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Management Of First And Second Degree Haemorrhoids With Combined Oral And Topical Unani Formulations

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ABSTRACT

Piles or Bawaseer (**Haemorrhoids**) is the most prevalent anorectal disorder and the most common cause of bleeding with stool. Patients with first degree (1^0) or second degree (2^0) Haemorrhoids may experience acute attacks of discomfort, pain and/or bleeding. The conventional approaches and some surgical procedures used in modern practice in grade 1 and grade 2 Haemorrhoids are associated with potential complications.

To assess the efficacy of Hamdoroid capsule in combination with Hamdoroid ointment on symptomatic first and second degree internal Haemorrhoids, a double blind placebo controlled clinical trial was carried out. Hamdoroid combination therapy provided marked improvement in mild to severe grades of symptoms in these patients. The improvement produced by the drug was significantly superior to that of placebo. The drugs were well accepted by the participants in this study and no noticeable side effects were detected.

Keywords: Piles, Bawaseer, Haemorhhoids, Unani, Laxative, Haemostatic

INTRODUCTION:

Piles or Bawaseer (**Haemorrhoids**) is the most prevalent anorectal disorder and the most common cause of bleeding with stool. Patients with first degree (1^0) or second degree (2^0) Haemorrhoids usually lack advanced prolapse of the supporting epithelial tissue of haemorrhoidal cushion. However, these patients may experience acute attacks of discomfort, pain and/or bleeding [1,2,3]. They may need treatment in the emergency department setting [4]. Haemorrhoidal bleeding is typical in occurrence and associated with anitis (inflammation of anal mucosa) that can be seen on proctoscopic examination; the pain and discomfort is because of anitis [1,3,5].

Despite thousands of years and millions of patients with pain, discomfort, bleeding and perceived embarrassment of Haemorrhoids, the standard treatments are, at best, imperfect [6]. Nowadays we still debate on which is the most effective and promising treatment to reduce the patients' ailments, as well as social high costs [1].

In grade 3 and 4 Haemorrhoids, haemorrhoidectomy is the authoritative treatment [7,8]. But, conventional approaches and some surgical procedures used in modern practice in grade 1 and grade 2 Haemorrhoids are associated with potential complications [6].

The management of Haemorrhoids with indigenous herbal medicines has been in practice since long and lots of Unani formulations are available in the Market, which are reported to be effective safely in relieving the symptoms of Haemorrhoids.

Hamdoroid capsule and ***Hamdoroid ointment*** are marketed products of Hamdard Laoratories, Ghaziaba (UP), India, for a very long time that have been catering relief to around thousands of patients without any adverse effects reported so far. However, no clinical trials have been conducted on the effects of these two drugs in the treatment of haemorrhoids. Hence, we intend to carry out a double blind placebo controlled clinical trial to assess scientifically the efficacy of Hamdoroid capsule in combination with Hamdoroid ointment on symptomatic first degree and second degree internal Haemorrhoids.

MATERIAL AND METHODS

This Clinical Study was conducted on patients having symptomatic first and second degree Haemorrhoids, who attended the out Patient Department of A & U Tibbia College Hospital Karol Bagh, New Delhi-110005, during the period of Oct. 2004-March 2005.

1. Investigational Product:

A combination of Hamdoroid capsule and Hamdoroid ointment was used in this clinical trial. The composition of Hamdoroid capsule and Hamdoroid ointment is given in Table 1 & Table 2.

Table 1: Composition of Hamdoroid capsule

Unani Name	**Botanical Name**	**Part Used**	**Quantity**
Rasaut	*Berberis aristata*	Root (Powder)	200 mg
Muqil	*Commiphora mukul*	Resin (Powder)	200mg
Neem	*Azadirachta indica*	Kernel (Powder)	50 mg
Ritha	*Sapindus mukorossi*	Stem Bark (Powder)	50 mg

Table-2: Composition of Hamdoroid Ointment

Unani Name	Botanical/Scientific Name	Form/Part Used	Percentage
Rasaut	*Berberis aristata*	Conc. Aq. Ext. of Leaves	5.0%
Maazu	*Quercus infectoria*	Conc. Aq. Ext. of Galls	3.0%
Neem	*Azadirachta indica*	Seed Oil	5.66%
Sat-e-Pudina	*Mentha piperita*	Menthol Crystals	0.33%
Kafoor	*Cinnamomum camphora*	Waxy Solid Mass	2.0%
Safeda Kashghari	*Plumbi Carbonate*	Powder	5.0%
Suhaga Saeeda	*Sodii Biboras*	Powder	3.0%
Roghan Arand	*Ricinus communis*	Seed Oil	2.33%

Conc. Aq. Ext. = Concentrated Aqueous Extract

Study Design:

The study was carried out as a *double blind, placebo-controlled, randomised clinical trial*. At the entry point (Week 0/ baseline) the patients were randomly assigned by simple random sampling using random number table to receive either *combination-A* (Placebo) or *combination-B* (Drug) under double blind conditions.

Hamdoroid capsule and Hamdoroid ointment and their placebos were supplied by *Hamdard National Foundation, New Delh*i, as *combination-A* and *combination-B* (blinded) and the blinding was broken down after the accomplishment of the study.

3. Study Population:

At the time of first report of the patients' detailed history was interrogated regarding age, sex, occupation, dietary, bowel and personal habits, family history of piles, bleeding per rectum and other symptoms pertaining to Haemorrhoids in general. Thorough general physical and systemic examinations of all the patients were made to exclude other pathological conditions, if any. A complete anorectal (digital P/R and Proctoscopic) examination was also conducted to establish the position, size of pile masses and the degree of inflammation, if present; and to detect any other anorectal pathology such as fistula and rectal prolapse etc. Only the patients who were diagnosed as the cases of First and Second degree Haemorrhoids were subjected to undergo blood examinations in order to exclude other latent pathological conditions and to evaluate the safety of the drug as well. Only eligible patients as per the inclusion and exclusion criteria were inducted in the study.

5. Inclusion Criteria:

Patients of both sexes, aged 25-60 years with symptomatic 1^0 & 2^0 Haemorrhoids confirmed by proctoscopic examination were included in the study. Written informed consent was obtained from each patient before initiating any study procedure.

6. Exclusion Criteria:

Patients with any co-existing anorectal pathology e.g. anal fissure, fistula-in-ano, carcinoma of rectum etc., were excluded. Pregnant and lactating women and patients having III & IV degree Haemorrhoids/ Complicated Haemorrhoids were also excluded.

9. Drug Administration and Dosage:

Hamdoroid capsule (Capsule-B) was administered to the patients in the dose of 2 capsules twice daily with plain water along with the local application of Hamdoroid ointment (Ointment-B). The patients were advised to apply 1 gm ointment twice daily after the evacuation of bowel (an applicator was also supplied to the patients). Placebo capsules (Capsule-A) and Placebo ointment (Ointment-A) were administered to the patients of control group in similar manner. The treatment was continued for a period of 6 weeks and follow up was carried out every fortnightly.

All patients were carefully questioned as regard to symptoms in an attempt to score their severity. Pain was assessed by using a pain score rating from 0 (= no pain); 1 (= mild); 2 (= moderate) and 3 (= severe pain). Similar scoring patterns were adopted for bleeding, itching, burning and mucous discharge. Bleeding was scored as 0 (= no bleeding; 1 (= slight or few drops); 2 (= moderate or less than 1 once) and 3 (= profuse or more than 1 once). In addition to the symptoms the degree of anitis (inflammation of anal mucosa) on and around the Haemorrhoids was evaluated by proctoscopic examination and scored as: 0 = no sign of mucosal inflammation, or a pink healthy mucosa; 1= mild anitis or no overt inflammatory findings; 2= moderate degree of congestion and 3 = severe anitis or overt signs of inflammation and oedema.

A total symptom score of 13-18 was regarded as severe; 7-12 as moderate; 1-6 as mild and no symptom was scored zero.

A symptom was considered to be completely relieved if its score becomes zero after treatment (absence of symptom =complete relief). Whereas, if the symptom score was decreased from previous score, it was considered as partially relieved and if the symptom score remained same as previous one, it was considered as no relief.

RESULTS:

A total of 53 patients of 1^0 & 2^0 Haemorrhoids (27 in Placebo group and 26 in Drug group) were registered over the study period (Oct. 2004- March 2005). Out of 53 cases, 12 subjects (4 in drug group and 8 in placebo group) dropped the study prior to the accomplishment of treatment period, either due to inefficacy or unknown reasons. Total 22 patients in Drug group and 19 patients in Placebo group completed the study up to 6 weeks (end of treatment) .The demographic data and baseline characteristics of patients are given in Table-3.

Table-3: Demographic data and baseline characteristics of patients

Characteristics/ Records		**Drug group (N=22)**	**Placebo group (N=19)**	**Total (N=41)**
Sex - N (%)	Male	17 (27.27)	14 (73.68)	31(75.61)
	Female	05 (22.73)	05 (26.31)	10 (24.93)
Age (years)	Mean ± SD	37.55 ± 12.89	31.37 ± 6.95	34.68 ± 10.89
BMI (kg/m^2)	Mean ± SD	22.80 ± 3.65	23.90 ± 11.84	23.31± 8.39
Family history of Piles N (%)	Present	03(13.64)	02(10.53)	05(12.20)
	Absent	19(86.36)	17(89.47)	36(87.80)
Duration of disease	Mean ± SD	4.08 ± 2.98	4.66 ± 3.34	4.35 ± 3.12
Degree of Piles -N (%)	I degree (prolapse -)	06(27.27)	06(31.58)	12(29.27)
	II degree (prolapse +)	16(72.23)	13(08.42)	29(70.73)
Location of Piles -N (%)	3’ o clock	02(9.09)	04(21.05)	06(14.64)
	7’ o clock	04(18.18)	03(15.79)	07(17.07)
	11’ o clock	05(22.73)	04(21.04)	09(21.95)
	3,7’ o clock	04(18.18)	03(15.80)	07(17.07)
	3’ 11’ o clock	0	01(5.26)	01(2.44)
	7’ 11’o clock	02(9.09)	01(5.26)	03(7.32)
	3’7’11’o clock	05(22.73)	03(15.79)	08(19.51)
Symptoms/signs -N (%)	Bleeding P/R	22(100)	18(94.74)	40(97.56)
	Pain on Defaecation	19(86.37)	18(94.74)	37(90.24)
	Mucous discharge P/R	16(72.72)	09(47.37)	25(60.07)

	Itching	18(81.82)	10(52.63)	28(68.29)
	Burning	18(81.82)	15(78.95)	33(80.49)
	Constipation	22(100)	19(100)	41(100)

N = number of patients; % = percent; SD = standard deviation; BMI =; body mass index

Effects of Drug Group:

Remarkable improvement in the form of complete relief in all symptoms was seen in 54-80% of patients in Drug group and significant improvement was achieved in all the three grades of symptom severity, as shown in Table-4.

Table-4: Effects of Hamdoroid combination therapy on various symptoms/signs: (N=22**)**

Symptoms/signs	Degree of severity	Number (%) of patients presented with Symp. /signs		N umber (%)of patients reported:		
		BT	AT	Complete relief	Partial relief	No relief
Bleeding	Mild	05(22.73)	02(9.09)	03(13.64)	0	02(9.09)
	Moderate	13(59.09)	01(4.55)	08(36.36)	04(18.18)	01(4.55)
	Severe	04(18.18)	01(4.55)	01(4.55)	02(9.09)	01(4.55)
Total N (%) with bleeding		22(100)	04(18.18)	12(54.54)	06(27.27)	04(18.18)
Pain	Mild	01(4.55)	0	01(4.55)	0	0
	Moderate	13(59.09)	01(4.55)	12(54.54)	0	01(4.55)
	Severe	05(22.73)	01(4.55)	02(9.09)	02(9.09)	01(4.55)
Total N (%) with pain		19(86.37)	02(9.10)	15(68.18)	02(9.09)	02(9.09)
Mucous discharge	Mild	02(9.09)	0	02(9.09)	0	0
	Moderate	12(54.54)	02(9.09)	09(40.91)	01(4.55)	02(9.09)
	Severe	02(9.09)	0	02(9.09)	0	0
Total N (%) with Muc.disch.		16(72.72)	02(9.09)	13(59.09)	01(4.55)	02(9.09)
Itching	Mild	14(63.64)	05(22.73)	09(40.91)	0	05(22.73)
	Moderate	04(18.18)	0	04(18.18)	0	0
	Severe	0	0	0	0	0
Total N (%) of with itching		18(81.82)	05(22.7)	13(59.09)	0	05(22.73)
Burning	Mild	06(27.27)	0	06(27.27)	0	0
	Moderate	11(50.00)	02(9.09)	07(31.82)	02(9.09)	02(9.09)
	Severe	01(4.55)	0	0	01(4.55)	0
Total N (%) with burning		18(81.82)	02(9.09)	13(59.09)	03(13.64)	02(9.09)
Inflammation	Mild	01(4.55)	0	01(4.55)	0	0
	Moderate	08(36.36)	01(4.55)	06(27.27)	01(4.55)	01(4.5)
	Severe	10(45.46)	01(4.55)	07(31.82)	02(9.09)	01(4.55)

Total N (%) with inflammation		19(86.37)	02(9.10)	14(63.64)	03(13.64)	02(9.09)
Prolapse	-	16(72.72)	03(13.64)	13(59.09)	0	03(13.64)
Constipation	-	22(100)	04(18.18)	18(81.82)	0	04(18.18)

Sym.= symptoms; N= number of patients; %= percentage; BT= before treatment

All 22 patients were presented with bleeding P/R, out of them 4 cases reported severe, 13 moderate and 5 cases reported mild bleeding at base-line. Complete relief was achieved in 12 (54.54%) cases, partial relief was obtained in 6 (27.27%) cases, while no relief was recorded in 4 (18.19%) cases, out of total 22 cases.

Five patients (22.73%) were accounted with severe, 13 (59.09%) with moderate and 1 (4.55%) with mild pain. Out of total 19 cases with pain, 15 (68.18%) cases got complete alleviation and 2 (9.09%) cases reported partial relief, whereas 2 (9.09%) cases did not get any relief in pain.

Mucous discharge was present in 16 cases, 13 (59.09%) patients gained complete abatement and 1 (4.55%) case got partial relief. No improvement in mucous discharge was reported by 2 (9.09%) patients.

Mild to moderate degree of itching was the complaint of 18 (81.82%) subjects out of them 13 (59.09%) patients reported complete relief, while 5 (22.73%) reported no improvement.

Burning at and around anus was present in 18 cases (11 with moderate; 6 with mild; and 1 with severe burning), out of them 13 (59.09%) relieved completely and 3 (13.64%) relieved partially, 2 (9.09%) cases did not observe any relief.

Constipation was reported by all 22 cases at base line, which was completely relieved in 18 (81.82%) cases and persisted in 4 (18.18%) cases even after completion of 6 weeks treatment.

Prolapse was the presenting symptom in 16 (72.72%) patients at base line, after 6 weeks treatment, only 3 (13.64%) cases reported prolapse on straining, which regressed spontaneously.

The time of relief from symptoms in most of the cases was averaged 10 days.

Proctoscopic examination in the patients of Drug group revealed marked regression in inflammation, which was present in 19 (86.37%) cases, amongst them complete regression was achieved in 14 (63.64%) cases, partial improvement was found in 3 (13.64%) cases, whereas inflammation persisted in 2 (9.09%) cases.

Proctoscopy also confirmed the shrinkage of pile masses to a lesser extent after 6 weeks treatment compared with that present at base line.

Effects of Placebo Group:

In placebo group no significant improvement in symptoms was obtained. As shown in Table-5, few patients reported negligible relief only in few symptoms; constipation was relieved only in 2 (10.53%) cases, while 3 (15.79%) cases got partial relief only in bleeding, pain, burning and inflammation.

Table-5: Effects of Placebo on various symptoms/signs: (N=19**)**

Symptoms/signs	Degree of severity	Number (%) of patients presented with Symp. /signs		N umber (%0 of patients reported:		
		BT	AT	Complete relief	Partial relief	No relief
Bleeding	Mild	05(26.32)	04(21.05)	0	01(5.26)	04(21.05)
	Moderate	09(47.37)	07(36.84)	0	02(10.53)	07(36.84)
	Severe	04(21.05)	04(21.05)	0	0	04(21.05)
Total N (%) with bleeding		18(94.74)	15(78.94)	0	03(15.79)	15(78.94)
Pain	Mild	03(15.79)	03(15.79)	0	0	03(15.79)
	Moderate	12(63.16)	09(47.37)	0	03(15.79)	09(47.37)
	Severe	03(15.79)	03(15.79)	0	0	03(15.79)
Total N (%) with pain		18(94.74)	15(78.95)		03(15.79)	15(78.95)
Mucous discharge	Mild	03(15.79)	03(15.79)	0	0	03(15.79)
	Moderate	04(21.05)	04(21.05)	0	0	04(21.05)
	Severe	02(10.53)	02(10.53)	0	0	02(10.53)
Total N (%) with Muc.disch.		09(47.37)	09(47.37)	0	0	09(47.37)
Itching	Mild	06(31.58)	06(31.58)	0	0	06(31.58)
	Moderate	04(21.05)	04(21.05)	0	0	04(21.05)
	Severe	0	0	0	0	0
Total N (%) with itching		10(52.63)	10(52.63)	0	0	10(52.63)
Burning	Mild	08(42.10)	07(36.84)	0	01(5.26)	07(36.84)
	Moderate	05(26.32)	03(15.79)	0	02(10.53)	03(15.79)
	Severe	02(10.53)	02(10.53)	0	0	02(10.53)
Total N (%) with burning		15(78.95)	12(63.16)	0	03(15.79)	12(63.16)
Inflammation	Mild	04(21.05)	02(10.53)	0	02(10.53)	02(10.53)
	Moderate	10(52.63)	09(47.37)	0	01(5.26)	09(47.37)
	Severe	05(26.32)	05(26.32)	0	0	05(26.32)
Total N (%) with inflammation		19(100)	16(84.22)	0	03(15.79)	16(84.22)
Prolapse	-	12(63.16)	12(63.16)	0	0	12(63.16)
Constipation	-	19(100)	17(89.47)	02(10.53)	0	17(89.47)

Sym.= symptoms; N= number of patients; %= percentage; BT= before treatment
AT= after treatment; Muc.dis= mucous discharge

Statistical Analysis of the Results:

Wilcoxon Signed Rank Test:

The value of Z was obtained +3.97 for positive differences and –3.97 for negative differences when pretreatment and post-treatment total scores (sum of all the symptom scores) of all the patients in **Drug group** were computed by applying Wilcoxon signed rank test. The test value +3.97 is greater than the table value of Z, 2.58 ($p< .01$) and –3.97 (test value of Z) is greater than the table value of Z, -2.58 ($p<. 01$). This explains that the difference between pretreatment and post-treatment total scores was highly significant; these results are computed in Table-6.

Table-6: Wilcoxon signed rank test for Drug group: (N=22)

Case No.	Total score *BT*	Total scores *AT*	Difference	Sign of difference	Actual rank	Place of rank	Rank given
1	16	3	+13	+	21	21	+21
2	11	1	+10	+	14	14	+15.5
3	11	12	-1	-	1	1	-1
4	13	15	-2	-	2	2	-3
5	02	0	+2	+	2	3	+3
6	12	1	+10	+	18	18	+19

7	10	0	+10	+	14	15	+15.5
8	05	1	+4	+	5	5	+5
9	09	1	+8	+	9	9	+10
10	02	0	+2	+	2	4	+3
11	13	4	+9	+	12	12	+12.5
12	06	1	+5	+	6	6	+6.5
13	12	1	+10	+	18	19	+19
14	11	1	+10	+	14	16	+15.5
15	11	1	+10	+	14	17	+15.5
16	09	0	+9	+	12	13	+12.5
17	05	0	+5	+	6	7	+6.5
18	11	0	+11	+	18	20	+19
19	09	1	+8	+	9	10	+10
20	10	4	+6	+	8	8	+8
21	15	1	+14	+	22	22	+22
22	10	2	+8	+	9	11	+10
Sum of the ranks given to positive differences= 249 Sum of the ranks given to negative differences= 4 Mean of the rank sum=126.5 Variance of the rank sum =948.75 Standard deviation=30.80							
Z for positive differences= +3.97, which is much greater than the table value of Z, + 2.58 **(p<. 01).**				Z for negative differences=-3.97, which is much greater than the table value of Z, -2.58 **(p<. 01).**			

BT= before treatment; AT= after treatment

In **placebo group** difference between pretreatment and post-treatment total scores was detected insignificant when analysed by Wilcoxon signed rank test, as calculated values of Z were +0.39 and –0.39 for positive and negative differences respectively; + 0.39 is smaller than table value of Z, +1.65 (p > .10) and – 0.39 is smaller than table value of Z, –1.65 (p > .10), these calculations are made clear from Table-7.

Table -7: Wilcoxon signed rank test for Placebo group: (N=19)

Case No.	Total score BT	Total scores AT	Difference	Sign of difference	Actual rank	Place of rank	Rank given
1	8	8	0	0	0	0	0
2	6	5	+1	+	1	1	+6
3	8	8	0	0	0	0	0
4	7	5	+2	+	12	12	+12.5
5	6	7	-1	-	1	2	-6
6	15	16	-1	-	1	3	-6
7	8	6	+2	+	12	13	+12.5
8	10	11	-1	-	1	4	-6
9	10	11	-1	-	1	5	-6
10	4	3	+1	+	1	6	+6
11	6	5	+1	+	1	7	+6
12	8	11	-3	-	14	14	-14
13	13	12	+1	+	1	8	+6
14	6	5	+1	+	1	9	+6
15	7	7	0	0	0	0	0
16	17	17	0	0	0	0	0
17	12	11	+1	+	1	10	+6
18	6	5	+1	+	1	11	+6
19	6	10	-4	-	15	15	-15
Sum of the ranks given to positive differences= 67 Sum of the ranks given to negative differences= 53 Number of tied observations= 4 Mean of the rank sum=60							

Variance of the rank sum =310 Standard deviation=17.60	
Z for positive differences= + 0.39, which is much smaller than the table value of Z, + 1.65 **(p >.10).**	Z for negative differences= - 0.39, which is much smaller than the table value of Z, - 1.65 **(p >.10).**

BT= before treatment; AT= after treatment

Unpaired Student's 't' Test:

Differences of mean of total symptom/sign scores of Drug group were compared with those of Placebo group by employing Unpaired Student's 't' test, which also revealed highly significant difference between the results of the two groups ($p < .001$). These results are shown in Table-8.

Table-8: Unpaired 't' test to compare the results of Hamdoroid combination with Placebo

Variable	**N**	$\bar{X}$	$\sum x^2$	$\sum (X-\bar{X})^2$	**SD^2**	**SD ±**	**SE ±**	**T_{39}**	**p**
Drug group	22	7.41	1597	389.32	11.38	3.37	1.06	6.09	<. 001
Placebo group	19	0.16	55	54.53					

N= number of patients; X= difference of observations; X = mean of difference; SD= standard deviation; SE= standard error; SD^2= combined variance; t= ratio of mean to SE; p= probability

$\sum x^2$ =Sum of the squares of difference

2.4. Adverse Effects:

Hamdoroid therapy was accepted well by the participants in the study, as compared with Placebo. Data from the physical examination, laboratory tests, and patient's interview for adverse events did not show any side/ toxic effects, only two patients in the Drug group complained epigastric discomfort soon after taking Hamdoroid capsule that subsided spontaneously despite ongoing treatment, no patient reported local irritation; and there was no any complication in either group. Laboratory investigation reports remained within their normal range after 6 weeks treatment.

DISCUSSION:

The results of the present study have demonstrated that Hamdoroid capsule with Hamdoroid ointment were highly effective in relieving the Haemorrhoidal symptoms. Acute attacks (grade 3 severity of pain and/or bleeding) were also relieved significantly with this treatment. An important feature of this study is that treatment outcome was not only based on symptoms, but also on objective healing criteria (regression of inflammation). A significant improvement produced by this combined oral and topical therapy in the proctoscopically observed inflammation deserves emphasis; however we lack histological data to confirm the results.

In majority of the cases of Drug group both the symptoms and objective inflammation scores were markedly reduced without producing complications and considerable side effects, however a very few number of patients reported inadequate response.

In contrast, the results of Placebo on various symptoms and signs in almost all the patients of Haemorrhoids were found unsatisfactory.

Hamdoroid capsule and Hamdoroid ointment seem to have therapeutic role in producing relaxation of the anal sphincter and reduction in inflammation and oedema due to which tremendous relief was obtained in various symptoms of Haemorrhoids in this clinical trial.

The reduction in inflammation and pain might be due to the local effects of analgesic property of Kafoor (*Cinnamomum camphora*) [9], and anti-inflammatory and healing promoting properties of Rasaut (*Berberis aristata*)[10], Roghan Neem (*Azadirachta indica*) [11], and Ritha *(Sapindus mukoressi)*[9].

Reduction in oedema, inflammation and pain [12] might also be due to oral administration of Rasaut (*Berberis aristata*), Mazu (*Querus infectoria*), Neem (*Azadirachta indica*) and Ritha *(Sapindus mukoressi).*

Marked relief in constipation in Drug group patients seems to be due to laxative property of Muqil (*Commiphora mukul*) and Arand (*Ricinus communis Linn*.) [16].

Application of topical Hamdoroid appears to be beneficial in relieving pain because of sedative and anaesthetic properties [13,14] of its ingredients Kafoor (Cinnamomum camphora), Sat-e-Pudina (*Mentha piperita*) Safeda Kashghari (*Plumbi Carbonate*) and Roghan-e-Arand (*Ricinus communis Linn*.) .

Kafoor (*Cinnamomum camphora*), Sat-e-Pudina (*Mentha piperita*), Maazu (*Querus infectoria*) and Roghan-e-Neem (*Azadirachta indica*) also possess antiseptic properties [9,15], which seem to be additionally helpful in inflammation relief and healing.

Bleeding episodes were arrested certainly because of the Haemostatic property [9] of Maazu (*Querus infectoria*) and Safeda Kashghari (*Plumbi Carbonate*) and astringent activities of Rasaut (*Berberis aristata*) and Suhaga (*Sodii Biboras*). Astringent activity [9] of these drugs also seems to be responsible for the shrinkage of pile masses and lessening of prolapse.

Arand (*Ricinus communis* Linn.) contain an albumin ricin; injection of sodium ricinoleate solutions are used as sclerosing treatment of varicose veins [11], the sclerosing action of Roghan-e- Arand (*Ricinus communis Linn*.) might be beneficial in the reduction of pile masses and prolapse as well.

Haemorrhoids are produced from the distal displacement of haemorrhoidal cushions as a result of increased resting anal pressure due to straining. Laxative effects of Hamdoroid combination may be helpful in avoiding straining, which in turn may reduce further displacement of anal cushions.

Hamdoroid combination by its diverse therapeutic properties may be advantageous in reducing pile masses, prolapse and further displacement of anal cushions. It may be prescribed to patients of 1^0 and 2^0 Haemorrhoids and its effects may further be evaluated on patients with more advanced degree who are reluctant to have recourse with surgery.

The long-term effects of Hamodroid combination therapy could not be addressed in this trial because of the short follow up period and limited time to complete the study. It would be sensible to have long-term follow up for patients with this treatment to see if symptoms recurred and how long after the initial treatment.

Though, with long-term treatment with Hamdoroid capsule and Hamdoroid ointment, a high recurrence rate is not expected.

CONCLUSION

Hamdoroid combination therapy provided marked improvement in mild to severe grades of symptoms in patients suffering from First and Second degree Haemorrhoids.. The improvement produced by the drug was significantly superior to that of placebo. The drugs were well accepted by the participants in this study and no noticeable side effects were detected. Further data are warranted and extensive research is obligatory to comment on the long-term course of the patients with this regimen.

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