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Evaluation of Using Dienogest and N-Acetyl Cysteine on the Volume of Uterine Leiomyoma

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Table 1: Comparison between two groups regarding demographic data of patients:

		Group A (Dienogest) (N=20)			Group B (NAC) (N=20)			t*	P value
		Range	Mean	SD	Range	Mean	SD		
Age		23.00-45.00	40.30	6.48	23.00-45.00	38.20	6.57	1.02	0.32
		N	%		N	%		X^{2**}	P value
Residence	Urban	15	75.0%		14	70.0%		0.13	0.72

	Rural	5	25.0%	6	30.0%		
Occupation	Housewife	19	95.0%	19	95.0%	0.00 FE	1.00
	Working	1	5.0%	1	5.0%		

*Student t test **Chi square test (FE: Fisher Exact)

Both groups have similar age distributions, with no significant difference (p = 0.32).
The distribution of patients based on residence and occupation is also similar between the groups (P value >0.05), indicating well-matched cohorts for demographic factors.

Table 2: Comparison between two groups regarding medical history of patients:

		Group A (Dienogest) (N=20)		Group B (NAC) (N=20)		X^{2*}	P value
		N	%	N	%		
Special habits	No	20	100.0%	20	100.0%	-	-
Past history of gynecologic cancer	No	20	100.0%	20	100.0%	-	-
Past history of pelvic infection	No	20	100.0%	20	100.0%	-	-

Medical history	Negative	20	100.0%	20	100.0%	-	-
Surgical history	Negative	12	60.0%	7	35.0%	2.51	0.11
	Positive	8	40.0%	13	65.0%		

*Chi square test

There are no significant differences between the groups in terms of special habits, history of gynecologic cancer, pelvic infection, or medical history.
A notable but non-significant trend is observed in the surgical history, where Group B has a higher percentage of positive surgical history (65% vs. 40%), though this difference is not statistically significant (p = 0.11).

Table 3: Comparison between two groups regarding Gynecological history of patients:

		Group A (Dienogest) (N=20)		Group B (NAC) (N=20)		X^{2*}	P value
		N	%	N	%		
Regularity of cycle	Regular	12	60.0%	10	50.0%	0.40	0.53
	Irregular	8	40.0%	10	50.0%		
Contraceptive methods	No	8	40.0%	7	35.0%	2.15	0.67

	IUD	10	50.0%	10	50.0%	FE	
	OCP	2	10.0%	1	5.0%		
	Tubal ligation	0	0.0%	2	10.0%		
Previous complications from contraceptive method	No	20	100.0%	20	100.0%	-	-

*Chi square test (FE: Fisher Exact)

Both groups show a similar distribution in terms of cycle regularity and contraceptive methods.
The use of contraceptive methods like IUDs is equally common in both groups (50%), suggesting similar baseline characteristics for contraceptive use.

Table 4: Comparison between two groups regarding obstetric history of patients:

		Group A (Dienogest) (N=20)			Group B (NAC) (N=20)			t*	P value
		Range	Mean	SD	Range	Mean	SD		
Duration since last delivery (years)		3.50-25.00	11.88	5.38	2.50-20.00	9.73	6.09	1.06	0.30
		N	%		N	%		X^{2**}	P value
Gravidity	0	3	15.0%		1	5.0%		8.75	0.47

	1	2	10.0%	3	15.0%	FE	
	2	5	25.0%	3	15.0%		
	3	3	15.0%	6	30.0%		
	4	3	15.0%	2	10.0%		
	5	2	10.0%	1	5.0%		
	6	1	5.0%	0	0.0%		
	7	1	5.0%	0	0.0%		
	8	0	0.0%	3	15.0%		
	9	0	0.0%	1	5.0%		
Gravidity	0	3	15.0%	1	5.0%	1.16 FE	0.73
	1-3	10	50.0%	12	60.0%		
	4 or more	7	35.0%	7	35.0%		
Parity	0	3	15.0%	5	25.0%	5.79 FE	0.47
	1	2	10.0%	2	10.0%		
	2	8	40.0%	3	15.0%		
	3	4	20.0%	5	25.0%		
	4	0	0.0%	2	10.0%		
	5	3	15.0%	2	10.0%		
	7	0	0.0%	1	5.0%		
Parity	0	3	15.0%	5	25.0%	5.79 FE	0.47
	1-3	14	70.0%	10	50.0%		
	4 or more	3	15.0%	5	25.0%		
Abortions	0	13	65.0%	8	40.0%	9.21 FE	0.03
	1	4	20.0%	7	35.0%		
	2	3	15.0%	0	0.0%		
	3	0	0.0%	4	20.0%		
	5	0	0.0%	1	5.0%		
Abortions	No	13	65.0%	8	40.0%	2.51	0.11

	Yes	7	35.0%	12	60.0%		
Living	0	3	15.0%	5	25.0%	5.56 FE	0.56
	1	4	20.0%	2	10.0%		
	2	5	25.0%	3	15.0%		
	3	6	30.0%	5	25.0%		
	4	1	5.0%	4	20.0%		
	5	1	5.0%	0	0.0%		
	7	0	0.0%	1	5.0%		
Living	0	3	15.0%	5	25.0%	2.70 FE	0.29
	1-3	15	75.0%	10	50.0%		
	4 or more	2	10.0%	5	25.0%		
Mode of delivery (years)	NVD	7	41.2%	5	33.3%	0.21	0.65
	CS	10	58.8%	10	66.7%		

*Student t test **Chi square test (FE: Fisher Exact)

The gravidity, parity, and history of abortions are distributed similarly across both groups, with no significant differences noted.
Group A shows a slightly higher mean duration since the last delivery compared to Group B, but this difference is not statistically significant (p = 0.30).

Table 5: Comparison between two groups regarding anthropometric measures of patients:

	Group A (Dienogest) (N=20)			Group B (NAC) (N=20)			t*	P value
	Range	Mean	SD	Range	Mean	SD		
Weight (Kg)	60.00-120.00	78.70	15.04	60.00-95.00	81.20	9.34	0.63	0.53
Height (cm)	158.00-173.00	164.90	4.64	158.00-172.00	166.75	4.46	1.29	0.21
BMI (Kg/m^2)	22.77-46.87	28.98	5.86	24.03-32.11	29.14	2.54	0.11	0.91

*Student t test

There are no significant differences in weight, height, or BMI between the two groups (P value>0.05), indicating that both groups are comparable in terms of anthropometric measures.

Table 6: Comparison between two groups regarding clinical examination of patients:

	Group A (Dienogest) (N=20)			Group B (NAC) (N=20)			t*	P value
	Range	Mean	SD	Range	Mean	SD		
Temperature	37.00-37.00	37.00	0.00	37.00-37.00	37.00	.00	-	-
Pulse	65.00-85.00	76.90	6.04	73.00-88.00	80.65	3.95	2.32	0.03
Systolic BP	90.00-120.00	110.50	9.45	90.00-120.00	106.00	8.83	1.56	0.13

Diastolic BP		60.00-80.00	72.00	8.34	60.00-80.00	67.00	8.65	1.86	0.07
		N	%		N	%		X^{2**}	P value
General appearance	Normal	20	100.0%		20	100.0%		-	-
Pallor	No	19	95.0%		20	100.0%		1.03 FE	1.00
	Yes	1	5.0%		0	0.0%			
Abdominal obstetric examination	Free	20	100.0%		19	95.0%		1.03 FE	1.00
	Distended abdomen	0	0.0%		1	5.0%			
local examination	Free	16	80.0%		11	55.0%		3.69 FE	0.22
	Vaginal bleeding	2	10.0%		7	35.0%			
	Bulky uterus	2	10.0%		2	10.0%			

*Student t test **Chi square test (FE: Fisher Exact)

The only significant difference observed is in the pulse rate, with Group B having a slightly higher mean pulse rate ($p = 0.03$). Other clinical parameters like temperature, systolic, and diastolic blood pressure do not differ significantly between the groups (P value >0.05).

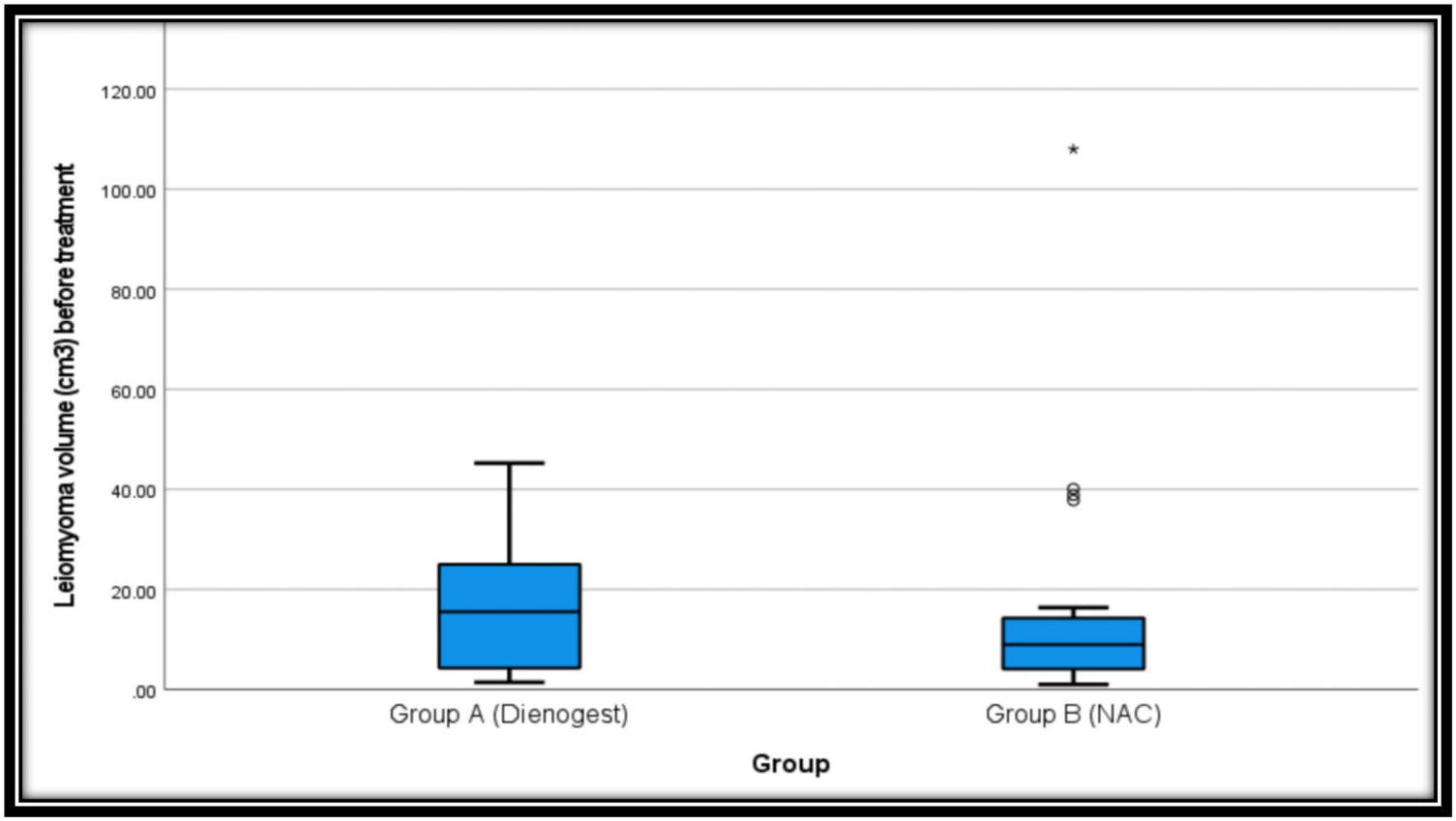
Table 7: Comparison between two groups regarding volume of leiomyoma before and after treatment (largest lesion):

	Group A (Dienogest) (N=20)			Group B (NAC) (N=20)			Z*	P value
	Range	Median	IQR	Range	Median	IQR		
Leiomyoma volume (cm^3) before	1.43-45.24	15.53	4.31-25.01	1.00-108.00	9.00	4.09-14.32	0.52	0.61

Leiomyoma volume (cm^3) after	2.66-76.36	19.54	8.25-32.61	3.24-115.90	13.13	7.74-24.16	0.50	0.63

*Mann Whitney U test

Median leiomyoma volume slightly increases after treatment in both groups, but the differences between the groups are not statistically significant ($p > 0.05$), indicating that both treatments had similar effects on leiomyoma volume.


Leiomyoma volume (cm3) before treatment
120.00
100.00
80.00
60.00
40.00
20.00
.00
Group A (Dienogest)
Group B (NAC)
Group

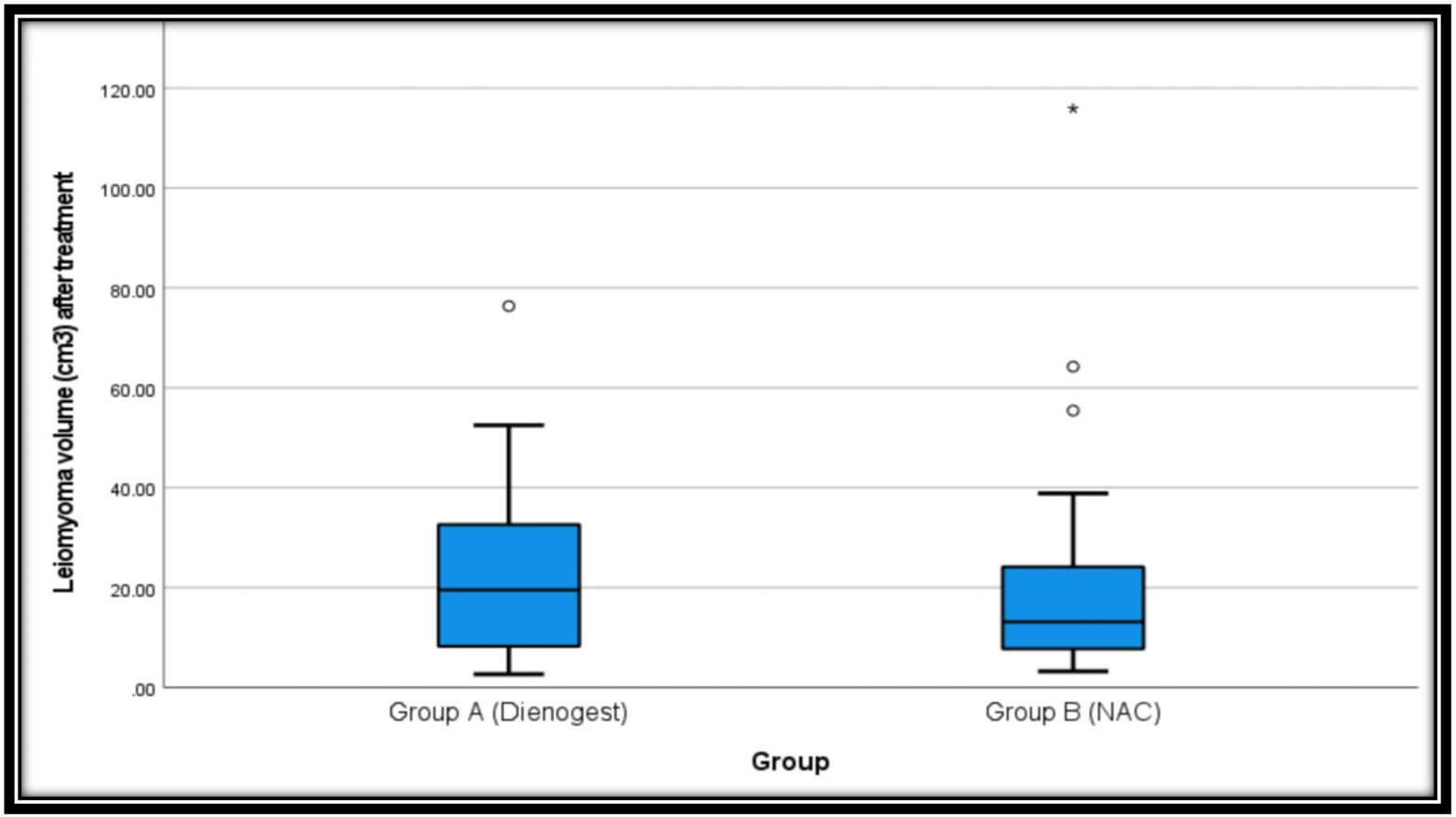
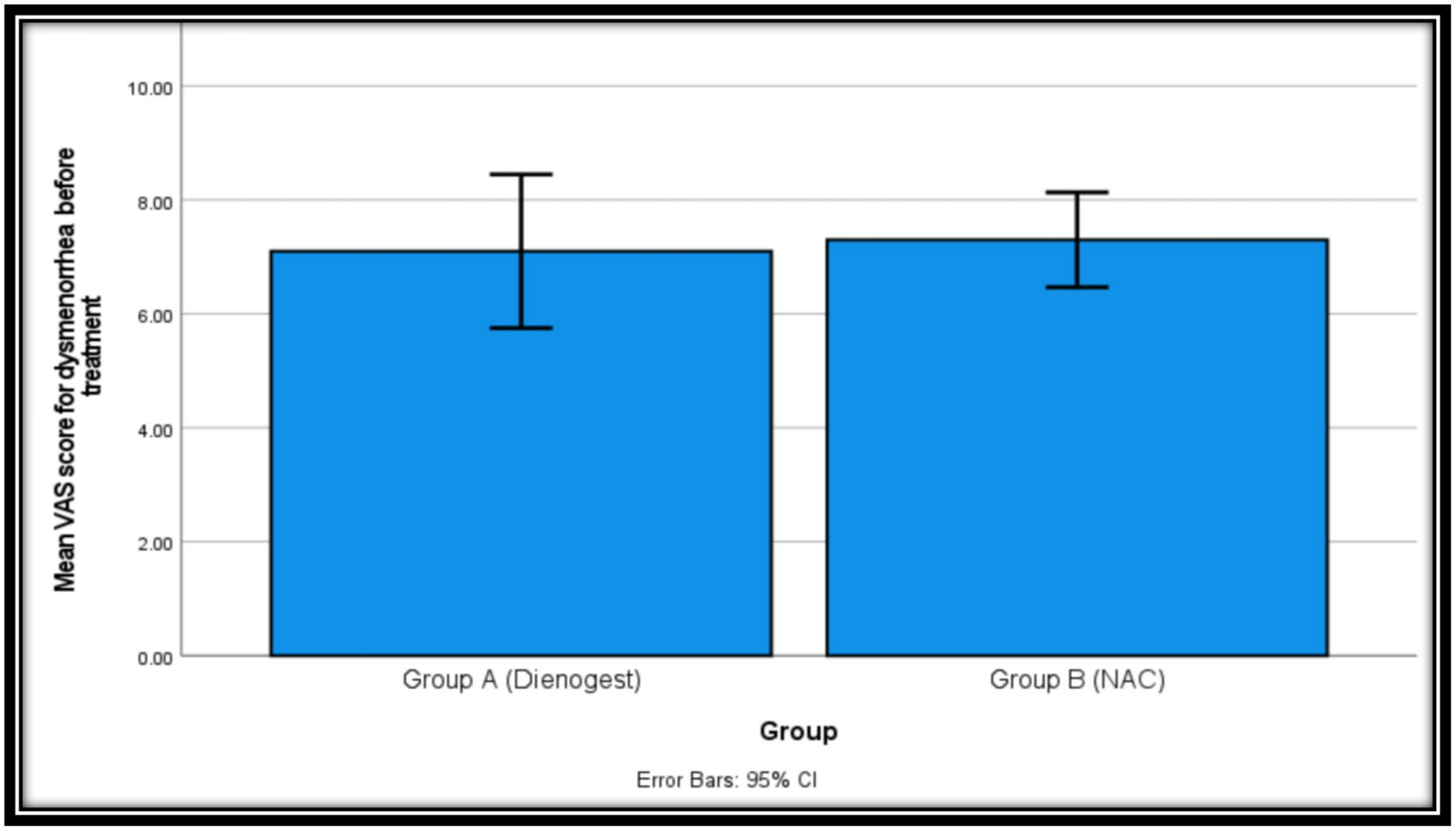


Table 8: Comparison between two groups regarding dysmenorrhea VAS score before and after treatment:

	Group A (Dienogest) (N=20)			Group B (NAC) (N=20)			t*	P value
	Range	Mean	SD	Range	Mean	SD		
VAS score for dysmenorrhea before	2.00-10.00	7.10	2.88	5.00-10.00	7.30	1.78	0.26	0.79
VAS score for dysmenorrhea after	.00-8.00	1.35	2.35	1.00-7.00	3.70	1.69	3.64	0.001

*Student t test

A significant reduction in VAS scores for dysmenorrhea is observed in both groups after treatment, with Group A showing a more pronounced improvement ($p = 0.001$).


Mean VAS score for dysmenorrhea before treatment
10.00
8.00
6.00
4.00
2.00
0.00
Group A (Dienogest)
Group B (NAC)
Group
Error Bars: 95% CI

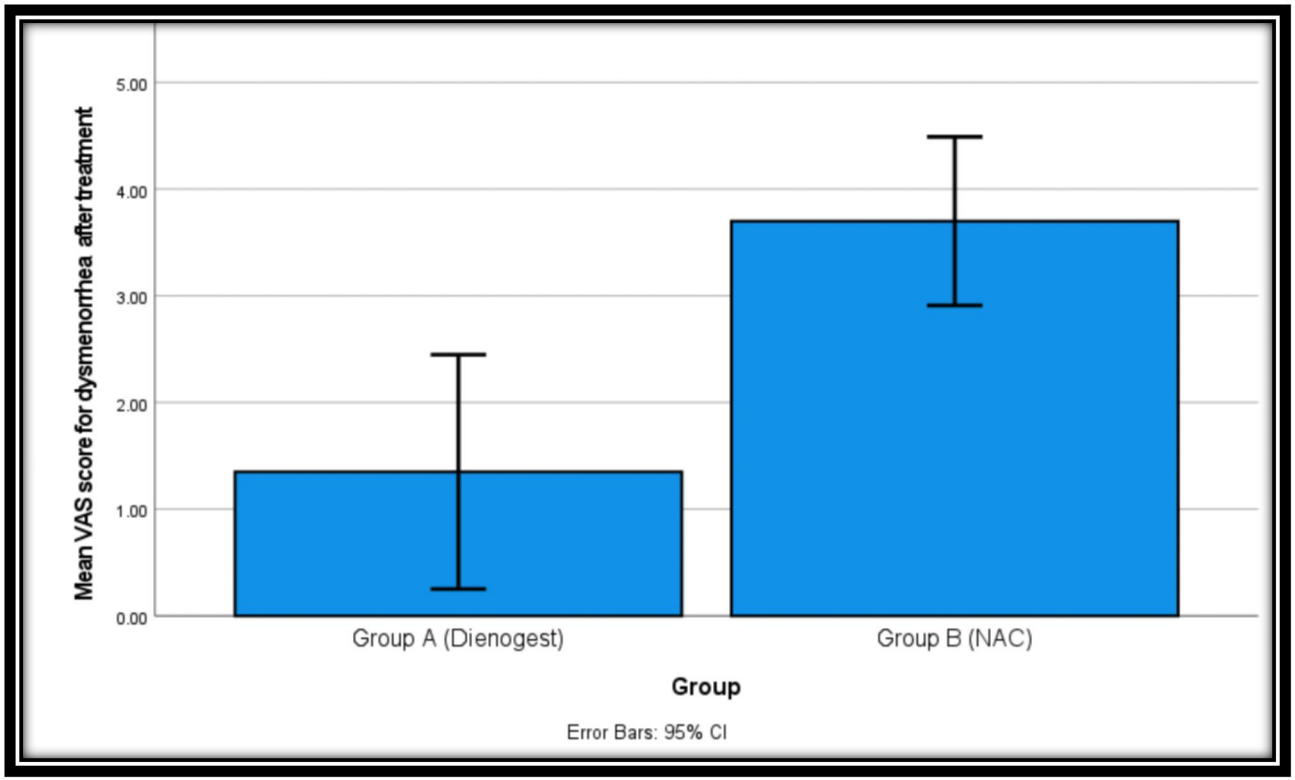
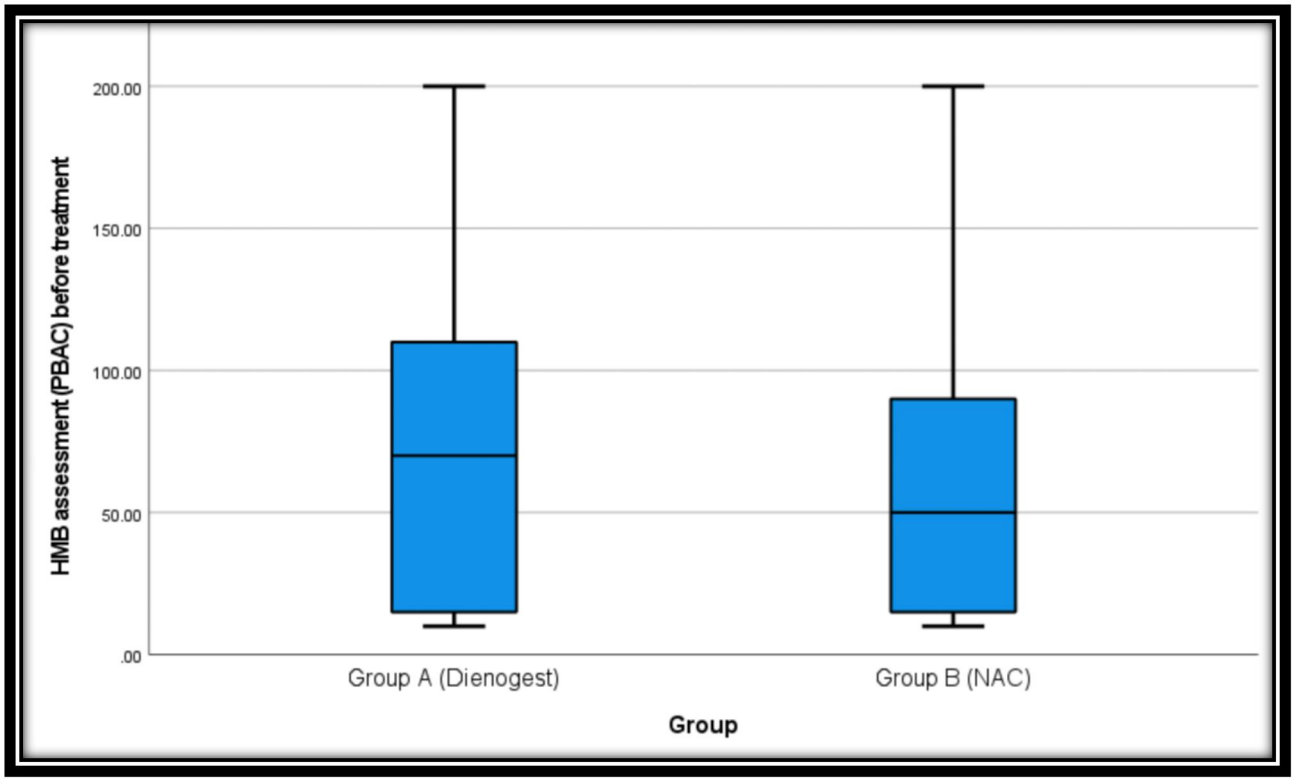


Table 9: Comparison between two groups regarding HMB assessment before and after treatment:

	Group A (Dienogest) (N=20)			Group B (NAC) (N=20)			Z*	P value
	Range	Median	IQR	Range	Median	IQR		
HMB assessment (PBAC) before	10.00-200.00	70.00	15.00-110.00	10.00-200.00	50.00	15.00-90.00	0.9	0.86
HMB assessment (PBAC) after	.00-200.00	.00	.00-9.00	3.00-200.00	25.00	15.00-70.00	4.10	0.00

*Mann Whitney U test

Group A shows a significant reduction in PBAC scores after treatment, indicating a better response to treatment compared to Group B (P value = 0.00).


HMB assessment (PBAC) before treatment
200.00
150.00
100.00
50.00
.00
Group A (Dienogest)
Group B (NAC)
Group

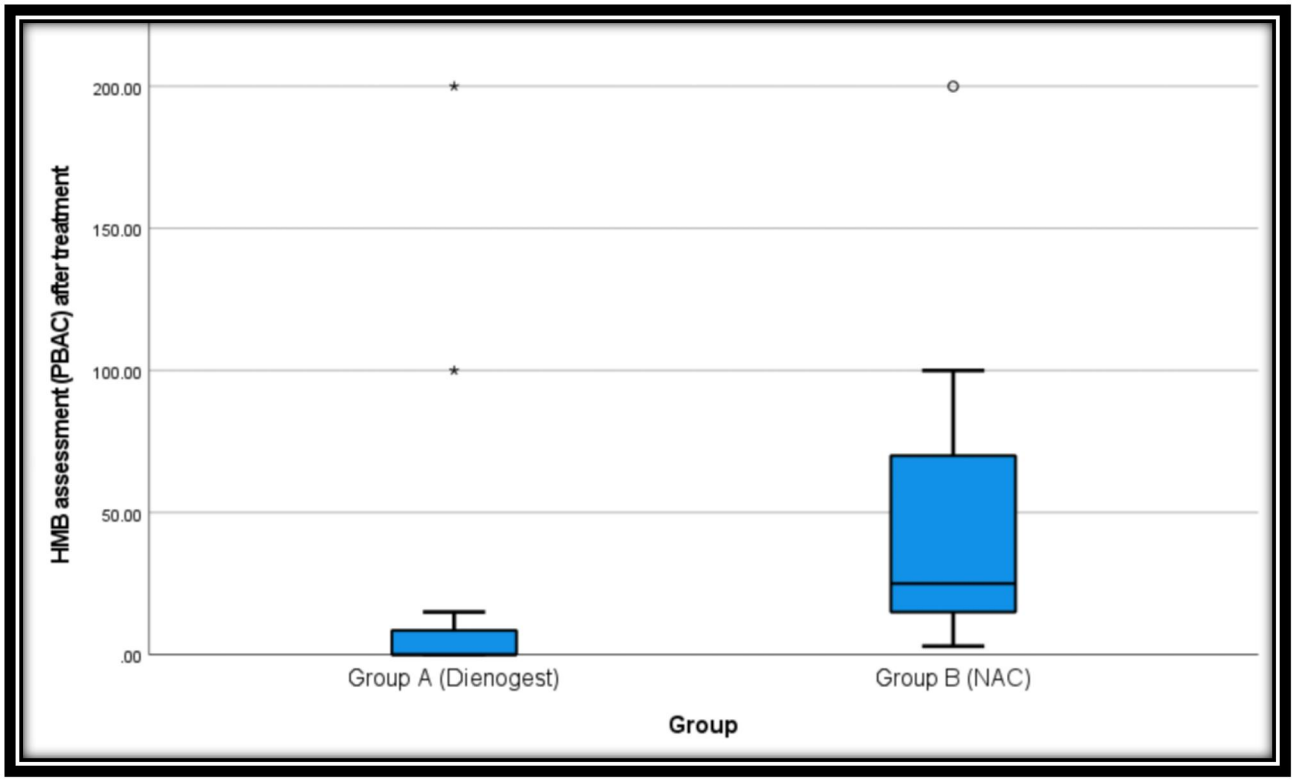
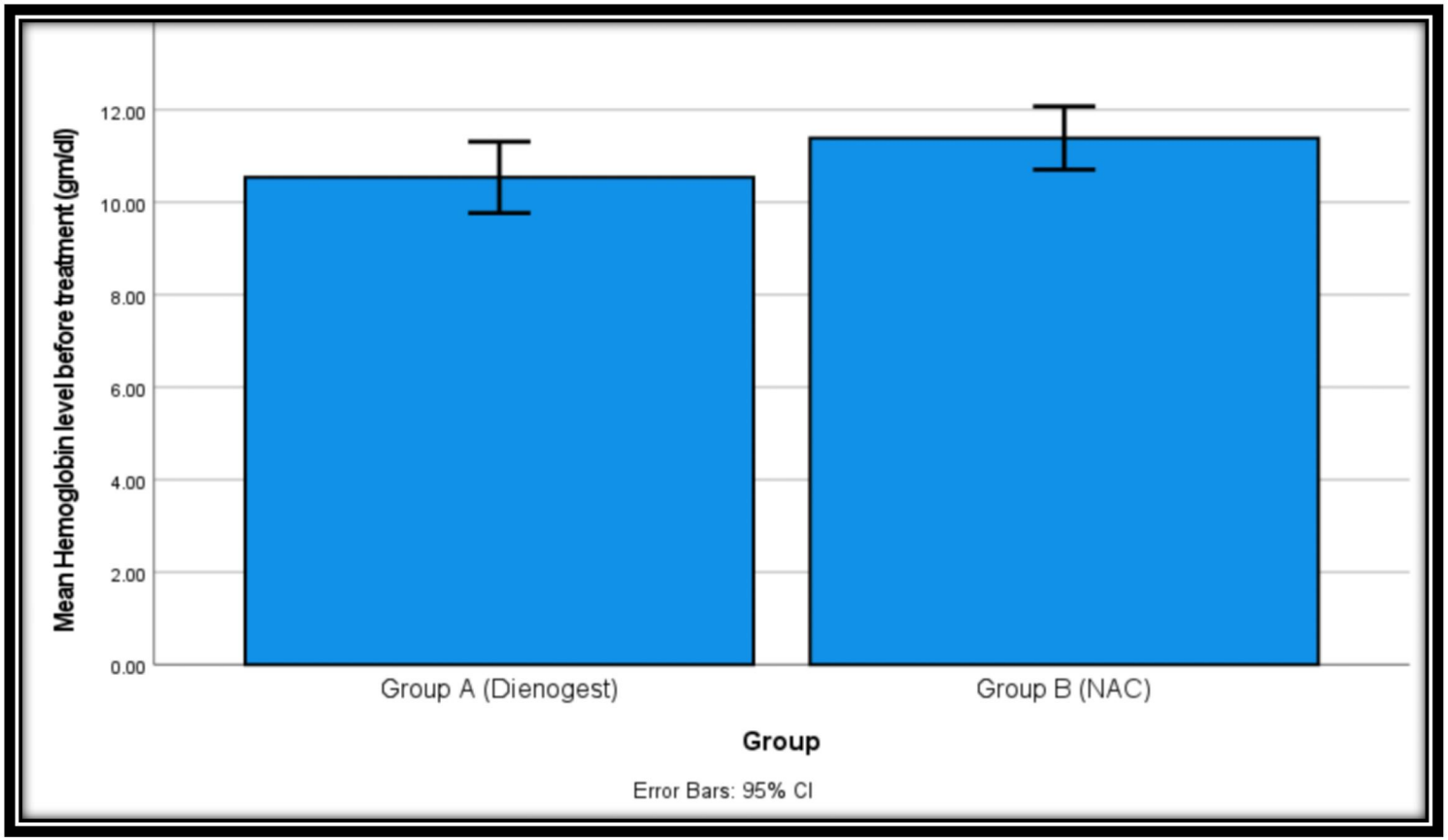


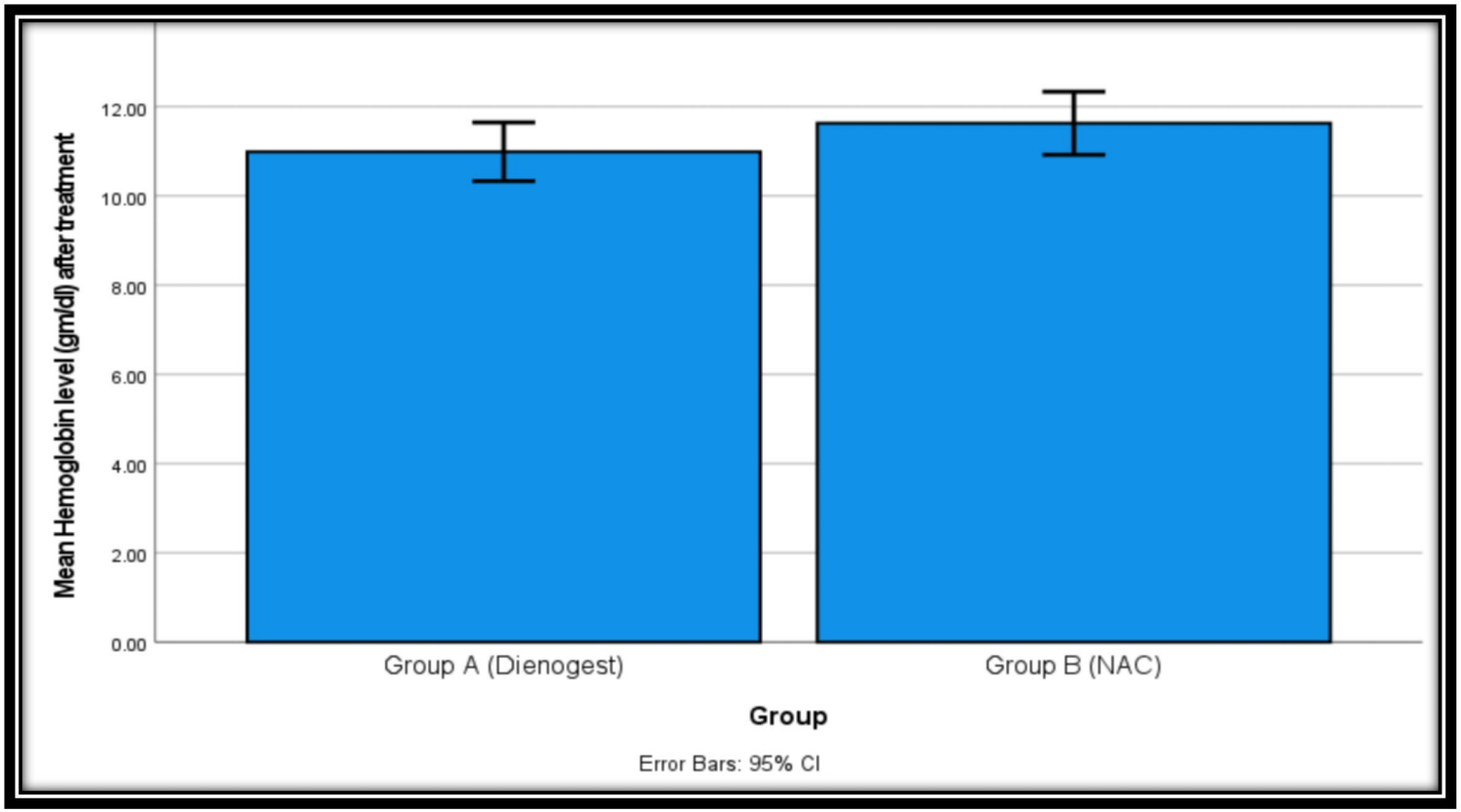
Table 10: Comparison between two groups regarding hemoglobin level before and after treatment:

	Group A (Dienogest) (N=20)			Group B (NAC) (N=20)			t*	P value
	Range	Mean	SD	Range	Mean	SD		
Hemoglobin level before	7.60-12.80	10.54	1.65	9.30-13.60	11.39	1.46	1.73	0.09
Hemoglobin level after	8.20-13.20	10.99	1.41	7.90-13.80	11.63	1.51	1.39	0.17

*Student t test

While hemoglobin levels increase slightly in both groups after treatment, the differences between the groups are not statistically significant ($p > 0.05$).


Mean Hemoglobin level before treatment (gm/dl)
12.00
10.00
8.00
6.00
4.00
2.00
0.00
Group A (Dienogest)
Group B (NAC)
Group
Error Bars: 95% CI



Comparison of outcome measures before and after treatment:

Table 11: Comparison between outcome measures before and after treatment in group A (Dienogest):

	Mean	SD	t*	P value
VAS score for dysmenorrhea before	7.10	2.88	7.74	0.00
VAS score for dysmenorrhea after	1.35	2.35		
Hemoglobin level before	10.54	1.65	2.78	0.01
Hemoglobin level after	10.99	1.41		
	Median	IQR	Z**	P value
Leiomyoma volume (cm3) before	15.53	4.31-25.01	2.78	0.01
Leiomyoma volume (cm3) after	19.54	8.25-32.61		
HMB assessment (PBAC) before	70.00	15.00-110.00	2.88	0.004
HMB assessment (PBAC) after	0.00	0.00-8.50		

*Paired-samples t test ** Wilcoxon Signed Ranks Test

Significant improvements are observed in VAS scores, HMB assessment, and hemoglobin levels after treatment, suggesting that Dienogest is effective. But leiomyoma volume is significantly increased after treatment.

Table 12: Comparison between outcome measures before and after treatment in group B (NAC):

	Mean	SD	t*	P value
VAS score for dysmenorrhea before	7.30	1.78	6.49	0.00
VAS score for dysmenorrhea after	3.70	1.69		
Hemoglobin level before	11.39	1.46	1.40	0.18
Hemoglobin level after	11.63	1.51		
	Median	IQR	Z**	P value
Leiomyoma volume (cm3) before	9.00	4.09-14.32	3.46	0.001
Leiomyoma volume (cm3) after	13.13	7.74-24.16		
HMB assessment (PBAC) before	50.00	15.00-90.00	1.78	0.08
HMB assessment (PBAC) after	25.00	15.00-70.00		

*Paired-samples t test ** Wilcoxon Signed Ranks Test

Similar to Group A, Group B also shows significant improvements in VAS scores and increase in leiomyoma volume, though the changes in hemoglobin levels and HMB assessments are less pronounced.