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Review Article

Consequences of Long-Term Use of Oral Corticosteroid Therapy in the Management of Asthma: Systematic Review

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Abstract

This study provides an overview of the consequence of the use of oral corticosteroid in the treatment of severe asthma in adults; it also identified recent evidence based alternative drug regimen for asthma management to prevent long term negative effect of oral corticosteroids. Asthma is a chronic inflammatory airway disease affecting about 300 million people globally. Approximately 4% to 8% of asthma patient's symptoms remain uncontrolled and exacerbations occur frequently despite high-intensity treatment, hence the need for corticosteroid treatment for sustain symptom control and to prevent flare-ups. Oral corticosteroids are powerful anti-inflammatory medicine which helps by quickly reducing the swelling in the lungs. There is no doubt that the use of oral corticosteroids (OCS) plays a vital role in the management of asthma, particularly in the management of acute exacerbations and severe asthma. However, there is clinical evidence that both long- and short-term use of corticosteroids in asthma has complicated relationship with some referring to them as a 'frenemy, as side effect of oral corticosteroids has detrimental effect on quality of life of asthma patients. The study utilized literature review of web-based articles and journals using multiple databases. Studies both on short term and long- term use of OCS was reviewed to have better understanding of the subject matter. Studies in children populations were excluded as the focus of this study is on adult patients living with asthma. Following the literature search, ten articles met the inclusion criteria and were selected. The study concluded that due to widely acknowledged side effects, and advances in care, there is clinical support for a shift away from a reliance on OCS in the treatment of severe asthma to other alternative management.

Keywords: Oral Corticosteroid, asthma, long term, side effect, adult.

INTRODUCTION

Asthma is a major non-communicable disease (NCD), affecting both children and adults. It causes inflammation and narrowing of the small airways in the lungs with asthma symptoms, such as any combination of cough, wheeze, shortness of breath and chest tightness etc (WHO, 2020). MedicineNet (2020) defined asthma as a clinical syndrome of chronic airway inflammation characterized by recurrent, reversible, airway obstruction. Airway inflammation also leads to airway hyper reactivity, which causes airways to narrow in response to various stimuli. The management of asthma is very important to reduce the burden of the disease and aid people living with asthma to enjoy normal and active life as it has no cure. The treatment of asthma depends on the symptoms. Asthma treatment may require fast-acting rescue medicines, long-term treatments, or both. (Webmed, 2020).

Asthma Australia (2021) opined that Oral corticosteroids are powerful anti-inflammatory medicine which helps by quickly reducing the swelling in the lungs hence relive asthma symptoms. They are much stronger than the inhaled corticosteroid in preventer inhalers. It further stated that long term oral corticosteroids could be prescribed for months or even years. This may be necessary to prevent regular flare-ups. Manchester University in its publication in Science Daily stated that current treatments for severe asthma often include high doses of corticosteroids, such as prednisolone, to control exacerbations (McMaster University, 2018). It

concluded that though oral corticosteroids are very helpful in asthma care, their long- term side effects are detrimental to the well- being and quality of life of persons living with asthma.

Some researchers on the other hand stated that OCS are effective at treating acute exacerbations, however, there is few empirical evidence regarding the efficacy of OCS at reducing the rate of exacerbations. There is evidence, although scarce, suggestive of high exacerbations rates in severe asthma patients even when receiving maintenance treatment with OCS (Katsounou, 2019). Clinical evidence suggests that both long- and short-term use of corticosteroids in asthma management poses threat to the patients. Side effects associated with short term use of oral corticosteroids include: Mood changes. Nausea, anorexia, vomiting, increased appetite, bloating and diarrhea or constipation. Long term use of oral corticosteroid is also associated with: bloating and rounding of face, headache, dizziness, weight gain, redistribution of body fat, water retention, cramps or weakness, slowed growth in children, changes to the skin, changes to the immune system, increased amounts of cholesterol in the blood, increased blood pressure etc (Asthma Australia, 2021).

The Global Initiative for Asthma (GINA) in their 2018 Global Strategy for Asthma Management and Prevention guidelines recommend the use of oral corticosteroids (OCS) for maintenance therapy only in patients with uncontrolled severe asthma and only as low-dosed and as short-term as possible (Global Initiative for Asthma, 2018). In addition, global guidelines are in place which relegate the use of OCS for acute exacerbations only and position them as a last-resort option for maintenance or long-term use in severe asthma. Over-reliance on oral corticosteroids (OCS) in the management of severe asthma cannot only cause significant health risks for the patients, but put unnecessary strain on the health systems (Politicopro, 2021). Global initiative for Asthma (2018) stated that a patient charter, developed by global experts in the disease area, makes it clear that people with severe asthma "deserve not to be reliant on OCS.

Despite wide evidence on the detrimental effect of OCS on persons living with asthma, many countries healthcare system are yet to take decisive political action to challenge existing approaches. This may be due to the continued inclusion of OCS in guidelines, together with their worldwide easy accessibility, familiarity of use, and low acquisition costs compared with newer targeted treatments. In addition, it is likely that some patients fail to benefit significantly from the OCS-sparing effect of biologic treatments because of differences in their susceptibility to OCS-related adverse effects, or because of their unwillingness to initiate new treatment options and reduce OCS use (Eugene et al. 2020). Due to these widely acknowledged side effects, and advances in care, there is clinical support for a shift away from a reliance on OCS in the treatment of severe asthma to other alternative asthma management as severe asthma is a prime example of where reform and prioritization can make a major difference to patient outcomes, while also positively impacting long term healthcare costs.

Objectives of the study

1. Identify the adverse effect of long-term use of oral corticosteroid therapy in the management of asthma
2. Identify alternative to oral corticosteroid therapy in asthma management
3. Evaluate the side effect of the alternative to oral corticosteroid in asthma management

Overview of Asthma

There has been an increase on the incident of bronchial asthma recently which has led to increase in asthma related morbidity and mortality rate globally across ages (Asthma Australia, 2021). This has been noted in different proportions and at varying rates across diverse geographical areas in the world (WHO. 2021). Asthma affected an estimated 300 million people in 2019 and caused 461000 deaths globally (WHO.2021). Asthma affects 68 per thousand individuals in most recent asthma surveys and it remains the leading cause of missed workdays. It is also responsible for 1.5 million emergency department visits annually and up to 500,000 hospitalizations. It is reported that Over 3,300 Americans die annually from asthma (Medicinenet, 2021).

Asthma results from complex interactions between an individual's inherited genetic makeup and interactions with the environment. The causes of asthma vary from person to person and the symptoms also varies. The following are risk factors for asthma: family history of allergic conditions, personal history of hay fever (allergic rhinitis), viral respiratory illness, such as respiratory syncytial virus (RSV), during childhood and Exposure to cigarette smoke (Medicinenet, 2021). World Health Organization stated that many different factors have been linked to an increased risk of developing asthma, although it is often difficult to find a single, direct cause.

- Asthma is more likely if other family members also have asthma – particularly a close relative, such as a parent or sibling.
- Asthma is more likely in people who have other allergic conditions, such as eczema and rhinitis (hay fever).
- Urbanisation is associated with increased asthma prevalence, probably due to multiple lifestyle factors.
- Events in early life affect the developing lungs and can increase the risk of asthma. These include low-birth weight, prematurity, exposure to tobacco smoke and other sources of air pollution, as well as viral respiratory infections.
- Exposure to a range of environmental allergens and irritants are also thought to increase the risk

of asthma, including indoor and outdoor air pollution, house dust mites, moulds, and occupational exposure to chemicals, fumes, or dust.

- Children and adults who are overweight or obese are at a greater risk of asthma (WHO, 2021).

Medications Used in Asthma Treatment

Treatment of asthma may include the use of single drug regimen or combine therapy depending on the severity of the asthma. Some of the medications are:

Bronchodilators- which could be short acting or long acting

Short-acting beta-agonists: they are the first choice for quick relief of asthma symptoms. They are typically used as "rescue" medications to provide *quick* relieve of asthma symptoms. They include albuterol (ProAir HFA, Proventil HFA, Ventolin HFA), epinephrine (Asthmanefrin, Primatene Mist), and levalbuterol (Xopenex HFA).

Long-acting bronchodilators: help control asthma symptoms by keeping the airways open for 12 hours. These medications include: Salmeterol (Serevent®), Formoterol (Foradil®), and Combination medications: salmeterol and fluticasone (Advair®).

Another set of medications used in asthma management are Anticholinergics such as ipratropium (Atrovent) which lessen mucus in addition to opening of airways. These set of medication takes longer time to work than short-acting beta-agonists. Also used in asthma management are oral corticosteroids such as prednisone, prednisolone, betamethasone and methylprednisolone. These group of medications used in asthma treatment reduces swelling (oedema) in the airways. Combination quick-relief medicines have both an anticholinergic and a short-acting beta-agonist (WebMed, 2021).

Most of these medications have short side effects while side effects of some are prolonged. Though there are inhaled corticosteroids used in asthma, oral corticosteroids are widely used due to its stronger effect than inhaled corticosteroids. (WebMed, 2021).

Alternative to Oral Corticosteroids in Asthma Management

Many studies have suggested that some oral corticosteroids such as dexamethasone are potent than others in the management of severe asthma and better patient adherence. Randomized trial study carried out by Natalia et al (2017) concluded that two doses of dexamethasone may be an effective alternative to a 5-day course of prednisone/prednisolone for asthma exacerbations, as measured by persistence of symptoms and quality of life at day 7. The study observed that adherence was greater in the dexamethasone group (99.3% vs 96.0%, P < .05). However, their side effects are similar and possess same detrimental effect on the patient. Extensive research carried out over years provided a favorable answer to the alternative to oral corticosteroid in the management of asthma. Studies have shown that monoclonal antibodies called biologics such as omalizumab (anti-immunoglobulin-E) or anti-interleukin (IL), IL-5 and IL-4/IL13, should be considered as alternatives to OCS in patients with uncontrolled severe asthma (William, 2019). Robinson (2018) stated that quality of life for individuals with severe asthma could be significantly improved with the use of monoclonal antibodies. Biologic drugs are genetically engineered proteins produced from the cells of a living organism, such as bacteria or mice, that is then modified to target specific molecules in humans (McGregor, 2018). They're designed to target specific substances in the immune system that cause inflammation. Omalizumab has 15 years of clinical experience with more than 800,000 patient-years of exposure which make it the first choice of add-on therapy in patients with severe allergic asthma. The study further stated that Omalizumab for the treatment of severe allergic asthma reduces exacerbations and very safe in the management of asthma (McGregor, 2018).

Currently there are five approved biologics for asthma – omalizumab, mepolizumab, reslizumab, benralizumab, and dupilumab – with several others currently in development (Robinson, 2018). Omalizumab targets allergy antibodies known as immunoglobin E (IgE). Mepolizumab, reslizumab, and benralizumab all target pathways that affect eosinophils, a cell involved in allergic inflammation. Dupilumab targets a receptor for two molecules that drive allergic inflammation (American Academy of Asthma Allery and Immunology, AAAAI, 2021). The primary benefit of biologics has been a decrease in the frequency of asthma exacerbations, including emergency room visits, hospitalizations, and need for oral steroids. Other benefits include reduced asthma symptoms, reduced dosage of other controller medication, and less missed school and work days. Biologics use in the treatment of asthma has shown to improve quality of life for patients with asthma. Some biologics has also been found to improve lung function in patients with severe asthma (AAAAI, 2021).

Adverse Effect of Biologics

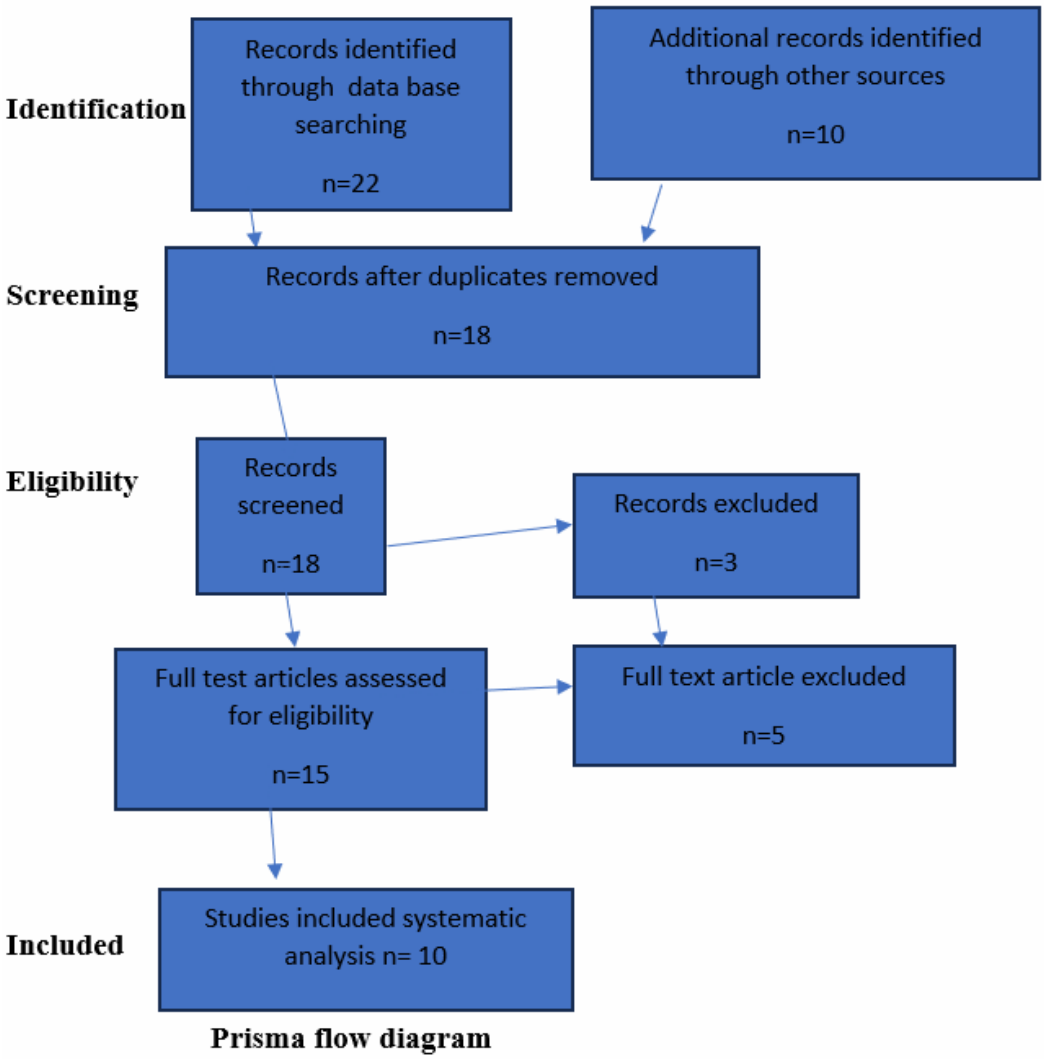
Corticosteroids such as prednisone or budesonide, work by suppressing the entire immune system. Biologics, on the other hand, work in a more selective way by targeting specific proteins in the immune system. Overall, studies have shown biologics to be very safe (William, 2019). For asthma, the targets are antibodies, inflammatory molecules, or cell receptors. By targeting these molecules, biologics work to disrupt the pathways that leads to inflammation that causes asthma symptoms. Common side effects include

soreness at the injection site, headache, sore throat, and fatigue. Studies reported

Small risk of anaphylaxis as side effect of Omalizumab, (AAAAI (2021). Biologics are relatively safe with few adverse effects that are not fatal as compared to oral corticosteroids in asthma management (McGregor, 2018).

METHODOLOGY

A systematic literature search for studies reporting primary data on the effect of oral corticosteroids was executed using the databases of medical literature analysis and retrieval system online (MEDLINE), Cumulative index to Nursing, Allied Health Literature (CINAHL), and library catalogues. Search engines such as goggle, Firefox, chrome and goggle scholar were used. Studies both on short term and long-term use of OCS were reviewed to have better understanding of the subject matter. Studies in paediatric populations were excluded, as the focus of this study is on adults living with asthma. Only studies written with English were reviewed.



Prisma flow diagram

Search strategy /Article selection and criteria

Search terms were developed based on the key words in the study title such as consequences of long-term use of oral corticosteroid, effect of oral corticosteroid on asthma patients etc. Forty- two electronic databases were searched online and articles screened. Some of the search includes: effect of oral corticosteroid, oral corticosteroid and asthma management, severe asthma and oral corticosteroids, a shift from oral corticosteroid in asthma care etc. The first step in article selection was to select the relevant articles by looking at the title to see if it meets the criteria, duplicates were removed based on inclusion criteria and limitations. After the articles' abstracts review, only qualified articles were selected.

Result of the selection: Ten studies provided a tripartite understanding of consequences of long-term oral corticosteroid therapy in asthma management: time to change the relationship, within the priority themes.

Ten articles reviewed and their finding

Article title	Year of publication	Methodology	Major findings
Severe asthma: oral corticosteroid alternatives and the need for optimal referral pathways	2021	Literature review	Several biologic therapies for the treatment of uncontrolled severe asthma are currently available. This is not surprising considering that OCS are acting mainly on type 2 inflammation, and the current biologic therapies target specific mediators of this pathway (i.e., IgE, IL-5, IL-4, IL-13).
Appropriate use of oral corticosteroids for severe asthma	2018	Overview	Even with the availability of the new biological therapies against IgE and Interleukin-5, it is likely that a large proportion of patients will continue to require OCS to control their asthma.
Overuse of Oral Corticosteroids, Underuse of Inhaled Corticosteroids, and Implications for Biologic Therapy in Asthma	2021	Cross-sectional study	This study concluded that in the majority of patients with severe asthma and high OCS use, at least 1 major modifiable factor can be identified that is likely to contribute to overuse of OCS which should be addressed before biologic therapy is considered in these patients.
Consequences of long-term oral corticosteroid therapy and its side-effects in severe asthma in adults: a focused review of the impact data in the literature	2018	Systematic literature	It is incumbent on every clinician to carefully weigh the potential benefit of preventing loss of asthma control against this risk before opting to prescribe long-term OCS therapy. Effective corticosteroid-sparing strategies must be used and should aim at short-term use with the lowest effective dose and start tapering as soon as possible until OCS therapy is terminated.
Perception of oral corticosteroids in adult patients with asthma in France	2020	Cross sectional descriptive study	Respondents reported having strategies to avoid OCS, mainly because of adverse effects. Though OCS for asthma treatment is perceived efficient but associated with severe adverse effects.
Adverse events profile of oral corticosteroids among asthma patients in the UK: cohort study with a nested case-control analysis	2018	Cohort study with a nested case-control analysis	Oral prednisolone use is associated with infections, gastrointestinal, neuropsychiatric, ocular, cardiovascular, metabolic, and bone-related complications among adult asthma patients.
Morbidity associated with oral corticosteroids in patients with severe asthma	2015	Cross-sectional	The study opined that it is surprising and disappointing that morbidity due to OCS usage in patients with airway disease is not well documented. It is unsatisfactory to extrapolate from studies carried out in non-respiratory conditions.
Effects of short-term oral corticosteroid intake on dietary intake, body weight and body composition in adults with asthma - a randomized controlled trial	2015	Controlled randomized study	There is need for information in an airway disease population we are approaching the biological treatment era and have within our sights treatments that offer a realistic potential to be alternatives to OCS and to allow patients already taking them to withdraw therapy safely.
How can we minimise the use of regular oral corticosteroids in asthma?	2020	Literature review	It was found that the benefits of regular OCS use in asthma outside episodes of exacerbations are poorly supported by the existing evidence. However, complete OCS elimination couldn't be achieved in any available studies for all patients and the panel felt that it was too early to conclude that regular OCS use could be declared criminal. Repeated or prolonged need for OCS beyond 1 year should indicate the need for referral to secondary/tertiary care
Systematic Literature Review of Systemic	2020	Systemic literature review	Systemic corticosteroid use to manage uncontrolled asthma and its associated healthcare burden may

Corticosteroid Use for Asthma Management			account for important health-related adverse effects. Corticosteroid use is prevalent in asthma management, and the risks of acute and chronic complications increase with the cumulative oral corticosteroid dosage.

DISCUSSION

Asthma is a chronic inflammatory airway disease affecting about 300 million people worldwide (WHO, 2019). Kauppi *et al.,* (2015) concluded that in approximately 4% to 8% of asthma patient's symptoms remain uncontrolled and exacerbations occur frequently despite high-intensity treatment, or they need systemic corticosteroid treatment for sustained symptom control. Hence the constant use of oral corticosteroid in asthma management. There is no doubt that the use of oral corticosteroids (OCS) plays a vital role in the management of asthma, particularly in the management of acute exacerbations and severe asthma, however, the side effect of oral corticosteroid is tremendous and these side effects can be fatal. The side effects also reduce the quality of life of persons living with asthma. And this is in consonance with the findings of Volmer *et al.,* (2018) which concluded that all long-term OCS therapies, independent of the dose, have been reported to elevate the risk of comorbidity and complications. Even "low" doses of OCS (according to guidelines) lead to complications. Based on the result of research carried out over the years on the effect of corticosteroid on asthma patient there is a call for a shift. Due to great concern on the detrimental effect of OCS, it is advocated that OCS should be replaced with treatment regimen that has less adverse effect for asthma suffers and this is in-line with the opinion of Robinson, (2018) who stated that quality of life for individuals with severe asthma could be significantly improved with the use of monoclonal antibodies by avoiding the many side effects of taking oral corticosteroids.

Oral Corticosteroids such as prednisone or budesonide suppresses the entire immune system which has detrimental effect on the general wellbeing of the patients. Biologics, on the other hand, work in a more selective way by targeting specific proteins in the immune system. Overall, studies have shown biologics to be very safe with minimal adverse effect in asthma management (William, 2019).

IMPLICATION OF FINDINGS

The detrimental effect of the prolong use of oral corticosteroids therapy in asthma management leads to development of co-morbidities which complicates asthma management. This study exposes the adverse effect of prolong use of oral corticosteroids on persons living with asthma and shows greater need of seeking alternative therapy as the negative effect preponderates its positive effect in asthma management. The study identified alternative therapy such as biologics that is efficient in asthma management with less adverse effect. Hence, the need for clinicians to cautiously identify with the novel biologics as an alternative and the need for restriction of Oral corticosteroids therapy to be considered. Policy making and regulatory approaches is encouraged for proper implementation.

CONCLUSION

One area in clear need of transformation is the prolong use of oral corticosteroid in asthma management Therefore, it is incumbent on every clinician to carefully and thoroughly weigh against the risk of side-effects of oral corticosteroids. Since alternate treatment with monoclonal antibodies called biologics such as omalizumab has proven efficient with minimal side effect, it is important that the complicated relationship between oral corticosteroids and asthma be reviewed in all healthcare institutions in accordance with best practice policies in order to improve quality of life of asthma patients. This will only be possible if policymakers and clinicians apply practical steps to scrutinize current care gaps that will enable the adoption of established best practices (Politicopro, 2021).

RECOMMENDATIONS

Healthcare policymakers should apply practical steps to scrutinize current care gaps in asthma management and enable the adoption of established best practices. Healthcare systems globally that is yet to adopt the use of biologics in place of oral corticosteroid should take decisive political action to challenge existing approaches in asthma treatment. New drug regimen such as biologics with less side effect should be adopted globally for the management of severe asthma.

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