REVIEW

Quality of Care in Inflammatory Bowel Disease: the Role of Steroid Assessment Tool (SAT) - a Review
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Abstract
Corticosteroids have an important role in induction of remission in inflammatory bowel disease, but they are not an indicated for maintenance treatment as they are associated with many side effects. Despite new efficient therapeutic options for maintaining remission, there is an excess in prescribing steroids in inflammatory bowel disease. Corticosteroid use was evaluated in international cohorts given that steroid free remission and avoiding serious side-effects of corticosteroids is a desirable goal. We discuss the role and the evidences on a secure web-based steroid assessment tool (SAT) which can be used as an instrument of evaluation of corticosteroid use, a quality indicator in inflammatory bowel disease.

Keywords: corticosteroids, steroid assessment tool, inflammatory bowel disease, steroid excess, quality of care.

INTRODUCTION
Corticosteroids (CS) remain effective anti-inflammatory and immunomodulatory drugs that still have an important role in induction of remission of acute flares of inflammatory bowel diseases (IBD), Crohn's disease (CD) and ulcerative colitis (UC), despite new therapeutic options.

Regardless of their therapeutic benefit in active IBD, CS use as a maintenance therapy is limited by the numerous side effects associated with their prolonged use and lack of efficiency in maintaining disease remission and evidence is mounting1.

Recently the Italian Group for the Study of Inflammatory Bowel Disease (IG-IBD) organized a campaign for improved IBD patients care and their

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first recommendation stated not to use steroids for maintenance therapy or prescribe it without a strong indication. Canada, known for its high incidence and prevalence of IBD, made five recommendations in a “Choosing Wisely” campaign for IBD, through a modified Delphi process which involved an expert panel of gastroenterologists. The first recommendation is not to use steroids as a maintenance therapy as they are associated with important side effects and if tapering steroids is not possible to use a steroid-sparing drug. Also, the British Society of Gastroenterology recently published a guideline on the management of inflammatory bowel disease and the section on the use of corticosteroids includes a statement that recommends against a prolonged use of steroids. The IBD UK group, a partnership between 17 professional and patient organizations, launched in June 2019 a new set of standards for IBD care. Steroid therapy should be used as recommended by guidelines and there is a strong recommendation to audit steroid use regularly. These actions lead the European Crohn’s and Colitis organization (ECCO) to propose strict guidelines on corticosteroids judicious use. Steroids treatment is not recommended as a maintenance therapy and steroid dependent patients should be considered for a steroid-sparing regimen.

QUALITY OF CARE

Management of IBD is complex, from diagnostic to monitoring disease activity and treatment and needs a multidisciplinary approach in order to have a good control of disease. There is a need for standard indicators to evaluate quality of care in IBD, but different strategies in management of IBD at national and international levels makes this goal difficult to achieve. Quality indicators (QI) are a measure for quality of care (QoC), can help us identify deficiencies in management, establish performance objectives and improve patients care.

In 2006, in the United Kingdom it was performed the first large audit in gastroenterology field – the UK IBD Audit, a partnership between gastroenterologists, surgeons, physicians and patients, with the aim of improving quality of care. After the first audit results, intervention strategies were developed and implemented with at least two follow up audits taking place afterwards.

The list of quality of care standards in IBD published this year by ECCO is divided in three main categories – structure indicators, process indicators and outcome measures which were rated according to their importance as essential, desirable and not important. Regarding steroid use it is considered essential that patients receiving more than two courses of steroids per year should be switched to steroid-sparing agents, patients should not receive more than 20 mg/day of prednisolone for more than 4 months and patients should not receive steroids for more than 9 months a year regardless of dose. Moreover, it is considered desirable that every centre should record the proportion of corticosteroid use at least once a year.

Worldwide, initiatives in defining quality of care in IBD resulted in sets of quality indicators with different aims. The American Gastroenterology Association (AGA) focused on process measures which were used by health insurance companies in order to avoid financial penalties by gastroenterologist treating IBD patients. Also, the Crohn’s and Colitis Foundation (CCFA) published a set of process and outcome quality indicators and the International Consortium for Health Outcomes Measurement (ICHOM) a set of quality outcome indicators, both of them mentioning steroid use as a quality indicator. Quality indicators were published in other countries as well, including Spain, Asia and Romania.

Despite these initiatives, quality indicators have a low percentage of use in everyday practice, as documented by Feuerstein and colleagues, with pneumococcal immunization, bone loss and influenza vaccination being the less evaluated measures.

In the United States, quality of care indicators related to steroid use were audited and comprised prolonged CS use of more than 60 days (16.1% UC patients and 12.6% CD patients), use of steroid-sparing therapy (52.5% of UC patients with prolonged CS use and 68.2% of CD patients with prolonged CS use) and bone loss assessment (11% UC patients from those with prolonged steroid use and 7.7% of new CD cases) in the outcomes of IBD patients exposed and non-exposed to an integrated model of care, demonstrating that patients integrated in a model of care unit benefit of a higher quality of care, with lower risk of surgical interventions and earlier introduction of steroid-sparing regimens. Similar results were obtained in a tertiary IBD center where an audit was made on quality of care using quality of care indicators, showing that objective monitoring and early treatment escalation avoids steroid dependency and emergency surgeries.
In Australia, an audit of IBD quality of care included 71 hospitals, with only one having a complete multidisciplinary IBD team and 24% of hospitals having a partial IBD team. Hospital with incomplete IBD multidisciplinary team had better results of process and outcome measures compared to hospitals without IBD specialists. Quality indicators bring us closer to quality improvement by tools that can be used to assess processes and outcomes in IBD care.

CORTICOSTEROIDS SIDE EFFECTS

Side effects associated to corticosteroids include an increased risk of infections, acne, Cushing syndrome, weight gain, hypertension, diabetes, osteoporosis, bone fracture, cataracts, glaucoma, mood changes. Use of corticosteroids was associated with a significant increased risk for opportunistic infections, especially in patients older than 50 years. The risk was higher when used in combination with immunomodulators and anti-TNF. A recent meta-analysis showed that IBD patients treated with combination therapy, especially anti-TNF with corticosteroids have a higher risk of severe infections. In the TREAT registry, prednisone use resulted to be a strong predictor for severe infections in IBD patients, after disease severity and use of narcotic analgesics. Initiation of corticosteroid treatment tripled the risk of Clostridium difficile infection when compared with other immunosuppressant drugs, with no relation to dose and duration of treatment. Also, the preoperative use of corticosteroids increases the risk of infectious complications in patients with IBD after abdominal surgery.

Patients with IBD have a reduced bone mineral density (BMD) that defines osteoporosis and the process is influenced by many factors like chronic inflammation, malabsorption, vitamin D deficiency and the use of corticosteroids. A systematic review and meta-analysis which included ten studies assessed the risk of fracture in IBD patients and concluded that the risk of overall fractures is similar to match controls, however it appears that there is an increased risk of spine fractures associated with steroid treatment. Also, IBD patients older than 65 years had an increased rate of fractures after initiation of steroid treatment.

Higgins and colleagues confirmed that corticosteroids increase the risk of venous thromboembolic events (VTE) by five-fold when compared to biologic treatment alone. A meta-analysis conducted to determine the risk of VTE associated to treatment with CS and anti TNFα showed that systemic corticosteroid treatment has a statistically higher risk of VTE in IBD patients compared with patients not treated with steroids. In the same time, it appears that anti TNFα treatment has a fivefold lower risk of VTE than corticosteroids. In a retrospective study in the US on 30,456 patients diagnosed with IBD, with the mean age of 60 years, the authors remark that in the group of patients not exposed to CS the risk of VTE doubled after diagnosis of IBD, in the group of CS user the risk tripled after diagnosis and increased more than 5 times at one year after CS exposure compared to the year prior to diagnostic.

Ocular manifestations in IBD are part of extraintestinal manifestations (EIM) of IBD and have a wide range of presentation forms, episcleritis being considered to be the most common one. Besides EIM, ocular manifestations can also be drug-related with cataracts and glaucoma being a complication of long exposure to systemic CS. The ophthalmologic complications of corticosteroids frequently affect the quality of life of IBD patients, that is why steroid users are more often referred to an ophthalmologist than non-users. Anxiety and depression are identified more frequently in IBD patients and the severity of symptoms is higher during acute flares of disease which can lead in turn to a slower remission of disease symptoms. Mood disorders and other psychiatric symptoms can be induced by systemic CS treatment. In a prospective observational study, authors observed that treatment with oral prednisone leads to a high percentage of temper change, especially hypomania, which returns to initial level when the treatment stops.

In order to improve quality of care in IBD patients and avoid steroid excess along with serious side-effects associated to steroid use, our aim was to evaluate our center on steroid use in IBD patients using a digital tool and assess the changes we have made after the first evaluation which took place last year.

STERIOD ASSESSMENT TOOL

In order to increase awareness of inappropriate steroid use in clinical practice, AbbVie in collaboration with 15 British gastroenterologists, developed a simple digital tool to evaluate steroid use – the steroid assessment tool (SAT). The first audit of steroid use in IBD using SAT was made in UK on 1176 IBD patients in a multi-centre prospective clinical audit showing a ste-
Corticosteroids have a main role in induction of remission of active IBD, but their use on the long-term is limited by adverse events and their inability to maintain remission. It becomes clear that achieving corticosteroid-free remission is an important goal in IBD patients.

Steroid prescription in United Kingdom (UK) was evaluated in several studies. One that included 1177 patients revealed that 30% of patients received corticosteroids in the last 12 months, with a steroid excess of 13.8%45. In another study from UK, disease activity correlated with steroid excess44. On the other hand, the use of steroid-sparing therapy is higher in UK (63% of patients were on thiopurines and 72% were on anti TNF treatment). In CD it was demonstrated that the use of biologic therapy and immunomodulators led to a lower steroid use49 and reduced mortality50.

Selinger and colleagues evaluated excess steroid use in IBD patients in a multi-centre study that included 1176 patients in 201543 and a reevaluation took place two years later on 2385 patients44. These two studies confirm steroid assessment as an indicator of quality of care in IBD. In the centres where measures were implemented after the first evaluation the steroid exposure drop from 30% to 23.8% and the steroid excess also decreased from 13.8% to 11.5%44.

In Asia, a multi-national audit on 1291 patients with IBD showed that 26.3% of patients received a prescription of CS in the last year, 4.7% of them had prolonged exposure to CS and 4.4% relapsed after stopping CS47. Data from the United States show that 32% of IBD patients were prescribed at least one course of steroid in the study period and 15% of them had prolonged exposure to CS42. In the pediatric population, steroid use was evaluated with SAT and result show that 16.6% of patients received orals steroids with 31.6% of them treated with CS for more than 3 months48.

In the UK the IBD Audit in 2006 it was noticed that 46% of CD patients receiving systemic corticosteroids have been on continuous treatment for more than 3 months, with bone protection being prescribed to only 45% of them and 18% performed a bone densitometry in 12 months from treatment initiation8. Only 41.1% of UC patients received bone protection medication. After intervention strategies were implemented, two more audits were made. The third one took place between 2010-2011 and showed an increase of patients receiving bone protection medication up to 70%51. Bone protection medication associated to steroids use, calcium and vitamin D, are prescribed in 38% of patients in Italy52. This illustrates the practical use of SAT in adjusting the therapeutic interventions for the patients.

CONCLUSIONS

Even though the last decade saw emerging a lot of new therapeutic options for treatment of IBD, the prescription of corticosteroids did not decline over time since they maintain an important role in remission of induction and are still recommended by the current guidelines53.

Steroid assessment tool (SAT) is an useful and easy to use not only as a quality indicator in IBD care but as an instrument to improve patients care in real life settings.

Compliance with ethics requirements: The authors declare no conflict of interest regarding this article. The authors declare that all the procedures and experiments of this study respect the ethical standards in the Helsinki Declaration of 1975, as revised in 2008(5), as well as the national law. Informed consent was obtained from all the patients included in the study.
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