

Summary of Disproportionality Analysis Using VigiBase

August 29, 2023

<p>Scope of investigation</p>	<p>Target drugs</p> <ul style="list-style-type: none"> • “Finasteride” and “Dutasteride” <p>Target events (suicide-related events)</p> <ul style="list-style-type: none"> • The following PT included in MedDRA v26.0 SMQ “Suicide/self-injury” “Assisted suicide,” “Columbia suicide severity rating scale abnormal,” “Completed suicide,” “Depression suicidal,” “Intentional overdose,” “Intentional self-injury,” “Poisoning deliberate,” “Self-injurious ideation,” “Suicidal behaviour,” “Suicidal ideation,” “Suicide attempt,” “Suicide threat,” “Suspected suicide,” and “Suspected suicide attempt”
<p>Outline of method</p>	<p>A disproportionality analysis for reports of suicide-related events associated with finasteride and dutasteride was performed using the dataset of the World Health Organization (WHO) Individual Case Safety Reports (ICSRs) Global Database (VigiBase)* as of May 28, 2023. Information components (ICs) were calculated as signal indices, and when the lower limit of the 95% confidence interval of IC (IC₀₂₅) was greater than 0, it was considered that a signal was detected. (Eur J Clin Pharmacol. 1998; 54: 315–21, Pharmacoepidemiol Drug Saf. 2009; 18: 427-36) VigiLyze, a signal detection/management tool of the WHO, was used for the data analysis.</p>
<p>Outline of results</p>	<p>Results</p> <p>The results of the disproportionality analysis for reports of suicide-related events associated with finasteride and dutasteride using VigiBase are shown in Table 1.</p> <p>For finasteride, the number of adverse drug reaction reports of “Depression suicidal,” “Self-injurious ideation,” “Completed suicide,” “Suicidal behaviour,” “Self-injurious ideation,” and “Suicide attempt” was significantly higher than would be expected for the entire database. On the other hand, no such tendencies have been observed for dutasteride which has a 5-alpha reductase inhibitory effect as with finasteride.</p>

Table 1: IC values for suicide-related events in the VigiBase dataset

Ingredients (Observed number of adverse drug reaction reports of the relevant ingredients)	PT	Number of reports of each PT (observed)	Number of reports of each PT (expected)	IC	IC ₀₂₅
Finasteride (19 913 events)	Depression suicidal	31	1	4.0	3.5
	Suicidal ideation	470	43	3.4	3.3
	Completed suicide	148	40	1.9	1.6
	Suicidal behaviour	11	2	2.3	1.3
	Self-injurious ideation	7	2	1.7	0.5
	Suicide attempt	51	29	0.8	0.4
	Suspected suicide	4	1	1.3	-0.4
	Intentional overdose	18	26	-0.5	-1.3
	Intentional self-injury	7	7	0.0	-1.3
	Suicide threat	1	0	1.3	-2.5
	Dutasteride (9 211 events)	Suicidal ideation	13	20	-0.6
Self-injurious ideation		2	1	0.9	-1.7
Completed suicide		6	18	-1.5	-2.9
Depression Suicidal		1	1	0.3	-3.4
Intentional overdose		3	12	-1.9	-3.9
Suicide attempt		3	13	-2.0	-4.0

Discussion based on the results

The results of the disproportionality analysis using VigiBase suggested a relationship between finasteride and suicide-related events[†].

While finasteride is approved in Japan only for the indication of “delaying the progression of male pattern baldness in men,” it is approved for male pattern baldness and prostatic hyperplasia in the US, the UK, and Canada. On the other hand, dutasteride is approved in Japan for the indication of “male pattern baldness in men” and “prostatic hyperplasia,” while it is approved only for prostatic hyperplasia in the US, the UK, and Canada. Based on the above, it should be noted that the distribution of the target disease may be different between patients receiving finasteride and

	dutasteride in VigiBase.
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*: VigiBase is the WHO global database of reported potential adverse reactions of medicinal products, developed and maintained by Uppsala Monitoring Center (UMC). The information comes from a variety of sources, and the probability that the suspected adverse reaction is drug-related is not the same in all cases.

†: The information does not represent the opinion of the WHO or UMC.