

## A Cross-Sectional Study on Dysfunctional Uterine Bleeding Treated with Hormones and Non – Hormones.

Dr. Swathi Boddupally<sup>1\*</sup>, N. Varsha<sup>1</sup>, P. Haritha<sup>1</sup>, T. Shruthi<sup>2</sup>, B. Shirisha<sup>2</sup>

<sup>1\*</sup>Assistant Professor, Bharat School of Pharmacy, Mangalpally, Ibrahimpatnam, Hyderabad

<sup>1</sup>Assistant Professor, Bharat School of Pharmacy, Mangalpally, Ibrahimpatnam, Hyderabad

<sup>1,2</sup>Department of Pharm D, Bharat School of Pharmacy, Mangalpally, Ibrahimpatnam, Hyderabad-501510

Submitted: 20-11-2023

Accepted: 30-11-2023

### ABSTRACT:

**Aims:** Aim of our study is to determine the effectiveness of hormonal and non-hormonal treatment for Abnormal uterine bleeding.

**Materials and methods:** Across-sectional study on dysfunctional uterine bleeding was done to evaluate the efficacy of hormonal and non-hormonal therapy in the department of gynaecology at Durgabai Deshmukh Hospital, a 300-bed multi-speciality hospital, from September 2021 to March 2022. Measures of averages, measures of variation, and tests of significance will be utilized. The results will be analysed by Z-test.

**Results:** A total of 160 women who were suffering from dysfunctional uterine bleeding were studied, of whom 80 were treated with hormonal therapy and the remaining 80 with non-hormonal therapy. Patient characteristics and number of patients treated with hormonal and non-hormonal therapy were compared. Hormonal therapy was mostly given to patients aged 40-50 years and 20-30 years, whereas non-hormonal therapy was mostly given to patients aged 30-40 years. Haemoglobin levels ranged from 11 to 12 g/dl in the majority of patients treated with hormonal and non-hormonal therapy. Most of the women in the study suffering from heavy menstrual bleeding had moderately severe bleeding. The majority of the women in the study with dysfunctional uterine bleeding who were treated with hormones and non-hormones changed four pads per day, bled for 6-8 days, were not having any comorbidities and shown positive response to the therapy given in both the groups.

**Conclusion:** In this study, we have concluded that both hormonal and non-hormonal therapy were found to be effective in treating dysfunctional uterine bleeding. But some patients preferred non-hormonal therapy because of the side effects of hormonal therapy, like fertility issues.

**Keywords:** Dysfunctional uterine bleeding, hormonal therapy, non-hormonal therapy,

tranexamic acid, combined oral contraceptives, NSAIDs

### I. INTRODUCTION

Excessively heavy, protracted, or frequent uterine bleeding that is not attributable to a pregnancy is referred to as dysfunctional uterine bleeding (DUB). Menorrhagia is defined as the loss of more than 80 mL of blood per period, and this excess of blood loss from the body will result in iron deficiency anaemia. <sup>[1]</sup> The prevalence of menorrhagia in healthy women ranges from 9% to 14%. <sup>[2]</sup> The prevalence of menorrhagia in healthy women ranges from 9% to 14%. <sup>[3]</sup> Some of the common causes of heavy menstrual bleeding are hormonal imbalance, dysfunction of the ovaries, uterine fibroids, polyps, adenomyosis, intrauterine devices, cancer, inherited bleeding disorders, pregnancy complications, and medications like anticoagulants, anti-inflammatory drugs, etc.

Non-hormonal therapy includes tranexamic acid and NSAIDs, whereas hormonal therapy includes combined oral contraceptives and progesterone-only preparations. Tranexamic acid is a synthetic lysine amino acid derivative, which diminishes the dissolution of haemostatic fibrin by plasmin in the presence of TXA, binding sites of the lysine receptor of plasmin for fibrin are occupied, preventing binding to fibrin monomers, thus preserving and stabilising fibrin's matrix structure. <sup>[4]</sup> Generally, women with menorrhagia have greater endometrial fibrinolytic activity, so the use of antifibrinolytic drugs such as tranexamic acid can be useful. This drug reduces blood loss by 50%. It is very beneficial for women with identified coagulopathies. Among the agents used in the treatment of menorrhagia, NSAIDs have the advantage of being taken only during menstruation. NSAIDs can be used, especially when there is pain associated with menstruation. The main mechanism of action of NSAIDs is the inhibition of the enzyme cyclooxygenase (COX). Cyclooxygenase is

required to convert arachidonic acid into thromboxane, prostaglandins, and prostacyclin. [5] Combined oral contraceptives induce regular shedding of a thinner endometrium while inhibiting ovulation, thus having the effect of treating menorrhagia and providing contraception. Progesterone—only preparations act by inhibiting the release of follicle-stimulating hormone from the anterior pituitary. Therefore, follicle development in the ovary is inhibited, and ovulation is prevented. [5]

## II. MATERIALS AND METHODS

For the present study, approval of the Institutional Ethics Committee, Durgabai Deshmukh Hospital (Registration No. ECR/477/Inst/AP/2013/RR-20) was taken. A cross-sectional study was conducted for 6 months in the Department of Gynaecology at Durgabai

Deshmukh Hospital, a 300-bed multi-speciality hospital.

The purpose of this study is to see the effectiveness of hormonal therapy and non-hormonal therapy in women suffering from dysfunctional uterine bleeding. Demographic data was gathered from the patient’s case report. Women suffering from dysfunctional uterine bleeding from menarche to menopause were included in the study. Pregnant women, women before menarche, and women after menopause were excluded from the study.

All characteristics have been descriptively summarized. The mean values have been measured using Microsoft Excel. Numbers and percentages were used in the data summaries for categorical data. Data analysis was conducted using the Z-test. The results obtained were presented using tables for easier understanding. [6]

**Table 1: Meanvalues of hormonal and non-hormonal therapy**

Category	Age	Weight	Haemoglobin	Days of bleeding	Number of pads changed per day
Hormonal therapy	33.53	58.55	10.76	6.56	4.15
Non-hormonal therapy	33.43	57.71	10.95	7.11	4.075

**Table 2: Z-Test for hormonal and non-hormonal therapy in relation to age**

Group	Hormonal therapy	Non-hormonal therapy
Mean	33.35443038	33.5443
Known Variance	80	80
Observations	79	79
Hypothesized Difference	Mean	
	0	
Z	-0.133419013	
P(Z<=z) one-tail	0.446931005	
z Critical one-tail	1.644853627	
P(Z<=z) two-tail	0.89386201	
z Critical two-tail	1.959963985	

H<sub>0</sub>: There is no significant difference between hormonal and non-hormonal therapy.

H<sub>1</sub>: There is significant difference between hormonal and non-hormonal therapy.

Z calculated value= -0.133

Zcritical value= 1.9599

The above table shows that there is no statistical difference between hormonal therapy and non-hormonal therapy with respect to age because Z calculated value(-0.133) is smaller than Z critical value(1.9599).

**Table 3: Z-Test for hormonal and non-hormonal therapy in relation to weight**

Group	Hormonal therapy	Non-hormonal therapy
Mean	58.44303797	57.74684
Known Variance	80	80
Observations	79	79
Hypothesized Mean Difference	0	
Z	0.489203046	
P(Z<=z) one-tail	0.312348977	
z Critical one-tail	1.644853627	
P(Z<=z) two-tail	0.624697953	
z Critical two-tail	1.959963985	

H<sub>0</sub>: There is no significant difference between hormonal and non-hormonal therapy.

H<sub>1</sub>: There is significant difference between hormonal and non-hormonal therapy.

Z critical value=1.95

Z calculated value=0.4892

The above table shows that there is no statistical difference between hormonal and non-hormonal therapy with respect to weight because Z critical value(1.95) is greater than Z calculated value(0.4892)

**Table 4: Z-Test for hormonal and non-hormonal therapy in relation to haemoglobin content**

Group	Hormonal therapy	Non-hormonal therapy
Mean	10.88101266	10.93418
Known Variance	80	80
Observations	79	79
Hypothesized Mean Difference	0	
Z	-0.037357324	
P(Z<=z) one-tail	0.48510005	
z Critical one-tail	1.644853627	
P(Z<=z) two-tail	0.9702001	
z Critical two-tail	1.959963985	

H<sub>0</sub>: There is no significant difference between hormonal and non-hormonal therapy.

H<sub>1</sub>: There is significant difference between hormonal and non-hormonal therapy.

Z critical value= 1.955

Z calculated value= -0.037

The above table shows that there is no significant difference between hormonal and non-hormonal therapy in relation to haemoglobin content because the Z critical value(1.955) is greater than Z calculated value(-0.037).

**Table5: Z-Test for hormonal and non-hormonal therapy in relation to days of bleeding**

Group	Hormonal therapy	Non-hormonal therapy
Mean	6.518987342	7.088608
Known Variance	80	80
Observations	79	79
Hypothesized Mean Difference	0	
Z	-0.400257038	
P(Z<=z) one-tail	0.344483604	
z Critical one-tail	1.644853627	
P(Z<=z) two-tail	0.688967208	
z Critical two-tail	1.959963985	

H<sub>0</sub>: There is no significant difference between hormonal and non-hormonal therapy.

H<sub>1</sub>: There is significant difference between hormonal and non-hormonal therapy.

Z critical value=1.95

Z calculated= -0.400

The above table shows that there is no significant difference between hormonal and non-hormonal therapy with respect to days of bleeding because Z critical value (1.95) is greater than Z calculated(-0.400).

**Table6: Z-Test for hormonal and non-hormonal therapy in relation to number of pads changed per day**

Group	Hormonal therapy	Non-hormonal therapy
Mean	4.139240506	4.063291139
Known Variance	80	80
Observations	79	79
Hypothesized Mean Difference	0	
Z	0.053367605	
P(Z<=z) one-tail	0.478719508	
z Critical one-tail	1.644853627	
P(Z<=z) two-tail	0.957439016	
z Critical two-tail	1.959963985	

H<sub>0</sub>: There is no significant difference between hormonal and non-hormonal therapy.

H<sub>1</sub>: There is significant difference between hormonal and non-hormonal therapy.

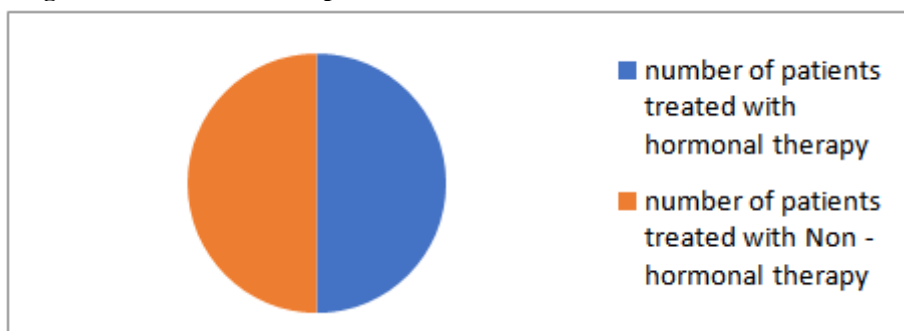
Z calculated =0.053

Z critical = 1.95

The above table indicates that there is no significant difference between hormonal and non-hormonal therapy because Z calculated (0.053) is smaller than Z critical(1.95).

### III. RESULTS

**Figure 1: Total number of patients treated with hormones and non-hormones**



80 subjects were given Hormonal therapy and remaining 80 were given non-hormonal therapy.

**Table 7: Incidence in relation to age**

Age of patient (in years)	Hormonal therapy		Non-hormonal therapy		Total
	Number	Percentage	Number	Percentage	
10-20	12	15%	8	10%	20
20-30	25	31.25%	22	27.50%	47
30-40	15	18.75%	28	35%	43
40-50	25	31.27%	18	22.50%	43
50-60	3	3.75%	4	5%	7
Total	80	100%	80	100%	160

The maximum number of patients treated with hormonal therapy were in age group of 20-30 years (25 patients) and 40-50 years (25 patients)

whereas highest number of patients treated with non-hormonal therapy were in the age group of 30-40 years (28 patients).

**Table 8: Incidence in relation to haemoglobin**

Haemoglobin in g/dl	Hormonal therapy		Non-hormonal therapy		Total
	Number	Percentage	Number	Percentage	
5-7	7	8.75%	7	8.75%	14
8-10	29	36%	32	40.32%	61
11-13	44	55%	41	51.40%	85
Total	80	100%	80	100%	160

The highest number of patients treated with Hormonal therapy (44 patients) and Non-Hormonal therapy (41 patients) have haemoglobin content ranging from 11-13 g/dl.

**Table 9: Incidence in relation to severity of bleeding**

Severity of bleeding	Hormonal therapy		Non-hormonal therapy		Total
	Number	Percentage	Number	Percentage	
Mild	18	22.50%	12	15%	30
Moderate	62	77.50%	68	85%	130
Total	80	100%	80	100%	160

Highest number of patients treated with hormonal (62 patients) and non-hormonal therapy (68 patients) have moderate severity of bleeding.

**Table 10: Incidence in relation to number of pads changed per day**

Number of pads changed per day	Hormonal therapy		Non-hormonal therapy		Total
	Number	Percentage	Number	Percentage	
3	16	20%	14	17.50%	30
4	36	45%	46	57.50%	82
5	28	35%	20	25%	48
TOTAL	80	100%	80	100%	100%

Highest number of patients treated with both hormonal (36 patients) and non-hormonal therapy (46 patients) changed 4 pads per day.

**Table 11: Incidence based on days of bleeding**

Days of bleeding	Hormonal therapy		Non-hormonal therapy		Total
	Number	Percentage	Number	Percentage	
3-5	23	28.75%	12	15%	35
6-8	45	56.25%	52	65%	97
9-11	12	15%	16	20%	28
TOTAL	80	100%	80	100%	160

Highest number of patients treated with hormones (45 patients) and non-hormones(52 patients ) bled for 6-8 days

**Table 12: Incidence based on comorbidities**

Comorbidities	Hormonal therapy		Non-hormonal therapy		Total
	Number	Percentage	Number	Percentage	
HYPERTENSION	7	8.75%	10	12.50%	17
DIABETES MILLITUS	3	3.75%	8	10%	11
HYPOTHYROIDISM	7	8.75%	1	1.25%	8
NONE	63	78.25%	61	76.25%	124
TOTAL	80	100%	80	100%	160

Highest number of patients treated with hormones (63 patients) and Non –Hormones (61 patients) did not have any comorbidity like hypertension,diabetes mellitus or hypothyroidism.

**Table 13: Incidence in relation to patient to therapy**

Response	Hormonal therapy		Non-hormonal therapy		Total
	Number	Percentage	Number	Percentage	
POSITIVE	77	96.25%	79	98.75%	156
NEGATIVE	3	3.75%	1	1.25%	4
TOTAL	80	100%	80	100%	160

Maximum number of patients treated with hormones (77 patients) and non-hormones (79 patients) have shown positive effect.

#### IV. DISCUSSION:

In this study, we evaluated non-hormonal (tranexamic acid, NSAID’S) and hormonal therapy (combined oral contraceptives, progesterone) on



various parameters, like age of the patient, haemoglobin content, days of bleeding by the patient, number of pads changed by the patient, and response shown by the patient to the drug. Both hormonal and non-hormonal therapy were found to be effective in treating dysfunctional uterine bleeding. But some patients preferred non-hormonal therapy because of the side effects of hormonal therapy, like fertility issues.

**Conflict of Interest:**

The authors have no conflicts of interest regarding this investigation.

**REFERENCE:**

- [1]. ROGER WALKER: Clinical pharmacy and therapeutics 7th edition (page no.: 663)
- [2]. Dipiro: Pharmacotherapy hand book 7th edition, McGraw- Hills companies,(page no.:(1332).
- [3]. [mayoclinic.org/diseases-conditions/menorrhagia/symptoms-causes/syc20352829](https://www.mayoclinic.org/diseases-conditions/menorrhagia/symptoms-causes/syc20352829)
- [4]. [reference.medscape.com/drug/lysteda-tranexamic-acid-oral999903#10](https://reference.medscape.com/drug/lysteda-tranexamic-acid-oral999903#10)
- [5]. [ncbi.nlm.nih.gov/books/NBK547742/](https://ncbi.nlm.nih.gov/books/NBK547742/)
- [6]. Vishweswaraa Rao K; Biostatistics in brief made easy, 1<sup>st</sup> edition ,Jaypee brothers Medical publishers,2010.