

Glucocorticoid Use and Misuse in a Rural Community of Kerala, India

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Abstract

Background: Glucocorticoids (GCs) are anti-inflammatory steroid medications prescribed globally by doctors for various illnesses and they are known to produce quick symptom relief. In India, they are among the cheapest and easily accessible over-the-counter medications. Thus, it can be misused, leading to many life-threatening illnesses such as diabetes mellitus, hypertension, overwhelming infections, Cushing's syndrome, and hypo-adrenal crisis. **Objective:** This study reports the misuse of GCs in a rural community in the state of Kerala, India, and compares it with the only other community GC misuse study in India, from the state of Bihar. **Methods:** A community-based cross-sectional survey of 452 households comprising 1,734 people was conducted in rural Konni, Kerala, during June and July of 2019. In each house, people who had been taking medications over the previous 6 months were interviewed. **Results:** Almost 2% ($n = 31$) had consumed one or more GCs in the last 6 months (95% CI: 1.3–2.5%). Of these, 26% ($n = 8$) were taking oral GCs and 36% ($n = 11$) of them were inappropriately using them based on current clinical guidelines. 29% ($n = 9$) had used GCs for more than 1 month. **Conclusions:** GC misuse exists in Kerala but not to the extent seen in Bihar. In Kerala, inhaled GCs are more common than oral GCs, and the prescription is obtained predominantly from qualified medical practitioners. The prevalence of prolonged GC use could be implicated as an underlying factor for diabetes, hypertension, osteoporosis, and cataracts. It is possible that approximately 220,000 people in Kerala may have a suppressed hypothalamus-pituitary-adrenal axis which can predispose them to a fatal hypo-adrenal crisis.

Keywords: Corticosteroid misuse, glucocorticoid use, India, Kerala, steroid abuse

INTRODUCTION

Glucocorticoids (GCs) are rapidly acting, anti-inflammatory drugs that can save lives. However, without proper monitoring, GC misuse can lead to numerous complications such as diabetes mellitus, hypertension, cataracts, osteoporotic fractures, mental health conditions, and exacerbation of infectious diseases.^[1–3] Other features of iatrogenic Cushing's syndrome include increased intraocular pressure, benign intracranial hypertension, and avascular necrosis of the femoral head.^[4,5] Abrupt discontinuation of GC, after a long period of misuse, can lead to a life-threatening hypo-adrenal crisis.^[6]

The popular media has several reports of the drastic effects of GC misuse. In 2017, a 45-year-old lady from New Delhi was reported to have consumed oral GCs for 20 years for her asthma which led to multiple bone fractures requiring surgical intervention.^[7] In 2015, an Indian woman in her mid-60s,

who took betamethasone for 15 years, developed cataracts and diabetes mellitus.^[8] The same article also reported that a 61-year-old man developed chronic obstructive pulmonary disease (COPD), who kept taking a daily steroid tablet for 1 year. Both these patients were given GCs and asked to come back for further consultation when their prescription was over. However, they continued to take the steroids even after the prescribed time. Commercial sex workers in Bangladesh are known to use GCs to improve physical appearance to attract

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clients.^[9-11] Thus, the issue of GC misuse is a complex problem across South Asia.^[12]

Most GC misuse can be explained by its wide availability, easy access, low cost, quick therapeutic benefit, and the lack of regular follow up after initial consultation. Although topical GC misuse in India is widely studied and documented,^[13] oral GC misuse, the more harmful route of administration, still remains an unaddressed problem in the Indian subcontinent. The first research study documenting oral GC misuse is based on a rural community in North India.^[14] Further study revealed that 34% of the people in North Bihar were taking oral GC for over 6 months prior to the study and 79% of these study participants had taken GCs for more than a month.^[15]

Data from the state of Bihar is not nationally representative. Bihar falls in the states where the epidemiologic transition has been occurring lately.^[16] Therefore, this current study was designed to address the issue of GC misuse in a population at the other end of the epidemiological transition in Kerala, India. This study evaluates the use of GC in a rural community in the state of Kerala and should provide a useful comparison to the available data from Bihar.

METHODS

A community-based cross-sectional survey was used to examine the prevalence of GC use in rural Kerala. This household-based field study was conducted from June to July 2019 in Konni Block, Pathanamthitta District, in Kerala, India. This area is served by the Rural Health Training Centre (RHTC) of the Institution. In Konni Block, the survey was conducted in three panchayats: Aruvapalam, Pramadam, and Konni that are within a 10 km radius of the RHTC. These three panchayats contain about 1500 houses with a total population of about 5,200 people.

Based on prior knowledge of incidence in Bihar^[15] but considering much-improved healthcare in Kerala,^[16] we assumed the prevalence of the misuse in Kerala to be about 10%. Thus, we calculated a sample size of 450 households with approximately 1700 participants. To ensure representative sampling of the region, a systematic sample of every third household from each panchayat was chosen.

Each permanent resident was interviewed about medications taken in the past 6 months, in addition to socio-demographic data such as gender, age, occupation, education level, health style behavior (type of health-care provider), and medical costs for each participant (direct costs such as medication, doctor’s visit and indirect costs such as travel, travel-companion, and loss of wages). All individuals who agreed to participate in this community-based survey signed the consent forms in their relevant language. For those who could not read and write, or were under the age of 18, the head of the household signed on their behalf.

To quantify inappropriate GC misuse, revised versions of the criteria in the previous study carried out in Bihar were used.^[15] The inclusion criteria for inappropriate use in this study were:

1. Prescription without a precise diagnosis (usually the doctor’s notes are written on the same paper as the prescription and stay with the patient),
2. incorrect indications by standard clinical and evidence-based practice guidelines,
3. duration of use which was longer than normally acceptable,
4. those taking more than the recommended dose,
5. a combination of the factors listed above.

The data collected was entered into Google Form at the end of each day. Analysis was done in both SAS University Edition and MS Excel. Descriptive statistics were calculated as percentages and 95% CI was calculated using VassarStats. Ethical clearance for this research study was obtained from the Institutional Ethics Committee.

RESULTS

We invited 1742 people from 452 households to participate in interviews over the study period. Eight people from three households declined, and a total of 1,734 people (449 households) comprised the study sample. Of these, 412 persons had taken some type of medication in the last 6 months. A total of 31 of the 412 people (7.5%) had taken some form of GC while eight of these 31 (26%) had taken oral GCs [Figure 1]. Data regarding routes of administration are presented in Table 1 and lengths (duration) of administration are given in Figure 2.

These participants had obtained their medications from multiple sources. Most (six out of eight) had obtained their prescription for the medication from hospital-affiliated doctors and one from a private practitioner. The remaining one was prescribed by a pharmacist.

The most common types of oral GCs used in Konni were prednisolone ($n = 3$), deflazacort ($n = 3$), methylprednisolone ($n = 1$), and hydrocortisone ($n = 1$). Half of the participants (four out of the eight) were using the GCs for musculoskeletal conditions and three participants reported that they were using them for respiratory illnesses. One participant was unsure of the reason for the GC prescription, despite using it for 35 years [Table 2]. Inhaled GC was only being used as a treatment for asthma and COPD. Four participants who reported GC use were using them topically.

The prevalence of the use of GCs, regardless of the route of administration, was 1.8% ($n = 1734$), (1.2% - 2.5% - 95% CI). We observed that 11 of the 31 (35%) were prescribed and/or were using these GCs inappropriately. Of these 31 participants,

Table 1: Glucocorticoid administration methods

		Frequency (N)	Percentage (%)
1	Inhalation	18	58
2	Oral	7	22.6
3	Topical	4	12.9
4	Inhalation and Oral	1	3.2
5	Inhalation and Nasal	1	3.2
	<i>Total</i>	<i>31</i>	<i>100</i>

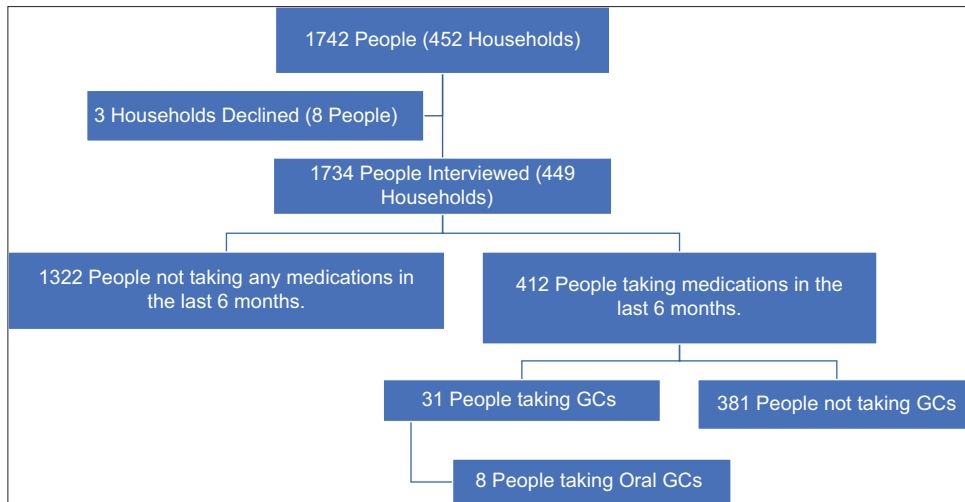


Figure 1: A depiction of the overall results with the number of households/people surveyed and the results of the number of people taking medications in the past 6 months. Of those, looking at the number of people taking glucocorticoids

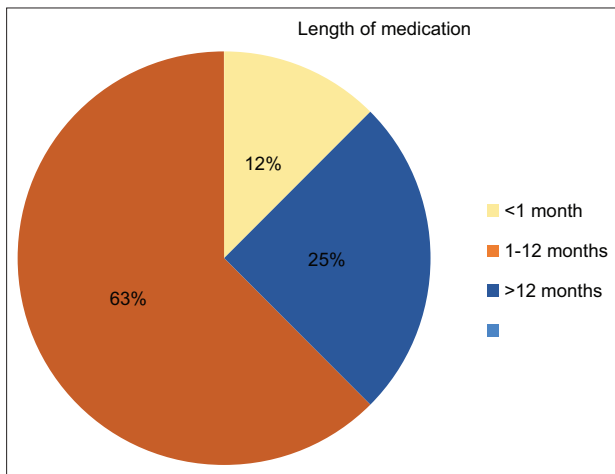


Figure 2: Duration of medicine usage. The duration for which the oral glucocorticoids were administered ranging from less than a month to more than a year ($n=8$)

eight were taking the GCs orally, all of them inappropriately. This makes the prevalence of oral GC misuse to be 0.46% (8 out of 1734) with a 95% CI of 0.21% - 0.94% [Table 3].

DISCUSSION

The population prevalence of GC misuse for this study is 0.63% (11 out of 1734). In the study carried out in North Bihar, the population prevalence was not calculated but has been estimated at 8.0% using an average household size of 5.2 from the census data in the East Champaran District.^[14,17] Although the prevalence of the misuse of GCs in Kerala was much lower than in Bihar, when the prevalence rate is scaled up to the total population, it would imply that up to 220,000 people in Kerala are at risk of having a suppressed hypothalamus-pituitary-adrenal (HPA) axis. Suppressed HPA axis in an individual can increase the risk of developing a hypo-adrenal crisis in the event of an intercurrent illness or

major stress. This 13-fold difference is as expected and is likely due to factors such as literacy rates, income levels, quality and availability of health care, and epidemiological transition level differences between the two states. For instance, the literacy rate in Kerala is higher than 95% while the literacy rate in Bihar is only 58%.^[14]

Kerala also has a higher doctor-to-population ratio when compared to Bihar.^[16] This could explain why, unlike Bihar, only one person in Kerala had obtained the GC from an untrained medical practitioner, while, for the others, doctors affiliated with hospitals provided these medications. In Bihar, the trained medical practitioners are located only in urban areas, so it costs less for people from rural communities to consult the local compounder or other untrained healthcare practitioners.

With regard to prescription refills, most of the participants in both Kerala and Bihar did not follow up with the prescribing physician and instead reported going to the pharmacy for medication refills.

Previous studies in India had looked at the perception of practicing physicians on the use of GCs as therapeutic options.^[18,19] Most of the doctors believe that medications other than GCs could be used to treat many of the conditions due to their adverse side effects. However, if prescribing GCs is the only option, then it is best to prescribe it at a minimal dosage.^[18] The *Journal of Medicine* (Bangladesh) provides a protocol that explains the use, abuse, and withdrawal of GCs and how to guide patients regarding the use of GCs.^[13]

When looking at the GCs used in the two states, the four oral GCs used in Kerala were deflazacort ($n = 3$), prednisolone ($n = 3$), hydrocortisone ($n = 1$), and methylprednisolone ($n = 1$) whereas in North Bihar the top three oral GC's used were dexamethasone, prednisolone, and betamethasone, respectively.^[14] Although there were fewer people in Kerala using oral GC's compared to Bihar, there is still a large number of them misusing GCs and taking them for much longer durations than the prescribed

Table 2: Patient reported reasons for oral GCs consumption

	Reason for GC use	Type of Oral GC		
		Deflazacort	Prednisolone	Hydrocortisone
1	Muscle dystrophy	2	-	-
2	Muscle Pain	1	-	-
3	Headache following Meningitis	-	-	1
4	Fever/Cough/Allergy	-	1	-
5	Arthritis	-	1	-
6	Asthma	-	1	-
7	Patient unaware of reason	-	1	-
	<i>Total</i>	<i>3</i>	<i>4</i>	<i>1</i>

Table 3: Frequency of GC use

	Variables	Frequency	Percentage (%)
1	Any medication used in past 6 months	412	23.8
2	Any GC used in past 6 months	31	1.8
3	Inappropriate GC use	11	0.63
4	Oral GC use >1 month (Risk of suppressed HPA axis)	8	0.46
	<i>Total</i>	<i>1734</i>	<i>100</i>

time. The discrepancies observed in the type of medication taken in Kerala versus Bihar can be largely explained by the socio-economic disparities between the regions. For instance, participants in Kerala reported using deflazacort, an expensive GC, while none in Bihar used it^[14,15]. The long acting and inexpensive GCs were barely used in Kerala but widely used in Bihar. Inhaled steroids were more common in Kerala, while in Bihar the cheaper oral GCs like prednisolone, dexamethasone, and bethamethasone are predominantly used.

In Kerala, ayurvedic and homeopathic medications are very also popular among the general population for a wide variety of chronic illnesses, such as arthritis, asthma, and eczema. They are generally preferred over allopathic system of medicines (modern Western medicines) as they are perceived to have no side effects. Our study results are likely to be an underestimate of GC misuse because the constituents of ayurvedic and homeopathic medicine are not clearly known. However, they are often suspected to contain GCs which contribute to some of their therapeutic benefits.^[19]

The two main reasons for GC use in Kerala appear to be chronic respiratory and musculoskeletal conditions. Fever, cough, and headaches (due to a past history of meningitis) were some of the other inappropriate reasons for prolonged GC use in Kerala. There was one participant with colon cancer who was consuming oral GCs for nearly 35 years.

Currently, we do not have enough information to estimate the impact of GC misuse on the prevalence of non-communicable diseases such as hypertension, diabetes mellitus, cataracts, and others. For this study, the definition of diabetes mellitus, hypertension, cataracts, and other co-morbidities were based on participant responses to the medication they were taking or by the name of the medication. Therefore, although

co-morbidities of the study participants were recorded, it is difficult to make meaningful conclusions on the validity of the stated reasons for oral GC use and also may not accurately reflect community prevalence. Furthermore, due to the small number of cases in Kerala, there was insufficient information to distinguish whether the GC misuse or the co-morbidity came first. However, anecdotal information from our participants suggests that this is likely. For instance, a 75-year-old man who took oral GCs for 35 years, developed diabetes mellitus after 6 years, and hypertension after 8 years.

In order to understand the larger impact of GC misuse, similar multicentric community studies need to be carried out across the country to obtain a better idea of the use and misuse of GCs. It could also be enhanced by including an assessment of fracture history, screening for cataracts, blood sugar, tuberculosis, and blood pressure of all participants above 18 years of age.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient (s) has/have

given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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