

## Glucocorticoid Use Audits

As practicing clinicians and endocrinologists, most of us can recall patients presenting with complications related to excess glucocorticoid use without a valid therapeutic indication. The three common situations encountered by clinicians include (1) Patients continuing to take glucocorticoids prescribed to them as a short course for respiratory, dermatological or rheumatologic ailments without informing the clinician who suggested glucocorticoids in the first place due to continued symptom relief, (2) patients prescribed glucocorticoids by unqualified medical practitioners for long durations for steroid responsive ailments, and (3) patients who are given unlabeled glucocorticoids as part of natural remedies for multiple ailments responsive to steroids.

Excess and prolonged glucocorticoid use results in exogenous Cushing's syndrome and present to clinicians with secondary diabetes, hypertension, early onset cataracts and/or glaucoma, osteoporotic fractures, opportunistic infections such as tuberculosis and invasive fungal infections and sometimes with depression and psychiatric illnesses. Rarely, clinicians also encounter features of adrenal insufficiency in patients admitted to hospital who have abruptly stopped glucocorticoid containing medications. A recent paper from North India suggested that 3.5% (5/141) of patients presenting to the medical ward with euvolemic hyponatremia had adrenal insufficiency secondary to undocumented steroid use including contamination of indigenous medications with steroids.<sup>[1]</sup>

In India, dermatologists have been regularly campaigning against the misuse of topical glucocorticoids for the last couple of decades. Over the years, they have produced a significant volume of data and papers from across the country documenting the degree of misuse.<sup>[2-7]</sup> This has led to the inclusion of many commonly available topical steroids as schedule H drugs by the regulators.<sup>[8]</sup> An elegant review identified the various stages at which topical steroids can potentially be misused including, (1) Manufacturing misuse including the manufacturing of clinically unproven combinations in an attempt to increase sales, (2) Marketing misuse – which includes marketing of potent glucocorticoid containing drugs to alternative practitioners who may not have a clear understanding of the potential long term consequences of the therapy, (3) Pharmacy and sales misuse, (4) Prescription misuse, and (5) Misuse by lay persons and unqualified practitioners.<sup>[9]</sup>

We recently published a review on steroid stewardship which is a systematic effort to prescribe glucocorticoids in a rational manner among patients who require this therapy. Steroid stewardship includes preprescription screening, rational prescription, and medical care during corticosteroid use along with appropriate monitoring after corticosteroid use has been discontinued. One of the pillars of steroid stewardship is patient

education about the duration of glucocorticoid therapy and the need to discontinue the treatment as advised. However, steroid stewardship is only possible when these agents are used rationally by qualified medical practitioners in health-care settings.<sup>[10]</sup>

As endocrinologists and clinicians dealing with most of the complications related to excess glucocorticoid use, we have unfortunately not produced enough data on the volume of misuse of oral glucocorticoids in the community from across the country. In first, in 2012, Nalli *et al.* documented that in a rural community in Bihar, 34% of subjects interviewed had taken oral glucocorticoids in the preceding 6 months. A large majority of these patients had taken steroids for more than a month.<sup>[11,12]</sup> In this issue of the journal, a similar community-based cross-sectional survey was undertaken in over 452 households consisting of 1734 subjects in rural Konni in Kerala by the same author. Rural Bihar and rural Kerala are two extremes of healthcare availability and education in India. However, surprisingly, despite better primary health care and literacy, about 2% of the rural population in Konni was taking steroids. All of them were prescription steroids, but in 11/1734 (0.6%), the prescription was considered inappropriate. These two community audits of glucocorticoid use/misuse suggest that there is a lot of data that needs to be generated to quantify the extent to glucocorticoid misuse in our country, which in turn will hopefully bring this problem to better focus and attention from drug regulators and lawmakers in our country.

In addition to the community-based audits described above, the following types of glucocorticoid audits that can be easily done include,

1. Manufacturing and sales Audits. Sunil Rathi in a letter published in 2009, noted that in his home district of Ujjain and neighboring Shahjapur district in Madhya Pradesh in the years from 2006 to 2008 over 22,000–30,000 bottles of pediatric betnesol drops manufactured by Glaxo Smith Kline Ltd were sold per year. If generic and other brands were also included, this figure went up to 40,000 bottles/year. The author notes that these sales are ongoing despite no effort by the company in promoting the product or any genuine indications for the use of these products in infants.<sup>[14]</sup> These types of simple total sale audits of glucocorticoids can help us visualize the extent of misuse in the various parts of the country
2. Pharmacy audits. Audits of pharmacists dispensing oral glucocorticoids have suggested poor knowledge about the indications and adverse events related to them.<sup>[15,16]</sup> Over-the-counter, dispensing of glucocorticoids and dispensing using out-of-date prescriptions are common

practices. An audit of these practices will add valuable information on the extent of glucocorticoid misuse in the community. The suggestion from Mathew *et al.* in their survey of 32 pharmacies operating within the municipality of Thiruvalla town suggests that glucocorticoids consist of approximately 1% of total pharmacy sales in the smaller private pharmacy while it only constituted 0.2% of the sales in a large pharmacy attached to a major teaching hospital.<sup>[16]</sup>

3. Audit of steroid contamination of alternate medications. Audits of steroid contamination in alternative medications are important to pinpoint another possible source of glucocorticoid misuse. Reports of adulteration of herbal medications, ayurvedic medications, and homeopathy medications have been reported. The highest percentage of adulteration being seen with ayurvedic preparations and unlabeled alternative preparations.<sup>[17,18]</sup>
4. Prescription audits. Audits of prescriptions for glucocorticoids in health care setting are the simplest way to ensure steroid stewardship.<sup>[19]</sup> Ensuring that all aspects of preprescription counseling along with clarity about the indication should be documented. The prescription should mention the type of steroid, the dosage, and clearly the duration of steroid use. Physicians should be encouraged to use more physiological steroids for replacement (hydrocortisone instead of prednisolone) in the lowest dose for patients with adrenal insufficiency
5. Laboratory Audits. Audits of the laboratory assessment of hypothalamic-pituitary axis and determining the etiology of secondary adrenal insufficiency and the prevalence of glucocorticoid-related suppression will also help in estimating the burden of glucocorticoid misuse in the community.

The present study by Mulavelelil *et al.*<sup>[13]</sup> is an important starting point at gathering data from various parts of the country regarding glucocorticoid use and misuse. In addition to community-based glucocorticoid use data, other forms of audits also help us in understanding the scope of the problem as described in Figure 1. The widespread use of glucocorticoids in the last couple of years during the COVID epidemic has brought focus to the adverse effects of glucocorticoids including an upsurge in the incidence of new diabetes and an accompanying epidemic of mucormycosis.<sup>[20]</sup> The time is right for endocrinologists to come together to generate the data and focus on regulated steroid use in the community and then put pressure on regulators and governments to curb unregulated steroid prescriptions.



**Figure 1:** The types of audits that can be done to establish the degree of glucocorticoid misuse in a community

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