Medicines Adverse Reactions Committee

Meeting date	10/09/2026	Agenda item	3.2.3
Title	**Finasteride and the risk of mood changes including suicidal ideation**		
Submitted by	Medsafe Pharmacovigilance Team	Paper type	For advice

Active ingredient	**Product name**	**Sponsor**
Finasteride	Propecia 1 mg tablet	Organon (New Zealand) Limited
	Profal 1 mg tablet	Teva Pharma (New Zealand) Limited
	Ricit 5 mg tablet	REX Medical Ltd

PHARMAC funding	Ricit (finasteride 5 mg tablet) is funded under special authority for symptomatic benign prostatic hyperplasia (BPH) when symptoms are not adequately controlled with non-selective alpha blockers or these are not tolerated or contraindicated.
Previous MARC meetings	None.
International action	Australia, EU, UK and Canada include warnings on the risk of depression and suicidal ideation in section 4.4 (or equivalent) of finasteride product information. These generally include advice on screening patients before starting treatment, monitoring for mood changes and for the 1 mg formulation, stopping treatment if these occur (see sections 2.5 and 2.6).
Prescriber Update	Post-finasteride syndrome (March 2016).
Classification	Prescription medicine
Usage data	25,305 people were dispensed finasteride 5 mg in 2024. No data available for 1 mg formulation.
Advice sought	**The Committee is asked to advise:** • Whether suicidal ideation should be listed in the finasteride 5 mg data sheet. • Whether warnings on mood changes, including suicidal ideation, should be included in the data sheets for finasteride 1 mg and/or finasteride 5 mg and if so, what advice should be included (eg, screening, monitoring and management).

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1 PURPOSE

There have been spontaneous case reports of mood changes, including suicidal ideation, in association with treatment with finasteride. Depression is currently listed as an adverse event in section 4.8 of the data sheets for both finasteride 5 mg (Ricit) and finasteride 1 mg (Propecia, Profal). Suicidal ideation is listed as an adverse event in section 4.8 of the data sheet for finasteride 1 mg (Propecia, Profal) only.

International regulators have recently reviewed this signal. For example, the United Kingdom (UK) finasteride 1 mg and 5 mg product information includes a warning on mood alterations and depression in section 4.4, which includes advice on monitoring and management. This was recently updated to state that sexual dysfunction may contribute to mood alterations.

This report reviews the evidence regarding a possible association between finasteride and mood changes, including suicidal ideation. The Committee is asked to advise whether changes to the New Zealand (NZ) finasteride data sheets are recommended. This includes whether there should be a warning in section 4.4 for finasteride 1 mg and/or 5 mg, and whether finasteride 5 mg should list suicidal ideation.

2 BACKGROUND

2.1 Finasteride

Finasteride is a 5-alpha reductase inhibitor (5-ARI). Finasteride inhibits type II 5-alpha-reductase which blocks the peripheral conversion of testosterone to dihydrotestosterone (DHT), reducing serum DHT levels. [1]

Finasteride is indicated at a dose of 5 mg daily for the treatment of benign prostatic hyperplasia (BPH) to reduce the risk of acute urinary retention and reduce the risk of surgery including transurethral resection of the prostate (TURP) and prostatectomy. In BPH, enlargement of the prostate gland is dependent on conversion of testosterone to DHT within the prostate. [2]

Finasteride is indicated at a dose of 1 mg daily for the treatment of androgenetic alopecia (AGA) in men. Finasteride inhibits type II 5-alpha-reductase in hair follicles and inhibits miniaturisation of scalp hair follicles. [1]

The most frequently reported adverse effects of finasteride are decreased libido and erectile dysfunction. In clinical studies in AGA, the most frequently reported events were decreased libido (1.8% finasteride vs 1.3 placebo), erectile dysfunction (1.3% finasteride vs 0.7% placebo) and decreased volume of ejaculate (0.8% finasteride vs 0.4% placebo). These events generally resolved after stopping treatment or with continued treatment in some cases. [1, 2]

Other adverse events reported in the post-marketing setting include decreased libido and sexual dysfunction continuing after discontinuation of treatment, depression, suicidal ideation, breast tenderness and enlargement, testicular pain, haematospermia and poor seminal quality. [1, 2]

Dutasteride is another 5-ARI that works in a similar way to finasteride. Dutasteride is included in some of the safety literature and international regulatory actions, but is not included in this report as it is not approved in NZ.

2.2 Androgenetic alopecia

Androgenetic alopecia (AGA) is thinning of the hair and balding due to a combination of the effects of androgens and genetic predisposition. AGA is caused by a genetic sensitivity to the effects of DHT, resulting in shortened growth (anagen) phase of the hair cycle and miniaturisation of hair follicles resulting in growth of progressively fewer and finer hairs.

In men, AGA is characterised by a receding hairline and hair loss on the top and front of the head. In women, AGA usually results in thinning of the hair of the mid-frontal part of the scalp and is usually less severe than in

men. AGA is common and the prevalence increases with age, from around 2% of men in their 20s to nearly half of men in their 70s. Hair loss can be associated with negative effects on psychological wellbeing, particularly in young people. [3, 4]

Approved pharmacological treatments for AGA are limited to topical minoxidil and oral finasteride 1 mg.

2.3 Benign prostatic hyperplasia

Benign prostatic hyperplasia (BPH) refers to hyperplastic changes in the prostate confirmed by histology. BPH may result in benign prostatic enlargement (BPE) leading to lower urinary tract symptoms (LUTS) including urinary frequency, nocturia, hesitancy, urgency, and weak stream. Complications include acute urinary retention, recurrent UTIs, hydronephrosis and renal failure.

The prevalence of BPH increases with age, with around half of men aged 50 years and older having pathological evidence of BPH, increasing to >80% in men aged 80 years and older. The prevalence of LUTS also increases with age. Risk factors for BPH include metabolic syndrome, diabetes, obesity and hypertension.

Alpha blockers such as doxazosin are the first line treatment for managing LUTS symptoms that affect quality of life. Finasteride may be added or used as monotherapy where there is inadequate response or alpha blockers are not tolerated. Where moderate to severe symptoms persist despite pharmacological treatment, prostate surgery may be required.

LUTS can have a significant impact on physical and mental quality of life and may increase the risk of depression. [5-7]

2.4 Depression and suicidal ideation

Depression is a common mental health condition characterised by depressed mood and/or loss of interest or pleasure in activities for a prolonged period. To meet diagnostic criteria, symptoms generally persist for at least two weeks and cause clinically significant distress or impairment. [8]

Depression is associated with a significantly increased risk of self-harm and suicide. Suicidal ideation refers to thoughts about suicide, ranging from passive thoughts to active thoughts involving intent or planning. Risk factors include prior suicide attempt, history of mental illness, chronic illness, life stressors, impulsive tendencies, substance use disorders, adverse childhood experiences, social isolation and exposure to violence. Rates of death by suicide are higher among men than women. [9]

Mood changes, including depression and suicidal ideation, have been reported by people taking finasteride. Reviews by the European Medicines Agency (EMA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA) found that most of these reports have been in people taking finasteride for AGA/hair loss, with fewer cases in people treated for BPH despite higher estimated usage in this population. A significant proportion (one third of the UK reports) also included symptoms of sexual dysfunction. [10, 11]

There are multiple factors that may contribute to these reports. The burden of BPH symptoms including sleep disturbance can impact quality of life and cause psychological distress. Hair loss is also associated with psychological distress. Finasteride can cause sexual adverse effects such as loss of libido and erectile dysfunction which have a relationship with depression. It is unclear whether the higher number of reports in people taking finasteride for AGA compared to BPH are related to the underlying condition, differences in patient populations, stimulated reporting or other factors.

A theoretical biological plausibility for a relationship between finasteride and depression has been suggested based on the involvement of 5-alpha-reductase in the production of neuroactive steroids that act on the GABA-A receptor, an inhibitory neurotransmitter receptor that has been linked to depression. Some animal studies have reported behaviour changes including depression-like behaviours in rats treated with finasteride but findings have been mixed. A mechanism has not been established in humans. [10]

2.5 Product information

A comparison of New Zealand and international product information for finasteride 1 mg (Propecia) and finasteride 5 mg (Proscar/Ricit/Profal) is shown in table 1.

The NZ finasteride 1 mg data sheet lists depression and suicidal ideation in section 4.8 but does not include a warning in section 4.4. The Australia, UK and Canada product information include warnings on screening patients for depression and suicidality, monitoring throughout treatment and after, and stopping treatment if mood changes occur. Some product information also states sexual dysfunction may contribute to mood changes.

The NZ finasteride 5 mg data sheet lists depression in section 4.8, but not suicidal ideation. There is no warning in section 4.4. The UK and Canada product information include warnings in 4.4 that are similar to the warnings for finasteride but do not include information on stopping treatment if mood changes occur.

Table 1: Comparison of New Zealand and international finasteride product information.

	Finasteride 1 mg tablet	**Finasteride 5 mg**
NZ	**Propecia** [1]	**Ricit** [2]
4.4	-	-
4.8	Psychiatric disorders: depression, suicidal ideation, decreased libido that continued after discontinuation of treatment.	Psychiatric disorders: Common: decreased libido. Unknown: decreased libido that may continue after discontinuation of therapy, depression
AU	**Propecia** [12]	**Proscar** [13]
4.4	Mood changes and depression There have been post-marketing reports of serious psychiatric symptoms in patients being treated with finasteride that sometimes continued after treatment discontinuation. Mood alterations including depressed mood, depression, suicidal ideation, have been reported in patients treated with finasteride (see Section 4.8 Adverse Effects (Undesirable Effects)). It is recommended that patients be screened for suicidal ideation, depression and/or associated risk factors before treatment initiation. Clinical monitoring of patients for signs and symptoms of psychiatric disorders should continue throughout treatment and after. If these occur, treatment with finasteride should be discontinued and patients should be advised to seek medical advice. Sexual dysfunction that may contribute to mood changes, including suicidal ideation, has been reported in some patients. Patients should be informed to seek medical advice in case they experience sexual dysfunction. Treatment discontinuation should be considered (see section 4.8 Adverse Effects (Undesirable Effects)). Sexual dysfunction has also been reported without psychological effects, such as mood changes or suicidal ideation.	Mood changes and depression There have been post-marketing reports of serious psychiatric symptoms in patients being treated with finasteride that sometimes continued after treatment discontinuation. Mood alterations including depressed mood, depression, suicidal ideation have been reported in patients treated with finasteride (see Section 4.8 Adverse Effects (Undesirable Effects)). It is recommended that patients be screened for suicidal ideation, depression and/or associated risk factors before treatment initiation. Clinical monitoring of patients for signs and symptoms of psychiatric disorders should continue throughout treatment and after. If these occur, patients should be advised to seek medical advice.
4.8	Psychiatric disorders: depression; decreased libido that continued after discontinuation of treatment; suicidal ideation.	Psychiatric disorders: depression; decreased libido that continued after discontinuation of treatment; suicidal ideation.

UK	**Propecia** [14]	**Proscar** [15]
4.4	Mood alterations and depression Mood alterations including depressed mood, depression and, less frequently, suicidal ideation have been reported in patients treated with finasteride 1 mg. Patients should be monitored for psychiatric symptoms and if these occur, treatment with finasteride should be discontinued and the patient advised to seek medical advice. Sexual dysfunction that may contribute to mood alterations, including suicidal ideation, has been reported in some patients. Patients should be informed to seek medical advice in case they experience sexual dysfunction. Treatment discontinuation should be considered (see section 4.8). Sexual dysfunction has also been reported without psychological effects, such as mood alterations or suicidal ideation. A patient card reminding of the above is provided with the package of Propecia.	Mood alterations and depression Mood alterations including depressed mood, depression and, less frequently, suicidal ideation have been reported in patients treated with finasteride 5 mg. Patients should be monitored for psychiatric symptoms and if these occur, the patient should be advised to seek medical advice.
4.8	Psychiatric disorders: Uncommon*: Decreased libido. Uncommon: Depression†. Not known: Anxiety, suicidal ideation. * Incidences presented as difference from placebo in clinical studies at Month 12. † This adverse reaction was identified through post-marketing surveillance but the incidence in randomised controlled Phase III clinical trials (Protocols 087, 089, and 092) was not different between finasteride and placebo.	Psychiatric disorders: Common: decreased libido. Unknown: decreased libido that may continue after discontinuation of therapy, depression, anxiety, suicidal ideation.

Canada	**Propecia** [16]	**Proscar** [17]
4.4	Psychiatric There have been post-marketing reports of serious psychiatric symptoms in patients being treated with finasteride that sometimes continued after treatment discontinuation. Mood alterations including depressed mood, depression, self-harm injury, suicidal ideation, as well as worsening of pre-existing depression (psychiatric disorder) have been reported in patients treated with finasteride (see 8 ADVERSE REACTIONS, 8.5 Post-Market Adverse Reactions). It is recommended that all patients be screened for suicidal ideation, self-harm, and depression and/or associated risk factors before treatment initiation. Clinical monitoring of all patients for signs and symptoms of psychiatric disorder should continue throughout treatment and after. If these occur, treatment should be discontinued and patients advised to seek medical advice, as soon as possible.	Psychiatric There have been post-marketing reports of serious psychiatric symptoms in patients being treated with finasteride that sometimes continued after treatment discontinuation. Mood alterations including depressed mood, depression, self-harm injury, suicidal ideation, as well as worsening of pre-existing depression (psychiatric disorder) have been reported in patients treated with finasteride (see 8 ADVERSE REACTIONS, 8.3 Post-Market Adverse Reactions). It is recommended that all patients be screened for suicidal ideation, self-harm, and depression and/or associated risk factors before treatment initiation. Clinical monitoring of all patients for signs and symptoms of psychiatric disorder should continue throughout treatment and after. If these occur, patients should be advised to seek medical advice, as soon as possible.
4.8	Psychiatric disorders: mood alterations and depression, decreased libido that continued after discontinuation of treatment. Mood alterations including depressed mood and, less frequently, suicidal ideation have been reported in patients treated with finasteride 1 mg. Patients should be monitored for psychiatric symptoms and if these occur, the patient should be advised to seek medical advice.	Psychiatric disorders: mood alterations and depression, decreased libido that continued after discontinuation of treatment. Mood alterations including depressed mood and, less frequently, suicidal ideation have been reported in patients treated with finasteride 5 mg. Patients should be monitored for psychiatric symptoms and if these occur, the patient should be advised to seek medical advice.
US	**Propecia** [18]	**Proscar** [19]
4.4	-	-
4.8	Nervous System/Psychiatric: depression, suicidal ideation and behaviour.	Post-market: Depression, suicidal ideation.

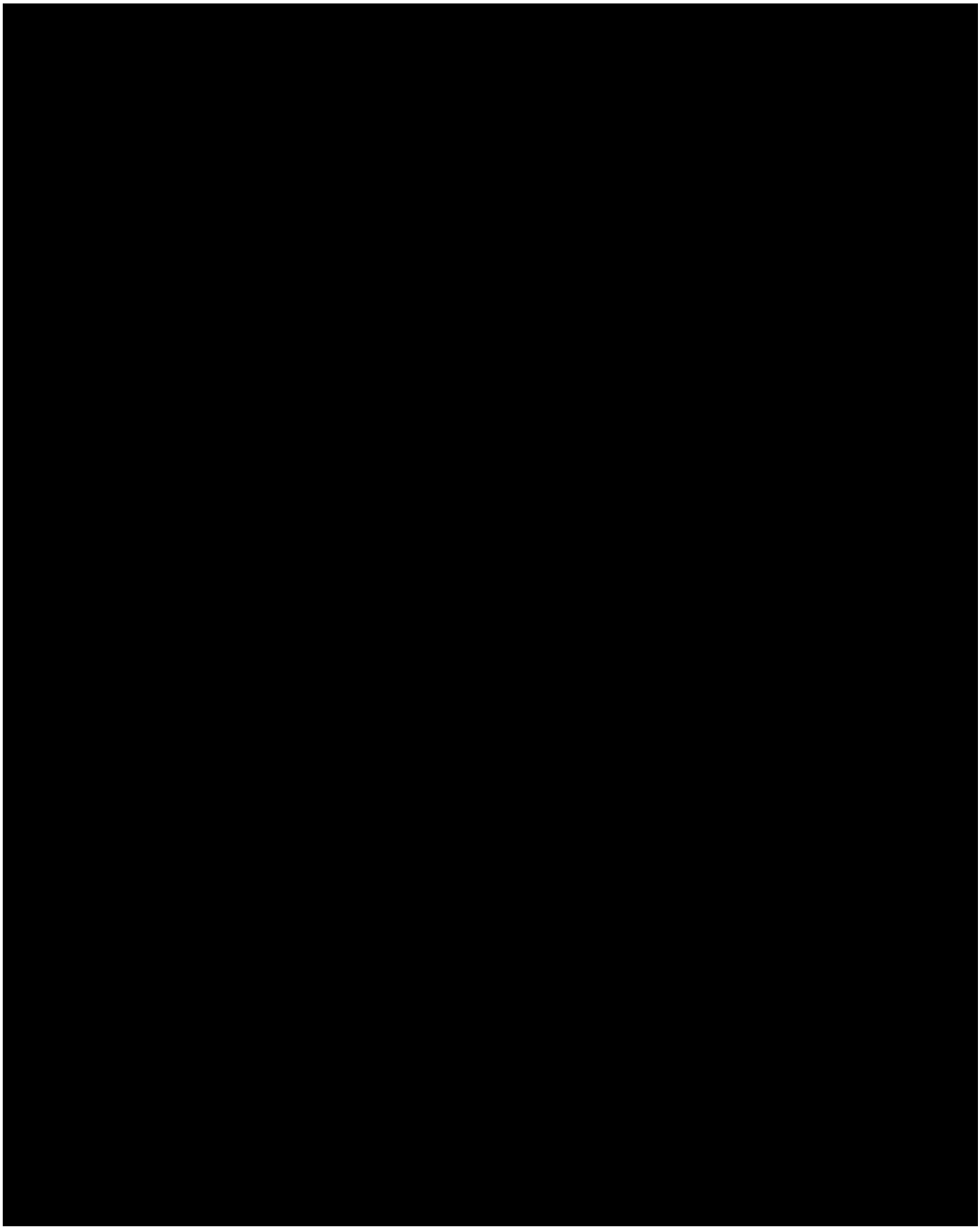
2.6 International regulatory action

Several regulators have reviewed a possible association between finasteride and depression and suicidal ideation. Actions taken are summarised in table 2 and are described in detail in subsequent sections.

Table 2: Summary of recent actions taken by international regulators

Regulator	Date	Action taken	Summary
TGA (Australia)	April 2026	[redacted]	• Serious psychiatric symptoms reported that sometimes continue after stopping treatment. • Includes depression and suicidal ideation. • Screen patients for history/risk factors before starting treatment. • Monitor patients throughout treatment and after. • If symptoms occur, stop treatment (1 mg only). • Sexual dysfunction may contribute to mood changes.
MHRA (UK)	May 2026	Additional information in section 4.4 of SmPCs (1 mg only). Advisory published in Drug Safety Update.	• Sexual dysfunction that may contribute to mood alterations, including suicidal ideation, has been reported. • Patients should be informed to seek medical advice if these symptoms occur. • Treatment discontinuation should be considered.
	April 2024	Introduced patient cards for finasteride (1 mg and 5 mg).	• Finasteride can cause side effects including depression and may lead to thoughts of suicide. • If you experience these symptoms, stop taking finasteride (1 mg only) and seek medical advice. • Decreased sex drive and erectile dysfunction have also been reported (which in some cases continued after treatment was stopped).
Health Canada	June 2026	Published updated Summary Safety Review. No changes to existing warnings.	• Health Canada continues to find a link between the use of finasteride and the risk of suicidal ideation. • The existing product information remains appropriate. • No conclusion on the relationship between sexual dysfunction and suicidal ideation while using finasteride.
EMA (Europe)	May 2025	Updated existing warnings. Patient card included in package (1 mg only). Direct healthcare professional communication (DHCP).	• Existing warnings listed mood changes including suicidal ideation. • New information states sexual dysfunction may contribute to mood changes.

2.6.1 Australian Therapeutic Goods Administration



[redacted]

2.6.2 United Kingdom Medicines and Healthcare products Regulatory Agency

2.6.2.1 Safety communication (May 2026)

In May 2026, the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) published information on a review of finasteride and dutasteride and the risk of suicidal thoughts and behaviours. Changes to the product information were recommended. [20]

Yellow Card data from 1994 to 31 May 2025 included 170 reports of suicidal ideation and related terms for finasteride (1mg and 5mg) and 5 reports for dutasteride 0.5mg. There were 19 fatal reports of suicide for finasteride and no fatal reports of suicide for dutasteride.

The PEAG and CHM advice included updating the product information of finasteride 1mg and retaining the UK finasteride patient cards for the 1mg and 5mg finasteride products. The data from Yellow Card reports were mainly from patients treated with 1mg finasteride for androgenetic alopecia, and the literature data showed mixed outcomes. The data for dutasteride was very limited and the dutasteride product information was updated as a precaution.

Advice for healthcare professionals:

- Finasteride is associated with depression, suicidal ideation and sexual dysfunction which may persist after treatment is stopped.
- Inform patients of the risks at point of prescribing and advise patients to read the Finasteride patient cards and the patient leaflet.
- The product information for finasteride 1 mg will be updated with a warning that sexual dysfunction may contribute to mood disorders, and that sexual dysfunction has also been reported without mood alterations.
- When prescribing finasteride, review their medical record, ask patients if they have a history of depression or suicidal ideation and review patients regularly for psychiatric and/or sexual side effects.
- Patients prescribed finasteride 1 mg should stop taking the medicine if they develop suicidal thoughts or depression and contact their healthcare professional as soon as possible.
- Patients prescribed finasteride 5mg or dutasteride should consult their healthcare professional as soon as possible if they develop suicidal thoughts or depression.
- Dutasteride works in a similar way to finasteride – therefore, as a precaution, a warning will be added to the dutasteride product information that mood alterations have been reported with the same class of medicine (finasteride).
- Patients prescribed finasteride or dutasteride should contact their healthcare professional if they experience sexual dysfunction.

The MHRA previously introduced patient cards describing these risks in April 2024 (see below).

2.6.2.2 Safety review of finasteride: public assessment report (April 2024) [11]

The MHRA conducted a literature review, covering the period 1 January 2017 to 16 February 2023, the time since the last significant MHRA regulatory action.

MHRA concluded there was sufficient evidence from the scientific literature to support the documented side effects of finasteride and the information already included in the product information. There was mixed evidence regarding the persistence of psychiatric and sexual side effects after stopping the medicine.

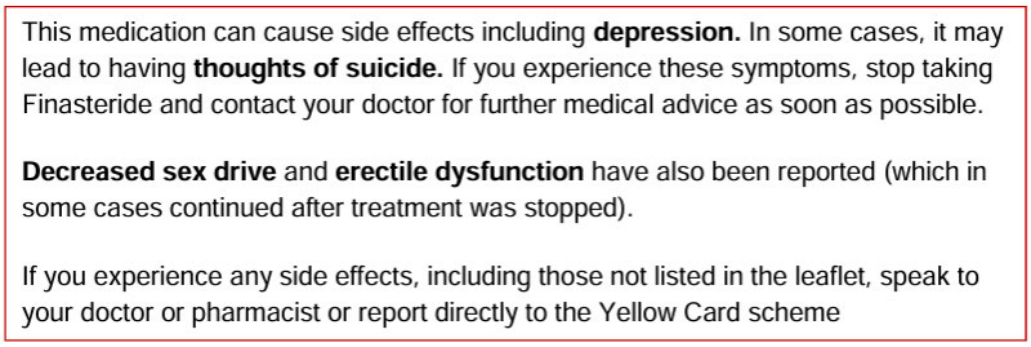
Limitations included recall bias, selection bias, small sample size and concerns regarding methodology. A possible reason for the inconsistency in the data is that many of the studies did not use validated tools for assessment of side effects, limiting comparison.

Some studies found that those with a personal history of a psychiatric disorder or a first degree relative with a psychiatric disorder are more likely to develop side effects with finasteride, although these studies had limitations.

Some studies have shown a similar side effect profile for both finasteride 1 mg and 5 mg dose, while others have suggested a higher risk of all side effects in men using finasteride for hair loss (1 mg dose). The authors attributed this to differing patient profiles.

While these sexual dysfunction and depression were already listed in the product information, additional risk minimisation measures were recommended. The PEAG recommended the introduction of a patient card inside the packaging to highlight some of the psychiatric and sexual side effects (figures 1 and 2). A Drug Safety Update (DSU) article was also published. It was also suggested to add 'suicidal ideation' to section 4.8 of the SmPC and PIL. The PEAG also supported continued work with other organisations regarding online prescribing of finasteride and to increase awareness of the potential side effects among healthcare professionals.

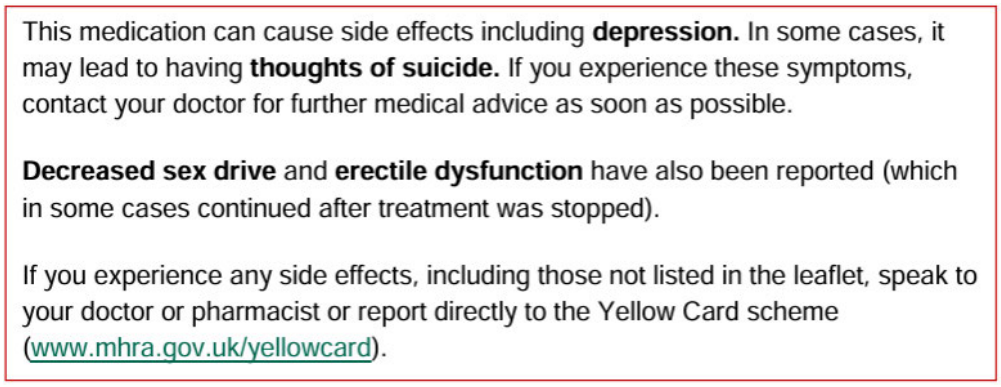
Figure 1: Patient card for finasteride 1mg


This medication can cause side effects including **depression.** In some cases, it may lead to having **thoughts of suicide.** If you experience these symptoms, stop taking Finasteride and contact your doctor for further medical advice as soon as possible.

Decreased sex drive and **erectile dysfunction** have also been reported (which in some cases continued after treatment was stopped).

If you experience any side effects, including those not listed in the leaflet, speak to your doctor or pharmacist or report directly to the Yellow Card scheme

Figure 2: Patient card for finasteride 5mg


This medication can cause side effects including **depression.** In some cases, it may lead to having **thoughts of suicide.** If you experience these symptoms, contact your doctor for further medical advice as soon as possible.

Decreased sex drive and **erectile dysfunction** have also been reported (which in some cases continued after treatment was stopped).

If you experience any side effects, including those not listed in the leaflet, speak to your doctor or pharmacist or report directly to the Yellow Card scheme (www.mhra.gov.uk/yellowcard).

2.6.3 Health Canada

In June 2026, Health Canada published an updated Summary Safety Review on the risk of suicidal ideation with finasteride and dutasteride, including a possible relationship between sexual dysfunction and suicidal ideation. Warnings on the risk of suicidal ideation were previously added to the Canadian finasteride product information in 2019 (see section 2.5 Product information). [21]

The review considered evidence from previous Health Canada reviews, the EMA's 2025 assessment, case reports from the Canada Vigilance database and the scientific literature.

At the time of the review, Health Canada had received 18 Canadian reports of suicidal ideation in patients taking finasteride or dutasteride who also reported sexual dysfunction. However, a conclusion on the relationship between these two adverse events could not be confirmed due to the complexity of the evidence and the presence of confounders.

Health Canada also reviewed the scientific literature that discussed a possible relationship between sexual dysfunction and suicidal ideation in patients using finasteride or dutasteride. However, due to the complexity of the evidence and the presence of confounders, the role of sexual dysfunction as a risk factor for suicidal ideation could not be confidently concluded.

Health Canada continued to find a link between the use of finasteride and the risk of suicidal ideation, and considered that this risk is appropriated labelled. There was limited evidence for dutasteride, but Health Canada concluded that this risk should be added to the product information as a precautionary approach.

2.6.4 European Medicines Agency

In August 2025, the EMA published the outcome of a review of measures to minimise risk of suicidal thoughts with finasteride and dutasteride medicines. [10]

A warning about mood changes including suicidal ideation was already included in the product information for finasteride 1 and 5 mg tablets. Following the review, the product information for finasteride 1 mg products was updated to state that patients need to seek medical advice if they experience problems with sexual function which are known side effects of the medicine and may contribute to mood changes.

A patient card was included in the packaging of finasteride 1 mg products (figure 3) and a direct healthcare professional communication (DHCP) was issued. [22, 23]

Figure 3: Finasteride 1 mg patient card

LABELLING: PATIENT CARD

[The patient card should be placed inside the outer packaging with the following text]

{Invented name} can cause adverse reactions including depressed mood, depression or suicidal thoughts. If you experience any mood alterations, stop taking finasteride and contact your doctor for further medical advice as soon as possible.

In some patients, impaired sexual function may contribute to mood alterations, including suicidal thoughts. If you experience symptoms of impaired sexual function, contact your doctor for further medical advice.

Below is a summary of the EMA review.

Post marketing safety data from EudraVigilance

There were 739 cases of suicide and related events for finasteride and dutasteride from EudraVigilance up to 31 October 2024. Using WHO-UMC causality assessment criteria, 16 cases were assessed as probably related, 309 cases as possibly related, while the remaining cases were assessed as ‘not assessable’ mainly due to a lack of relevant information (346), as unlikely (49) or as unrelated (18).

Amongst the 325 probable or possible cases identified, 313 cases were reported with finasteride and 13 with dutasteride (1 case reported the use of both finasteride and dutasteride). The most reported indication in these cases was alopecia and related terms (262). Indications related to benign prostate hyperplasia were reported in 24 cases. Age was available for 202 cases with a median age of 30 years for finasteride and 57 years for dutasteride.

The most common preferred term (PT) was 'suicidal ideation', reported in 261 possibly related cases and in all probably related cases. The PT 'completed suicide' or 'suicide attempt' was reported in 37 cases assessed as possibly related and 2 probably related cases.

Among the 39 cases of completed suicide and suicide attempt, 32 cases concerned the indication of alopecia, and 6 cases of benign prostate hyperplasia. In 16 cases, the PT 'depression suicidal' was reported. In 8 of the 39 cases, psychiatric disorder was reported in medical history.

There were 187 cases identified where a combination of sexual and psychiatric adverse events occurred despite medicine withdrawal.

Literature data

The scientific literature reviewed included systematic reviews by Pompili et al. (2021) and Uleri et al. (2024), (see section 3.1.4).

Pharmacovigilance database and disproportionality studies by Ali et al. (2015), Baas et al. (2018), Nguyen et al. (2021), Gupta et al. (2025) were reviewed.

Recent cohort studies by Pennap et al (2024), Welk et al (2017), Kim et al (2020), Garcia-Argibay et al (2022) and Laanani et al (2023) were reviewed (summarised in section 3.1.2).

Irwig et al (2012) and Irwig et al (2020) (see section 3.1.5) described depressive symptoms and suicidal thoughts amongst former finasteride users with persistent sexual side effects.

Clinical trial data

There were no cases of suicide or suicidal ideation in trials of finasteride 1 mg and 5 mg. The clinical trial data did not support an increased risk of suicidality associated with finasteride- or dutasteride-containing medicinal products.

Discussion on safety

EudraVigilance data highlighted cases of suicide and related events for finasteride, especially in the indication of male androgenetic alopecia, and only limited evidence for dutasteride.

Cohort studies in the BPH indication did not identify an increased risk of suicide associated with finasteride or dutasteride. The systematic review by Pompili et al. (2021) reported an increased risk but limited study data on the risk of suicide prevented any conclusions about the strength of the evidence.

Studies that suggested an increased risk of suicide in patients with male androgenetic alopecia presented major limitations, including limited numbers of reports, small sample sizes, use of spontaneous reports for calculating incidence rates and possible simulated reporting. While these studies raised concerns, no definitive conclusions could be drawn regarding the risk of suicide.

The lower risk of suicidal ideation observed in patients taking finasteride 5 mg compared to those taking finasteride 1 mg remains unexplained based on the reviewed literature.

In terms of risk factors that could increase the risk of developing suicidal ideation and behaviours, the review of the scientific literature did not allow for any definitive conclusions. Some publications suggested that sexual dysfunction, sometimes persistent, and history of mood disorders may be possible contributing conditions. However, Welk et al. (2017) and Kim et al. (2020) did not find an increased risk of suicide amongst 5-ARI users with underlying depression or any psychiatric disorder.

Non-clinical aspects

Several nonclinical studies have reported neuropsychiatric effects of finasteride in rodents, including depression-like and anxiety-like behaviours, cognitive impairments, and altered gene expression related to mood regulation and neuroplasticity. However, the findings across studies are inconsistent, and given the high doses used (exceeding the recommended maximum daily dose in humans) and the non-oral routes used, the clinical relevance and translatability of these results to humans remain limited and uncertain.

Stakeholder input

PRAC received over 150 interventions from patients or family members, not-for-profit organisations, healthcare professionals and academia. These interventions concerned individual testimonies or personal views, and/or the sharing of data or information in the form of publications, links to medical journals, pharmacovigilance data, or links to media outlets, social media communities, and websites of not-for-profit and patient organisations.

Benefit-risk balance

Both finasteride and dutasteride belong to the class of 5-ARI and inhibit the type II 5-AR, which reduces the conversion of testosterone to DHT. The review noted that 5-ARI may play a role in neuropsychiatric side effects by altering neuroactive steroids and their metabolites, but these effects have not yet been fully characterised. The non-clinical data reviewed did not allow conclusions.

The efficacy of finasteride- and dutasteride-containing medicinal products in the authorised indications is considered well-established.

Some data suggested that sexual dysfunction may play a contributory role in suicidal ideation in some patients treated with finasteride for male androgenetic alopecia. As a result, PRAC concluded this information should be reflected in the product information of these products.

PRAC noted that most cases of suicidal ideation were reported following treatment with finasteride for male androgenetic alopecia, despite a considerably larger exposure from treatment for benign prostate hyperplasia. In order to increase awareness amongst patients, PRAC recommended the introduction of a patient card in finasteride 1 mg product packaging.

Studies in BPH did not find an increased risk of suicide with finasteride 5 mg overall.

PRAC did not identify sufficient evidence linking suicidal ideation to dutasteride-containing medicinal products. However, based on the common mechanism of action of 5-ARIs, PRAC agreed that a warning on depression and suicidal ideation should be included in the product information as a precautionary measure.

A direct healthcare professional communication (DHPC) was also agreed, together with a communication plan to inform relevant healthcare professionals of the new measures to minimise the risk of suicidal ideation for finasteride- and dutasteride-containing medicinal products.

PRAC concluded that the benefit-risk balance of medicinal products containing finasteride 1 mg for oral use, finasteride 5 mg for oral use and dutasteride for oral use remains favourable subject to the agreed amendments to the product information and risk minimisation measures.

2.7 Usage

There were 27,283 people who received a community dispensing of finasteride 5 mg in 2025 (table 3). Dispensing data is not available for finasteride 1 mg because this is not publicly funded.

Table 3: Dispensings of finasteride 5 mg

Year	Number of dispensings	Number of people
2021	70,826	19,601
2022	77,831	21,557
2023	85,381	23,502
2024	94,463	25,305
2025	103,227	27,283

Source: Health New Zealand. Pharmaceutical data web tool: version published 7/8/2026. https://tewhatuora.shinyapps.io/pharmaceutical-data-web-tool/ (accessed 18 August 2026)

3 SCIENTIFIC INFORMATION

3.1 Published literature

3.1.1 Search strategy

Databases searched: Medline, PsycInfo, Scopus, and Embase.

1. Finasteride.mp. or *Finasteride/ or ("5-Alpha Reductase Inhibitor*" or "5α-Reductase Inhibitor*")

2. (mood or psych* or depres* or suici* or "self-harm" or "self harm" or anxiety or mental).tw.

3. 1 and 2

4. limit 3 to (english language and yr="2015 -Current")

The publications are presented in the following order: cohort studies, other studies, systematic reviews and meta-analyses and literature case reports.

3.1.2 Cohort studies

The findings of cohort studies investigating the risk of depression and suicidal ideation are summarised in table 4 below and reviewed in detail in the subsequent sections.

Table 4: Summary of cohort studies (significantly elevated risks bolded)

Publication	Participants	Exposure/comparison	Outcomes	Results
Gotor-Rivera 2026	Patients with a diagnosis of **AGA** (n= 448,750) or **BPH** (n=1,484,562) up to 24 June 2024 in the TriNetX database (global) Excluded: psychiatric history	5-ARI treatment vs 'baseline cohort (regardless of treatment)'	Depressive episode, major depressive episode, dysthymia History of self-harm Suicidal ideation Suicide attempt	AGA Depressive episodes aRR: 0.816 (95% CI: 0.695-0.958) Suicidal ideation aRR: 1.1 (0.467-2.589) Suicide attempt: no events BPH Depressive episodes aRR: 0.837 (0.801-0.874) Suicidal ideation aRR: 1.093 (0.842-1.418) Suicide attempt: 1 (0.416-2.402)
Wang 2025	UK Biobank study participants aged 40-69 years ('n' not reported) Excluded: history of depression or suicidal/self-harm behaviours	Finasteride treatment vs unexposed	Depression Suicide	Depression aHR: 1.24 (0.99-1.56) Suicide aHR: 0.94 (0.42-2.11)
Neubauer 2025	112,873 male **AGA** patients in the TriNetX database (global) between 2004 and 2024 Excluded: prior mood disorder	5-ARI treatment vs unexposed	Mood disorders	Mood disorder HR (finasteride): 0.979 (0.921-1.040)
Lyakhovitsky 2024	307 **BPH** and 23,227 **AGA** patients in the Israel Clalit Health Services database (2019-2020) and 1,218 and 39,444 healthy controls Excluded: history of finasteride use or psychiatric conditions	Finasteride treatment (AGA/BPH) vs no finasteride treatment (healthy controls)	Mental health diagnoses	AGA **Depression OR: 1.4 (1.13–1.84)** BPH Depression OR: 1.241 (0.326-4.722)
Pennap 2024	1,032,070 male US Medicare beneficiaries with **BPH** aged ≥65 years	5-ARI treatment vs alpha blocker treatment	Intentional self-harm (ISH) Suicide	ISH HR: 0.88 (0.62-1.25) Suicide HR: 0.82 (0.54-1.24)
Laanani 2023	287,363 men aged 50 years or older initiating finasteride (5 mg only) or dutasteride in the French National Health Data System	Finasteride 5 mg vs dutasteride 0.5 mg	ISH hospitalisation Suicide	ISH/suicide HR: 1.21 (0.87–1.67)

Publication	Participants	Exposure/comparison	Outcomes	Results
Yeon 2022	20,111 men newly diagnosed with **BPH** in a South Korean health insurance database Excluded: prior BPH or mental disorder/self-harm, non-psychiatric hospitalisation >2 weeks, organic brain disease	5-ARI vs alpha blockers	Depression Antidepressant use Anxiety disorder	Depression HR: 0.91 (0.61-1.36)
Garcia-Argibay 2022	2,236,876 men aged 50 to 90 years from 1 July 2005 to 31 December 2018 in Swedish national registers Excluded: 5-ARI without BPH diagnosis, outcome before start of follow-up	5-ARI or alpha blocker (AB) vs unexposed	Depression Suicide Dementia	**Depression aHR (finasteride): 1.61 (1.48-1.75)** **Depression aHR (dutasteride): 1.68 (1.43-1.96)** **Depression aHR (AB): 1.95 (1.86-2.04)** **Depression aHR (5-ARI+AB): 2.21 (2.06-2.38)** Suicide aHR (finasteride): 1.22 (0.99-1.49) Suicide aHR (dutasteride): 0.98 (0.62-1.54) **Suicide aHR (AB): 1.52 (1.34-1.72)** **Suicide aHR (5-ARI+AB): 2.23 (1.87-2.66)**
Kim 2020	51,466 men aged ≥60 years with health examinations in 2005 and 2006 in a South Korean health insurance database	5-ARI vs unexposed	Suicide	Suicide HR = 1.02 (0.70–1.48)
Welk 2017	93,197 men aged ≥66 years in Ontario, Canada, who were new 5-ARI users between 2003 and 2013 and PS-matched unexposed controls (from linked administrative databases) Excluded: depression in prior 5 years	5-ARI vs unexposed	Depression Self-harm Suicide	**Depression HR (first 18 m): 1.94 (1.73-2.16)** **Self-harm HR (first 18 m): 1.88 (1.34-2.64)** Suicide HR (overall): 0.88 (0.53-1.45)
Hagberg 2017	77,732 men ≥18 years between 1 January 1992 and 31 December 2013 with **BPH** (UK CRPD) Excluded: prior depression, suicidal behaviour or antidepressants	5-ARI vs AB	Antidepressant-treated depression	Depression aIRR: 0.94 (0.85-1.04)

3.1.2.1 Gotor-Rivera et al, 2026 [24]

Title: Association between 5-alpha reductase inhibitors and suicidal ideation and behaviors: A retrospective cohort study using the TriNetX dataset.

Methods: This was a retrospective study using the TriNetX Global Collaborative Network database that included patients with a diagnosis of AGA or BPH up to 24 June 2024. Each diagnostic group was stratified in a baseline cohort (regardless of treatment), a 5-ARI cohort (either dutasteride or finasteride), individual finasteride and dutasteride cohorts, and a cohort without 5-ARI exposure. Exclusion criteria included psychiatric history or treatment. The outcomes were depressive episode, major depressive episode, dysthymia, history of self-harm, suicidal ideation and suicide attempt. A 1:1 propensity score-matched analysis adjusted for psychiatric history or sexual dysfunction.

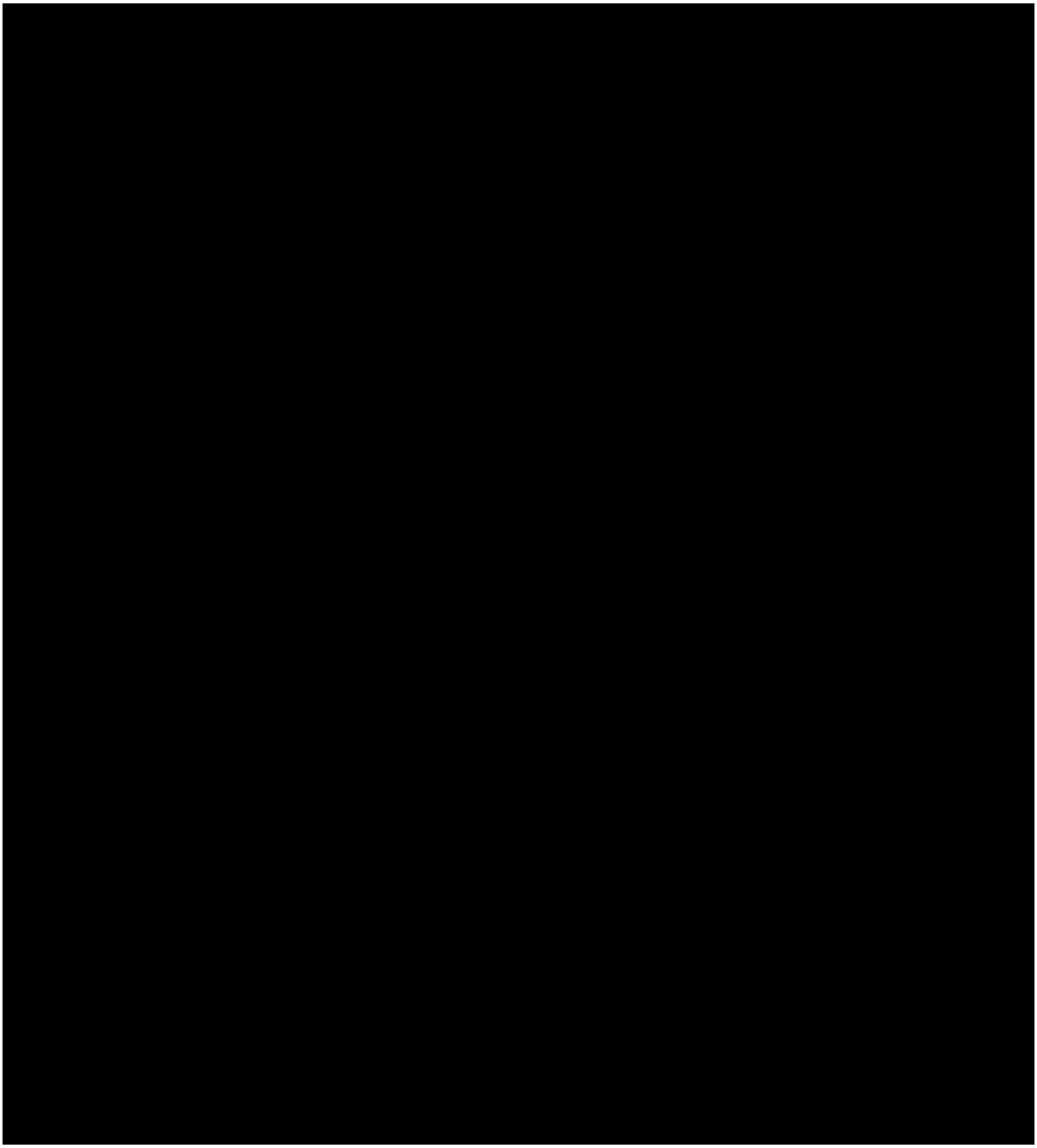
Results: Among patients with AGA, treatment with 5-ARIs was associated with a significantly lower risk of depressive episodes (adjusted risk ratio: 0.816, 95% CI: 0.695-0.958) and dysthymia (adjusted risk ratio: 0.614, 95% CI: 0.38-0.99) compared to the baseline cohort. No significant differences were observed in the risk of suicidal ideation and suicide attempt between patients treated with 5-ARIs and untreated controls (table 5).

Among patients with BPH, there was a significantly lower risk of depressive episodes and major depressive disorder associated with 5-ARI treatment and no increased risk of suicidal ideation or attempts compared to the baseline cohort. However, there was an increased risk of suicidal ideation for the cohort treated with 5-ARI compared to those not treated with 5-ARI (table 6).

Discussion: The authors concluded that under supervision by trained physicians, 5-ARI appear safe in patients without psychiatric comorbidities. Limitations include residual confounding, selection bias, and coding errors.

Table 5: Statistical analysis of patients with androgenic alopecia





3.1.2.2 Wang et al, 2025 [25]

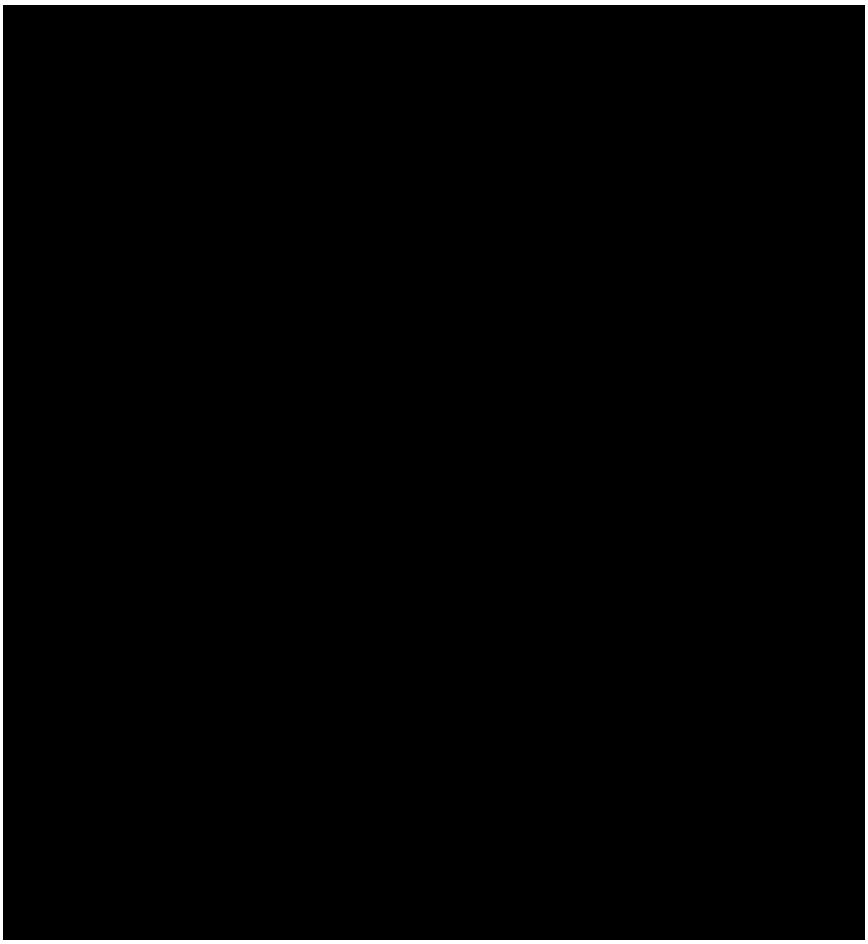
Title: Finasteride use does not lead to depression or suicide: insights from a large-scale cohort study and Mendelian randomization analysis.

Aim: to evaluate the potential risk of depression or suicide intention related to the finasteride prescription.

Methods: The dataset of finasteride medication (ukb-b-2029) from the Genome Wide Association Study (GWAS) study of the MRC-IEU consortium conducted in the European population was used as the exposure of the two-sample Mendelian randomisation (MR) analyses. Datasets whose traits contained 'depression' or 'suicide' were selected for acquiring outcome data. AGA was also used as the exposure in the MR analyses (figure 4). The authors also used a COX regression model on the large-scale UK Biobank cohort. The UKB study contains clinical data (diagnoses/prescriptions) of more than 500,000 people aged 40-69 years.

Patients with baseline depression or suicidal/self-harm behaviours were excluded. Demographic variables (age at recruitment, sex, ethnicity), social life variables (employment status, Townsend deprivation index, educational levels) and personal lifestyles (sleep pattern, smoking status, and alcohol drinking) were used as covariates.

Figure 4: Mendelian randomisation analysis design

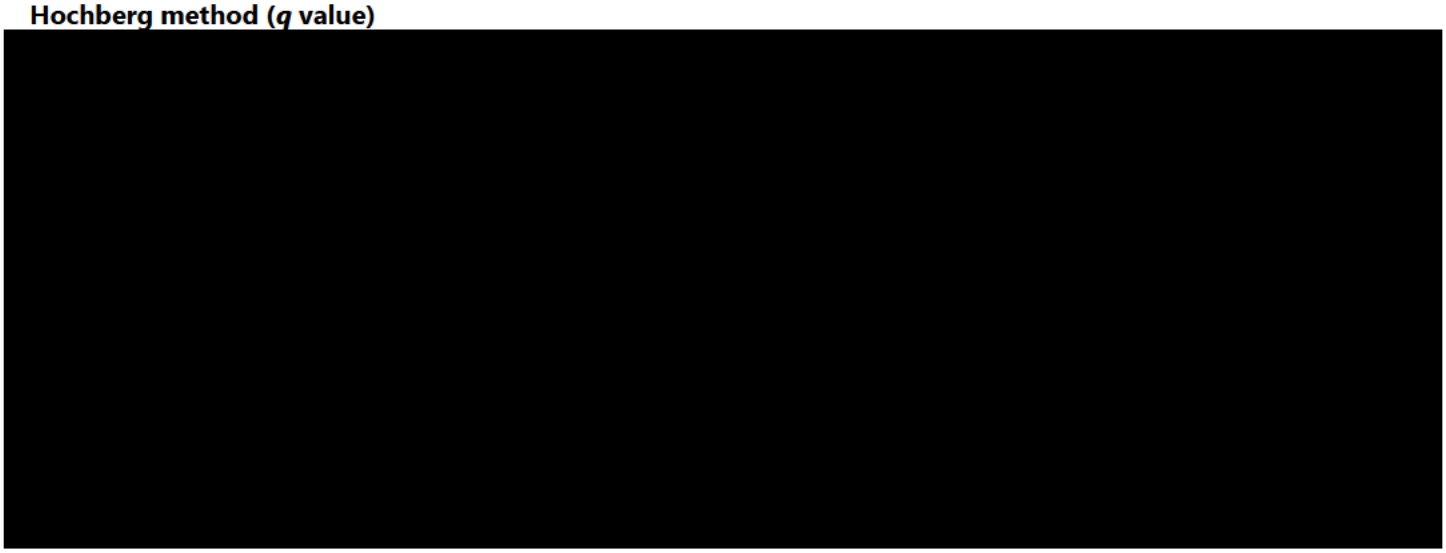


Note: Mendelian randomisation is an analytical method that uses genetic variants as instrumental variables for modifiable risk factors that affect population health with the aim of overcoming unmeasured confounding. Two sample Mendelian randomisation uses two different study samples to estimate the instrument-risk factor and instrument-outcome associations to estimate a causal effect of the risk factor on the outcome. This data is obtained from large genome-wide association studies (GWAS).

Mendelian randomisation depends on three assumptions: that the genetic variants associate with the risk factor of interest (relevance assumption), that there are no unmeasured confounders of the associations between genetic variants and outcome (independence assumption) and that the genetic variants affect the outcome only through their effect on the risk factor of interest (exclusion restriction). [26]

Results: After a series of the two-sample MR analyses, two outcomes were identified as the potential results of the finasteride use, including one depression outcome (Depression 1, p = 0.030) and one suicide outcome (Suicide 1, p = 0.010). However, after the FDR (potential false discovery rate) correction (Benjamini-Hochberg method), the causal relationships were no longer significant (figure 5).

Figure 5: Forest plot showing the results of MR analysis after being corrected by the Benjamini-Hochberg method (*q* value)



In the UKB cohort, the median follow-up periods for depression and suicide were 13.7 and 13.74 years respectively. During this follow-up period, 14,883 depression cases and 1,299 suicide cases were reported in the total population. There were 2.89 newly reported depression cases in every 1,000 finasteride users per year, while 2.90 were reported in the control population. The HRs were not significantly different for finasteride users compared to non-users before or after adjustment (figure 6).

Figure 6: Forest plot showing the altered risk of depression or suicide between finasteride users and non-users



Discussion: This study did not support a causal relationship between finasteride use and the increased risk of depression. Limitations included availability of only one dataset of finasteride use, and use of the Benjamini-Hochberg method for FDR correction may incur the risk of overlooking a potential association.

3.1.2.3 Neubauer et al, 2025 [27]

Title: No increased risk of mood disorders in male androgenetic alopecia patients treated with dutasteride and finasteride: A retrospective cohort database study.

Aim: examine mood disorder (MD) risk in 5-ARI-treated AGA patients.

Methods: TriNetX was queried on 17 October 2024 for male AGA patients on dutasteride or finasteride without prior MDs (cohort) and compared to 5-ARI-naïve AGA patients (controls), 2004-2024. Patients with BPH and prior sexual dysfunction were excluded. MD rates were compared ≥1 day following 5-ARI prescription between treatment arms and controls using Cox proportional hazards analysis to calculate HRs with age and race as covariates.

Results: 355 dutasteride-treated, 25,703 finasteride-treated patients, and 86,815 controls were included. Finasteride-treated patients were older than controls and more likely to be white.

Overall, finasteride was not associated with mood disorders compared to untreated controls (0.979, 95% CI 0.921-1.040) but older age and being white or black were associated with mood disorder risk (table 7).

Conclusions: 5-ARIs for AGA treatment were not associated with increased mood disorder risk. Limitations include retrospective design, potential miscoding, unknown medication adherence and AGA severity.

Table 7: Hazard ratios and 95% confidence interval for mood disorders* in dutasteride and finasteride patients.

[redacted]

Comments

This was a brief report and no supplementary materials were available. There could be residual confounding from differences in AGA severity and unmeasured comorbidities affecting mood disorder risk.

3.1.2.4 Lyakhovitsky et al, 2024 [28]

Title: The risk of psychiatric disorders in finasteride users with benign prostatic hyperplasia and androgenetic alopecia: A population-based case-control study.

Aim: to determine whether finasteride therapy for BPH and AGA is associated with the emergence of mental health conditions.

Methods: Patients with BPH who received finasteride 5 mg daily and patients with AGA who received finasteride 1 mg daily in 2019 and 2020 were included, using the Clalit Health Services database (Israel). Patients with history of finasteride use or psychiatric conditions were excluded. The comparator groups were healthy controls matched on age, gender, ethnicity and primary clinic location. Patients were followed for 2 years from the index date. Multivariate logistic regression models for BPH adjusted for age, ethnicity, SES, smoking, obesity, diabetes, hypertension and hyperlipidaemia. Multivariate logistic regression models for AGA adjusted for age, ethnicity, SES, smoking and obesity.

Results: The BPH analysis included 307 BPH patients and 1,218 matched controls with similar baseline characteristics and similar all-cause mortality. The overall rate of mental disorders was 2.3%. No variable, including finasteride use, was found to be related to depression or anxiety (table 8).

Table 8: Evaluation of risk factors for depression and anxiety in patients with benign prostatic hyperplasia by multivariate regression models.



The AGA analysis included 23,227 AGA patients and 39,444 matched controls. Smoking and obesity were less prevalent among AGA patients compare to controls and all-cause mortality was lower. The overall rate of mental disorders was 1.02%. Age, smoking and finasteride were all positive predictors of depression, while higher SES, smoking and finasteride were all positive predictors of anxiety. For finasteride, the models found an OR of 1.4 (95% CI: 1.13–1.84; p = 0.003) for depression and 1.4 (95% CI: 1.14–1.83; p = 0.002) for anxiety (table 9).

Table 9: Evaluation of risk factors for depression and anxiety in patients with androgenetic alopecia by multivariate regression models.



Discussion: the rate of new mental health conditions was low. Finasteride-treated AGA patients had higher rates of anxiety and depression compared to controls without AGA. Limitations included lack of clinical information on disease severity. Patients with anxiety and depression may be more motivated to seek treatment for AGA.

Comments

This has been included in the cohort study section rather than case-control section due to methods used. The comparator group was healthy controls which may bias the risk estimate away from the null.

3.1.2.5 Pennap et al, 2024 [29]

Title: Suicide and intentional self-harm among older men treated with 5-alpha reductase inhibitor or alpha-blockers for benign prostatic hyperplasia.

Aim: To compare the risk of intentional self-harm (ISH) and suicide in older men using 5-ARI and alpha-blockers (AB) for BPH.

Methods: This retrospective cohort study included new users of 5-ARI or AB for BPH aged 65 years or older, with no use in the previous year. Medicare data from 2007-2016 was linked to the National Death Index (NDI). ISH was identified using ICD diagnosis codes and suicides were identified through cause-of-death information from the NDI. Inverse probability of treatment weighted (IPTW) Cox proportional hazards regression compared time-to-event between treatment groups, with robust variance estimation. Covariates included sociodemographic characteristics, medical comorbidities (including neuropsychiatric conditions, prior ISH, and other conditions that might influence risk of self-harm), medicines for chronic physical and mental health conditions, healthcare utilisations and calendar year of study entry.

Results: There were 181,441 5-ARI users (64,352 dutasteride, 117,089 finasteride), and 850,629 alpha-blocker users (778,366 tamsulosin, 41,129 alfuzosin, 31,134 silodosin) included in the study. There were 154,710 person-years of follow-up for 5-ARI use (mean 0.85 years per patient), and 631,990 person-years for alpha-blocker use (mean 0.74 years per patient).

Before IPTW, the 5-ARI and AB groups differed (SMD >0.1) with respect to age, prescriber specialty, nicotine dependency, opioid use and healthcare utilisation. After IPTW, the groups were similar. In the unweighted sample, 8% of 5-ARI users and 10% of alpha-blocker users had a depressive disorder diagnosed in the 1-year baseline period, and 7% and 9% had an anxiety disorder diagnosed, respectively.

In the unweighted sample, 0.02% (n = 43) of 5-ARI users and 0.03% (248) of alpha-blocker users died by suicide during follow-up, with similar numbers of ISH outcomes (0.03% (48) among 5-ARI users and 0.03% (240) among alpha-blocker users).

The weighted HR for ISH (5-ARI vs alpha-blocker) was 0.88 (95% CI 0.62-1.25), and the weighted HR for suicide was 0.82 (95% CI 0.54-1.24) (figure 8). Cumulative incidence is shown in figure 7. The suicide outcome failed to meet the proportional hazards assumption test; however, a piecewise Cox model (1-60 days, 61 + days) found no statistically significant interaction by time segment.

Subgroup and sensitivity analyses were generally consistent with the results of the main analysis though HRs for dutasteride were lower than those for finasteride (figure 9).

Discussion: This study found no increase in self-harm/suicide among older Medicare beneficiaries using 5-ARIs for BPH, relative to users of alpha-blockers. The authors acknowledged that ascertainment of non-fatal ISH in healthcare claims can be challenging but expected that NDI data on death from suicide was complete. There may be residual confounding. For example, lower baseline prevalence of depression and anxiety among 5-ARI users may reflect preferential prescribing of alpha-blockers for patients with psychiatric comorbidities. The outcomes were infrequent, constraining the statistical precision of risk estimates. Users of finasteride 1 mg (alopecia dose) were excluded.

Figure 7: Weighted cumulative incidence plot for combined outcome of intentional self-harm diagnosis or suicide.



Figure 8: Hazard ratios (5-ARI vs AB) for subgroup analyses, combined outcome of suicide or ISH.



Figure 9: Hazard ratios (5-ARI vs alpha blocker) for sensitivity analyses, combined outcome of suicide or ISH.



3.1.2.6 Laanani et al, 2023 [30]

Title: Suicidal risk associated with finasteride versus dutasteride among men treated for benign prostatic hyperplasia: nationwide cohort study.

Aim: to assess the risk of suicidal behaviours with finasteride relative to dutasteride.

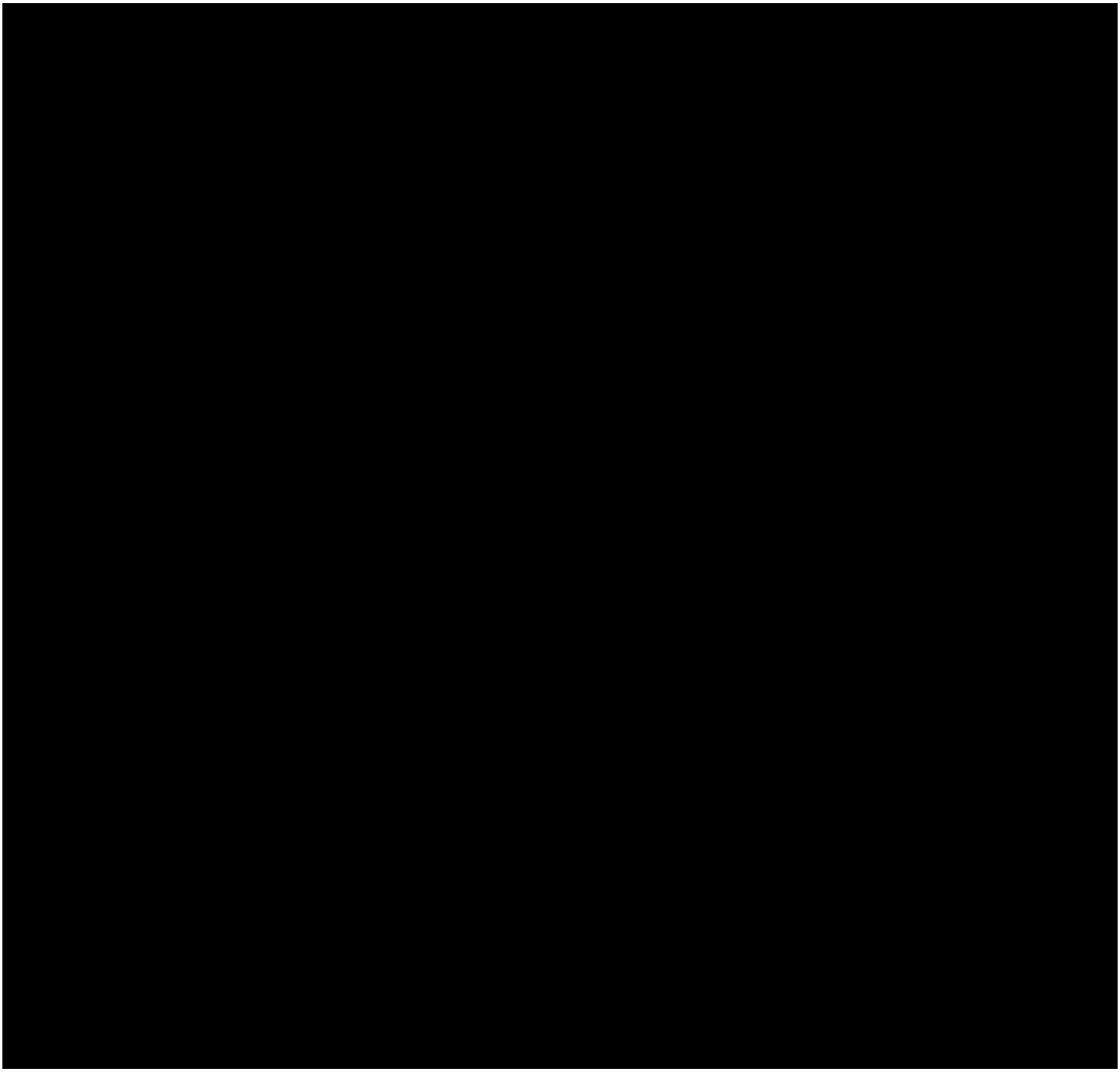
Methods: Using the French National Health Data System (SNDS), men aged 50 years or older initiating finasteride 5 mg or dutasteride 0.5 mg in France between 1 January 2012 and 30 June 2016 were included and followed until outcome (suicide death identified from death certificate or self-harm hospitalisation), treatment discontinuation or switch, death, or end of study on 31 December 2016. The year 2011 was used to check for the absence of finasteride or dutasteride use.

Cox proportional hazards models used IPTW to control for the following potential confounders: age, year of treatment initiation, pre-existing prostatic and psychiatric conditions and treatments, comorbidities used in the Charlson index. Analyses were stratified according to psychiatric history. Analyses were also performed censoring the follow-up at 90 days.

Results: The cohorts included 69,786 finasteride new users (31,344.9 PY), and 217,577 dutasteride new users (110,329.4 PY). Baseline characteristics were similar between groups. There were 18 (0.03%) suicide deaths and 34 (0.05%) first self-harm hospitalisations in the finasteride group and 47 (0.02%) suicide deaths and 87 (0.04%) first self-harm hospitalisations in the dutasteride group.

In the IPTW adjusted analyses (table 10), finasteride treatment was not associated with suicide death or self-harm hospitalisation compared to dutasteride treatment (composite HR = 1.21; 95% CI: 0.87–1.67). In stratified analyses, no associations were seen except in some cases when analysis was restricted to individuals with a history of mood disorders.

Table 10: IPTW adjusted analyses for risk of suicide death and self-harm hospitalisation associated with finasteride compared to dutasteride.



Discussion and conclusions: This study found no increased risk of suicidal behaviour in men treated for BPH with finasteride compared to those treated with dutasteride. There was an association with suicide death or severe self-harm (as defined by the use of a violent suicidal means or admission to an intensive care unit) for patients with a history of mood disorders. However, these results were based on a small number of events and should be interpreted with caution.

Information on AGA was not available in the data source. The authors note that some prescribers may be more inclined to use finasteride than dutasteride in men with AGA which is a potential source of confounding.

Comments

This study did not find an association between suicide death or self-harm hospitalisation in new users of finasteride compared to dutasteride. This comparison would not capture a class effect of 5-ARIs.

To reduce confounding by indication, the study population was restricted to men aged 50 years and older and finasteride users were limited to those exposed to the 5 mg formulation to exclude treatment for hair loss. Information on AGA was not available in the data source and could not be included as a covariate.

3.1.2.7 Yeon et al, 2022 [31]

Title: Depression risk associated with the use of 5α-reductase inhibitors versus α-blockers: A retrospective cohort study in South Korea.

Aim: to compare the risk of depression associated with 5-ARI versus alpha blockers (AB).

Methods: This was a retrospective cohort study using a nationwide claims database from the Health Insurance Review and Assessment Service (HIRA) in South Korea. The study included men who were newly diagnosed with BPH and initiated treatment with a 5-ARI or AB between 1 July 2013 and 30 June 2015.

The following outcomes were classified according to ICD-10 codes and antidepressant prescriptions: (1) depression (ICD-10 code and antidepressant), (2) antidepressants only (prescribed more than two times), (3) depression diagnosis, (4) anxiety disorder (ICD-10 code), (5) extensive depression (diagnosis of depression, insomnia or anxiety disorder at least once).

The study excluded people previously diagnosed with BPH or mental disorders and self-harm and those prescribed relevant medicines in the two years before their index date. Also excluded were people who used both 5-ARI and AB, were hospitalised for longer than two weeks (not treated by psychiatry department), or hospitalised or treated for organic brain disease after the index date. This was to limit the potential confounding of serious concurrent medical illness.

Covariates included demographics, healthcare usage patterns, medical history and concomitant medicines in the year prior to the index date. To account for confounding, 1:1 propensity score (PS) matching was used.

Results: After exclusions, there were 1,461 5-ARI users and 18,650 AB users identified. After 1:1 PS matching, baseline characteristics were balanced between the groups.

The analysis did not find an increased risk of depression diagnosis/treatment following 5-ARI treatment compared to AB treatment, including when stratified by 5-ARI type (figures 10 and 11).

Discussion: Limitations acknowledged by the authors include residual confounding due to unmeasured covariates, coding inaccuracy or incomplete data, inadvertent inclusion of people with AGA, and restrictions on amount of data that could be extracted from the claims database.

Comments

This study included patients newly diagnosed BPH who initiated a 5-ARI or alpha blocker, and there may be confounding by indication as finasteride is not usually a first-line monotherapy for PBH. It is unclear which variables were included in PS-adjusted models.

Figure 10: Hazard ratios for depression and anxiety disorders among BPH patients exposed to 5-ARI versus AB.



Figure 11: Hazard ratios for depression and anxiety disorders among BPH patients exposed to finasteride or dutasteride versus AB.



3.1.2.8 Garcia-Argibay et al, 2022 [32]

Title: Association of 5α-reductase inhibitors with dementia, depression, and suicide.

Aim: To investigate the association of 5-ARI use with all-cause dementia, Alzheimer disease, vascular dementia, depression, and suicide.

Methods: This was a cohort study using Swedish national registers that followed men aged 50 to 90 years from 1 July 2005 to 31 December 2018. The exposures of interest were dispensed finasteride, dutasteride or alpha blockers. Individuals receiving 5-ARI treatment without a diagnosis of BPH were excluded. Outcomes included depression and suicide. Individuals with an event before the start of follow-up were excluded.

Obesity, eating disorders, hypertension, type 2 diabetes, lipid disorders and use of β-blockers were included as time-varying variables in the model. The was also adjustment for year of start of follow-up.

A Cox proportional hazards regression model with attained age as the underlying timescale was fitted to evaluate the association between 5-ARI exposure and each outcome.

Results: The cohort included 2,236,876 men, of whom 79,227 men started 5-ARI treatment (70,645 finasteride and 8,774 dutasteride), 198,766 started AB treatment, and 121,409 received both 5-ARI and ABs.

The cumulative hazard function for each drug and outcome is shown in figure 12.

Men taking finasteride or dutasteride were at increased risk of depression (finasteride: HR, 1.61 [95%CI, 1.48-1.75]; dutasteride: HR, 1.68 [95%CI, 1.43-1.96]) compared to unexposed men. Men taking ABs or 5-ARI and ABs in combination were also at increased risk of depression (HR, 1.95 [95% CI 1.86-2.04] and 2.21 [2.06-2.38]) (table 11).

When stratified by time exposed to each drug, all types of treatment were associated with higher risk of depression compared with no treatment, and the magnitude of association was higher for treatments involving α-blockers than 5-ARIs. HRs appeared to decrease with increasing duration of exposure. For suicide, no significant associations were found with 5-ARIs in any of the exposure periods. Treatment with α-blockers was associated with a higher risk for the exposure periods up to 48 months (table 12).

Discussion: The authors concluded that individuals receiving 5-ARI treatment may be at increased risk for depression. Possible limitations include misclassification of exposure, outcomes and covariates. The authors noted that owing to statistical power constraints, after restricting 5-ARI users to those who started treatment at least 4 months after the start of the prescription database, the estimates become more imprecise.

Figure 12: Cumulative hazards of depression and suicide outcomes for unexposed individuals and those receiving 5α-reductase inhibitor and α-blocker treatment.



Table 11: Results from the time-varying Cox proportional hazards regression model displaying the association between each type of drug with outcomes.



Table 12: Results from the time-varying Cox proportional hazards regression model stratified by type of drug displaying the association of time under exposure with outcomes[a]



3.1.2.9 Kim et al, 2020 [33]

Title: The association of 5α-reductase inhibitor with suicidality.

Aim: To determine the risk of suicide after the use of a 5-ARI.

Methods: The Korean National Health Insurance Service (NHIS) database was used to identify men aged 60 years or older who underwent health examinations between 2005 and 2006. Individuals using a 5-ARI were compared with nonusers based on drug exposure between 2003 and 2006. Individuals using a 5-ARI were additionally divided into tertiles based on exposure. The incidence of completed suicide was documented during 7 years of follow-up, starting 1 January 2007. Individuals taking 5-ARI before 1 January 2003 and those who died before 1 January 2007 were excluded. Suicide was identified using ICD-10 codes for cause of death in the death registry data from the NHIS database.

Covariates included age, smoking status, income, alcohol use, psychiatric disorders, substance use disorder, Charlson comorbidity index, BMI, systolic blood pressure, total cholesterol and fasting serum glucose. Presence of underlying psychiatric disorders were determined from hospital visits between 2003 and 2006. Cox proportional hazards models were applied to assess the hazard ratios (HRs) for suicide with or without 5-ARI use.

Results: There were 51,466 people included in the study, of whom 5,445 were 5-ARI users and 46,021 were non-users. The mean 5-ARI exposure values were 12.4, 64.4, and 399.8 defined daily doses (DDD) among the first, second, and third tertiles of the 5-ARI user group respectively. 5-ARI exposure was associated with older age, higher income, never smoking, no alcohol use and higher Charlson comorbidity index.

A total of 277 (0.54%) individuals committed suicide during the 7-year follow-up period. Compared with 5-ARI nonusers, the risk of suicide was not elevated among 5-ARI users (HR = 1.02, 95% CI = 0.70–1.48) (table 13). When stratified by amount of exposure, and by previous psychiatric disorder, there was no significant difference in risk of suicide.

Discussion: This study did not find an increased risk of suicide in 5-ARI users compared to non-users. Limitations included that 5-ARI exposure after the index date was not accounted for. Suicide incidence was likely underestimated due to limited sensitivity of suicide identification in registries.

Table 13: Association between 5-ARI exposure and suicide.



Comments

The use of a shared index date is likely to introduce bias. Exposed individuals that died by suicide before the index date were excluded from the study. Exposure to 5-ARI during the follow-up period was not taken into account.

Because underlying psychiatric disorders were determined from hospital visits, information on psychiatric history may be incomplete. Psychiatric diagnoses that occurred before the index date but after commencing 5-ARI were classified as underlying/baseline psychiatric disorders in the adjusted analysis and stratified analysis. As acknowledged by the authors, information on suicide may be incomplete.

3.1.2.10 Welk et al, 2017 [34]

Title: Association of suicidality and depression with 5α-reductase inhibitors.

Aim: To determine if there is an increased risk of suicide, self-harm, or depression among older men starting a 5α-reductase inhibitor for prostatic enlargement.

Methods: This was a population-based, retrospective, matched cohort study using linked administrative data for men aged 66 years or older in Ontario, Canada, who initiated a new prescription for a 5-ARI between 2003 and 2013 (with no exposure in the prior 2 years). Participants were matched to men not prescribed 5-ARIs

using a propensity score that included 44 variables including age, socioeconomic status, medical comorbidities, medicine use, healthcare utilisation and medical investigations and procedures.

The primary outcome was suicide. The secondary outcomes were self-harm and incident depression. Self-harm included emergency department visits for a suicide attempt or parasuicide behaviour and psychiatric hospital admission for recent self-harm or thoughts of self-harm. To identify incident cases of depression, patients with an existing history of depression in the 5 years prior to the index date were excluded for the analysis of this outcome. Patients were observed for these outcomes during continuous medicine usage (defined as prescription filled within 1.5x number of days supplied) plus one year.

Results: After matching, there were 93,197 pairs included in the analysis, with a median age of 75 years. The absolute risk of suicide was very low in both exposed and unexposed men (0.04%), and there was no significantly increased HR among men exposed to 5-ARI (HR 0.88; 95% CI 0.53-1.45) (table 14).

The secondary outcomes of self-harm and incident depression violated the statistical test and graphical assessment of proportionality and were stratified by 3 time periods to maintain proportionality. Among men exposed to 5-ARIs, there was a significantly increased hazard of self-harm (HR 1.88; 95% CI 1.34-2.64) and depression (HR 1.94; 95% CI 1.73-2.16) during the first 18 months of use (table 14). The hazard for self-harm was not significantly elevated after the initial 18 months, whereas the hazard for depression was lower in magnitude but still significantly elevated for the remainder of the follow-up period (HR 1.22; 95% CI 1.08-1.37).

Prior depression and recent antidepressant use did not have a significant statistical interaction with the primary outcome of suicide and the prior self-harm subgroup was too small to fit to a statistical model. The findings were similar when stratified by initial type of 5-ARI (table 15).

Discussion: This study did not find a significant increase in the risk of suicide among older men using 5-ARIs for BPH, and prior depression or antidepressant use did not modify this result. The study did find a significantly increased risk of self-harm during the first 18 months of treatment and new diagnoses of depression throughout follow-up among men exposed to 5-ARI.

The authors note that limitations of the study include the possibility of misclassification of key study variables, and residual confounding. Non-differential misclassification of outcomes is likely and would generally bias results toward the null. The true incidence of suicide was likely underestimated. Surveillance and the propensity for a patient to be diagnosed with self-harm and depression may have been different after the initiation of the 5-ARI. LUTS may be related to depression, and the authors tried to adjust for this by matching on a history of depression and balancing recent use of alpha-blockers or overactive bladder medication, and prior BPH diagnosis or transurethral prostate surgery.

Table 14: Risk of suicide, self-harm, and depression among men exposed to 5-ARI compared with matched unexposed men[a]



[redacted]

Table 15: Primary and secondary outcomes stratified by initial 5-ARI type

[redacted]

3.1.2.11 Hagberg et al, 2017 [35]

Title: Risk of incident antidepressant-treated depression associated with use of 5α-reductase inhibitors compared with use of α-blockers in men with benign prostatic hyperplasia: a population-based study using the clinical practice research datalink.

Aim: To estimate the risk of incident antidepressant-treated depression in men with BPH who were prescribed 5-ARIs compared with those prescribed alpha-blockers.

Methods: This was a retrospective cohort study with a nested case-control analysis, using the United Kingdom's Clinical Practice Research Datalink. The study population included all men ≥18 years between 1 January 1992 and 31 December 2013 who had a diagnosis of BPH and received a prescription for either a 5-ARI (finasteride or dutasteride) and/or an AB (alfuzosin, doxazosin, indoramin, prazosin, tamsulosin, and terazosin). The cohort entry date was the date of first 5-ARI or AB prescription. Men with a diagnosis of depression or suicidal behaviours (ideation or attempts), or men who received prescriptions for antidepressant medicines prior to cohort entry were excluded.

Cases of 'treated depression' were defined as men with a Read code for a depression diagnosis and who received a prescription for an antidepressant within 90 days of the depression diagnosis. For the nested case control analysis, cases were matched to up to four controls on year of birth (±2 yrs), general practice attended, index date and start year in the CPRD (±2 yrs).

Covariates of interest included age, calendar year, BMI, smoking status, presence of other psychiatric illness, hypertension, cardiovascular disease, coronary heart disease, kidney failure, cancer, substance abuse, sexual dysfunction, suicidal behaviours and concomitant medicines.

Results: There were 77,732 men with BPH included in the study. There were 2,842 cases of treated depression. The mean length of follow-up was >4 years.

The IR of treated depression was similar for each exposure: 7.6 (95% CI 6.9–8.3) per 1000 PY for users of 5-ARIs only, 6.1 (95% CI 5.3–7.0) for users of 5-ARI + AB, and 7.8 (95% CI 7.5–8.1) for users of ABs only (table 16). The IRRs of treated depression, adjusted for age group, calendar year, and timing of study drug exposure for users of 5-ARIs only and users of 5-ARIs + ABs were 0.94 (95% CI 0.85–1.04) and 1.04 (95% CI 0.89–1.21), respectively.

Table 16: Cohort analysis: incident rates and incident rate ratios for antidepressant-treated depression by exposure



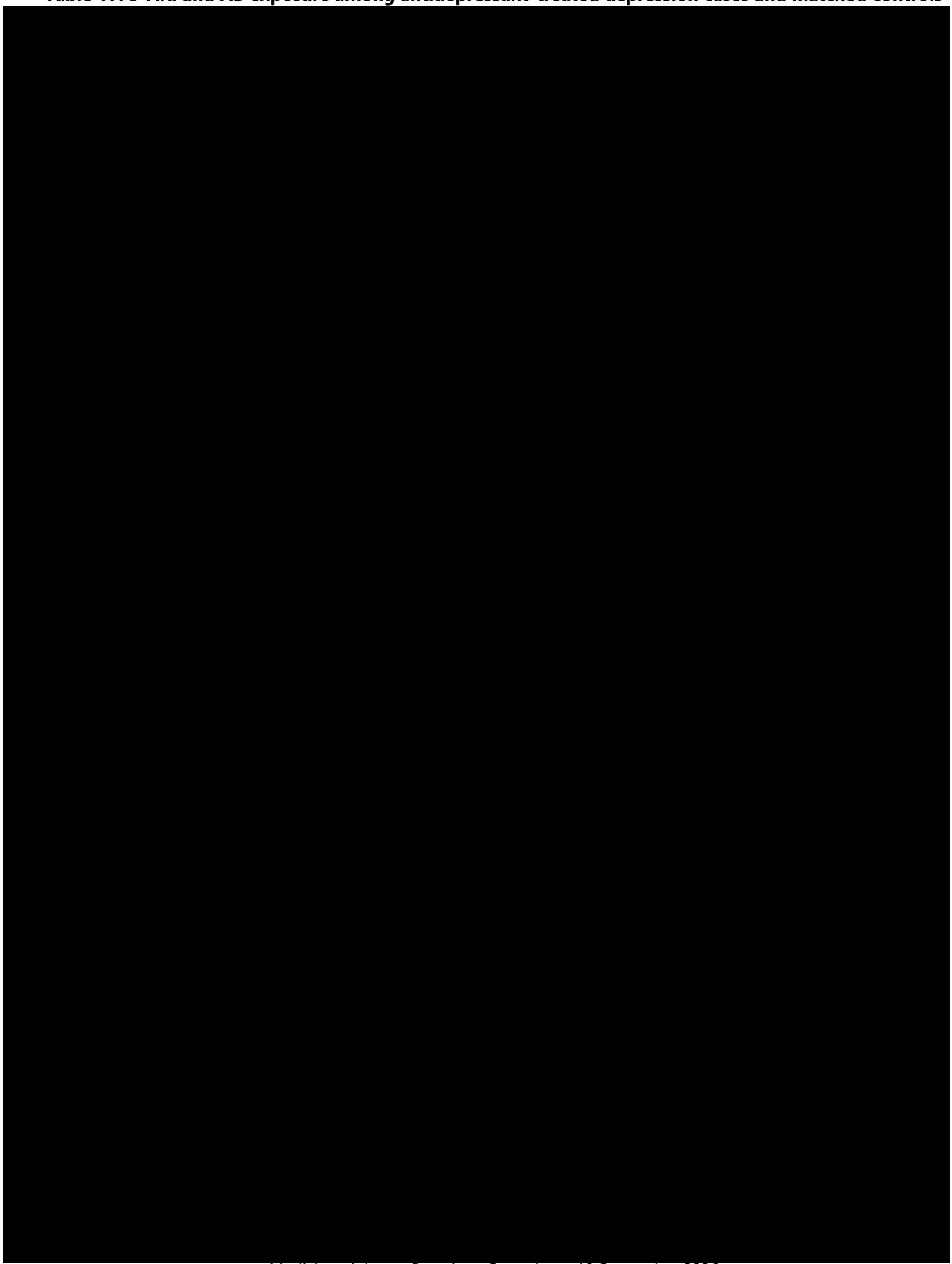
In the nested case-control analysis, treated depression cases were more likely than controls to be smokers or ex-smokers, or to have comorbidities, alcohol or drug abuse, suicidal behaviour, or other psychiatric illnesses recorded before the index date. Cases also had longer duration of BPH.

Compared with users of ABs only, there was no effect of 5-ARIs only on the risk of treated depression (OR 0.88, 95% CI 0.78–1.01) or of 5-ARI + AB (OR 0.90, 95% CI 0.73–1.10) (table 17). The results remained null regardless of number of prescriptions received, timing of exposure to a study drug or duration of BPH. Similar results were seen in the age stratified analysis and sensitivity analysis restricted to cases and controls without a history of psychiatric illness.

Discussion: The study found that in a population of men with treated BPH, use of 5-ARIs did not increase the risk of incident antidepressant-treated depression when compared with use of ABs only. The risk of antidepressant-treated depression increased with longer duration of BPH, independent of exposure to 5-ARIs or ABs. This suggests BPH itself is associated with a higher risk of depression.

The authors noted that no information was available on socioeconomic status or race/ethnicity. Clinical guidelines for BPH and depression changes during the study period. Depression not treated with antidepressants or treated >90 days after diagnosis was not captured.

Table 17: 5-ARI and AB exposure among antidepressant-treated depression cases and matched controls



3.1.3 Other studies

Other relevant studies are summarised below. The literature search retrieved many disproportionality analyses based on pharmacovigilance databases. These were not included as they are based on spontaneous reporting data and lack denominator information.

3.1.3.1 Heerfordt et al, 2025 [36]

Title: Finasteride use and suicide attempts through self-poisoning: a case-control study.

Aim: To investigate the potential link between finasteride use and suicide attempts by self-poisoning.

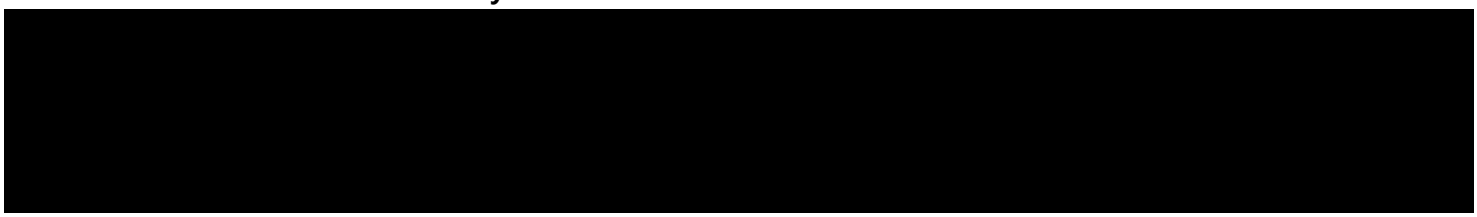
Methods: Case-control study. Cases of poisoning with suicidal intent in men were identified from the Danish Poison Information Center (DPIC) between 2008 and 2013. For each case, 10 controls matched by age, sex, date, and type of residence municipality were selected from the general Danish population using the Danish Civil Registration System. The index date for cases was date of suicide attempt, and for controls it was date of inclusion in the study. Data on filled finasteride prescriptions in the year prior was obtained from the Danish National Prescription Registry. Data on bipolar disorder and schizophrenia diagnosis at public hospitals were collected from the Danish Psychiatric Central Research Register.

Conditional logistic regression was used to analyse the association between finasteride use and the risk of suicide attempts, both unadjusted and adjusted for bipolar disorder, schizophrenia and occupational status.

Results: There were 3,366 cases of suicide attempts identified which were matched with 33,660 controls, with a mean age of 40.1 years (SD 16.4). Cases were much more likely than controls to be on public benefits and have a diagnosis of bipolar or schizophrenia.

Among the control group, 0.35% (*n* = 117) had used finasteride, compared with 0.36% (*n* = 12) in the case group. The analysis showed no significant association between finasteride treatment and the risk of suicide attempts, with an odds ratio of 1.03 (95% confidence interval 0.56–1.88, *P* = 0.93). After adjustment for schizophrenia, bipolar disorder and occupational status, the aOR was 0.88 (95% CI 0.45–1.71, P = 0.71) (table 18).

Table 18: Use of finasteride in the year before the index date



Discussion: The study found no association between finasteride use and the risk of suicide attempts through self-poisoning, but the broad confidence intervals suggest uncertainty.

3.1.3.2 Dyson et al, 2020 [37]

Title: Lack of association between 5α-reductase inhibitors and depression.

Aim: To evaluate 5-ARI exposure and depression risk using sequence symmetry analysis.

Methods: National Veterans Health Administration administrative data were used to identify 53,848 male patients initiating a 5-ARI from 1 October 2013 to 30 September 2014, with a 1-year look back period. Incident depression events were assessed separately using incident antidepressant prescription and depression diagnosis. Symmetry ratios were calculated as the ratio of patients with an incident depression event in the year following 5-ARI initiation to the year preceding initiation. An outcome counterfactual analysis was used to examine possible surveillance bias. An exposure counterfactual analysis was conducted among veterans initiating alpha-blocker. Depression events in close proximity to 5-ARI initiation (±14 days) were censored to minimise risk of detection bias.

Results: The final primary analysis cohort consisted of 53,848 male veteran patients initiating a 5-ARI. The majority of patients were Caucasian (75.0%) and received finasteride (99.7%). Most patients (61.3%) received ≥270 days' supply of medicine.

The primary outcome of antidepressant initiation was observed in 2,563 patients following 5-ARI initiation and 3,051 patients preceding 5-ARI initiation (figure 13). The resulting SR of 0.84 (95% CI 0.80-0.89) indicated that 5-ARI initiation was not associated with an increased risk new antidepressant initiation. For the secondary outcome measure 3,502 patients had an incident depression diagnosis following 5-ARI initiation vs 4,241 patients prior to 5-ARI initiation. The resulting SR was 0.83 (95% CI 0. 79-0.86). Similar results were seen in the analyses stratified by antidepressant class and age group and for the composite outcome (table 19) and the exposure counterfactual analysis for alpha-blockers (I1-ARA) (table 20).

The outcome counterfactual analysis for prescription of other medicine classes did not highlight surveillance bias as the distribution of SRs was centred around 1.

Discussion: 5-ARI initiation was not associated with increased depression risk. Depression onset was more likely to precede 5-ARI initiation than follow it. SSA potentially suffers from detection bias, which was mitigated using a censoring window, as depression events in close proximity are unlikely to be caused by 5-ARI exposure but rather emerge as incidental findings from the process of clinical care. SSA is also susceptible to surveillance bias, but this was not evident from the outcome counterfactual analysis. There is potential for misclassification of patients receiving prescriptions outside of the VA service.

Figure 13: Sequence symmetry analysis of 5-ARI initiation and incident antidepressant prescribing



Table 19: Sequence symmetry analysis of 5-ARI initiation and risk of incident depression events

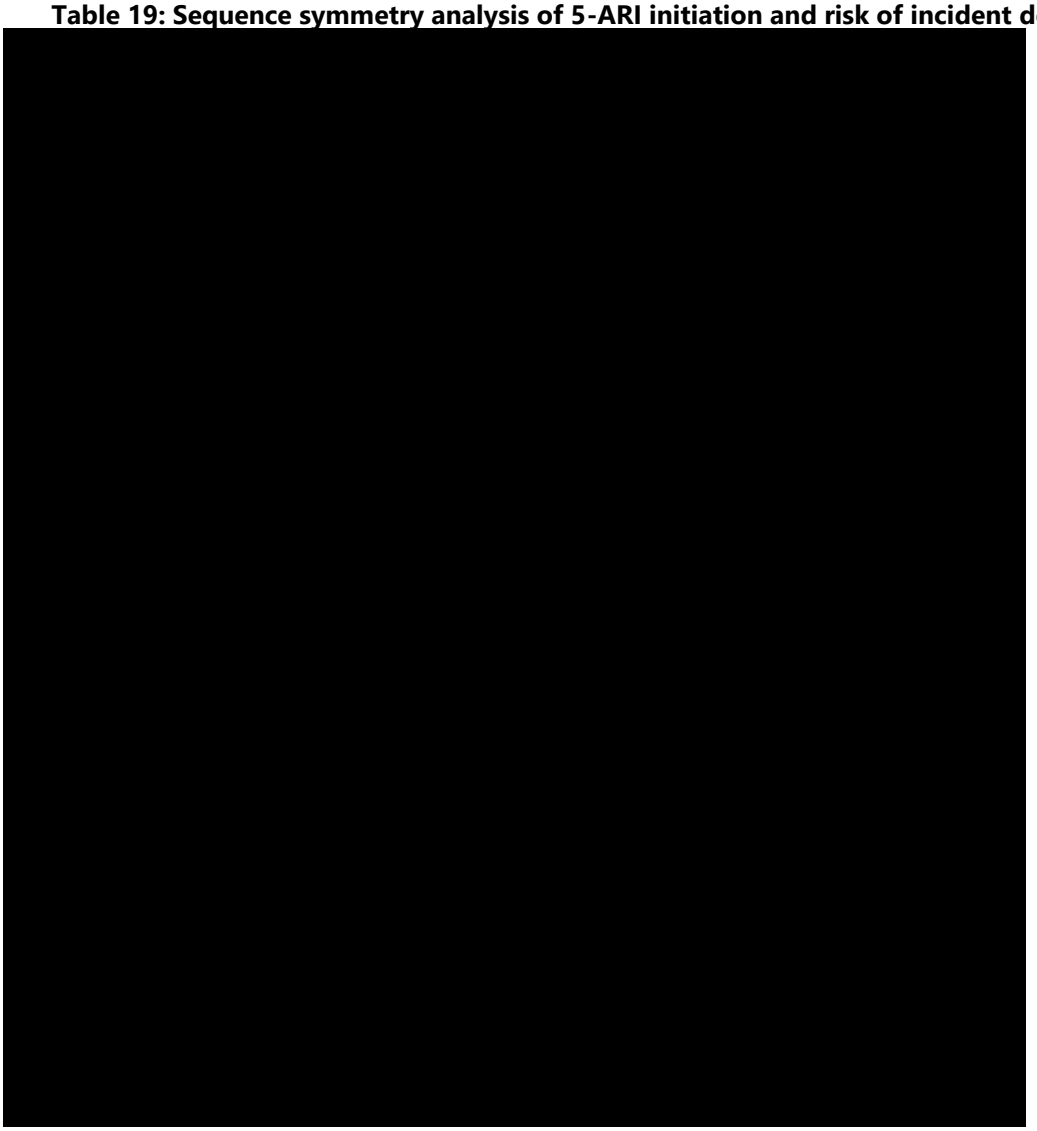


Table 20: Sequence symmetry analysis of a 1-ARA initiation and incident antidepressant prescribing



3.1.3.3 Unger et al, 2016 [38]

Title: Long-term consequences of finasteride vs placebo in the prostate cancer prevention trial.

Aim: To examine the long-term beneficial and adverse consequences of finasteride.

Methods: Long-term clinical trial follow-up. In the Prostate Cancer Prevention Trial (PCPT), 18,882 men age ≥55 years, with normal digital rectal examination and prostate-specific antigen (PSA) of ≤3.0 ng/mL, were randomly assigned between 1993-1997 to receive finasteride daily or placebo daily for 7 years. The trial was closed early because of the positive finding of a reduction in prostate cancer in the finasteride arm.

This study used linked data from the PCPT and Medicare claims. Events were determined from start of Medicare claims coverage using HCPCS and ICD9 diagnosis codes. Medicare claims were available starting on 1 January 1999, whereas registrations to the PCPT occurred from 1994 to 1997. Therefore, the study was unable to rule out events that existed prior to registration to the PCPT according to claims data.

Patients were examined by randomized study arm (finasteride vs placebo) for long-term consequences of the intervention. An event was identified as any hospital claim, or two or more physician or outpatient claims at least 30 days apart, including cardiac, endocrine, and sexual dysfunction, depression, diabetes, and BPH–related events.

Results: A total of 13,935 of 18,880 participants (73.8%) in the PCPT were linked to Medicare claims, with median Medicare follow-up assessment time of 16 years from trial registration.

The 10-year cumulative incidence of depression was 18.9% on the finasteride arm and 17.6% on the placebo arm. In the adjusted multivariable Cox regression, the risk of depression was higher in the finasteride arm (HR 1.10, 95% CI 1.01 to 1.19, P=0.04) (table 21).

The 10-year cumulative incidence of BPH-related events (primarily LUTS) was 67.8% on the placebo arm and 65.3% on the finasteride arm; with adjustment, this difference represented a 6% reduction with finasteride (HR 0.94, 95% CI 0.89 to 1.00, P=0.03).

In the sensitivity analysis, the HR for depression among participants who received at least two years of finasteride or placebo intervention was 1.12 (95% CI 1.01 to 1.23, P=0.02). The HR for BPH-related events was 0.91 (95% CI 0.86 to 0.97, P=0.006). Among participants who did not develop prostate cancer on study, the HR for depression was 1.08 (95% CI 0.98-1.18. P=0.12).

A time-dependent covariate pertaining to being on study intervention was added in a separate sensitivity analysis to account for whether depression and BPH-related events were observed primarily on or off intervention and whether these patterns differed by arm. Both depression and BPH-related events were more likely to be observed while on intervention (71% more likely, P < .0001, and 17% more likely, P=0.03, respectively). However, using an interaction test, there was no evidence that the pattern of more depression and fewer BPH related events for patients assigned to the finasteride arm differed depending on whether patients were on or off intervention.

Discussion: Finasteride patients from the PCPT had a lower long-term incidence of BPH-related events and a higher incidence of depression. A prior examination of patient-reported outcomes from the PCPT found no evidence of an adverse impact of finasteride on mental health. The authors were unable to examine the impact of baseline conditions (eg, pre-existing depression) and whether patients received finasteride after completion of their study intervention. Because the analysis did not adjust for multiple comparisons, marginal results may be more likely to be because of chance.

Table 21: Cumulative incidence of long-term consequences of finasteride vs placebo for the prevention of prostate cancer



3.1.3.4 Cross-sectional studies, surveys and other descriptive studies

Table 22: Summary of cross-sectional studies, surveys and other descriptive studies

Publication	Methods	Findings
Jędrzejczyk 2026 [39]	Review of 129 men with AGA or BPH who reported persistent symptoms after stopping finasteride.	Mean age at clinical evaluation was 47.1 ± 1.46 years. Median treatment duration was 24 months (IQR: 12.5–36), and the median time from discontinuation to evaluation was 8 months (IQR: 1–17). Erectile function score remained stable over time (mean IIEF: 15.2 ± 0.46 at baseline vs. 15.4 ± 0.47 at 6 months). Depressive symptoms decreased from 12.4 ± 0.41 to 9.1 ± 0.41, and anxiety scores from 3.29 ± 0.23 to 2.54 ± 0.20 over the same period, without normalisation in most patients. Greater cumulative finasteride exposure and older age were associated with more severe sexual and psychological symptoms after treatment discontinuation.

Publication	Methods	Findings
Dixon 2026 [40]	A survey was distributed via online forums and social media.	310 individuals completed the survey, with an average age of 34.5 years and 85.8% being male. Most obtained finasteride through a dermatologist (37%) and 32% obtained it online. 40% were aware that finasteride could lead to sexual dysfunction while taking it. Side effects were the primary reason for discontinuation (89.7%). SD during treatment included reduced libido (73.9%), erectile dysfunction (ED; 71.0%) or vaginal dryness, and orgasmic dysfunction (56.8%), with 36% reporting symptoms starting within the first week of taking medication. After stopping, persistent SD increased to 85.9% (libido), 83.3% (ED/vaginal dryness), and 66.7% (orgasmic dysfunction). Additional symptoms included cognitive impairment (76.6%), mood changes (76.6%), and skin changes (53.1%), among others. Prior to use, 56.6% reported no depression/anxiety versus only 9.4% post-use and severe depression/anxiety increased from 1% to 31.1%. 65.4% experienced suicidal thoughts at least 1-2 times per week.
Khera 2020 [41]	Evaluation of ED and depression in 25 former 5-ARI users with AGA.	Median age in 5-ARI group was 38; median 5-ARI duration 18 months. IIEF score was higher in 5-ARI group compared to controls. 17 subjects (68%) had a penile vascular abnormality on PDDU. The 5-ARI group had a higher median PHQ-9 score s [10 (6.5–16) *vs.* 1 (0–2) ($P<0.001$)]. Two people committed suicide during or after the study.
Walf 2018 [42]	Review of forum posts on finasteride side effects.	244 cases were identified. Age was not available in most posts. Where available, 88% were aged 20-39 years. 32% reported antiandrogenic effects (incl. sexual dysfunction), 19% reported estrogenic effects (incl. gynecomastia), 30% reported central effects (incl. neuropsychiatric), and 5% reported non-specific effects (incl. cardiovascular). 14% reported effects in all categories.
Ganzer 2018 [43]	Online survey in AGA with depression and anxiety scales.	97 men completed the survey. All had taken finasteride 1 mg for AGA for at least 3 months and had sought treatment for physical and psychological symptoms after stopping. Overall, the men reported that they were generally in good health (90%). 55% reported a pre-existing psychiatric diagnosis and 29% reported a psychiatric diagnosis in a first degree relative. 49% reported a clinically significant BDI score, with most in the moderate to severe range. TIPI scores reflected that participants were extroverted, agreeable, emotionally stable and open to experiences. In the free text responses, themes of despair, fear and hopelessness were identified.
Basaria 2016 [44]	Assessment of characteristics of 25 men with AGA reporting persistent symptoms after discontinuation of finasteride.	Symptomatic finasteride users were similar in body composition, strength, and nucleotide sequences of androgen receptor genes to asymptomatic finasteride users and nonusers. Symptomatic finasteride users had impaired sexual function, higher depression scores, a more negative affectivity balance, and more cognitive complaints than comparison groups but had normal objectively assessed cognitive function. There was no evidence of androgen deficiency, decreased peripheral androgen action, or persistent peripheral inhibition of SRD5A. Symptomatic finasteride users revealed depressed mood and fMRI findings consistent with those observed in depression.

Publication	Methods	Findings
Caruso 2015 [45]	Measured neuroactive steroids in 'post-finasteride' patients with AGA and healthy controls.	At the examination, finasteride patients reported muscular stiffness, cramps, tremors and chronic fatigue in the absence of clinical evidence of any muscular disorder or strength reduction. Although severity of the anxious/depressive symptoms was quite variable in their frequency, overall all the subjects had a fairly complex and constant neuropsychiatric pattern. Assessment of neuroactive steroid levels in CSF showed a decrease of PROG and its metabolites, dihydroprogesterone (DHP) and tetrahydroprogesterone (THP), associated with an increase of its precursor pregnenolone (PREG). A significant decrease of dihydrotestosterone (DHT) associated with an increase of T as well as of 3-beta-diol was detected. Changes in neuroactive steroid levels also occurred in plasma. An increase of PREG, T, 3-alpha-diol, 3-beta-diol and 17-beta-estradiol was associated with decreased levels of DHP and THP.
Pietrzyk 2015 [46]	Survey of 4,035 patients with BPH.	Most respondents were aged 61–80 years, the medium city dweller, with secondary education, married, and professionally active or pensioner. Comorbidities were reported in 83.4 %; the most common were hypertension (53.6%), coronary artery disease (18.4%), dyslipidaemia (17.6%), and type 2 diabetes (16.7%). More than half were treated for BPH for >3 years. TURP was performed in 1.3%. 47.5% were on ARA monotherapy and 40.2% were on dual ARA-ARI treatment. ED based on IIEF-5 was diagnosed in 71.9% and 30.2% were treated for ED. Depressive symptoms were found in 22.4%, which were moderate/severe in 1.6%. Occurrence and severity were associated with older age, lower education level, widowed or single marital status, sedentary lifestyle, comorbidities, longer duration of treatment, polytherapy, LUTS severity and ED.
Irwig 2012 [47]	Interviewed 61 former finasteride users with AGA and persistent sexual side effects (>3 months).	The mean age of the finasteride participants was 31 years and 87% were white. 83% had persistent sexual dysfunction for ≥1 year after stopping finasteride. Rates of depressive symptoms (BDI-II ≥14) were 75% in former finasteride users compared to 10% of healthy controls with AGA. Moderate to severe symptoms were present in 64% vs 0%. Suicidal thoughts were present in 44% vs 3%.

3.1.4 Systematic reviews and meta-analyses

3.1.4.1 Nguyen et al, 2026 [48]

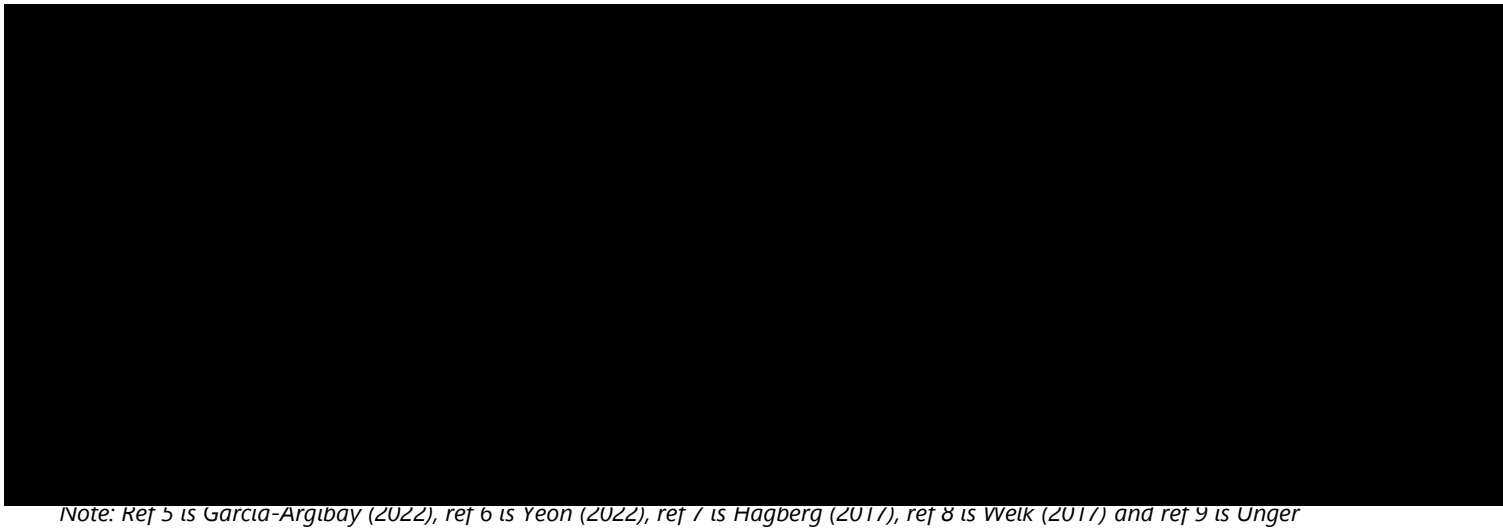
Title: Depression risk of 5-alpha reductase inhibitors: impact of active-comparator versus non-drug user control groups on risk measurement.

Aim: to quantify the depression risk associated with 5-ARIs and evaluate how control group selection contributes to the heterogeneity of reported results.

Methods: This systematic review and meta-analysis included case-control and cohort studies in men exposed to 5-alpha reductase inhibitors (5-ARIs) compared to men not exposed to 5-ARIs. The outcome examined was risk of depression and/or suicide reported as OR/RR/IRR/HR and 95% CI.

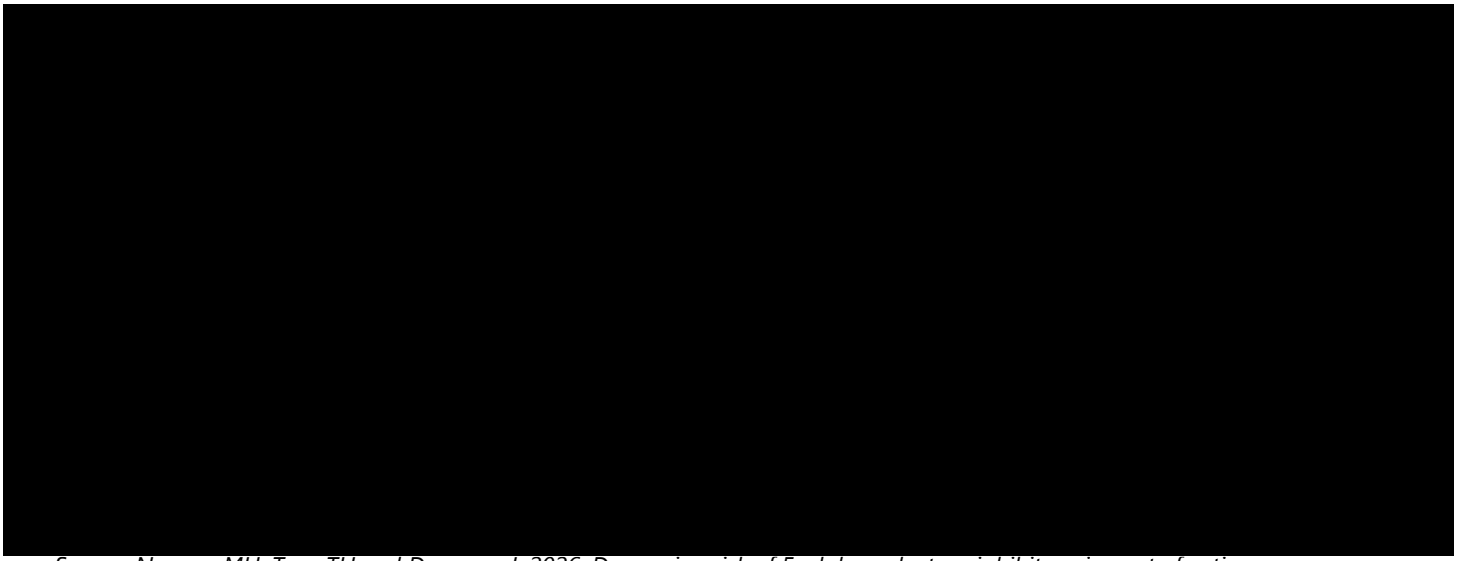
Results: Five studies involving a total of 2,517,859 patients were included. All were cohort studies, with the exception of Unger et al, which was derived from a preventive randomized controlled trial (RCT). Three of the cohort studies employed a 1–2-year look- back period to minimise prevalent user bias. Most studies included men aged at least 50 years or older, except for Hagberg et al which included younger participants (figure 14).

Figure 14: Characteristics of included studies.



Note: Ref 5 is García-Argibay (2022), ref 6 is Yeon (2022), ref 7 is Hagberg (2017), ref 8 is Welk (2017) and ref 9 is Unger (2016).
Source: Nguyen MH, Tran TH and Donovan J. 2026. Depression risk of 5-alpha reductase inhibitors: impact of active-comparator versus non-drug user control groups on risk measurement. Postgrad Med 138(2): 154-161. DOI: 10.1080/00325481.2026.2633464 (accessed 14 July 2026).

For the outcome of depression, the pooled analysis estimated an HR of 1.31 (95% CI: 0.98 – 1.76) for 5-ARI users compared to non-users. However, there was substantial heterogeneity across studies (I^2 = 95.5%, τ^2 = 0.0984, p < 0.0001), indicating considerable variability in treatment effects (figure 15).



Source: Nguyen MH, Tran TH and Donovan J. 2026. Depression risk of 5-alpha reductase inhibitors: impact of active-comparator versus non-drug user control groups on risk measurement. Postgrad Med 138(2): 154-161. DOI: 10.1080/00325481.2026.2633464 (accessed 14 July 2026).

There were no significant differences in depression risk between finasteride (HR 1.38, 95% CI 0.51–3.72) and dutasteride users (HR 1.45, 95% CI 0.51–4.10) (figure 16).

The leave-one-out sensitivity analysis provided pooled HRs that were consistent with the original pooled HR.

Figure 16: Pooled effect estimates for dutasteride and finasteride.



Source: Nguyen MH, Tran TH and Donovan J. 2026. Depression risk of 5-alpha reductase inhibitors: impact of active-comparator versus non-drug user control groups on risk measurement. Postgrad Med 138(2): 154-161. DOI: 10.1080/00325481.2026.2633464 (accessed 14 July 2026).

When stratified by control group, observational studies comparing 5-ARIs to non-drug users showed a significantly increased risk of depression with moderate heterogeneity (HR = 1.77, 95% CI: 1.50 - 2.07). In contrast, studies using active comparator (alpha-blocker/tamsulosin) showed a decreased risk (HR = 0.89, 95% CI 0.86 – 0.92) with minimal heterogeneity across studies (figure 17).

Figure 17: Pooled effect estimates stratified by control groups (excluding Unger et al).



Source: Nguyen MH, Tran TH and Donovan J. 2026. Depression risk of 5-alpha reductase inhibitors: impact of active-comparator versus non-drug user control groups on risk measurement. Postgrad Med 138(2): 154-161. DOI: 10.1080/00325481.2026.2633464 (accessed 14 July 2026).

Discussion: This analysis found that 5-ARI users had a significantly increased risk of depression when compared to non-drug users and a decreased risk when compared to alpha-blocker users. Given that most participants in this meta-analysis were aged 50 or older and diagnosed with BPH, alpha-blocker users represent a more appropriate control group. The authors concluded that the risk of depression associated with 5-ARI use for BPH in men aged 50 and older is likely minimal.

3.1.4.2 Uleri et al, 2024 [49]

Title: Association of 5α-Reductase Inhibitors with Depression and Suicide: A Mini Systematic Review and Meta-analysis.

Aim: To investigate the association between 5-ARI use and the risk of depression or suicide.

Methods: Studies were eligible for inclusion in the review and meta-analysis if they included male patients exposed to 5-ARIs in comparison to a control group without 5-ARI exposure to assess the risk of depression or suicide in a prospective or retrospective setting.

Results: Five studies were included in the review (4 cohort studies and 1 randomised controlled trial) (table 23). Risk of bias was judged as low for 4 studies and moderate for 1 study.

Table 23: Characteristics of the studies included in the review and meta-analysis

[redacted]

Four studies reported data on the association between 5-ARI use and the risk of depression. Pooled analysis revealed no statistically significant association (aHR 1.30, 95% CI 0.85–2.00; p = 0.23) and significant heterogeneity (figure 18).

Three studies reported data on the association between 5-ARI use and the risk of suicide. Pooled analysis revealed no statistically significant association (aHR 1.30, 95% CI 0.65–2.61; p = 0.45) and significant heterogeneity (figure 18).

Sensitivity analysis for finasteride and dutasteride individually yielded similar findings. When the analysis was restricted to patients without a prior diagnosis of depression, the results were similar (aHR for suicide 1.00, 95% CI 0.68– 1.46; p = 0.98).

Discussion: The meta-analysis revealed no evidence of an association between 5-ARI exposure and the risk of depression or suicide. The results for depression were primarily influenced by the study by Yeon et al, which used control patients with LUTS/BPO and found no statistically significant association between 5-ARI use and depression. This study reinforces the notion that LUTS/BPO acts as a confounding variable. Two studies investigated the dose-effect relationship between 5-ARI use and depression.

The majority of the studies involved patients who were treated with 5-ARIs for BPO rather than for AGA. Although both conditions are linked to depression, they may impact the risk of depression and suicide differently.

Limitations include lack of high-quality data, significant heterogeneity suggesting potential confounding and risk of misclassification bias.

Figure 18: Forest plots of the risk of (A) depression and (B) suicide stratified by the use of 5a-reductase inhibitors.



3.1.4.3 Saengmearnuparp et al, 2021 [50]

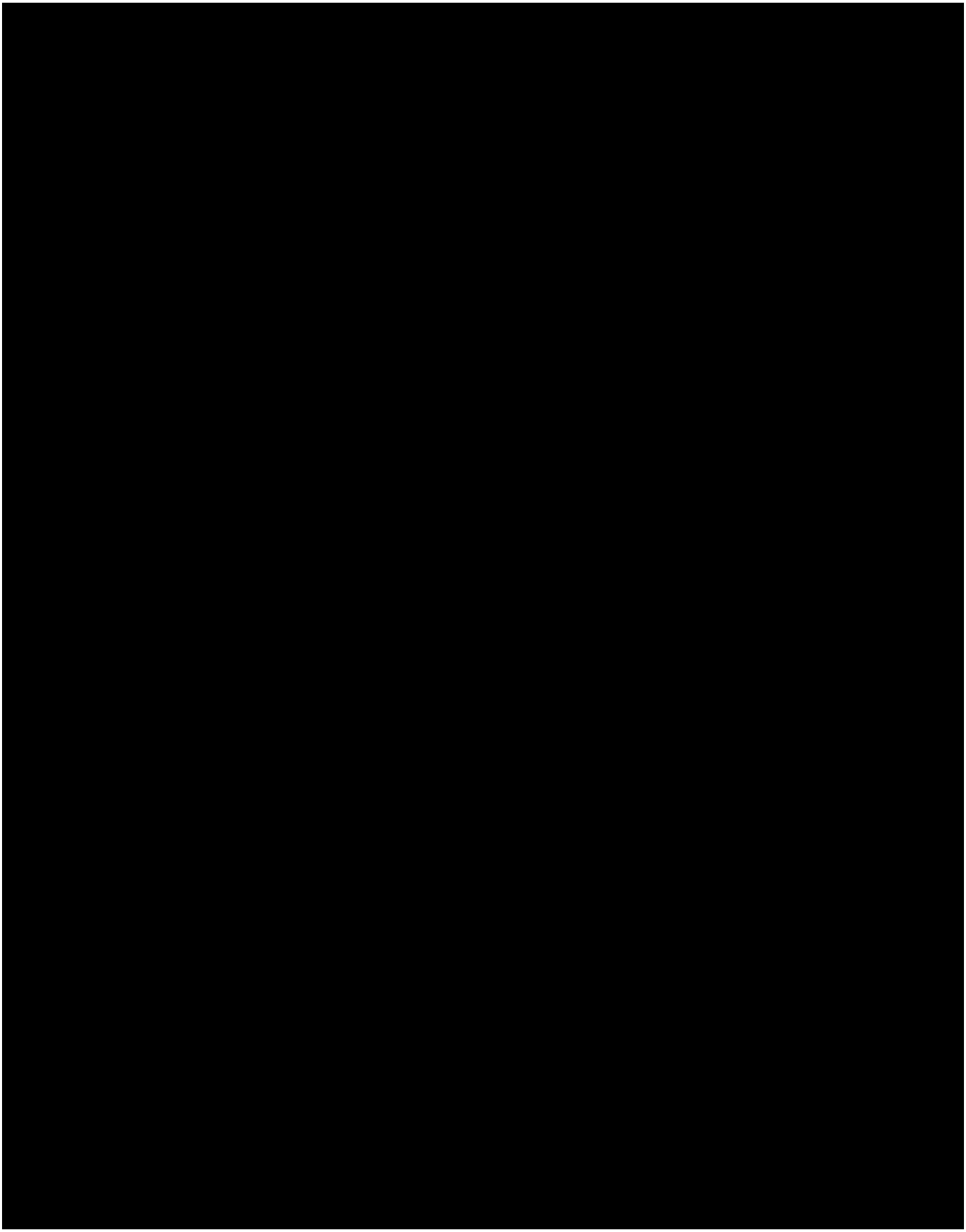
Title: The connection of 5-alpha reductase inhibitors to the development of depression.

Aim: to summarise and discuss the association between 5-ARIs and depression as well as possible mechanisms.

Methods: This systematic review included in vivo and clinical studies from 2002 to 2021 retrieved using the PubMed search terms "depression", "depressive symptoms", "MDD", "anxiety", or "suicidal idea", and "5-alpha reductase inhibitors", "finasteride", "dutasteride", "5-ARIs".

Results: Clinical studies describing an association between 5-ARIs and depression are summarised in table 24. There were inconsistent findings among clinical studies which varied in study design and quality. Little evidence was identified on the risk of suicidal ideation.

Table 24: Clinical studies on an association between oral 5-alpha reductase inhibitor and depression.



3.1.4.4 Pompili et al, 2021 [51]

Title: Risk of depression associated with finasteride treatment.

Methods: This systematic review included finasteride studies reporting on mood changes and suicidal ideation based on international diagnostic criteria and standardised rating scales. Studies were excluded if they did not use standardised methods to assess mood disorder or if they described neurosteroid metabolism. Pooled rates of depression and suicidal ideation/behaviour were presented.

Results: 14 studies were included (table 25).

Table 25: Characteristics of 14 studies of psychiatric and other adverse effects of finasteride treatment



The risk of clinical depression averaged 3.32% (CI, 3.21%–3.43%), based on the pooled ratio of 3,393/102,520. Seven reports provided data on depression risk without exposure to finasteride, which averaged 2.54% (2.44%–2.64%), based on the pooled ratio of 2,465/96,934 subjects. The average risk of depression was 1.31 times higher among subjects exposed to finasteride (X^2 = 106, P < 0.0001).

A random-effects meta-analysis of risk of depression based on the 7 reports with both finasteride-exposed subjects and unexposed controls found a significantly greater risk of depression associated with finasteride treatment (pooled odds ratio, 2.14 [1.40–3.27]; z score, 3.53, P < 0.0001), with a high level of interstudy heterogeneity (I^2 = 91.6%) (figure 19).

There were 5 studies reporting suicidal risk with finasteride of which 2 studies included people not receiving finasteride. Their respective rates averaged 24.4% (0.00%–59.0%) versus 1.92% (0.00%–21.3%) with a 12.7-fold difference that was not statistically significant (t score, 1.08; P = 0.165). The contingency-pooled proportions of subjects with suicidal ideation or behaviour with versus without finasteride averaged 21.2% (21.0%–21.5%) versus 14.0% (13.8%–14.2%) (x2 = 1659, P < 0.0001).

Figure 19: Random-effects meta-analysis of risk for depression with versus without exposure to finasteride.



Discussion: The authors concluded that finasteride is associated with depression, sexual dysfunction and suicidal ideation but further studies are needed. Limitations included variability in study methods and reported prevalences of outcomes, and lack of control groups in many studies. The results may be confounded by prior history of depression and sexual dysfunction.

Comments
The meta-analysis included studies with no control group and cross-sectional studies of people reporting persistent adverse effects of finasteride that are subject to selection bias.

3.1.4.5 Baldessarini et al, 2021 [52]

Title: Further studies of effects of finasteride on mood and suicidal risk.

This meta-analysis in a letter to the editor updates the results of Pompili et al, 2021 (above) to include 2 additional studies, a disproportionality analysis by Nguyen et al, 2021 and a cohort study by Dyson et al, 2020. The updated, pooled OR for depression was 1.65 (1.14–2.39, z = 2.67, P = 0.008) (table 26).

Table 26: Studies of risks of depression with finasteride and other 5-α-reductase inhibitors



[redacted]

Comments

One of the studies added to the meta-analysis was a disproportionality study from a pharmacovigilance database. Disproportionality analyses are subject to reporting bias and confounding, and lack denominator information on total patient exposure.

3.1.4.6 Kim et al, 2020 [53]

Title: Risk of depression after 5 alpha reductase inhibitor medication: meta-analysis.

Aim: to investigate the risk of depression after taking 5-ARI and to quantify the risk using meta-analysis.

Methods: Study inclusion criteria were as follows: 1) interventions included administration of 5-ARI, 2) participants were diagnosed with depression disorder, suicide and/or suicidal thinking. Comparators included non-exposure of 5-ARI, placebo, or adrenergic alpha-antagonist. Outcomes were reported as HRs or ORs.

In order to identify the moderator effect, continuous variables (age and number of patients) and binary variables (study type: cohort/non-cohort; control type: adrenergic alpha-antagonist/non-expose of 5-ARI) were analysed.

Results: Five studies were included in the review (table 27). Irwig (2012) was excluded from the quantitative analysis.

Table 27: Characteristics of included studies.

[redacted]

The pooled overall HR for the 5-ARI was 1.23 (95% CI: 0.99–1.54) in the random effects model (figure 20). The pooled overall OR for 5-ARI medicine versus the control group was 1.19 (95% CI: 0.95–1.49) in the random effects model (figure 21).

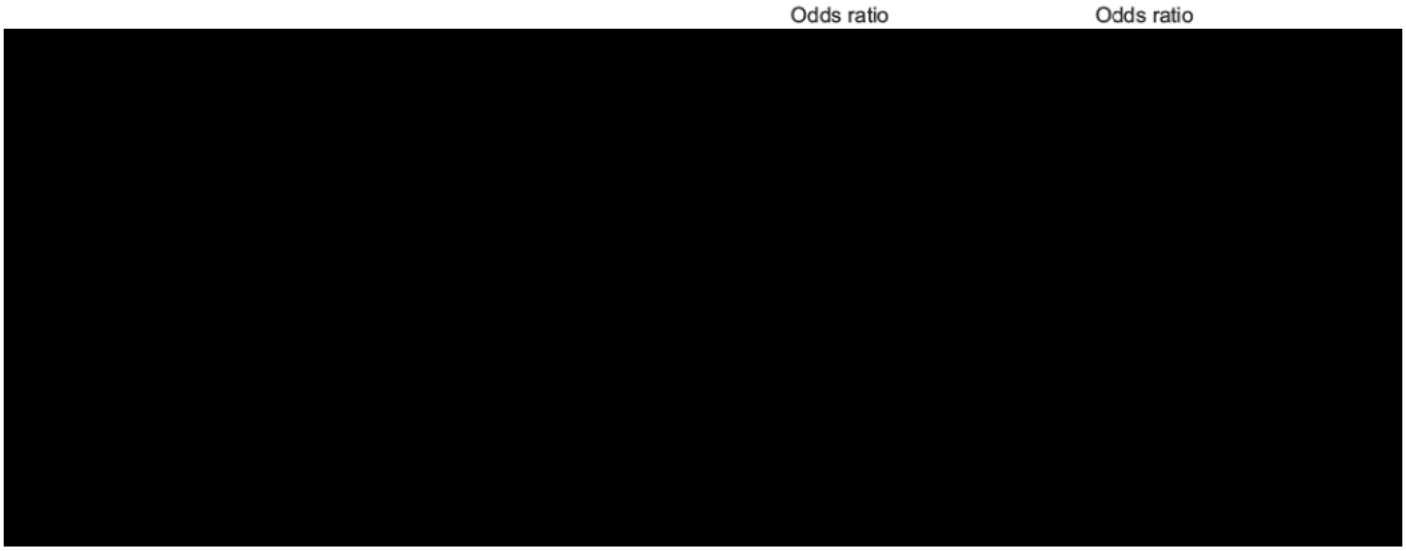
Meta-regression analysis did not find a significant effect of number of patients, age, study type, and control type on HR/OR.

Figure 20: Hazard ratio of depression among men exposed to 5-ARI.



SE: standard error, CI: confidence interval, df: degree of freedom.
Source: Kim JH, Shim SR, Khandwala Y, et al. 2020. Risk of Depression after 5 Alpha Reductase Inhibitor Medication: Meta-Analysis. World J Mens Health 38(4): 535-544. DOI: 10.5534/wjmh.190046 (accessed 14 July 2026).

Figure 21: Odds ratio of depression among men exposed to 5-ARI



SE: standard error, CI: confidence interval, df: degree of freedom.
Source: Kim JH, Shim SR, Khandwala Y, et al. 2020. Risk of Depression after 5 Alpha Reductase Inhibitor Medication: Meta-Analysis. World J Mens Health 38(4): 535-544. DOI: 10.5534/wjmh.190046 (accessed 14 July 2026).

Discussion:

The risk of depression following 5-ARI use was not significantly increased.

3.1.4.7 Deng et al, 2020 [54]

Title: Association between 5-alpha reductase inhibitor use and the risk of depression: a meta-analysis.

Aim: To explore the association between 5α-reductase inhibitors (5-ARIs) use and risk of depression based on published literature through a meta-analysis.

Methods: Controlled clinical studies exploring an association between 5-ARIs use and the risk of depression up to Jun 2019 were included. For the included case-control studies, odds ratios (ORs) of 5-ARIs use on the risk of depression were extracted and converted to risk ratios (RRs).

Results: Six studies with a total of 265,672 participants were included, of which 4 were cohort studies and 2 were cross-sectional studies (table 28).

Table 28: Characteristics of included studies.



Source: Deng T, Duan X, He Z, et al. 2020. Association Between 5-Alpha Reductase Inhibitor Use and The Risk of Depression: A Meta-Analysis. Urol J 18(2): 144-150. DOI: 10.22037/uj.v16i7.5866 (accessed 14 July 2020).

Unadjusted RRs of 5-ARIs use on the risk of depression could be extracted or calculated from 5 clinical studies. The pooled risk ratio was 1.89 (95% CI: 1.28-2.78) with significant heterogeneity (figure 22). Multivariable adjusted RRs were available in two studies (figure 23). Mean differences of BDI-II score were available for two scores (figure 24).

In subgroup analyses, dutasteride showed a significantly increased risk of depression (RR 1.53, 95% CI 1.37-1.70) but finasteride did not (RR 1.34, 95% CI 0.96-1.87). This was based on 3 studies with finasteride and only one article with dutasteride.

Conclusion: 5-ARIs could potentially increase the risk of depression. Further studies are needed.

Figure 22: Forest plot of unadjusted RR and 95% CIs of 5-ARI use for risk of depression.



Figure 23: Forest plot of multivariable adjusted RR and 95% CIs of 5-ARI use for risk of depression.



3.1.5 Literature case reports

Literature case reports are summarised in table 29.

Table 29: Summary of literature case reports

Author, year	Summary
Lonergan 2024 [55]	A 45-year-old male presented to endocrinology after taking finasteride for hair loss for 20 years. He reported new onset reduced libido, penile shrinkage, fatigue, new food intolerances and agitated depression which was the predominant symptom in this case. He described the emergence of gynaecomastia, which was evident on examination, as well as muscle atrophy. Biochemistry was unremarkable including testosterone 24.6 nmol/L (8.6-29.0), oestradiol 100 pmol/L (50 – 159), LH 7.1 IU/L (1.7-8.6), FSH 16.8 IU/L (1.5-12.4), urinary free cortisol 177 nmol/24h (12-486) and urinary steroid profile. He was offered IM testosterone followed by hCG which he declined based on advice from an online post-finasteride patient forum.

Wesley 2022 [56]	A 44-year-old male presented for voluntary psychiatric admission following several months of difficulty sleeping and suicidal ideation. He was a former finasteride user, which he stopped taking in 2014 after 11 years of use. Since then, he endorsed sexual dysfunction, anxiety, weakness, and "central nervous system problems," which he attributed to finasteride. He had a history of obsessive-compulsive disorder and major depressive disorder, with no pertinent medical history. Initial mental status exam revealed a calm, cooperative male appearing stated age without any obvious motor or gait abnormalities. Speech was fast, but not pressured, and mood was anxious. Affect was constricted, but associations were appropriate. Thought process was linear but ruminative. Thought content was notable for suicidal ideation and guilt. He denied hallucinations. Cognition was intact.
Li 2022 [57]	Three cases are reported of persistent sexual and mental health problems after using finasteride. The men began finasteride use between 20 and 28 years of age, and were of Han Chinese ethnicity. The duration of intermittent finasteride use ranged from 1.5 to 2 years. The specific time of the onset of adverse effects (AEs) ranged from 2 to 12 months. After finasteride cessation, Case 1 and Case 2 experienced symptom improvement for a period of time and then suffered from exacerbated symptoms. All of the patients suffered from erectile dysfunction, anxiety, depression, feelings of isolation, and insomnia. The most frustrating symptoms included insomnia, anxiety, depression, ED, and low libido. Case 2 had gynecomastia and case 1 and 2 had muscular tremor. Physical examination of Case 1 and Case 2 found testicles that were significantly reduced in size. Case 1 had a low level of total testosterone (TT) (2.78 ng/mL) after the discontinuation of finasteride for 7 months. Apart from Case 3, who had chronic rhinitis, the other patients had no long-term drug administration history and no baseline medical or psychiatric evaluation prior to finasteride use. All patients were using several medicines and alternative/herbal treatments for their symptoms.
Irwig 2020 [58]	This case series reports the clinical histories and symptoms of six men in USA, the UK and France who took finasteride for AGA and died by suicide. They began finasteride between the ages of 19 and 36 years and died between the ages of 25 and 42 years. The duration of finasteride use ranged from 9 days to 6 years. The time from finasteride cessation to death ranged from 6 months to 10 years. The onset of adverse effects began while the cases were taking finasteride but the exact onset in relation to medicine exposure was not specified in the medical records. Cases 1 and 2 experienced a worsening of symptoms after finasteride discontinuation. All of the cases reported erectile dysfunction and insomnia. The most debilitating symptoms were insomnia, fatigue, depression, anxiety and isolation. The symptoms are detailed in table 32, below.

	Table 30: Case descriptions  Apart from one person who had hyperlipidaemia, there was no record of concomitant medicines or medical conditions, including baseline psychiatric diagnoses. Case 1 was found to have had two low levels of total testosterone (7.6 and 4.7 nmol/L) 5 months after discontinuation of finasteride. After the development of persistent sexual events, depression and other symptoms, 4 out of the 6 cases took other medicines at various times. Case 1 took citalopram and zopiclone. Case 2 took dihydrotestosterone, exemestane, letrozole, lorazepam, zolpidem and thyroid and adrenal supplements. Case 4 took clomiphene, clonazepam, diazepam, eszopiclone and propranolol. Case 6 took bupropion, clomiphene, intracavernosal prostaglandins, sildenafil and zopiclone.
Garcia Moreno 2020 [59]	A 29-year-old male with depressive symptoms and worsening of symptoms was referred to an outpatient mental health service. He had no previous personal psychiatric history, no drug abuse or psychopharmacological treatment but had been taking finasteride for the previous 3 years. He reported sad mood, anxiety, irritability, inhibition, apathy, poor initiative to carry out activities, early awakening, low hedonic capacity, thoughts of death and failures in cognitive sphere. He did not report a previous trigger. He was started on vortioxetine 10 mg and was encouraged to discontinue finasteride. He recovered over the next three months.

3.2 CARM data

There have been 17 reports to the NZ pharmacovigilance database describing mood changes with finasteride. The PTs reported were anxiety, emotional lability, irritability, apathy, anger, crying, emotional distress, anhedonia, mental disorder NOS and flat affect. Two reports included suicidal ideation. Fourteen of the reports had information (dose or indication) suggesting finasteride was used for AGA. Eleven of the reports

co-reported symptoms of sexual dysfunction such as decreased libido and erectile dysfunction. The reports are summarised in table 31.

Table 31: Summary of NZ reports of mood changes with finasteride

Report ID	Report date	Age, sex	Medicines	Reaction	Details
071412	04/2006	52 M	Finasteride [redacted]	Atrial fibrillation Palpitation Anxiety	[redacted]
087618	12/2009	34 M	Finasteride [redacted]	Emotional lability Headache Insomnia Irritability	
098514	11/2011	27 M	Finasteride [redacted]	Depression Libido decreased Memory loss Thinking abnormal Tinnitus	

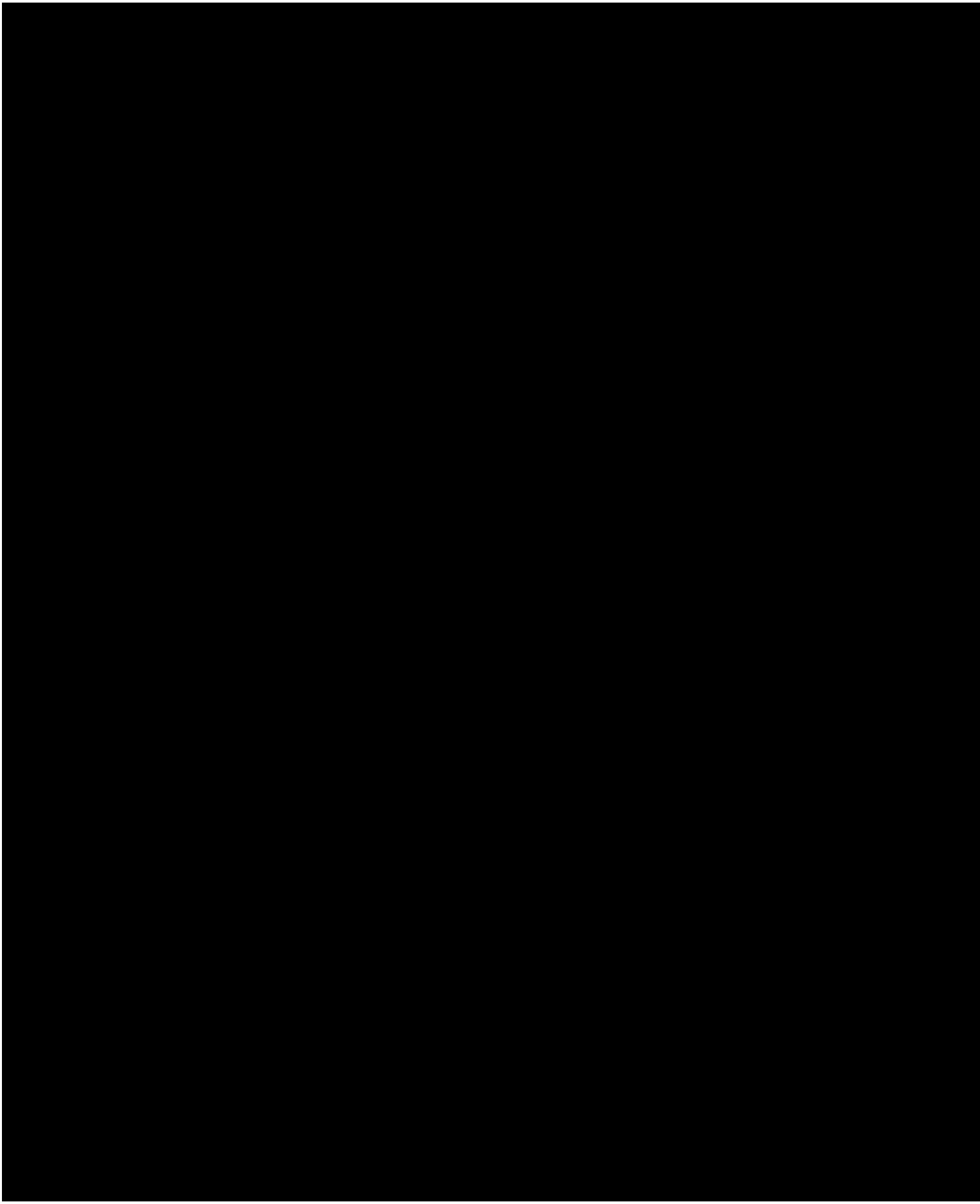
Report ID	Report date	Age, sex	Medicines	Reaction	Details
118931	12/2015	88 M	Finasteride [redacted]	Apathy Depression	[redacted]
121041	06/2016	30 M	Finasteride [redacted]	Anger Insomnia Withdrawal syndrome	
121804	08/2016	48 M	Finasteride [redacted]	Concentration impaired Depression Insomnia Libido decreased Memory impairment	
134433	09/2019	37 M	Finasteride [redacted]	Anxiety Apathy Crying Depression Erectile dysfunction	
139102	11/2020	76 M	Finasteride [redacted]	Anxiety Depression Memory impairment	
139208	12/2020	27 M	Finasteride [redacted]	Anxiety Depression Erectile dysfunction Libido decreased	

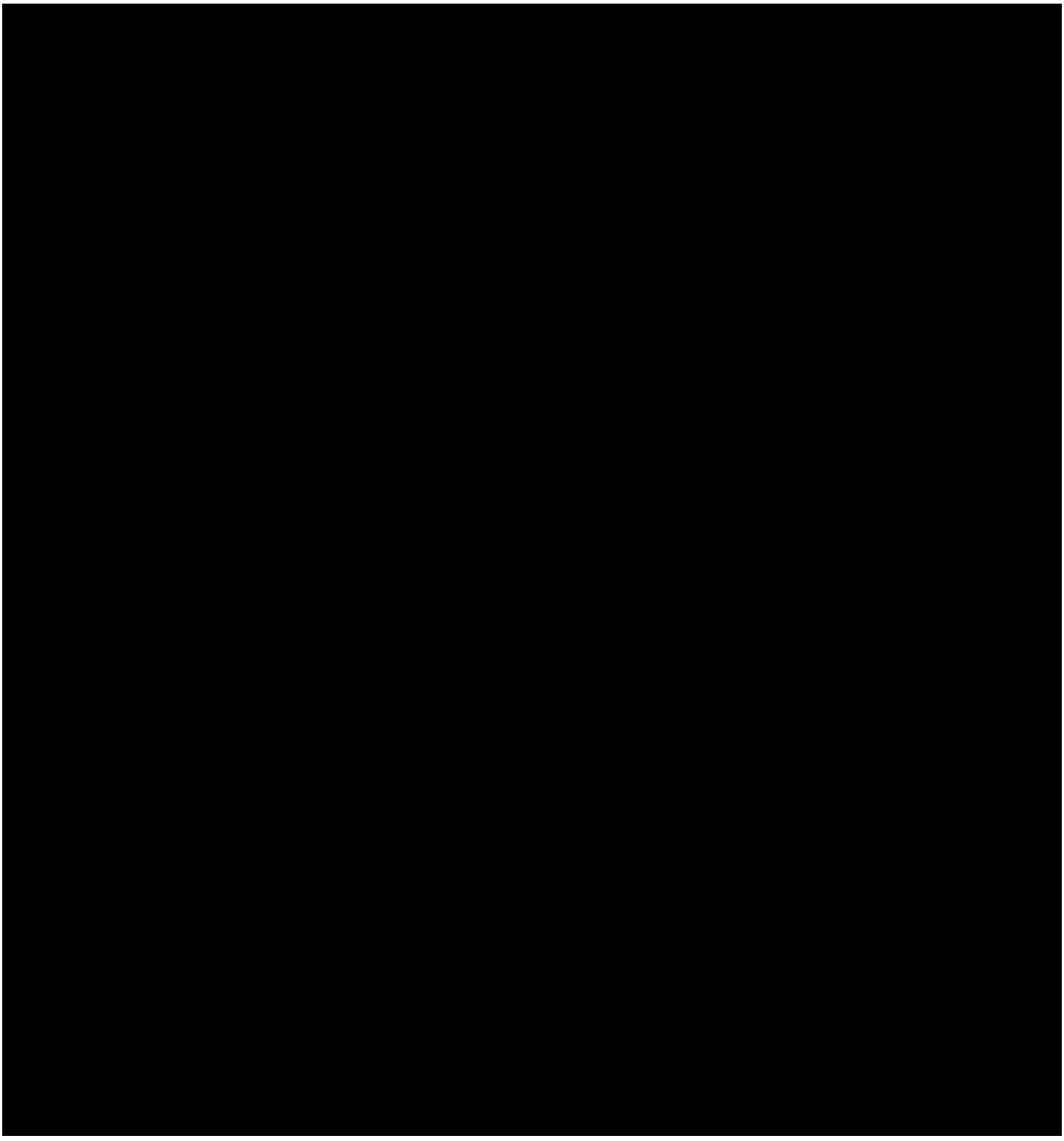
Report ID	Report date	Age, sex	Medicines	Reaction	Details
142523	10/2021	22-24 M	Finasteride [redacted]	Anxiety Depression Erectile dysfunction	[redacted]
147320	04/2023	30 M	Finasteride [redacted]	Loss of libido Erectile dysfunction Penis disorder Low mood Anxiety Dark circles under eyes Memory loss Mental concentration difficult Suicidal ideation	
NZ-Medsafe-154632	12/02/2024	Unk.	Finasteride [redacted]	Anxiety Depressed mood Emotional distress Erectile dysfunction Penile pain Penile size reduced	
NZ-Medsafe-158483	06/09/2024	29 M	Finasteride [redacted]	Anhedonia Memory impaired Slowed thinking Mental function decreased Muscle atrophy Sebum deficiency Body temperature decreased Dry skin Skin thinning of	

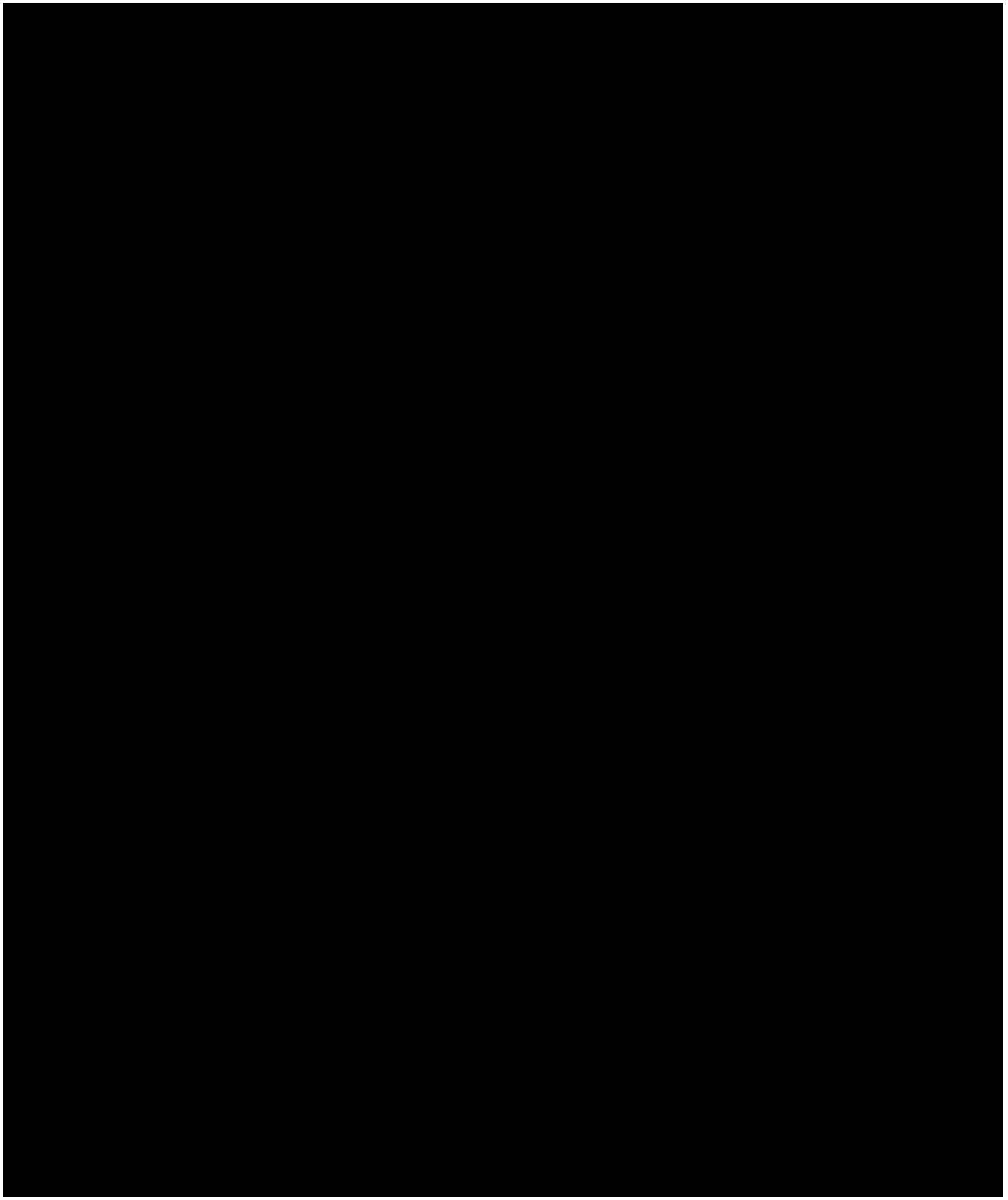
Report ID	Report date	Age, sex	Medicines	Reaction	Details
				Breast enlargement male Loss of libido Erectile dysfunction Organic erectile dysfunction Inhibited male orgasm Semen volume decreased Weak ejaculation Penile size reduced Genital hypoaesthesia Testicular atrophy Tinnitus Suicidal ideation	[redacted]
NZ-Medsafe-160005	07/12/2024	19 M	Finasteride	Sexual dysfunction Sexual arousal decreased Erectile dysfunction Mental disorder NOS	
NZ-Medsafe-161290	06/03/2025	55 M	Finasteride [redacted]	Memory loss Insomnia Anxiety	

Report ID	Report date	Age, sex	Medicines	Reaction	Details
NZ-Medsafe-162604	23/05/2025	55 M	Finasteride [redacted]	Amnesia Anxiety Asthenia Incorrect dose administered Post 5-alpha-reductase inhibitor syndrome Vision blurred	[redacted]
NZ-Medsafe-165336	9/12/2025	34 M	Finasteride [redacted] Concomitant: minoxidil, tretinoin, sertraline, quetiapine, lorazepam	Loss of libido Erection decreased Penile numbness Scrotal disorder Flat affect	

[redacted]







4 DISCUSSION AND CONCLUSIONS

Literature

Eleven cohort studies reviewed the risk of depression/mood disorders with 5-ARI exposure; seven also reported on risk of suicide. Many of the studies focussed on patients with BPH and there was limited evidence in the AGA population. Five studies only included patients with BPH, two included both BPH and AGA patients and one only included patients with AGA. Three studies were not limited by indication but were restricted to older participants and were therefore focussed on BPH patients.

In five studies, the comparison group was unexposed to 5-ARIs and also did not necessarily have AGA/BPH (healthy controls) and in two studies the unexposed group had the condition of interest (BPH/AGA). Three studies used people exposed to alpha-blockers as the comparison group and one study compared finasteride and dutasteride.

Three of the cohort studies found significantly increased risks. A study by Lyakhovitsky et al (2024) found an increased risk of depression in patients with AGA who used finasteride. However, the comparison group was unexposed healthy controls and there may have been confounding by indication.

A study by Garcia-Argibay et al (2022) found an increased risk of depression in men aged 50 to 90 years associated with finasteride, dutasteride, alpha blockers and combination treatment compared to unexposed men in the overall cohort. The risk of suicide was not significantly elevated in men who used 5-ARIs but was significantly elevated with alpha blockers and combination treatment.

A study by Welk et al (2017) in men aged ≥66 years found increased risks of depression and self-harm, but not suicide, with 5-ARI exposure compared to matched unexposed controls.

A limitation affecting interpretation of these studies is that the choice of comparator group may result in confounding by indication. There may also be misclassification of both exposure and outcomes in database studies. For example, the number of suicides may be underestimated.

A 10-year follow-up study of men in the Prostate Cancer Prevention Trial (PCPT) found a modestly increased risk of depression in the finasteride arm compared to the placebo arm.

Meta-analyses have not highlighted an increased risk of depression with 5-ARIs but study heterogeneity makes comparison difficult.

Reported cases

There have been 17 case reports in New Zealand of mood changes following finasteride use, reporting the PTs anxiety, emotional lability, irritability, apathy, anger, crying, emotional distress, anhedonia, mental disorder NOS and flat affect. Two reports included suicidal ideation. [redacted] Eleven of the reports co-reported symptoms of sexual dysfunction such as decreased libido and erectile dysfunction.

EMA and MHRA reviews have also noted that most case reports were in people using finasteride for AGA and many co-report symptoms of sexual dysfunction.

[redacted]

A theoretical biological plausibility for a relationship between finasteride and depression has been suggested based on the involvement of 5-alpha-reductase in the production of neuroactive steroids, but a mechanism has not been established.

There are several factors that may contribute to reports of depression and suicidal ideation. The burden of BPH symptoms including sleep disturbance can impact quality of life and cause psychological distress. Hair loss is associated with psychological distress. Finasteride can cause sexual adverse effects such as loss of libido and erectile dysfunction, which have a relationship with depression. It is unclear whether the higher number of reports in people taking finasteride for AGA compared to BPH are related to the underlying condition, differences in patient populations, stimulated reporting or other factors.

International regulatory action

Several international regulators have reviewed this signal and have added warnings on mood changes, including suicidal ideation and depression, to their local finasteride product information. In general, these warnings state that patients should be screened for these conditions before initiation and monitored throughout treatment. For finasteride 1 mg, indicated for AGA, there is generally advice to discontinue finasteride if mood changes occur. Some product information also states that sexual dysfunction may contribute to mood changes and treatment discontinuation should be considered if these symptoms occur.

Currently, the New Zealand data sheets list depression and suicidality for finasteride 1 mg and depression only for finasteride 5 mg. There are no warnings or advice on monitoring in section 4.4.

5 ADVICE SOUGHT

The Committee is asked to advise:

- Whether suicidal ideation should be listed in the finasteride 5 mg data sheet.
- Whether warnings on mood changes, including suicidal ideation, should be included in the data sheets for finasteride 1 mg and/or finasteride 5 mg and if so, what advice should be included (eg, screening, monitoring and management).

6 ANNEXES

None.

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