and group 2 (lidocaine+IUI):

Study group	Group 1 n=60 n.	%	Group 2 n=55 n.	%	z	p
Type of infertility:						
a-primary	51	85%	41	74.5%	0.63	>0.05
b-secondary	9	15%	14	25.5%	1.25	>0.05
Previous trials:						
a-IUI	4	6.7%	10	18.2%	1.77	<0.05
b-ICSI	1	1.7%	1	1.8%	0.06	>0.05

As shown, there is a statistically significant increase ($p < 0.05$) in the numbers of couples with previous IUI trials in group 2 than group 1.

Figure 7: showing the type of infertility in group 1 (IUI only):

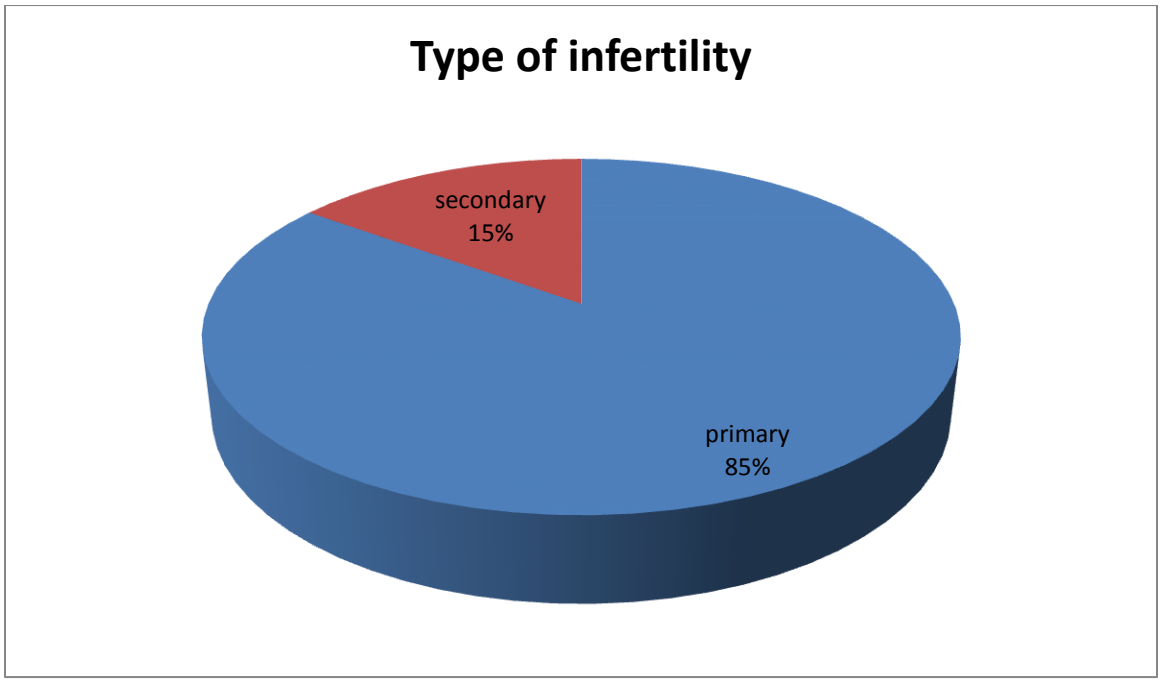
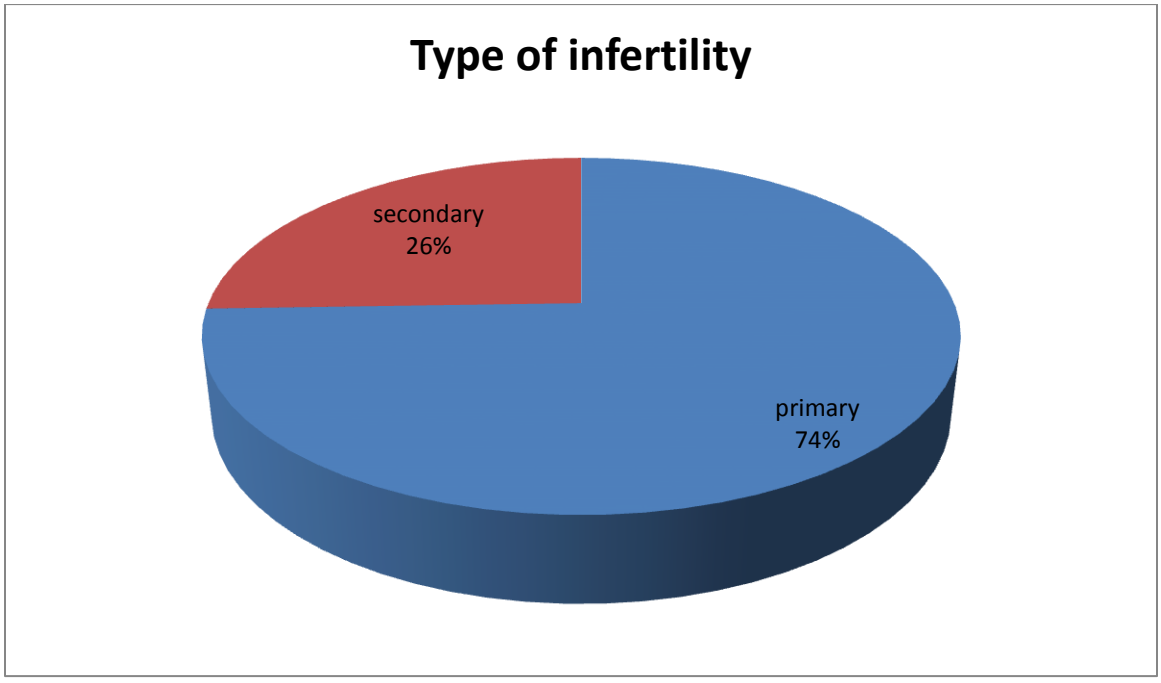
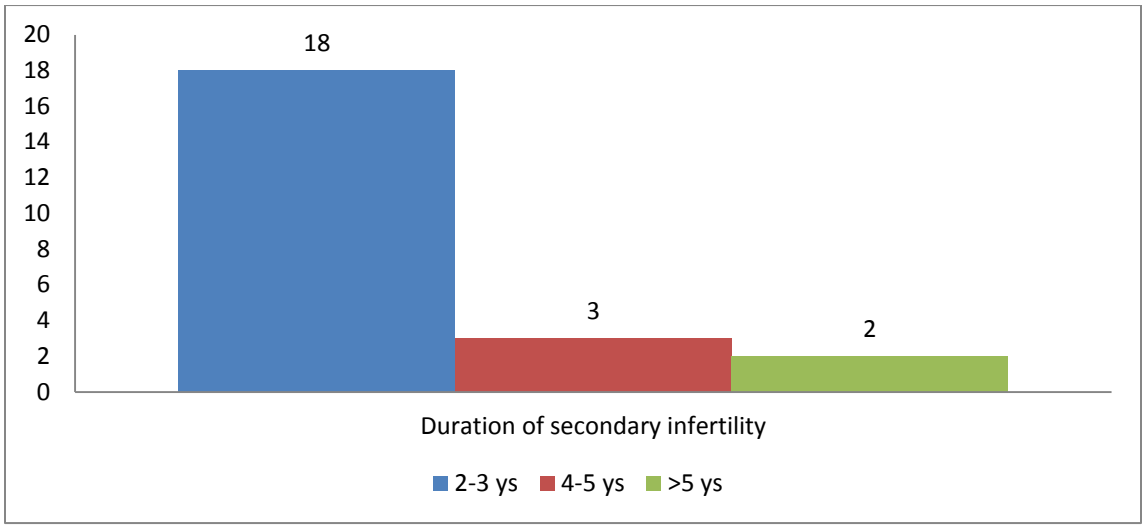


Figure 8: showing the type of infertility in group 2 (lidocaine+IUI):



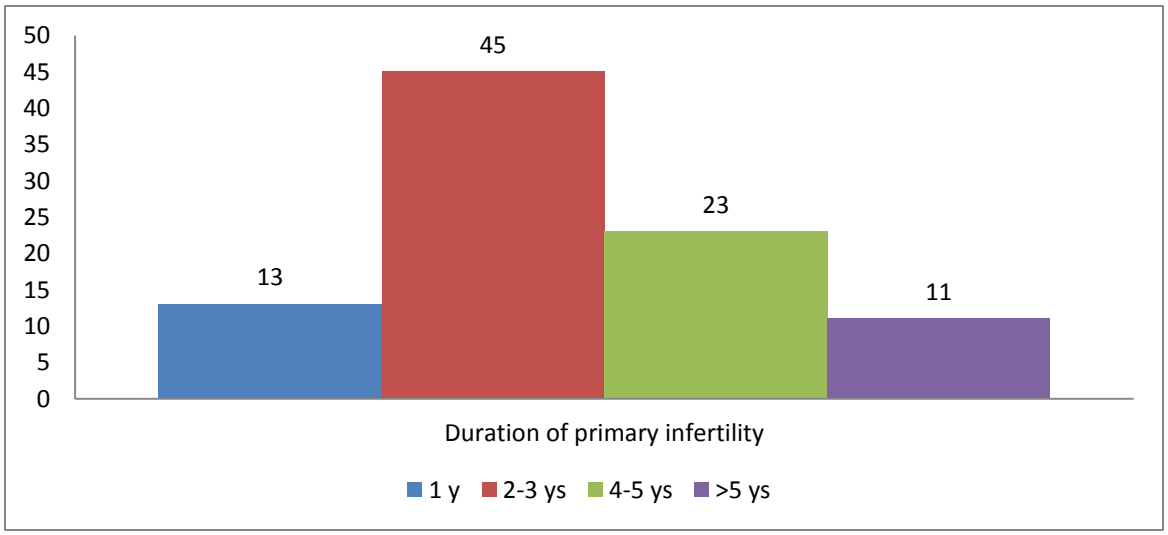
Primary infertility represented 85% of the cases in group 1 (IUI only) compared to 74% in group 2 (lidocaine+IUI) (Fig. 7&8).

Figure 9: Duration of secondary infertility cases:



As shown, the duration of infertility in cases of secondary infertility were 2-3 years in 18 cases, 4-5 years in 3 cases and more than 5 in 2 cases with no cases less than 2 years or more than 6 years.

Figure 10: Duration of primary infertility cases:



As shown, the duration of infertility in cases of primary infertility were 1 year in 13 cases, 2-3 years in 45 cases, 4-5 years in 23 cases and more than 5 in 11 cases with no cases more than 8 years.

Table 7: Hormonal profile in group 1 (IUI only) and group 2 (lidocaine+IUI):

Study cases	Group 1 n=60 $\bar{x}$±SD	Group 2 n=55 $\bar{x}$±SD	t	p
FSH	5.7±1.3	5.5±1.3	0.82	>0.05
LH	6.9±2.6	7.2±2.5	0.63	>0.05
Prolactin	18.3±2.8	17.4±4.1	1.36	>0.05

There were no significant differences in the hormonal profile in both study groups.

Table 8: Sperm count and motility (a+b) of the husbands in group 1 (IUI only) and group 2 (lidocaine+IUI):

Study cases	Group 1 n=60 $\bar{x}$±SD	Group 2 n=55 $\bar{x}$±SD	t	p
count	54.6±20.1	53.6±21.1	0.25	>0.05
Motility(a+b)	53.2±10.2	52.1±8.7	0.62	>0.05

As shown, there were no significant differences in the count or the motility (a+ b) in both groups.

Table 9: Ultrasonic parameters of the ovaries in group 1 (IUI only) and group 2 (lidocaine+IUI):

Study cases	Group 1 n=60 $\bar{x}$±SD	Group 2 n=55 $\bar{x}$±SD	t	p
No. of follicles	1.9±0.9	2.02±0.9	0.54	>0.05
Size of follicles	19.5±1.4	19.9±1.9	1.28	>0.05
Endometrial Thickness	6.2±1.4	6.5±1.5	1.11	>0.05

As demonstrated, no significant differences in the number of follicles, size of the follicles or the endometrial thickness.

Data from group 1 (IUI only)

Data from the pregnant and non-pregnant cases in group 1 (IUI only) were compared:

Table 10: Comparison of some clinical data in the pregnant and non-pregnant cases in group 1(IUI only):

Group 1 cases	+ve cases n=6 $\bar{x}$±SD	-ve cases n=54 $\bar{x}$±SD	t	p
Age	25.2±4.7	25.5±3.9	0.15	>0.05
weight	70.3±12.9	79.2±9.8	1.64	>0.05
height	1.67±0.1	1.68±0.1	0.12	>0.05
BMI	24.9±4	27.9±2.4	1.8	>0.05
Duration of infertility	2.2±1.7	3.1±1.7	1.23	>0.05

As shown, there were no significant differences in age, height, BMI and duration of infertility between pregnant and non-pregnant cases.

Table 11: Comparison of type of infertility and previous trials in the pregnant and non-pregnant cases in in group 1(IUI only):

Group 1	+ve cases n=6		-ve cases n=54		z	p
	n.	%	n.	%		
Type of infertility:						
a-primary	4	66.7%	47	87.1%	0.51	>0.05
b-secondary	2	33.3%	7	12.9%	1.22	>0.05

This table shows no significant difference between both pregnant and non-pregnant cases in group1 regarding type of infertility. As for previous trials, there were 4 cases of previous IUI and 1 case of previous ICSI trial in non-pregnant but no previous trials in pregnant cases.

Table 12: Hormonal profile in group 1(IUI only) according to pregnancy outcome:

Group 1	+ve cases $\bar{x}$±SD	-ve cases $\bar{x}$±SD	t	p
FSH	6.3±1.4	5.7±1.3	1.01	>0.05
LH	6.1±2.6	7.1±2.6	0.89	>0.05
Prolactin	18.4±3.6	18.3±2.9	0.07	>0.05

As shown in, there was no significant difference in FSH, LH & prolactin in either pregnant or non-pregnant cases.

Table 13: Sperm count and motility (a+b) of the husbands in group 1(IUI only) according to pregnancy outcome:

Group 1	+ve cases $\bar{x}$±SD	-ve cases $\bar{x}$±SD	t	p
count	70.0±20.2	52.9±20.1	1.97	>0.05
Motility(a+b)	49.2±11.3	53.7±9.9	0.94	>0.05

This table shows that there was no significant difference in sperm count & motility (a+b) in both pregnant and non-pregnant cases.

Table 14: Ultrasonic parameters of the ovaries among group 1(IUI only) according to pregnancy outcome:

Group 1	+ve cases $\bar{x}$±SD	-ve cases $\bar{x}$±SD	t	p
No. of follicles	2.3±0.7	1.9±0.9	1.29	>0.05
Size of follicles	18.9±2.6	19.6±1.4	0.65	>0.05
Endometrial Thickness	7±1.5	6.1±1.4	1.4	>0.05

This table shows that although there is a relative increase in both the no. of follicles and endometrial thickness in pregnant compared to non-pregnant cases, but this increase is non-significant.

Data from group 2 (lidocaine+IUI)

Table 15: Clinical data of group 2 (lidocaine+IUI) according to pregnancy outcome:

Group 2	+ve cases n=8 $\bar{x}$±SD	-ve cases n=47 $\bar{x}$±SD	t	p
Age	25.8±2.1	25.9±3.2	0.11	>0.05
weight	61.1±10.3	73.6±9.0	3.23	<0.01
height	1.59±0.1	1.64±0.1	1.31	>0.05
BMI	23.9±2.1	27.3±2.6	4.08	<0.01
Duration of infertility	3.4±1.5	3.1±1.4	0.53	>0.05

As shown above, the pregnant cases had highly significant lower body weight and BMI than non-pregnant cases.

Table 16: Type of infertility and previous trials of IUI or ICSI of group 2 (lidocaine+IUI) according to pregnancy outcome:

Group 2	+ve cases n=8 n.	%	-ve cases n=47 n.	%	z	p
Type of infertility:						
a-primary	6	75%	35	74.5%	0.02	>0.05
b-secondary	2	25%	12	25.5%	0.03	>0.05
Previous trials:						
a-IUI	0	0%	10	21.3%	-	-
b-ICSI	0	0%	1	2.1%	-	-

There were no significant differences in the type of infertility between both pregnant and non-pregnant cases.

Table 17: Hormonal profile of group 2 (lidocaine+IUI) according to pregnancy outcome:

Group 2	+ve cases $\bar{x}$±SD	-ve cases $\bar{x}$±SD	t	p
FSH	5.1±1.1	5.7±1.3	1.16	>0.05
LH	5.2±1.6	7.6±2.5	3.57	<0.01
Prolactin	18.2±1.5	17.2±4.4	1.2	>0.05

This table shows highly significant lower LH levels in pregnant cases than non-pregnant cases.

Table 18: Sperm count and motility (a+b) of the husbands in group 2 (lidocaine+IUI) according to pregnancy outcome:

Group 2	+ve cases $\bar{x}$±SD	-ve cases $\bar{x}$±SD	t	p
count	78.1±23.3	49.5±17.8	3.31	<0.01
Motility(a+b)	53.8±10.3	51.8±8.5	0.52	>0.05

This table shows a highly significant increase in pregnant than non-pregnant cases in sperm count/ml and a slight non-significant increase in the motility grades (a+b).

Table 19: Ultrasonic parameters of the ovaries among group 2 (lidocaine+IUI) according to pregnancy outcome:

Group 2	+ve cases $\bar{x}$±SD	-ve cases $\bar{x}$±SD	t	p
No. of follicles	2.8±0.9	1.9±0.9	2.62	<0.05
Size of follicles	18.7±0.9	20.1±2.1	3.17	<0.01
Endometrial Thickness	7.1±1.1	6.3±1.5	1.79	>0.05

This table shows a significant increase in the no. of follicles, a highly significant less follicular size and a non-significant higher increase in endometrial thickness in pregnant cases.

Analysis of the pregnant cases

Table 20: Pregnancy rate in group 1 (IUI only) and group 2 (lidocaine+IUI):

Pregnancy rate	No.	%	z	p
Group 1 n=60	6	10.0	0.7	>0.05
Group 2 n=55	8	14.5		

There is an apparent increase in pregnancy rate in group 2 (lidocaine+IUI) (14.5%) compared to group 1 (IUI only) (10%). However, the difference was not statistically significant.

Table 21: Ongoing pregnancy (OP) and live birth rate (LBR) in group 1 (IUI only) and group 2 (lidocaine+IUI):

Study groups	Group 1 n=60 n.	%	Group 2 n=55 n.	%	z	p
OP:						
YES	5	8.3%	7	12.7%	0.43	>0.05
ABORTION	1	1.7%	0	0%	1.05	>0.05
LBR:						
YES	4	6.7%	6	10.9%	0.5	>0.05

There was a persistent increase in group 2 (lidocaine+IUI) regarding ongoing pregnancy (12.7% Vs 8.3%) and birth rate (10.9% Vs 6.7%) over group 1 (IUI only). However, the difference was not statistically significant. There was one case in group 1, known to have had an ongoing pregnancy but was missed after that and not known if she gave LBR or not. There was one case in group 2, proved to have clinical pregnancy by u/s (gestational sac is seen with fetal echo at 6wks), but after that the case was missed. Also one case in group 2 is still pregnant.

Table 22: Clinical data of pregnant cases in group 1 (IUI only) and group 2 (lidocaine+IUI):

Pregnant cases	Group 1 n=6 $\bar{x}$±SD	Group 2 n=8 $\bar{x}$±SD	t	p
Age	25.2±4.7	25.8±2.1	0.29	>0.05
weight	70.3±12.9	61.1±10.3	1.44	>0.05
height	1.67±0.1	1.59±0.1	0.9	>0.05
BMI	24.9±4	23.9±2.1	0.56	>0.05
Duration of infertility	2.2±1.7	3.4±1.5	1.37	>0.05

There were no statistically significant differences between pregnant cases in both groups.

Table 23: Hormonal profile of the pregnant cases in group 1 (IUI only) and group 2 (lidocaine+IUI):

pregnant cases	Group 1 $\bar{x}$±SD	Group 2 $\bar{x}$±SD	t	p
FSH	6.3±1.4	5.1±1.1	0.75	>0.05
LH	6.1±2.6	5.2±1.6	1.74	>0.05
Prolactin	18.2±1.5	18.2±1.5	0.13	>0.05

This table shows no statistically significant difference in hormonal profile between pregnant cases in both groups.

Table 24: Sperm count and motility (a+b) of the husbands in the pregnant cases in group 1 (IUI only) and group 2 (lidocaine+IUI):

pregnant cases	Group 1 $\bar{x}$±SD	Group 2 $\bar{x}$±SD	t	p
count	70±20.2	78.1±23.3	0.69	>0.05
Motility(a+b)	49.2±11.3	53.8±10.3	0.78	>0.05

This table shows no statistically significant difference in semen characters in both groups.

Table 25: Ultrasonic parameters of the ovaries among pregnant cases in group 1 (IUI only) and group 2 (lidocaine+IUI):

pregnant cases	Group 1 $\bar{x}$±SD	Group 2 $\bar{x}$±SD	t	p
No. of follicles	2.3±0.7	2.8±0.9	1.17	>0.05
Size of follicles	18.9±2.6	18.7±0.9	0.18	>0.05
Endometrial Thickness	7±1.5	7.1±1.1	0.138	>0.05

This table shows no statistically significant difference between pregnant cases in both study groups.