



TO STUDY EFFECT OF MOMETASONE FUROATE CREAM ON BLOOD PRESSURE, BLOOD SUGAR AND BLOOD CALCIUM IN HEALTHY VOLUNTEERS

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ABSTRACT

Corticosteroids are mainly used to reduce inflammation and suppress the immune system. Corticosteroids are used in a variety of conditions, ranging from brain tumours to skin diseases. Short-term corticosteroid use is associated with generally mild side effects, including cutaneous effects, electrolyte abnormalities, hyperglycemia, pancreatitis, hematologic, immunologic, and neuropsychologic effects. Long-term corticosteroid use may be associated with more serious side effects, including osteoporosis, hypertension, adrenal insufficiency, gastrointestinal, hepatic, and ophthalmologic effects, hyperlipidaemia, growth suppression, and possible congenital malformations. Blood

pressure, blood sugar and blood calcium level were measured before and four hour after drug application. There is no clinical significant different in blood pressure, blood sugar and blood calcium before and four hour drug application.

KEYWORDS: topical, mometasone furoate cream, blood pressure, blood sugar, blood calcium.

Aims: To study effect of mometasone furoate cream on blood pressure, blood sugar and blood calcium in healthy volunteers.

INTRODUCTION

Corticosteroids are mainly used to reduce inflammation and suppress the immune system. Corticosteroids are used in a variety of conditions, ranging from brain tumours to skin diseases. They are used to treat conditions such as asthma, allergic rhinitis and hay fever, atopic eczema, chronic obstructive pulmonary disease (COPD), painful and inflamed joints,

muscles and tendons, lupus, inflammatory bowel disease (IBD) – including Crohn's disease and ulcerative colitis, giant cell arteritis and polymyalgia, rheumatic arthritis and multiple sclerosis (MS). Corticosteroids can also be used to replace certain hormones in Addison's disease that are not being produced by the body naturally.

There are different topical corticosteroids used in skin diseases. e.g. clobetasol, mometasone, beclomethasone, betamethasone, desonide, fludrocortisone. Use of these steroids depends on strength of corticosteroids and anatomic location. Mainly corticosteroids are administered by oral, parenteral and topical route. Topical corticosteroids are often considered to have greater safety than oral corticosteroids.

Short-term corticosteroid use is associated with generally mild side effects, including cutaneous effects, electrolyte abnormalities, hyperglycemia, pancreatitis, hematologic, immunologic, and neuropsychologic effects. Long-term corticosteroid use may be associated with more serious side effects, including osteoporosis, hypertension, adrenal insufficiency, gastrointestinal, hepatic, and ophthalmologic effects, hyperlipidaemia, growth suppression, and possible congenital malformations.^[1]

In the skin diseases, corticosteroids are used for few days to few weeks and use of different corticosteroids according to potency depends on site (location) of application and severity of disease. Adverse effects of corticosteroids depend on potency of corticosteroids and duration of treatment. High potency corticosteroids are used for longer duration in the treatment of diseases like psoriasis, discoid lupus and other. Use of corticosteroids for longer duration affects blood pressure, blood glucose and calcium level and these effects are depends on blood concentration of corticosteroid. In topically used corticosteroids, the extent of percutaneous absorption is determined by many critical factors such as formulation, vehicle, anatomical site of application, integrity of the epidermal barrier, use of occlusive dressing and concentration and frequency of application.^[2]

Thus, this study was aimed to evaluate the effects of mometasone furoate on blood pressure, blood sugar and blood calcium level in healthy human volunteers.

MATERIAL AND METHOD

This study was conducted in MGM Medical College and Hospital Kamothe, Navi Mumbai in healthy volunteers. Ten healthy volunteers the age group of 18 to 50 years enrolled in the

study. Study was carried out after the permission of Institutional Ethics Committee, proper consents were taken from each healthy volunteer before enrolling in the study. Before enrolment of healthy volunteers in the study, they were explained each and every information of study including use of study, effects and side effect of drug, procedure of blood pressure measurement, blood sugar and calcium level estimation, drug application and blood samples collection. One FTU (fingertip unit)(0.5 gm) mometasone furoate cream 0.01 % w/w was applied on 4 cm × 4 cm area on medial superior side of forearm. Blood pressure, blood sugar and blood calcium level were measured before and four hour after drug application. Three ml blood was collected in plain tube for calcium estimation before and four hour after drug application.

Inclusion criteria

1. Human subjects who were willing to participate in the study.
2. Age 18 to 50 years.

Exclusion criteria

1. Volunteer using oral or topical corticosteroid.
2. Hypertensive and hypotensive human subjects
3. Obese subjects.
4. Diabetic patients

Methods

Blood pressure measurement

Blood pressure was measured before and four hour after drug application in sitting position by using mercury sphygmomanometer.

Blood collection

Blood samples were collected before and 4 hr after drug application.

Blood sugar measurement

Blood sugar level were measured before and four hour after drug application by glucometer.

Blood calcium measurement

Serum samples stored in plain tube were used for calcium investigation. Estimation of calcium done by OCPC method (O – cresolphthalein complexone).

Statistical analysis: Calculated mean, standard deviation and applied t-test.

Correlation done by Karl Pearson test

RESULTS

This study was conducted in MGM Medical College and Hospital Kamothe, Navi Mumbai in healthy volunteers. Study was carried out after the permission of Institutional Ethics Committee, proper consents were taken from each healthy volunteers and patients before enrolling in the study.

Blood pressure (mm Hg) (Table: 9)

Sr. no	Age in year	Sex	Baseline BP (mm Hg) At 11 a.m.		1 st day BP (mm Hg) At 3 p.m.		2 nd day BP (mm Hg) At 11 a.m.	
			S	D	S	D	S	D
1	21	M	126	80	124	80	124	78
2	36	M	142	84	146	84	140	82
3	27	M	136	78	136	80	138	80
4	24	M	128	80	130	78	130	80
5	45	M	148	84	154	88	148	84
6	38	M	134	82	136	80	136	80
7	38	M	116	76	120	76	118	78
8	42	M	126	80	128	80	124	80
9	29	M	124	82	124	82	122	82
10	44	M	138	86	140	86	136	86
Mean (mm Hg)			131.8	81.2	133.8	81.4	131.6	81

S = Systolic blood pressure; D = Diastolic blood pressure

The baseline systolic blood pressure ranged from 116 mm Hg to 148 mm Hg (mean 131.8 mm Hg, SD = 9.5). The diastolic blood pressure was between 76 mm Hg and 86 mm Hg (mean 81.2 mm Hg SD = 3) on first day. Four hour after 1 FTU of mometasone furoate cream application, the systolic blood pressure was raised on an average by 2 mm Hg whereas rise in diastolic blood pressure was less than 1 mm Hg. Both changes were not significant clinically. On second day, the systolic blood pressure was on an average less than the first day and practically no change was observed in diastolic blood pressure. No volunteers developed frank hypertension.

Blood sugar (mg/dl) (Table: 10)

Sr. no	Age in year	Sex	Blood sugar (mg/dl)	
			Before	After
1	21	M	76	84

2	36	M	91	90
3	27	M	96	102
4	24	M	102	107
5	45	M	112	109
6	38	M	93	99
7	38	M	86	85
8	42	M	116	125
9	29	M	89	94
10	44	M	118	112
Mean (mg/dl)			97.9	100.7

The baseline blood sugar level ranged from 76 mg/dl to 116 mg/dl (mean 97.9 mg/dl, SD = 13.8) on first day. Four hour after 1 FTU of mometasone furoate cream application, the blood sugar level ranged from 84 mg/dl to 125 mg/dl (mean 100.7 mg/dl, SD = 13.0) Blood sugar level was raised on an average by 2.8 mg/dl. This change was not significant statistically and clinically. No volunteers developed frank hyperglycemia.

Blood calcium (mg/dl) (Table: 11)

Sr. no	Age in year	Sex	Blood calcium (mg/dl)	
			Before	After
1	21	M	8.6	8.6
2	36	M	9.4	9.3
3	27	M	8.1	8.2
4	24	M	8.6	8.8
5	45	M	7.9	7.9
6	38	M	8.8	8.9
7	38	M	9.7	9.6
8	42	M	8.5	8.5
9	29	M	8.2	8.2
10	44	M	7.9	7.9
Mean (mg/dl)			8.6	8.6

The baseline blood calcium level ranged from 7.9 mg/dl to 9.7 mg/dl (mean 8.6 mg/dl, SD = 0.6) on first day. Four hour after 1 FTU of mometasone furoate cream application, the blood calcium level ranged from 7.9 mg/dl to 9.6 mg/dl (mean 8.6 mg/dl, SD = 0.6) there was minor changes in the blood calcium level. No volunteers developed frank hypercalcemia.

Comparison of blood pressure, blood sugar and blood calcium before and after mometasone furoate application in healthy volunteers (Table 12)

		Mean	SD
SBP (mm Hg)	Before	131.8	9.5
	After	133.8	10.7
DBP (mm Hg)	Before	81.2	3.0

	After	81.4	3.7
Blood Sugar (mg/dl)	Before	97.9	13.8
	After	100.7	13.0
Blood Calcium (mg/dl)	Before	8.6	0.6
	After	8.6	0.6

Comparison of systolic and diastolic blood pressure before and after mometasone furoate topical application in healthy volunteers: (Table 12)

Mean systolic and diastolic blood pressure before the mometasone furoate application was 131.8 +/- 9.5 mm Hg and 81.2 +/- 3.0 mm Hg and after the mometasone furoate application was 133.8 +/- 10.72 mm Hg and 81.4 +/- 3.6 mm Hg respectively.

There was statistically significant difference in systolic blood pressure ($P = 0.023$) but not in diastolic blood pressure ($P = 0.726$) after the mometasone furoate application. Difference in systolic blood pressure was not significant clinically.

Comparison of blood sugar level before and after mometasone furoate topical application in healthy volunteers: (Table 12)

Mean blood sugar level before the mometasone furoate application was 97.9 +/- 13.8 mg/dl and after the mometasone furoate application was 100.7 +/- 12.9 mg/dl.

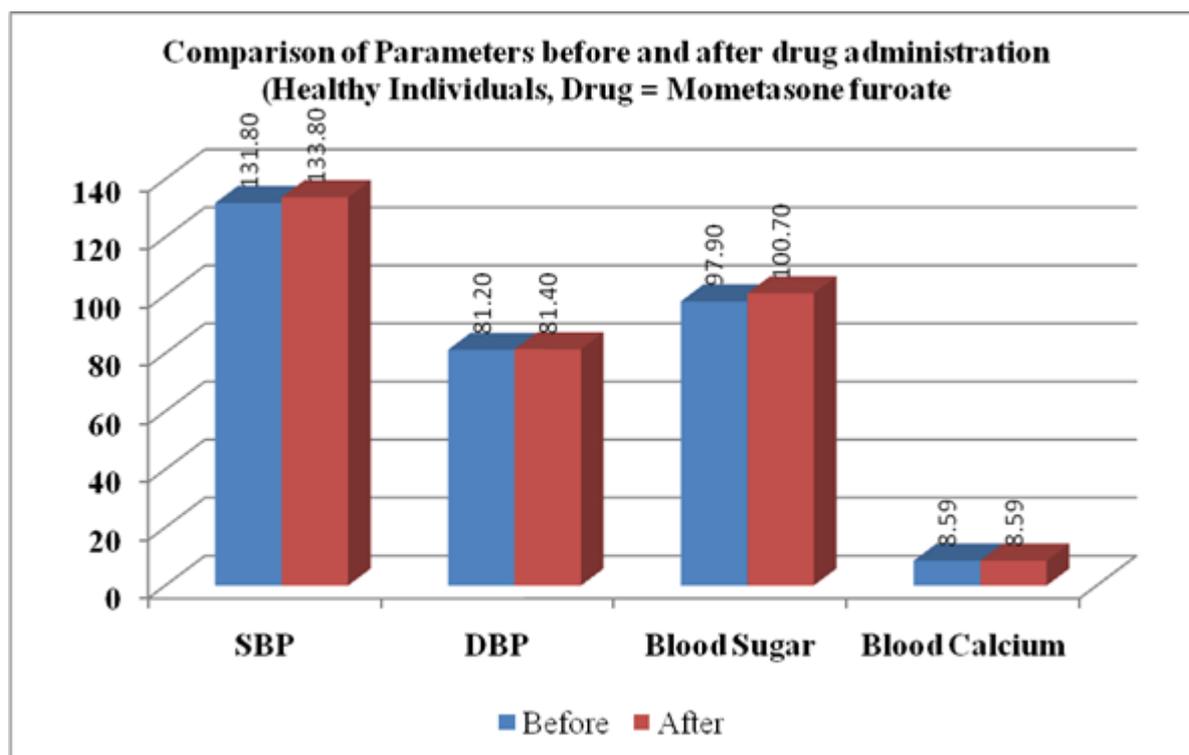
There was no significant difference in blood sugar level ($P = 0.118$) after the mometasone furoate application in healthy volunteers.

Comparison of blood calcium level before and after mometasone furoate topical application in healthy volunteers: (Table 12)

Mean blood calcium before the mometasone furoate application was 8.6 +/- 0.6 mg/dl and after the mometasone furoate application was 8.6 +/- 0.6 mg/dl.

There was no significant differences in blood calcium level ($P = 0.895$) after the mometasone furoate application in healthy volunteers.

Graph 3.



Significant at $P < 0.05$; Name of test: t-test

DISCUSSION

Short-term corticosteroid use is associated with generally mild side effects, including cutaneous effects, electrolyte abnormalities, hyperglycemia, pancreatitis, hematologic, immunologic, and neuropsychologic effects. Long-term corticosteroid use may be associated with more serious side effects, including osteoporosis, hypertension, adrenal insufficiency, gastrointestinal, hepatic, and ophthalmologic effects, hyperlipidemia, growth suppression, and possible congenital malformations.^[3]

Mometasone has not changed systolic or diastolic blood pressure appreciably in volunteers. Blood sugar level and calcium level has remained normal. This could be because of lower potency and drug getting metabolized in the skin tissue. Molecular weight of mometasone furoate is 521.4 respectively. Weight for weight there will be lessor number of molecules of mometasone and plus it is the least potent. Mometasone does not produced effects on systolic blood pressure, diastolic blood pressure, blood sugar level and blood calcium level.

CONCLUSION

Mometasone furoate after single application to skin in normal volunteers have not produced any change in blood pressure, blood sugar and blood calcium levels after four hours.

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