



SAFETY AND EFFECTIVENESS OF EUPHORBIA PROSTRATA & CALCIUM DOBESILATE IN TREATMENT OF ALL GRADES OF HEMORRHOIDS

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ABSTRACT

Background: The study entitled “Safety and effectiveness of Euphorbia Prostrata and Calcium Dobesilate in treatment of all grades of hemorrhoids” was carried out in 50 patients. The Primary objective of this study were to assess the safety and effectiveness of drug in all grades of hemorrhoids and the secondary objective is assessment of incidence of hemorrhoidal disease in patients taking heavy spices and having family history and to assess the disease in idifferent age groups and gender. **Method:** This prospective observational study was conducted for a period of 6 months from 30 october 2018-30 march 2019 at lalita super specialities hospital, Guntur. Those patients who

meet the study criteria were enrolled in to the study. A suitable data collection form was designed for use in the study. Disease condition was observed by signs and symptoms and physical examination. How well the euphorbia prostrata and calcium Dobesilate helped in reducing signs and symptoms was observed. All the relevant and necessary data for study was collected from treatment charts, interviewing patients and patient’s care takers and entered in data collection forms. All the collected raw data was entered in excel and for analysis purpose SAS 9.0 version was used. The statistical analysis was done in SAS Software by an appropriate statistical procedure like proc freq, proc means, proc tabulate, proc report, proc G-chart and to report the tables Out put delivery system was used. **Results:** Out of 55 cases, 50 patients completed the study protocol. After 2 weeks of treatment with

the drug no one reported the symptoms in patients with grade 1 and grade 2 hemorrhoids. In grade 3, 3(15%) patients had some amount of symptoms, so they were asked to continue consuming Tablet for 2 more weeks. At the end of 4 weeks, 2 of the 3 patients completely relieved from symptoms, while the remaining patient continue to have symptoms and thus they were considered treatment failure. In grade 4, out of 3 patients no one got relieved from symptoms in the first two weeks of the treatment and they were asked to continue the treatment for two more weeks. And again no one got recovered from symptoms at the end of 4 weeks. **Conclusion:** The study indicates that two weeks of treatment with 100 mg of euphorbia prostrata and 500 mg of calcium Dobesilate could be adopted as one of the drug of choice for the treatment of grade I,II,III haemorrhoids.

KEYWORDS: Hemorrhoids, euphorbia prostrata, calcium dobesilate.

I. INTRODUCTION

Hemorrhoids are one of the most common anorectal conditions leads to enlargement and displacement of anal cushions. It effects the millions of people around the world and represents the medical and socio economic problem.^[1] These hemorrhoids are normal vascular anal structures with rich blood supply and easy to engorge and due to high sensitive location leads to the anal pathology.^[2] Many elements are involved in the developments of hemorrhoids such as constipation, diarrhea, prolonged sitting which effects the submucosal arteriovenous cushions.^[3] common symptoms associated with hemorrhoids are pruritis, discomfort, bleeding, prolapsed, mucus discharge.^[4] Hemorrhoids are classified into four types based on the location and extent of prolapse. Hemorrhoidal classification helps to select the treatment which effects the cure and outcomes of the condition.^[5] Based on their appearance and degree of prolapse, known as Goligher's classification:

Grade I: The anal cushions bleed but do not prolapsed. Grade II: The anal cushions prolapse through the anus on straining but reduce spontaneously. Grade III: The anal cushions prolapse through the anus on straining or exertion and require manual replacement into the anal canal. Grade IV: The prolapse stays out at all times and is irreducible. Euphorbia prostrata is a new molecule used for the treatment of early grades of hemorrhoids. This drug contains active constituents such as flavonoids, tannins and phenolic compounds. Flavonoids and phenolic compounds have anti inflammatory, anti oxidant, hemostatic, vasoprotective and antithrombotic actions. tannins have astringent and hemostatic properties which will cures the hemorrhoidal symptoms.

II. MATERIALS AND METHODS

Study design: This is a prospective observational study on safety and effectiveness of euphorbia prostrata and calcium dobesilate in the treatment of all grades of hemorrhoids.

Study site: The study was done in outpatient department of Lalitha Super Specialities Hospital, Kothapeta, Guntur, Andhra Pradesh-522001.

Study duration: The study was carried out for a period of six months i.e; from 30 October 2018- 30 March 2019 at Lalitha Super Specialities Hospital, Guntur.

STUDY CRITERIA

Inclusion criteria

1. Patients of both gender.
2. Patients between the ages of 18 and 75 years, who were diagnosed to have grade 1 to grade 4 hemorrhoids, and had no abnormalities on physical examination.
3. Patients who willing to participate in the study with a written informed consent form.
4. Patients with some comorbid conditions like hypertension, diabetes, thyroid, seizures.

Exclusion criteria

1. Patients not willing to participate in the study.
2. Pregnant and lactating women were excluded.
3. Patients who were using other drugs or any surgical procedure for hemorrhoids and having associated anal fissure or infective anal pathologies, like cryptitis or proctitis, and secondary hemorrhoids were excluded from the study.
4. Patients participating in any other clinical trial or using any other investigational drug were also excluded.
5. Patients who meet the study criteria are enrolled into the study.

Procedure and Methodology

Patients who visited outpatient wards in the general medicine department of Lalitha Super Specialities Hospital and who meet the study criteria are enrolled into the study. Relevant data such as demographic details, disease history, diagnosis, drug name, dose, route, frequency, duration of therapy, total pills per day, laboratory data, allergy status will be collected from medical records of the patient and by patient interview where ever required are collected and documented. Changes to drug therapy, if any will be noted on daily basis & documented. A suitable data collection form is designed for use in the study. Monitor the patient about the allergic reactions that may occur. Complete follow up should be done every 2 weeks by

phone calls and during visits until symptoms are relieved.

Statistical analysis

All the collected raw data was entered in excel and for analysis purpose SAS 9.0 version was used. The statistical analysis was done in SAS Software by an appropriate statistical procedure like proc freq, proc means, proc tabulate, proc report , proc G-chart and to report the tables Out put delivery system was used .

III. RESULTS

Over 6 months period of our study, we have collected 50 patients, who were diagnosed with hemorrhoids based on the criteria (signs, symptoms, physical examination). Initially 55 patients were included in our study, 5 patients were excluded from our study due to no proper follow up.

Table 5.1: Age Distribution.

Age In Years	Number of Patients	Percentage
21-30	6	12%
31-40	15	30%
41-50	16	32%
51-60	6	12%
61-75	7	14%
TOTAL	50	100%

Table 5.1 shows the age factor of the patients. The mean age of the patient was 42 years. most of patients are at 31-50(62%) have more chances of hemorrhoids. 30% (15 patients out of 50) at the age 31-40 years, 32%(16 patients out of 50) at the age 41-50 years, 14%(7 patients out of 50) at the age 61-75years ,12% (6 patients out of 50) at the age 51-60 years, 12% (6 patients out of 50) at the age 21- 30 years were observed.

FIGURE 5.1: AGE DISTRIBUTION

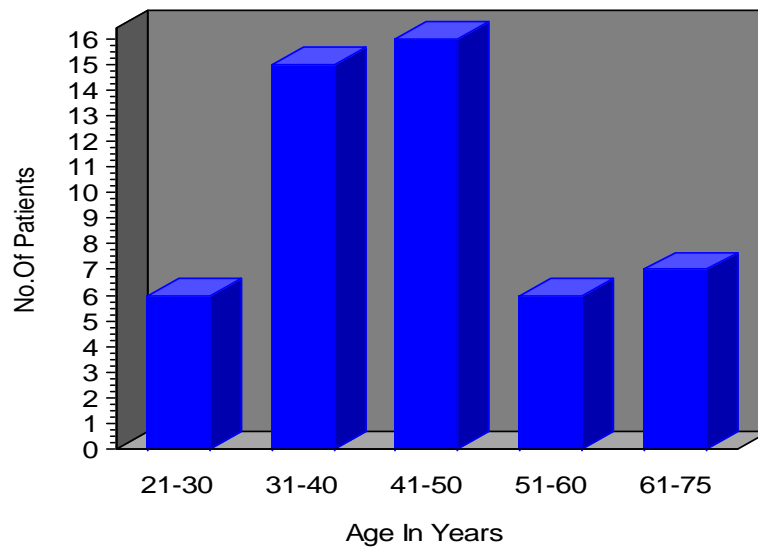


Table 5.2: Gender Distribution.

Gender	Number of Patients	Percentage
Males	26	52%
Females	24	48%
TOTAL	50	100%

Table 5.2; shows that among 50 patients 26(52%) are male and 24(48%) patients are female. However our studies shown that it is nearly common in both males and females.

FIGURE 5.2: GENDER DIFFERENTIATION

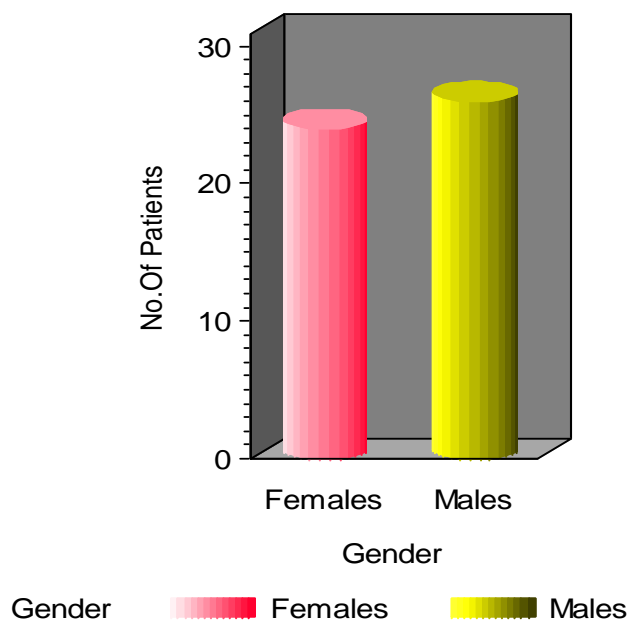
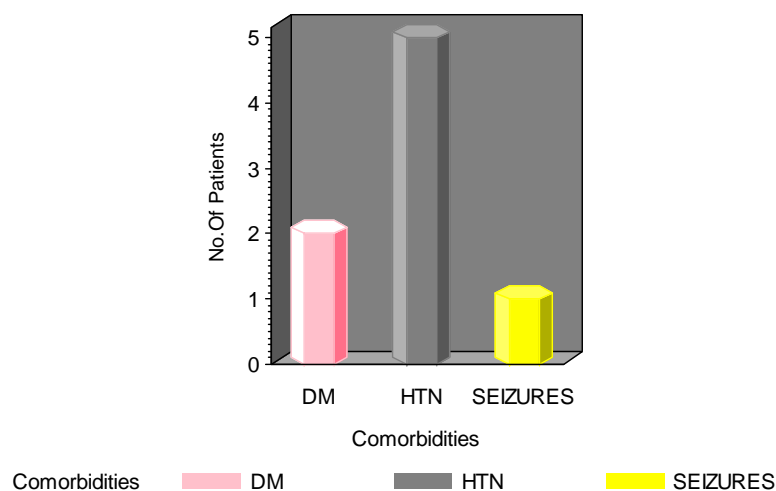


Table 5.3: Comorbidities.

Comorbidities	Number of Patients	Percentage
Hypertension	5	10%
Diabetes mellitus	2	4%
Seizures	1	2%

Table 5.3 shows the comorbidities reported. Of all 50 patients, 5(10%) patients are with comorbidity of hypertension, 2(4%) are with DM and 1(2%) patient with seizures.

FIGURE 5.3:COMORBIDITIES

**Table 5.4: Family History.**

Family History	Number Of Patients	Percentage
Present	28	56%
Absent	22	44%
TOTAL	50	100%

Table 5.4 shows the patient distribution according to family history. Among 50 patients 28(56%) patients have family history of hemorrhoids and 22(44%) patients have no family history. Presence of family history increases the risk of hemorrhoids.

FIGURE: 5.4 FAMILY HISTORY

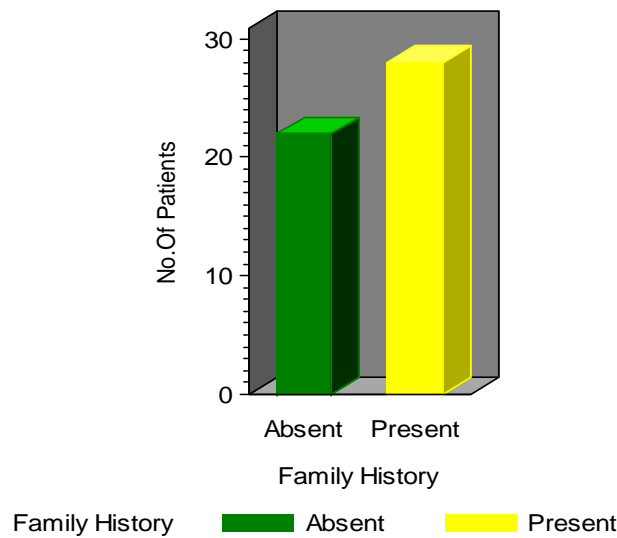


Table 5.5: Food Habits.

Food Habits	Number of Patients	Percentage
Vegetarian	10	20%
Non Vegetarian	40	80%

Table 5.5 shows the patient distribution based on their food habits. Among 50 patients, 40(80%) are non vegetarians and remaining 10(20%) patients are vegetarians. Risk of haemorrhoids is more in non vegetarian group. spices alone do not cause bleeding hemorrhoids, spicy foods may lead to stomach upset that intensifies hemorrhoid problems.

Figure 5.5:FOOD HABITS

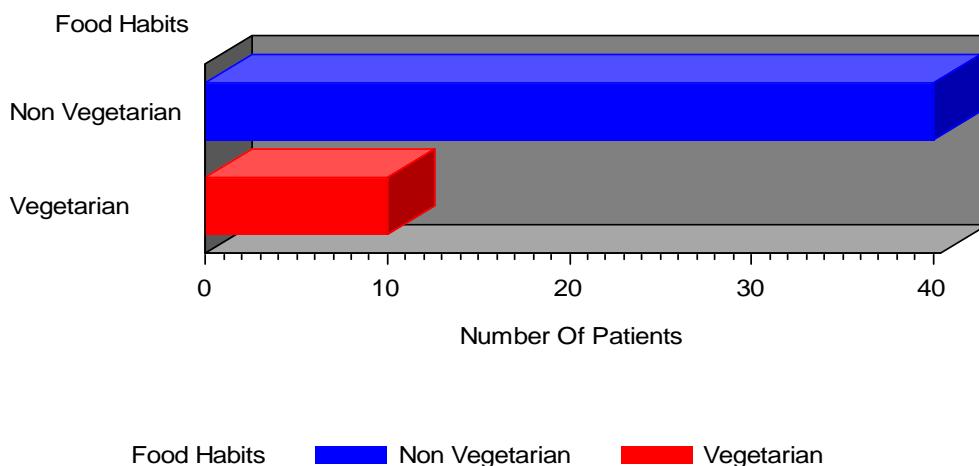
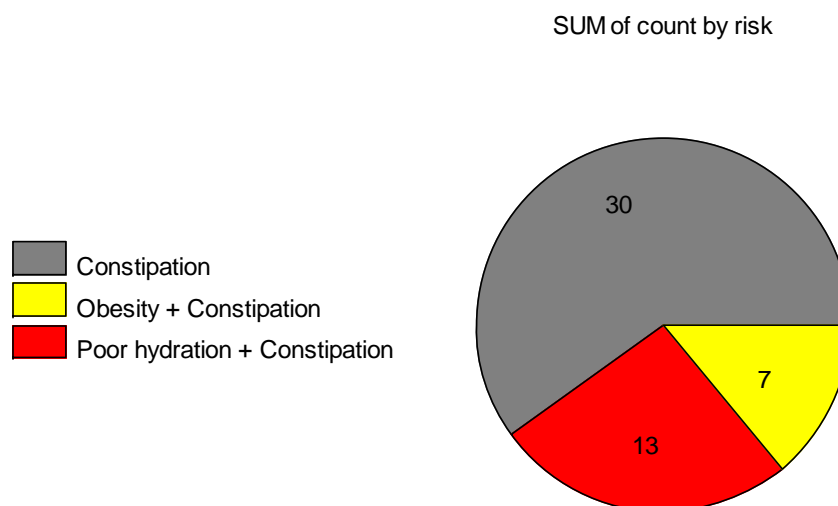


Table 5.6: Risk Factors.

Risk Factor	Number Of Patients	Percentage
Constipation	30	60%
Obesity + Constipation	7	14%
Poor hydration + Constipation	13	26%

Table 5.6 shows the patients distribution based on their risk factor. Among 50 patients 30 (60%) patients have constipation, 7(14%), patients have obesity with constipation, 13 (26%) patients have poor hydration with constipation.

Figure 5.6: RISK FACTORS**Table 5.7: Life Style Changes.**

Life Style	Number Of Patients	Percentage
Primary	20	40%
Secondary	30	60%

Table 5.7 shows the patients distribution based on life style. Among 50 patients, 30(60%) patients are with sedentary life style and 20(40%) patients are with primary. Sedentary life style increases the risk of haemorrhoids by increasing the intra abdominal pressure.

FIGURE 5.7: LIFE STYLE CHANGES

BLOCK CHART OF Number of patients

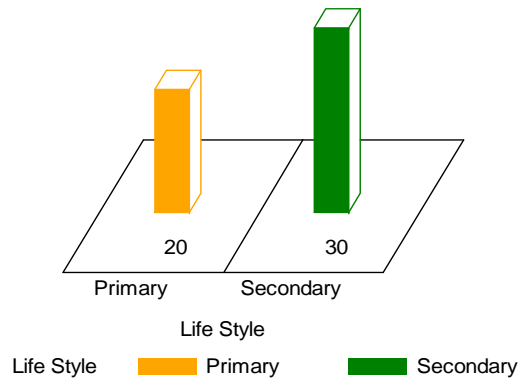


Table 5.8: Grade Wise Distribution.

Life Style	Number Of Patients	Percentage
GRADE-I	9	18%
GRADE -II	19	38%
GRADE -III	19	38%
GRADE -IV	3	6%
TOTAL	50	100%

Table 5.8 shows the patients with different grades of hemorrhoids. Among them, 9 (18%) patients have grade-1 hemorrhoids, 19(38%) patients have grade-2, while 19(38%) have grade-3 and 3(6%) patients have grade-4 hemorrhoids.

Figure: 5.8 GRADE WISE DISTRIBUTION

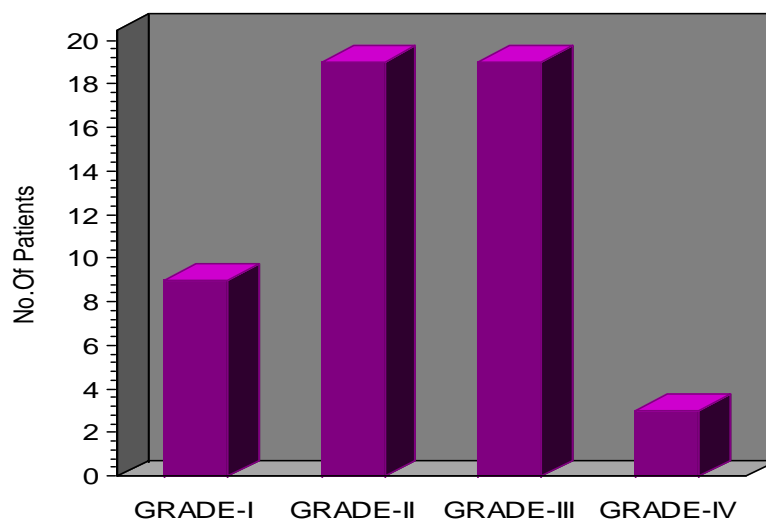


Table 5.9: Statistical Analysis of Symptoms in Grade-1 Before and After Treatment With Euphorbia Prostrata and Calcium Dobesilate.

Reported Symptoms	Before Treatment		After Treatment	
	No.Of Patients	percentage	No.Of Patients	percentage
Symptoms				
Bleeding	5	55.6	0	0
Pruritis	4	44.4	0	0

Table 5.9 shows that, out of 50 patients, only 9 patients are under Grade -1. Among these 9, Symptom of bleeding was observed in 5(55.6%) patients and pruritis was observed in 4 (44.4%) patients at baseline data. After 2 weeks of treatment with euphorbia prostrata and calcium dobesilate no patient was reported with symptoms of bleeding and pruritis. Hence the treatment is effective for grade-1 patients.

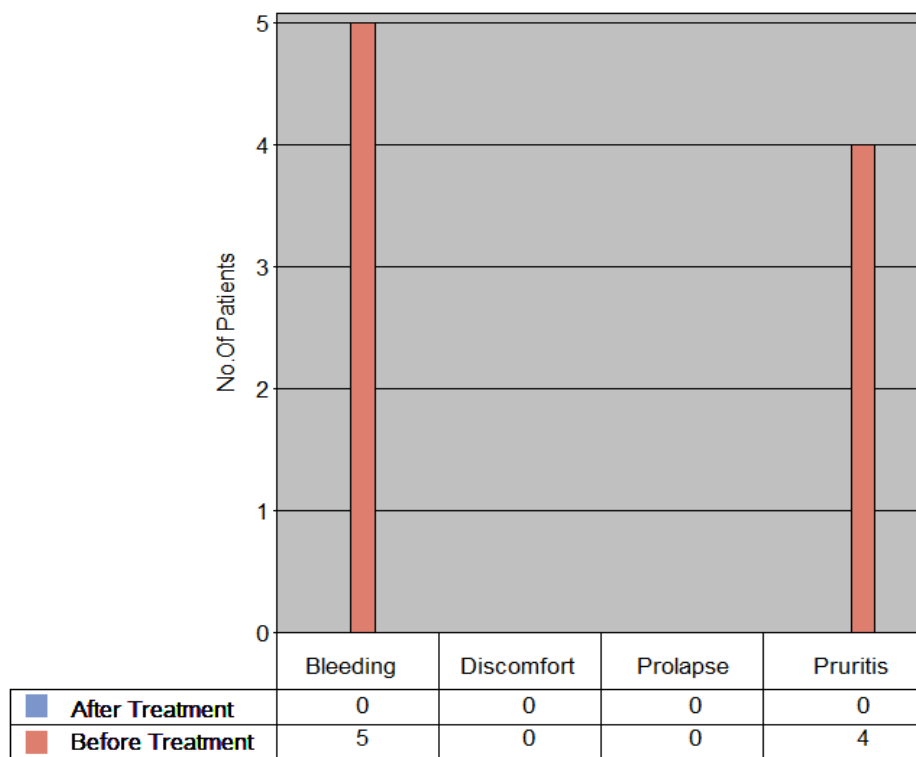


Figure 5.9: Treatment For Grade-1 Patients.

TABLE: 5.10 Statistical Analysis of Symptoms In Grade-2 Before And After Treatment With Euphorbia Prostrata & Calcium Dobesilate.

Reported Symptoms	Before Treatment		After Treatment	
	No.Of Patients	percentage	No. of Patients	Percentage
Symptoms	19	100	0	0
Bleeding				
Discomfort				
Prolapse				
Pruritis				

Table 5.10 shows that, out of 50 patients, only 19 patients are under Grade -2. Among these 19, Symptom of bleeding was observed in 19(25.68%) patients, Discomfort was observed in 19(25.68%) patients, Prolapse was observed in 19(25.68%) patients and pruritis was observed in 17(22.97%) patients at baseline data. After 2 weeks of treatment with euphorbia prostrata and calcium dobesilate no patient was reported with symptoms of bleeding, discomfort, prolapse and pruritis. Hence the treatment is effective for grade-2 patients.

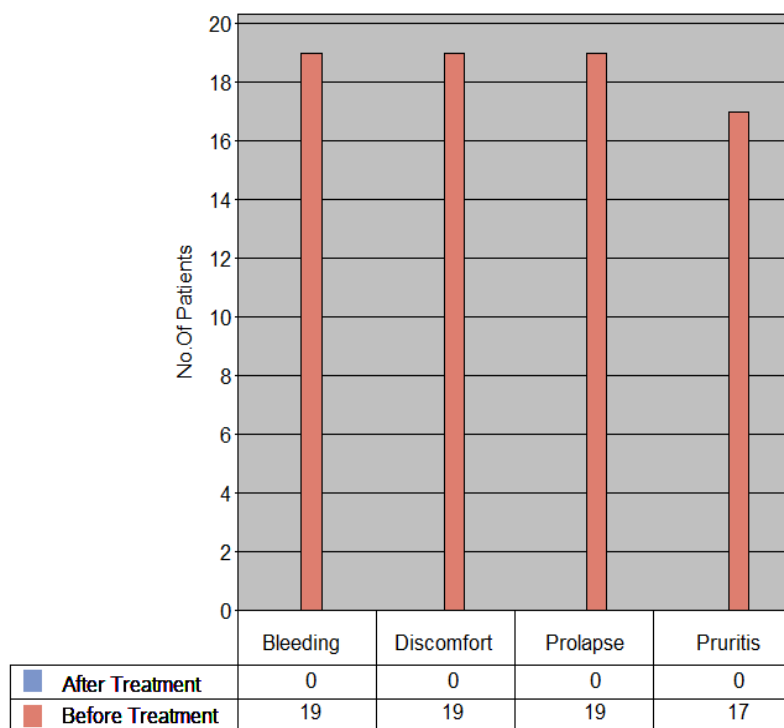


Figure 5.10: Treatment For Grade- 2 Patients.

Table 5.11: Statistical Analysis of Symptoms In Grade-3 Before And After Treatment With Euphorbia Prostrata & Calcium Dobesilate.

Reported Symptoms	Before Treatment		After 2 weeks Treatment		After 4 weeks Treatment	
	No.Of Patients	percentage	No.Of Patients	percentage	No.Of Patients	percentage
Symptoms	19	100	3	15.78	1	5.26
Bleeding						
Discomfort						
Prolapse						
Pruritis						

TABLE.5.11 shows that, out of 50 patients, only 19 patients are under Grade -3. All the 19 patients were reported with Symptoms of bleeding, Discomfort, Prolapse and pruritis at baseline data. After 2 weeks of treatment with euphorbia prostrata and calcium Dobesilate, 3(15.78%) of 19 patients were having symptoms of bleeding and discomfort, 2(10.5%) of patients were having prolapse and 5(26.3%) of patients having pruritis. After 4 weeks of treatment symptoms were gradually improved. Bleeding, Discomfort, Prolapse were observed in 1(5.26%) out of 19 patients and pruritis was observed in 2(10.52%) out of 19 patients. Hence, it is found to be statistically significant.

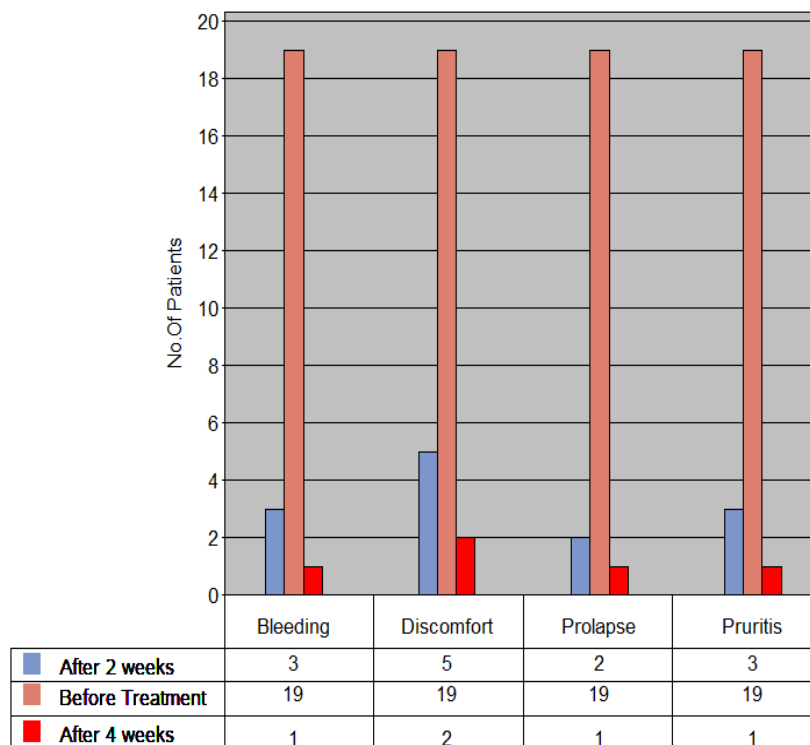


Figure 5.11: Treatment for Grade-3 Patients.

Table 5.12: Statistical Analysis of Symptoms in Grade-4 Before and After Treatment With Euphorbia Prostrata & Calcium Dobesilate.

Reported Symptoms	Before Treatment		After 2 weeks Treatment		After 4 weeks Treatment	
	No. of Patients	percentage	No. of Patients	percentage	No. of Patients	percentage
Symptoms	3	100	3	100	3	100
Bleeding						
Discomfort						
Prolapse						
Pruritis						

TABLE.5.12 shows that, of all 50 patients only 3 patients are under grade-4. Symptoms of bleeding, discomfort, pruritis and prolapse are observed in all the 3(100%) patients. After 4 weeks of treatment the symptoms were not subsided. Hence, treatment is not effective for grade 4 patients as it is the severe stage of hemorrhoids.

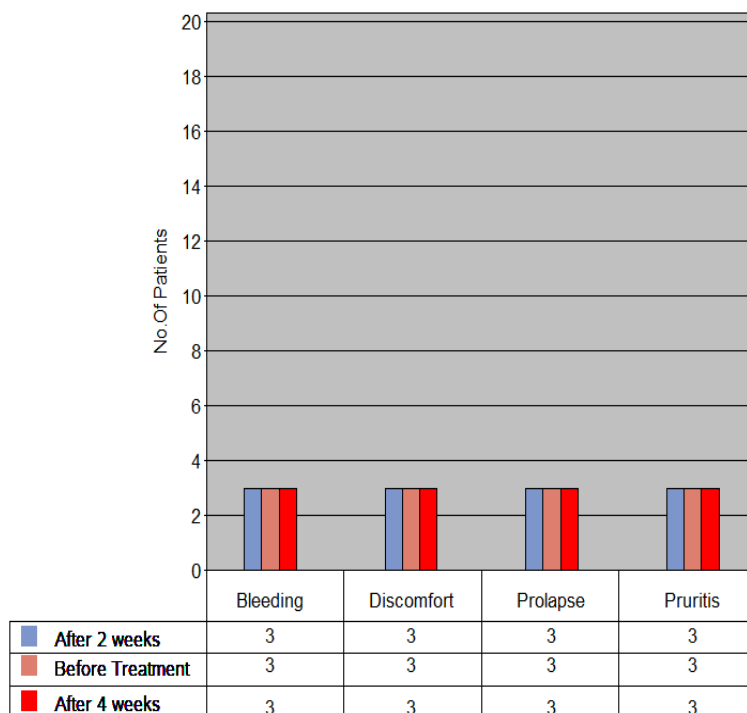


Figure 5.12: Treatment for Grade-4 Patients.

V. DISCUSSION

Our study involves monitoring of safety and effectiveness of euphorbia prostrata and calcium dobesilate in treatment of all grades of hemorrhoids by assessing signs and symptoms of the patients as a primary objective and the study includes some of the secondary objectives like

assessment of incidence of hemorrhoidal disease in patients taking heavy spices & having family history and To assess the incidence of disease in different age groups & gender.

In our study 26 were males and 24 were females. our studies shown that it is nearly common in both males and females. The mean age of patient was 42 years (range 21-75 years) and more chances of hemorrhoids observed in age group of 31-50(62%). In our study, 28(56%) patients have family history of haemorrhoids, 22(44%) patients have no family history. Presence of family history increases the risk of haemorrhoids. In our study, Among 50 patients, 40 of them are non vegetarians and remaining 10 patients are vegetarians. spices alone do not cause bleeding hemorrhoids, spicy foods may lead to stomach upset that intensifies hemorrhoid problems. Heavy spicy foods increases the risk of hemorrhoids. Results showing that Constipation is the main risk factor for hemorrhoids. Sedentary life style increases the risk of hemorrhoids by increasing intra abdominal pressure. Being physically inactive can put more pressure around anal area.

As Regard Bleeding Per Rectum

In grade 1, At the end of two weeks of treatment every one had complete cessation of bleeding In grade 2, all of the 19 patients had complete cessation of bleeding at the end of two weeks.

In grade 3, out of 19 patients, 16 (84.2%) had complete cessation of bleeding at the end of two weeks. But 3 (15.8%) had some amount of bleeding, so they were asked to continue consuming medication for 2 more weeks. At the end of 4 weeks, 2(10%) of the 3 patients with complete cessation of bleeding while the remaining patient continue to have bleeding and thus they were considered treatment failures amounting to a total of 5% treatment failure. In grade 4, out of 3 patients no one got relieved from bleeding in the first two weeks of the treatment and they were asked to continue the treatment for two more weeks. And again no one got recovered from bleeding at the end of 4 weeks. So, all of the grade 4 patients are considered as treatment failures.

As Regard Pruritis

In grade 1, Every one had completely relieved from the itch at the end of two weeks. In grade 2, out of the 19 patients 17 patients reported anal itch. At the end of two weeks every one had completely relieved from itch. In grade 3, out of 19 patients, 16 (84.2%) had completely relieved from the itch at the end of two weeks. 3 (15.8%) had some amount of itch, so they

were asked to continue consuming Sitcom forte for 2 more weeks. At the end of 4 weeks, 2 of the 3 patients with completely relieved from itch, while the remaining patient continue to have pruritis and thus they were considered treatment failures amounting to a total of 5% treatment failure. In grade 4, out of 3 patients no one got relieved from pruritis in the first two weeks of the treatment and they were asked to continue the treatment for two more weeks. And again no one got recovered from itch at the end of 4 weeks. So, all of the grade 4 patients are considered as treatment failures.

As Regard Prolapse

In grade 1, there is no prolapse of hemorrhoids. In grade 2, all of the 19 patients had completely relieved from prolapse at the end of two weeks. In grade 3, out of 19 patients, 18 (94%) had completely relieved from the prolapse at the end of two weeks. 2 (6%) had some amount of prolapse, so they were asked to continue the medication for 2 more weeks. At the end of 4 weeks, 1 of the 2 patients were completely relieved from prolapse, while the remaining patient continue to have symptom and thus they were considered as treatment failures amounting to a total of 5% treatment failure. In grade 4, out of 3 patients no one got relieved from prolapse in the first two weeks of the treatment and they were asked to continue the treatment for two more weeks. Again no one got recovered from prolapse at the end of 4 weeks. So, all of the grade 4 patients are considered as treatment failures.

As Regard Discomfort OR Heaviness

In grade 1, no one had heaviness. In grade 2, all of the 19 patients had completely relieved from discomfort at the end of two weeks. In grade 3, out of 19 patients, 14 (74%) had completely relieved from the discomfort at the end of two weeks. 5 (26%) had some amount of heaviness, so they were asked to continue consuming Sitcom forte for 2 more weeks. At the end of 4 weeks, 3 of the 5 patients with completely relieved from heaviness, while the remaining patients continue to have symptom and thus they were considered treatment failures amounting to a total of 2 (10)% treatment failure. In grade 4, out of 3 patients no one got relieved from heaviness in the first two weeks of the treatment and they were asked to continue the treatment for two more weeks. And at again no one got recovered from itch at the end of 4 weeks. So, all of the grade 4 patients are considered as treatment failures.

V. CONCLUSION

In this study, we observed that the safety and effectiveness of euphorbia prostrata(100mg) and calcium dobesilate(500mg) in the treatment of all grades of haemorrhoids. In this study

we monitored the safety and effectiveness of drug sitcom forte (euphorbia prostrata 100mg and calcium dobesilate 500mg) in all grades of hemorrhoids. The treatment was effective in treating grade 1, grade 2 and In grade 3 hemorrhoids. In grade 3, out of 19 patients 16 were completely relived from the symptoms at the end of 2 weeks of treatment. 3 patients had some amount of bleeding and puritis. So these patients given with extra 2 weeks of treatment. At the end of 4 weeks, 2 of the 3 patients are completely relieved and reamaing one patient failed to respond to the treatment. But the patients with grade 4 was not improved by the treatment over first 2weeks. The treatment was extended for another 2 more weeks, but there is no improvement. Then Grade 4 patients were suggested for a surgery by the physician. Finally it can be concluded that safety and effectiveness of euphorbia prostrata and calcium dobesilate was associated with significantly greater improvement in Grade 1,Grade 2 and Grade 3 Hemorrhoids and not effective in Grade 4. Life style changes reduce the symptoms of hemorrhoids.

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