



Risk associated with the use of 5-alpha reductase inhibitors with minoxidil in treatment of male androgenetic alopecia – literature review

Maciej Kuca^{1,A-F}✉, Karolina Jaglarz^{1,A-B,D}, Marcin Cholewa^{2,B-E}, Julia Wójcik^{3,B-D},
Wiktoria Maria Szymańska^{3,D-E}, Maksymilian Janeczek^{3,C-E}, Maria Partyka^{3,B,D-E},
Karolina Kinga Kantor^{3,B-D}, Kacper Wojciech Pamuła^{3,B,D-E}, Julia Plewniak^{3,D-E}

¹ Intensive Care Unit, Oncology Centre, Katowice, Poland

² Department of General and Oncological Surgery, Provincial Hospital of St. Luke, Tarnów, Poland

³ Faculty of Medical Sciences, Medical University of Silesia, Katowice, Poland

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Abstract

Introduction and Objective. Male androgenic alopecia (AGA), is an age-related, genetic, progressive condition affecting more than half of the male population over the age of fifty. 5-alpha reductase inhibitors combined with minoxidil, commonly used in AGA therapy, are associated with potential risk of side-effects. The aim of the article was to ascertain the risk connected with the use of 5-alpha reductase inhibitors with minoxidil in AGA treatment.

Review Methods. A comprehensive evaluation of the literature was conducted utilizing the electronic databases: PubMed and Google Scholar. Key terms included “androgenic alopecia”, “finasteride”, “dutasteride”, “minoxidil”, “5α-reductase inhibitors”, “side-effects”, and variations of these terms. The literature review considered articles published between 2016 – 2024.

Brief description of the state of knowledge. The only two drugs registered in the treatment of male AGA are finasteride 1mg and topical minoxidil. Most common side-effects of finasteride 1 mg are erectile dysfunctions, decreased libido and ejaculatory dysfunctions. Dutasteride is used in AGA therapy off-label and associated with similar side-effects as finasteride. The side-effects of 5-alpha reductase inhibitors usually pass after cessation of the therapy. Side-effects with topical minoxidil are highly uncommon. However, some patients using minoxidil 5% may suffer from scalp irritation, hypertrichosis and pruritus.

Summary. 5-alpha reductase inhibitors with minoxidil in AGA therapy, administered in accordance with the Polish Dermatological Society's recommendations and the current state of medical knowledge, have a minimal risk of side effects.

Key words

androgenic alopecia, finasteride, dutasteride, minoxidil, 5α-reductase inhibitors, side effects

INTRODUCTION AND OBJECTIVE

Male pattern hair loss, known as male androgenic alopecia (AGA), is an age-related, genetic, progressive condition histologically defined by a decrease in size (‘minituration’) of hair follicles [1]. The disease can be typically characterized by a distinctive receding frontal hairline [2], most common among male Caucasians followed by Asians and African Americans [3]. After the age of fifty half of the male population presents symptoms of balding and by the age of eighty, up to 80% of males can develop androgenetic alopecia [4]. Given that hair can be crucial for person's self-identity and self-perception, the quality of life can be greatly affected by hair loss [5] raising the need to create effective treatment methods against balding. As the name androgenic alopecia

indicates, an over-reaction to androgens is the primary cause of the illness [3]. While testosterone levels are comparable in people with and without AGA, those with AGA have higher levels of unbound testosterone or active testosterone [2,3]. Men with an AGA predisposition convert testosterone in the hair follicle more efficiently to dihydrotestosterone (DHT) which shortens subsequent anagen cycles, therefore decreasing hair follicles in size [2]. This process involves an enzyme called 5α-reductase [6] making the 5α-reductase inhibitors an effective treatment option for patients suffering from male pattern hair loss [7]. The most often used 5α-reductase inhibitors are finasteride and dutasteride [8]. Superior results in AGA treatment, however, can be obtained by combining 5α-reductase inhibitors with hair growth stimulation achieved by using minoxidil, a vasodilator that causes hypertrichosis as a side-effect [9,10]. Given the fact that the symptoms of AGA can be easily spotted by the patients in the initial phase of the disease and in most cases the diagnosis is made through clinical examination

✉ Address for correspondence: Maciej Kuca, Intensive Care Unit, Oncology Centre, Katowice, Poland
E-mail: maciej.kuca99@gmail.com

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combined with trichoscopy [11], it is not uncommon to implement pharmaceutical treatment even at a young age. However, AGA is a progressive condition that requires continuous use of medications to sustain the effects of the therapy leading to possible side-effects of long-term treatment [12]. An increasing number of medical professionals choose to treat patients with androgenetic alopecia on their own, thanks to the accessibility of cost efficient, effective therapy, and the relative simplicity with which the right diagnosis can be made, raising the need of clear guidelines on how to approach male pattern hair loss in everyday situations.

OBJECTIVE

Taking into consideration difficulties connected with extended medical intervention and possible adverse effects that may persist even after cessation of the therapy, the aim of the review is to assist clinicians in making decisions about implementing the treatment of AGA in their practices, choosing the right combination as well as form of pharmaceuticals, and controlling potential negative implications that may occur during and after the therapy by outlining various risks associated with medical interventions concerning 5 α -reductase inhibitors and minoxidil.

REVIEW METHODS

A comprehensive evaluation of the literature was conducted between 10.09.2024 – 17.09.2024, utilizing the electronic databases: PubMed and Google Scholar. Key terms included 'androgenic alopecia', 'finasteride', 'dutasteride', 'minoxidil', '5 α -reductase inhibitors', 'side-effects', and variations of these terms. The literature review considered clinical trials, double-blind randomized controlled trials, meta-analysis, reviews and systematic review articles published between 2016 -d 2024, paying particular attention to articles published in the last five years. In addition, the guidelines concerning androgenic alopecia treatment from the Polish Dermatological Society were included. Findings from case reports were excluded from the review.

STATE OF KNOWLEDGE

Hair loss. The first step to effective and safe treatment of androgenic alopecia is to make a correct diagnosis. There are two main types of hair loss: scarring (cicatricial) and non-scarring (non-cicatricial) [13,14,15], this differentiation is of a great importance because non-scarring alopecias can be easily recognized and treated by any doctor, while scarring alopecias are better assessed by a dermatologist [14]. Cicatricial alopecia is defined by damaged hair follicles, skin scarring and permanent hair loss. This type of hair loss is significantly more uncommon and most often specialized tests, such as a scalp biopsy, are necessary to make the correct diagnosis [15]. Given the fact that AGA is a subtype of non-cicatricial alopecia [14,15] and differential diagnosis of hair loss combined with head skin scarring is beyond the scope of this study, cicatricial alopecia will not be further discussed in this article.

AGA, being the most frequent cause of nonscarring alopecia [15], has its unique features that distinguish it from other subtypes of non-cicatricial alopecia (Tab. 1) and can be of assistance in evaluating patients presenting with hair loss. If the diagnosis of AGA is made, a number of other factors need to be carefully taken into consideration, including: the patient's age, level of progression, dynamics of hair loss, family history of androgenic alopecia and, most importantly, the patient's expectations for his own appearance and acceptance of long-term treatment. The Hamilton-Norwood classification system can be a useful tool in assessing the severity of hair loss, monitoring the changes in the subsequent meetings and determining the effectiveness of the therapy [16]. It can be used by comparing the patient's hair loss pattern with visual images representing the specific balding patterns in the system. Before prescribing 5 α -reductase inhibitors or minoxidil the patient also needs to be made aware of the fact that while correct treatment is relatively safe and can stop or postpone the progression of hair loss, hair lost so far will in most part not regrow and there are risks associated with the therapy that need to be considered [9,17].

Table 1. Causes of non-cicatricial alopecia

Type	Clinical features
Androgenetic alopecia	A vertex hair loss with a progressive fronto-temporal recession. May result in total hair loss with some hair remaining on the temporal parts of scalp. Alopecia present in family history [3,14,15].
Alopecia areata	Acute, one or more round patches of hair loss with broken hair shafts. May be located on a beard. Autoimmune origin of the disease. [14,15,18].
Telogen effluvium	A diffuse, frequently sudden loss of hair that starts three months following a stressful event and usually lasts less than half a year. May also be chronic. Hair can be easily removed in a pull test [14,15,19].
Anagen effluvium	Non-scarring alopecia subtype frequently linked to chemotherapy. Hair loss starts acutely after taking medications affecting mitotic activity and results in a severe and diffuse alopecia [14,15].
Loose anagen hair syndrome	Hair loss of possible genetic origin affecting primarily young, blonde females with a previous history of hair loss. Hair can easily be pulled out without causing pain [15].
Trichotillomania	Compulsive hair pulling resulting in alopecia and possible scalp scarring often characterized as a psychiatric disorder [14,15,20].
Trichorrhexis nodosa	A unique reaction of the hair shaft to external trauma that causes hair to break or stop growing. Can be a result of extensive hairstyling [14,21].
Tinea capitis	Common scalp hair infection, mostly affecting children, caused by dermatophyte fungus. It might present clinically as mild scaling with little hair loss as well as massive inflammatory pustular plaques with widespread alopecia [14,22].

Available treatment. Each year, an increasing number of men choose to pursue treatment for androgenetic alopecia. The widespread availability of social media and a culture that places a high value on appearance are among the factors driving the rising interest in newer and more advanced techniques for hair loss prevention. Although AGA is a common condition, treating it can be very difficult [3]. To date, the US Food and Drug Administration (FDA) has approved oral finasteride and topical minoxidil as the only two pharmaceuticals available for the treatment of AGA [3,11,23]. On the other hand, a number of studies have demonstrated the efficacy of non-FDA-approved therapies

in the management of AGA [3,24]. Numerous debates could be sparked by this circumstance, particularly regarding the safety of taking off-label drugs. Table 2 summarises the most often used therapies involving 5 α -reductase inhibitors and minoxidil based on the Polish Dermatological Society's diagnostic and therapeutic recommendations for the treatment of AGA [24]. It is worth mentioning that dutasteride, used in the off-label recommendations, should be taken into consideration if a course of treatment with 1 mg of finasteride for a year proves to be insufficient [24]. However, the difference between finasteride and dutasteride, as well as the correct dosage of these pharmaceuticals, will be covered in depth in later sections of the article.

Patients beginning AGA therapy should be informed that stopping the medication would likely cause their hair loss to progress again, and long-term treatment is usually necessary to maintain the desired results [11]. In order to ensure that the patient adheres to the treatment recommendations, long-term therapy requires finding a suitable balance between the desired effects of treatment and any adverse effects, as well as the treatment's cost and patient's convenience.

Table 2. Recommended forms of treatment for male androgenic alopecia

Drug	Recommended form and dose [24]	FDA approved
Finasteride	1mg (tablet) once a day	Yes
Minoxidil	5% (fluid) topical treatment twice a day	Yes
Finasteride + Minoxidil	1mg Finasteride (tablet) once a day and 5% (fluid) topical treatment twice a day	Yes
Dutasteride	0,5mg (tablet) once a day	No, off-label use only

Finasteride. The history of research, leading to the introduction of 5 α -reductase inhibitors into the treatment of male AGA, dates back to the 1940s, when James Hamilton published the results of his research on the influence of hormonal stimulation on the development of male pattern baldness [25]. These discoveries led many years later to the invention of the substance now known as finasteride, which was approved by the FDA in 1992 for the treatment of benign prostatic hyperplasia (BPH), and five years later for the treatment of male AGA [25,26]. One notable difference is that while a 5 mg dose is registered for the treatment of BPH, a 1 mg dose has been approved for the treatment of AGA [24,25,26]. This distinction is significant because registered 1 mg finasteride pharmaceuticals are often much more expensive than the 5 mg medications available on the market. This may lead to a situation in which patients, guided by financial considerations as well as the vision of potentially better therapy effects associated with the use of a dose five times higher than the registered one, may pressure their doctors to prescribe an off-label dose of 5 mg. However, this action is related to an increased prevalence of serious side-effects [8,12,27]. Given that the risk associated with the use of 5 α -reductase therapy combined with minoxidil is the primary concern of this article, most common and other possible side-effects of the mentioned drugs were presented collectively in Table 3. To more accurately evaluate potential hazards, it should be noted that different publications on the subject of the side-effects of finasteride vary greatly in their definition of the dangers connected to the treatment [2,8,11,24,25,26,27,28]. According to the recommendations of the Polish Dermatological Society, the majority of patients

find finasteride to be well-tolerated. It does not interfere with food or other medications and can be taken at any time of day, with or without food [24] increasing patients' compliance.

Based on the literature, sexual dysfunctions are the most significant concern when analyzing the adverse effects associated with finasteride therapy [8,24]. The symptoms most frequently reported by patients are: erectile dysfunctions, decreased libido and ejaculatory dysfunctions [2,8,24,25,26,28]. Depending on the source, reports on the prevalence of the disorders in question range from 0.8% [24] to over 10% of patients [2]. It is well established that some patients presented persistence of these side-effects even a year after cessation of the therapy [2]. These findings lead to a contentious debate in the scientific community on the potential existence of post-finasteride syndrome, which is discussed further in this article [12,24,27]. Due to the reports mentioned above finasteride should be taken cautiously given that it might cause significant and long-lasting negative effects in certain men [11,12,27]. Nevertheless, it has been discovered that the frequency and severity of the majority of finasteride's side-effects were considerably higher when patients were informed about them before starting therapy, and lower (or even disregarded) when they were not previously warned [11]. This fact may lead to the conclusion that in matters as intimate as sexual health, some patients may over-interpret their symptoms, or even attribute existing disorders to the AGA therapy. This issue requires further double-blind studies to be definitively resolved.

Table 3. Side effects of finasteride, dutasteride and minoxidil

Drug	Most common side effects	Other possible side effects
Finasteride	Erectile dysfunction [2,8,24,25,26,28] Decreased libido [2,8,24,26,28] Ejaculatory dysfunction [2,8,24,25,26,28]	Gynecomastia [24,25,28] Orthostatic hypotension [2,25] Post-finasteride syndrome [2,25] Orgasm dysfunction [8] Dizziness [2,25] Low sperm count [24] Reduced penile sensitivity [27] Testicular pain [24] Testicular reduction [27] Muscular atrophy [27] Dyspnea [25] Rhinitis [25] Skin rash [25] Anxiety [28] Depression [28] Memory disturbance [28] Headache [28] Gingival hypertrophy [28]
Dutasteride	Erectile dysfunction [2,8] Decreased libido [2,8] Ejaculatory dysfunction [2,8]	Decreased arousal [8] Gynecomastia [3] Mood changes [3] Post-finasteride syndrome [32] Low sperm count [33] Allergic reaction [34] Dizziness [34] Heart failure [34] Hair loss [34] Testicular pain [34] Testicular swelling [34]
Minoxidil	Scalp irritation [2,24,39] Hypertrichosis [2,3,24,39] Pruritus [2,39] Hair shedding [24,39]	Postural hypotension [39] Oedema [2,3,39] Increased heart rate [2] Pericardial effusion [2] Congestive heart failure [2] Allergic reactions [2] Headaches [3] Contact dermatitis [3] Dizziness [3]

Post-finasteride syndrome. Finasteride has long been regarded as a medication that is safe, well-tolerated, and has infrequent, reversible adverse effects [12]. In recent years, both in the medical literature and in non-medical sources, there have been more and more reports about persisting side-effects of 5-alpha reductase inhibitors therapy, which last for more than three months after the end of the treatment [12,27,29]. Persisting sexual, neuropsychiatric and physical problems were the most frequently reported symptoms [12,27]. The Polish Dermatological Society's recommendations noted that the majority of the initial information about this syndrome came from non-medical media, and cite the views of experts who maintained that there had been insufficient evidence to support the existence of post-finasteride syndrome [24].

It is important to note that since the recommendations mentioned above were published in 2018, research has been conducted to ascertain the legitimacy of the allegations regarding post-finasteride syndrome in the medical literature. Nevertheless, the papers that explored this subject were unable to categorically refute or affirm the syndrome's existence [12,27]. One important and unquestionable piece of clinical data found in the majority of finasteride and dutasteride studies was that the usage of these medications was linked to the development of sexual dysfunctions, which could persist in a limited number of men regardless of their age, dosage or length of the therapy [12]. If it is real, it appears to manifest in vulnerable individuals, even in response to brief exposures and low doses [27]. The findings of these investigations may suggest that finasteride is still a reasonably safe medication; however, the case for its administration to patients who have had depression, sexual dysfunction or infertility in their medical history should be thoroughly and individually evaluated [27]. There are still no studies on the topic worldwide, which highlights the necessity for research that will definitively address this problem [29].

Dutasteride. Both type 1 and type 2 isoenzymes of 5 α -reductase are selectively and competitively inhibited by dutasteride [24,30]. It has been found that dutasteride exhibits three times the potency of finasteride in inhibiting the Type I enzyme and 100 times the potency in inhibiting the Type II enzyme [2]. Despite having been initially registered for BPH, this drug is frequently used off-label to treat AGA (also in Poland) [2,24,30]. In recognition of an overwhelming number of academic research supporting the efficacy and safety of dutasteride, regulators in South Korea and Japan have even approved oral dutasteride (0.5 mg/d) for the treatment of male AGA [31]. Oral dutasteride's most frequent side-effects are erectile dysfunction, decreased libido, and ejaculatory dysfunction due to its comparable mechanism of action to finasteride [2]. Other possible side effects are presented in Table 3. The number of side-effects for finasteride presented in the Table exceeding those for dutasteride is mainly due to the greater number of articles about finasteride's side-effects, and not because dutasteride is a safer drug. Described in scientific articles and The Summary of Products Characteristic adverse effects for dutasteride are practically identical to those for finasteride [2,3,8,32,33,34]. There is a case to be made that, despite the fact that finasteride and dutasteride-treated individuals experienced identical sexual adverse effects [32], dutasteride-related occurrences were more frequent [33]. However, certain studies suggest that both medications were linked to a higher risk, albeit

the increase for dutasteride was not statistically significant [32]. Additionally, there have been concerns regarding the likelihood of post-finasteride syndrome developing when using dutasteride [32].

In recent years, studies examining the effectiveness of mesotherapy using dutasteride have been gaining popularity in order to achieve maximum treatment effects with minimal side-effects, which in the future may be a safer alternative for oral therapy [35,36,37,38]. There is ongoing debate over whether dutasteride is a better first-line treatment for AGA than finasteride. In the scientific literature, there are claims that dutasteride is more effective than finasteride and has comparable side-effects [24,30], nevertheless, other research suggest that finasteride is the better option when treating AGA [11]. This issue needs to be clarified by future research. If a year-long course of treatment with finasteride at a dose of 1 mg proves to be unsatisfactory, the Polish Dermatological Society recommends considering the use of dutasteride [24].

Minoxidil. The oral version of minoxidil was first administered in the 1960s as a vasodilator to treat hypertension [2,39]. However, the discovery of hypertrichosis, a side-effect associated with long-term oral minoxidil use, led to the creation of a topical formulation intended to stimulate hair growth [2]. Currently, topical minoxidil (5% solution, 2% solution and 5% foam) is the only over-the-counter (OTC) drug licensed by the FDA to treat male AGA [39]. Minoxidil can be used both as monotherapy and in combination with 5-alpha reductase inhibitors for better results [24]. Although topical minoxidil has a great safety record, the medication's effectiveness is still limited [40] and once the medication is stopped, the hair growth can be reversed [41]. There is a case to be made for oral minoxidil as a safe, efficient treatment option for individuals in reasonably good health who are experiencing side effects from topical forms [42]. This opinion raises a lot of controversy in the scientific community due to the complications associated with this form of therapy. Whereas topical solutions typically have non-life-threatening side-effects, oral minoxidil is not FDA-approved for use in AGA and may produce very serious cardiovascular symptoms (Tab. 3) [2,39]. Because of these side-effects, oral medication is not a good first-line treatment compared to topical minoxidil [2] and should be avoided, especially in individuals with coronary artery disease or a recent myocardial infarction [43]. It is important to remember that adverse reactions from topical minoxidil treatment are typically dose dependent and more common when 5% solutions are used rather than 2%. There may be a connection between skin irritation and the use of propylene glycol, which is absent from the 5% foam, potentially making this form of medication safer to use [2]. The Polish Dermatological Society's recommendations highlight the potential for temporary hair loss that may occur six to eight weeks after treatment starts and subsequently reverse in the following months [24,39]. It is best to see a doctor if it persists for more than two weeks [39]. Moreover, it is critical to administer the drug at least two hours before going to bed to prevent medication transfer to the face through pillows, and hypertrichosis caused by this transition [24]. However, when used correctly, topical minoxidil remains a very safe form of therapy mainly related to temporary irritation and itching [2,39].

SUMMARY

Each year an increasing number of men express interest in the potential prevention of hair loss as well as viable treatment options for AGA. This suggests that not just dermatologists but all practicing physicians will at some point meet patients who are interested in beginning AGA therapy. Due to potential implications associated with hair loss medications, the knowledge of how to use them correctly comes of a great importance. In order to ensure the safety of patients, it is imperative that clinicians have insight into potential side-effects related to hair loss treatments. This will allow them to not only effectively carry out treatment plans initiated by other specialists, but also to actively discuss AGA therapy with patients who may be interested in starting the therapy. When administered in accordance with the recommendations of the Polish Dermatological Society and the current state of medical knowledge, 5-alpha reductase inhibitors with minoxidil – the most widely used treatment for male pattern hair loss – have a minimal risk of side-effects.

Finasteride 1 mg, registered for the treatment of AGA, can be taken with or without meals, at any time of day, and does not interfere with other medications. However, the most prevalent adverse effects of finasteride's 1mg are erectile dysfunction, decreased libido and ejaculatory dysfunction, although in most cases these side-effects pass soon after the medication is stopped.

Dutasteride, the second drug in the 5-alpha reductase inhibitor class, is often used off-label due to its non-registration for the treatment of AGA, and is associated with similar side-effects as finasteride. 5-alpha reductase inhibitors are most often used in combination with topical minoxidil 5%, which is registered for AGA therapy and safe to use, rarely causing side-effects. However, some patients using minoxidil 5% may suffer from scalp irritation, hypertrichosis and pruritus; it is also possible to experience hair shedding, which should be consulted with a doctor if it lasts longer than two weeks.

There are also other forms of the drugs described in this article available on the market, as well as other drugs potentially effective in the treatment of AGA, but using them off-label may be associated with additional risk.

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