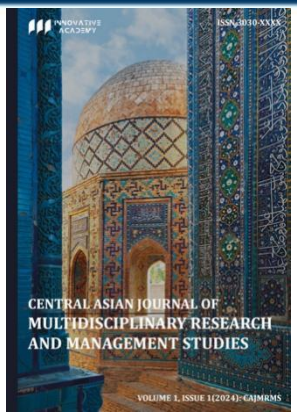

ANALYSIS OF THE PREVALENCE OF IRON DEFICIENCY ANEMIA AND THE PHARMACOLOGICAL PROPERTIES OF DRUGS USED FOR THEIR TREATMENT

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ABSTRACT

About one in four people worldwide suffer from iron ID, the most common micronutrient deficiency. Children, women of reproductive age, and those living in low- and middle-income nations are disproportionately affected. With effects ranging from decreased physical performance and quality of life in adults to increased risks during pregnancy, including low birth weight, preterm delivery, and maternal mortality, as well as impaired cognitive and motor development in children, it substantially adds to the global burden of disease. Though clinical and functional abnormalities, including exhaustion, immunological dysfunction, and cognitive deficiencies, can happen even in the absence of anemia, ID frequently occurs before IDA. According to the World Health Organization, iron deficiency anemia (IDA) affects 30% of the population worldwide, making it the most prevalent dietary deficiency. Reduced dietary iron and decreased iron absorption are additional contributing factors to IDA, even though gastrointestinal bleeding and women's menstruation are the most frequent causes. Restoring iron reserves and bringing hemoglobin levels back to normal should be the goals of treatment for patients with IDA. This has been demonstrated to enhance pregnancy outcomes, morbidity, quality of life, and the prognosis for chronic illnesses. Numerous chronic inflammatory diseases, such as inflammatory bowel disease, chronic kidney disease, and congestive heart failure, are associated with iron deficiency. An updated summary of the diagnosis and treatment of IDA in patients with chronic illnesses, both before and during pregnancy, will be given in this article. Along with a summary of the cost comparison of the various iron formulations now available on the market, we will go over the advantages and disadvantages of oral versus intravenous iron replacement in each group.

Introduction. Hemoglobin levels below two standard deviations of the mean for the patient's age and gender are referred to as anemia. An crucial part of the hemoglobin molecule is iron. Iron deficiency, which causes microcytic and hypochromic red blood cells on the peripheral smear, is the most prevalent cause of anemia in the globe. Age, gender, and socioeconomic position all affect the causes of iron insufficiency. The patient frequently complains of vague symptoms like exhaustion and dyspnea when exerting themselves. Iron supplementation and reversing the underlying disease are the two main forms of treatment. Although oral iron supplements are the most common, intravenous iron may be necessary in some circumstances. It has been discovered that patients with iron-deficient anemia experience more adverse events and a longer hospital stay. The most prevalent deficiency illnesses, iron deficiency (ID) and ID anemia (IDA), can arise as separate conditions or as a result of a comorbidity such menorrhea, inflammatory bowel disease (IBD), or heart disease (HD). Our goal was to evaluate the prevalence of ID/IDA, related comorbidities, trivalent ferric maltol-focused medication treatments, and healthcare resource use (HRU) and related expenses in Germany because real-world data are few [1-7]. The primary causes of ID/IDA are insufficient iron intake from malnutrition, decreased intestinal iron absorption from gastrointestinal disorders and medication treatment, and higher iron requirements in children and adolescents due to rapid growth, as well as in menstruation or pregnant women. Additional causes of ID/IDA include any chronic blood loss, which can be brought on by menorrhagia, gastrointestinal lesions, and anticoagulant medication, as well as the combination of chronic blood loss and reduced iron absorption in conditions like chronic heart failure and inflammatory bowel disease. In addition to causing ID/IDA, a number of these disorders also exacerbate it. ID/IDA impairs survival and quality of life in heart failure and raises the chance of hospitalization. For ID with iron-deficient erythropoiesis and IDA, therapeutic iron supplementation is recommended. The underlying reason and its reversibility, clinical characteristics and patient intolerances all play a significant role in the compound selection and administration route. For many years, ID/IDA has been treated with oral bivalent iron (Fe^{2+}) preparations as ferrous fumarate, ferrous gluconate, and ferrous sulphate [8-13]. Poor intestinal absorption of bivalent iron preparations, however, poses a significant challenge as it might result in negative gastrointestinal effects and decreased patient compliance. Parenteral iron replacement is recommended in Europe for patients who need a quick ID/IDA correction or who do not respond to or are intolerant to oral iron. However, the inconvenience of intravenous infusion, increased health care expenses, and the possibility of allergic reactions are all linked to parenteral iron substitution. Trivalent (Fe^{3+}) oral iron preparations, such as ferric oxide polymaltose complexes and ferric maltol, are increasingly being considered as an option in cases of intolerance to bivalent oral iron preparations. These preparations are prescribed in Germany and other countries. Ferric iron enters the intestinal mucosa in a complex form following oral ingestion of ferric maltol, which is anticipated to lead to a more effective absorption with enhanced tolerance. Ferric maltol has been approved for the treatment of ID in Europe and has been proposed as a substitute for parenteral iron substitution in patients with inflammatory bowel disease due to its positive effects on hemoglobin levels in patients and its excellent safety profile [14-21]. A deeper understanding of the patient's characteristics is necessary to design and optimize treatment recommendations because of the various causes and effects of ID/IDA, associated comorbidities, and available treatment options. Nevertheless, there is a dearth of empirical data on regional ID/IDA prevalences, the burden of comorbidity that goes along with them, and trends in drug treatment and healthcare resource usage (HRU). Therefore, we conducted a retrospective, non-interventional, matched cohort study to determine the prevalence of ID/IDA in Germany. We also described the population of patients with ID/IDA in terms of clinical and epidemiological characteristics, ferric maltol-focused treatment patterns, HRU, and related costs. Claims data from patients with ID/IDA and a matched control group,

spanning an observational period from 2016 to 2021, served as the basis for our investigation [22-28].

The main purpose of this brief review is to analyze the prevalence of iron deficiency anemia and the pharmacological properties of drugs used to treat them, based on authoritative scientific papers on modern measures.

Treating Iron Deficiency: Prevention and Replacement Treatment. The three most popular methods for treating ID and boosting iron absorption are fortification (adding iron to food during processing or through biofortification), supplementation (taking higher doses of iron independently of meals), and dietary modification (improving the variety, nutritional value, and bioavailability of iron in the diet). These techniques can be applied separately or in tandem. A customized yet coordinated strategy that takes into account particular physiological needs, dietary habits, and risk factors is needed to address IDA across age groups. Because of their fast growth and low iron stores, infants and young children benefit most from fortified foods, iron-rich supplemental feeding, and micronutrient powders, which are single-dose sachets that contain a combination of vital vitamins and minerals that are added to home-cooked meals to prevent and treat micronutrient deficiencies [13-18]. Strategies such as targeted supplementation and culturally appropriate dietary recommendations are necessary for adolescents and women of reproductive age in order to satisfy their increased iron needs due to menstruation, pregnancy, or growth. The use of well-tolerated iron formulations, food fortification, and routine monitoring are necessary because adults and older people frequently struggle with chronic diseases, inflammation, or decreased absorption. The implementation of food fortification programs using commonly consumed staples, lowering intake of iron inhibitors, utilizing low-dose or alternate-day iron supplementation to improve adherence and minimize side effects, and increasing dietary diversity with iron-rich and absorption-enhancing foods are common solutions despite these population-specific differences. These tactics can work in concert to enhance iron status throughout life and guarantee advantages at the individual and population levels when tailored to local dietary patterns and backed by public health education [24-31].

New Advances in Intravenous and Oral Treatments for Iron Deficiency. Improved IV treatments and a number of new oral formulations have surfaced in recent years. Iron reserves are restored by oral supplements, however adherence is sometimes hampered by GI side effects. IV treatments enable quick replacement, especially in cases where oral medication is ineffective or inappropriate, whereas more recent oral formulations seek to increase absorption or improve tolerability. The interaction between stomach acid and ferrous iron (Fe^{2+}), which is more reactive than ferric iron (Fe^{3+}), contributes to GI adverse effects. Fe^{2+} is converted to Fe^{3+} by gastric acid, which facilitates absorption after duodenal enzymes decrease Fe^{3+} back to Fe^{2+} prior to small intestine uptake by DMT-1. Ferric iron (Fe^{3+}) is complexed with citrate to create ferric citrate, an oral iron formulation. It was first approved by the FDA to treat IDA in CKD patients who were not receiving renal replacement therapy after being used as a phosphate binder. Although ferric citrate was linked to slightly higher GI side effects such diarrhea and constipation, clinical trials showed that it considerably raised Hb levels when compared to a placebo. Research revealed that patients with more severe ID had higher Hb improvements. The substance received approval for medical use in the US in 2019 and the EU in 2016 [22-31]. It has demonstrated a favorable safety profile, with GI side effects such as nausea, constipation, and diarrhea occurring at rates comparable to placebo in phase III trials. Similar to the placebo group, about 10% of IBD patients in studies stopped their therapy because of side symptoms. Despite being significantly more costly, ferric maltol is a prospective oral substitute for conventional ferrous salts due to its unique mechanism and trial-proven effectiveness. The European Medicines Agency's recent favorable assessment of Xoanacyl® (ferric citrate formed as a coordination complex) is a hopeful development as research into novel iron delivery systems continues.

Xoanacyl®, which is intended for persons with CKD who also have ID and hyperphosphatemia, has two mechanisms: it binds dietary phosphate and delivers absorbable iron. While the unabsorbed portion binds phosphate and lowers serum phosphorus, ferric iron (210 mg per 1 g tablet) is reduced and absorbed in the GI tract to stimulate Hb production. In addition to lower phosphate levels, clinical trials in non-dialysis CKD patients showed improved Hb levels and transferrin saturation. Phosphate-lowering effectiveness was similar to sevelamer carbonate in dialysis-dependent patients. Typical side effects include nausea, diarrhea, and abdominal pain [12-19].

Prevalence, Causes, and Outcomes of Anemia, ID, and IDA. Anemia is a condition characterized by a reduced number of red blood cells or a decreased concentration of Hb, resulting in diminished oxygen transport to body tissues. According to the World Health Organization (WHO), anemia affects 30% of non-pregnant women, 37% of pregnant women, and 40% of children under five worldwide. Despite other causes like malaria, thalassemia, and sickle cell trait, ID remains the leading cause of anemia, making IDA the most common form of the condition. It is estimated that more than 1.2 billion people suffer from IDA worldwide, with prevalence varying significantly between low- and high-income countries. Adults may also have health issues such as depression, restless legs syndrome, tiredness and exhaustion, diminished cognitive and intellectual abilities, trouble focusing, and decreased productivity at work. Individuals and entire populations are less able to work as a result of IDA, which has detrimental effects on the economy and the advancement of the country [7-11]. The immune system, thyroid gland, brain, and the synthesis and metabolism of catecholamines and other neurotransmitters, as well as the metabolism of drugs, all depend on iron for proper operation. Anemia is a known risk factor for hospitalization, poor surgical results, and increased all-cause death in older persons (>65 years). ID and IDA are severe conditions that have an adverse effect on children's behavior, growth, and cognitive and motor development. Additionally, they make people more vulnerable to infections, which could raise the chance of dying from serious childhood diseases like malaria. Even in ID without IDA, there may be irreversible harm to mental and psychomotor development. The disease may hinder optimal developmental potential in addition to negative health implications. One study, for example, discovered that even when their iron levels were restored, infants who were born with low levels of iron exhibited decreased activity in brain areas linked to cognitive control by the time they were eight to eleven years old [13-21]. Low iron levels during pregnancy can have an impact on birth weight, increase the risk of preterm birth, and potentially raise the mother and child's mortality risks. When ID manifests without symptoms or anemia, some experts wonder if it's always a problem. For example, one study indicated that women in clinical trials who were iron deficient and felt exhaustion, had an improvement in energy levels after taking iron supplements. In contrast, the same intervention had no effect on the energy levels of women who were iron deficient but did not feel weariness. According to this study, medication can ameliorate ID-related clinical disease, at least in adults. However, it is still unclear if medication would result in any discernible improvement when there are no symptoms and merely low iron levels. In general, IDA has been examined more thoroughly than ID without anemia [23-31].

Discussion. The prevalence, related comorbidities, and treatment trends of ID/IDA patients in Germany from 2016 to 2021 are reported here. Overall, the prevalence of ID/IDA remained stable at 3.34% during the observational period, according to our retrospective claim analysis. The prevalence was higher in women than in men, peaked when they were of reproductive age, and then started to rise after the age of 70. The incidence rose with age in men. Compared to age- and sex-matched control subjects, patients with ID/IDA had more comorbidities, and this number rose even more when the concomitant conditions—heart disease, inflammatory bowel disease, and menorrhagia—were examined. As a result, higher HRU and expenses were associated with ID/IDA. Patients with ID/IDA who also had heart disease had the highest

ID/IDA-related expenses, which rose with the number of concurrent conditions. Parenteral iron supplementation and oral bivalent iron preparations, mostly iron sulfate, were administered to the majority of ID/IDA patients receiving iron supplements. Ferric maltol prescriptions rose during the period, although oral trivalent iron treatments were rarely recommended. The low switching rates of patients with ID/IDA treated with ferric maltol suggest that this may be because of improved tolerance [3-9]. Our retrospective claim analysis revealed that the estimated prevalence of ID/IDA in Germany was somewhat lower than in other western nations. This could be due to variations in the underlying data sets. However, the higher occurrence in women is a recognized fact. Menstrual blood loss, irregular uterine bleeding, iron deficiency or malabsorption, and food intolerances are some of the multifactorial causes of ID/IDA in women. ID/IDA can develop from the depletion of iron stores caused by a single factor, such as excessive menstrual blood loss, or moderate blood loss combined with other factors. Poor perioperative, maternal, fetal, and neonatal outcomes are associated with maternal IDA. Individuals who were older also had a higher prevalence of ID/IDA. An proper treatment is necessary to enhance prognosis since lower iron status and disrupted iron metabolism have been linked to a number of age-related illnesses and disorders. The comorbidity burden rose with ID/IDA and concomitant disorders, especially cardiac disease, when compared to matched control persons. Up to 61.2% of heart failure patients with anemia and 45.6% of those without anemia are diagnosed with ID, which is frequently linked to chronic heart failure. ID deteriorates the prognosis for heart failure, even in those without anemia [11-19]. It has been demonstrated that ID/IDA affects physical and cognitive function, as well as quality of life, in menorrhea and inflammatory bowel disease. Consequently, compared to matched controls, patients with ID/IDA had higher HRU and related expenses. With more all-cause hospitalizations, outpatient services, and sick days per patient, along with corresponding expenses, ID/IDA-related costs rose when one of the concurrent disorders under analysis was present. In our investigation, we identified three main limitations. First, even though many patients may purchase their oral iron over-the-counter, over-the-counter drugs are not included in the database; instead, only oral iron preparations prescribed by doctors and reimbursed by the SHI are categorized as health claims. Second, only a subset of German SHI enterprises contributed data for our study's InGef sample database. Nonetheless, it has been adequately shown that the data are representative of the German population in terms of sex, age, area, illness, mortality, and drug use. Third, our investigation solely compared ferric maltol before and after the index. Norgine, the company that holds the market authorization for FERACCRU® (ferric maltol), provided financing for the study, which focused on ferric maltol. Although the authors confirm that funding had no influence on the study's conduct, this link should be taken into account when analyzing the results. The case for ferric maltol's comparatively higher tolerance needs to be supported by comparative research, particularly comparisons with other iron preparations. This is the first study to look at the prevalence of ID/IDA, related comorbidities, and drug treatment patterns in such a broad population in Germany, despite these constraints [21-28].

Conclusion. Throughout the study period, the frequency of ID/IDA in Germany remained consistent, although it was much greater in older adults and women of reproductive age. Patients with ID/IDA had a higher burden of comorbidity than matched control subjects, and this burden increased as more concomitant disorders were examined. As a result, the expenses associated with ID/IDA and HRU rose. Although oral trivalent iron preparations were recommended less frequently, the majority of patients with ID/IDA who were prescribed iron preparations were prescribed either parenteral iron supplements or oral bivalent iron preparations. Ferric maltol prescriptions rose, possibly due to improved tolerance, as seen by the low switching rates among ferric maltol-treated patients with ID/IDA.

In conclusion, despite the diversity of ID/IDA in terms of etiology, comorbidities, and outcomes, ongoing surveillance of the prevalence may aid in identifying groups at higher health risk, such as older adults and women of reproductive age. We anticipate that our study will assist policymakers and medical professionals in formulating plans to further lessen the impact of ID/IDA. As a result, the authors have worked directly for Norgine, the study's sponsor, or have served as project consultants or subcontractors. Part of the focus of this work was FERACCRU® (ferric maltol), which is owned by Norgine. The study's design, which partially centers on Norgine's product, has been impacted by Norgine sponsorship. The funding source's interests are reflected in the study's focus on ferric maltol, even if the authors claim that this funding had no influence on how the study was conducted, how the results were interpreted, or whether the results could be published without restrictions. Comparative evaluations of other treatments for iron insufficiency are not included in this publication by the authors.

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