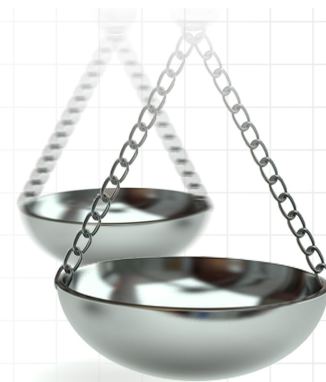




A plain language summary of the likelihood of symptom relief for patients taking fesoterodine for overactive bladder

Journal of **Comparative Effectiveness Research**

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Summary

What is this summary about?

This is a summary of a study originally published in *Neurourology and Urodynamics*. Overactive bladder is a medical condition that causes an urgent need to urinate, which can cause accidental urination. Fesoterodine is a medication used to treat overactive bladder. Because we don't know how likely it is that an individual patient will achieve a level of improvement in their overactive bladder symptoms, researchers analyzed results of 6 studies of patients with overactive bladder who were treated with fesoterodine.

How to say

(double click to play sound)...

• **Fesoterodine:** feh-sow-teh-ruh-deen

What were the results?

Although complete resolution of all symptoms was rare with fesoterodine treatment, a resolution of accidental urination was more common, which is the most important treatment goal for many patients. After taking fesoterodine, episodes of accidental urination were more likely to be reduced or completely absent than episodes of an urgent need to urinate.

What do the results of the study mean?

These results can help patients with overactive bladder understand their own chances of treatment success with fesoterodine and can help doctors support their patients on what to expect regarding their specific symptoms and concerns.

Who is this article for?

This article may be useful for people with overactive bladder and their families and caretakers, patient advocates, and healthcare providers (e.g., doctors, nurses, nurse practitioners, physician assistants) who treat people with overactive bladder.

Where can I find the original article on which this summary is based?

You can read the original article published in the journal *Neurourology and Urodynamics* for free at:
<https://onlinelibrary.wiley.com/doi/10.1002/nau.24706>

- Toviaz (fesoterodine) is approved to treat the condition that is discussed in this summary. Approval varies from country to country; please check with your local health provider for more details.
- This summary reports the combined results of 6 studies. The results of individual studies may vary from the combined study results presented here. Individuals should make treatment decisions based on all available evidence.

Future
Medicine  part of 

Why was this study needed?

What is overactive bladder?

Overactive bladder is a medical condition that causes an urgent need to urinate, which can result in accidental wetting through urine leakage. It is more common in older adults and can get worse over time.

What is fesoterodine?

Fesoterodine is a medication that can reduce accidental urination by allowing people to control both the urgent need to urinate and the number of times they need to urinate during the day and/or during the night.

What was the purpose of this study?

- Although studies have shown that fesoterodine can be helpful for treating overactive bladder, the results represent the average improvement for the typical patient.
- Therefore, we don't know how likely it is that any individual patient will achieve a certain level of improvement in their symptoms.
- We also don't know if the level of improvement differs between different groups of patients.
- Knowing this information would help doctors to support their patients on what to expect from treatment with fesoterodine.

What happened during the study?

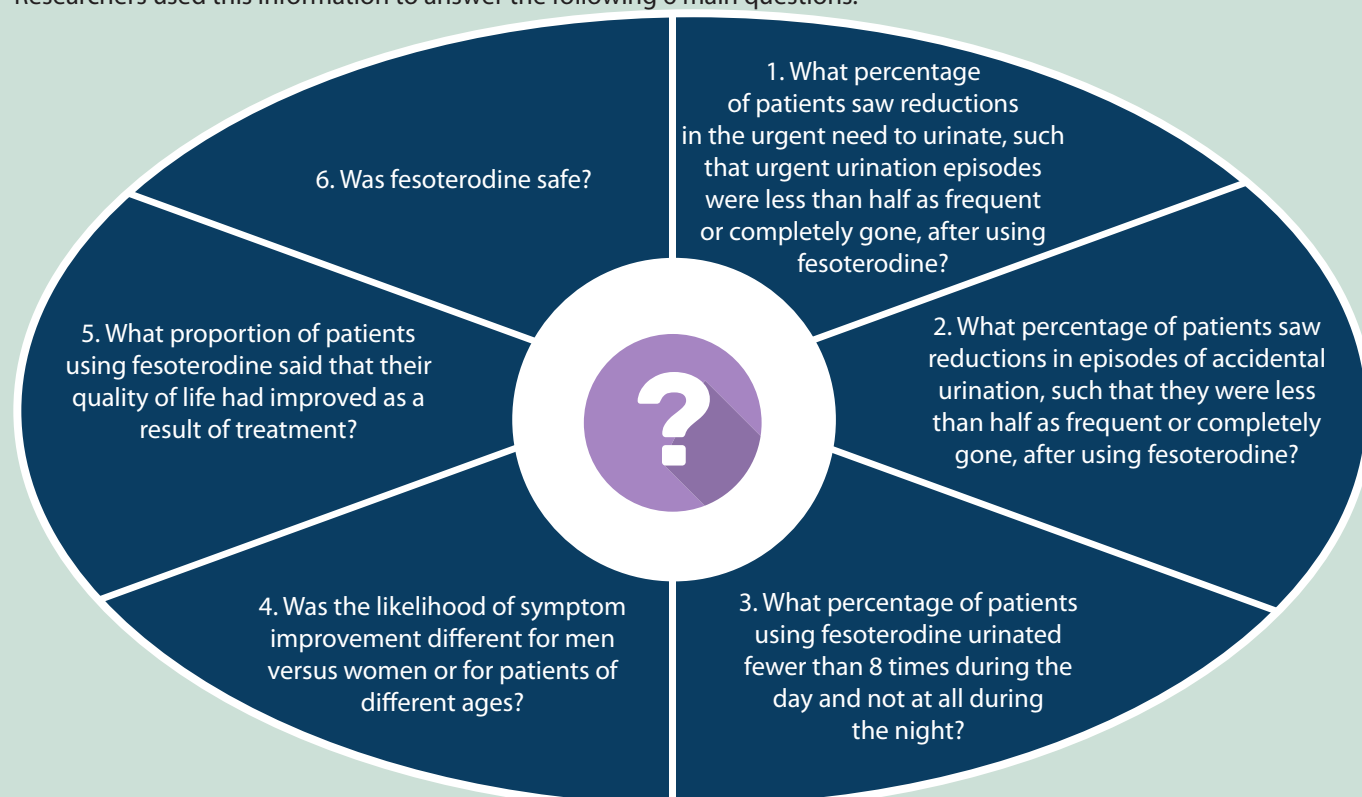
How was this study done?

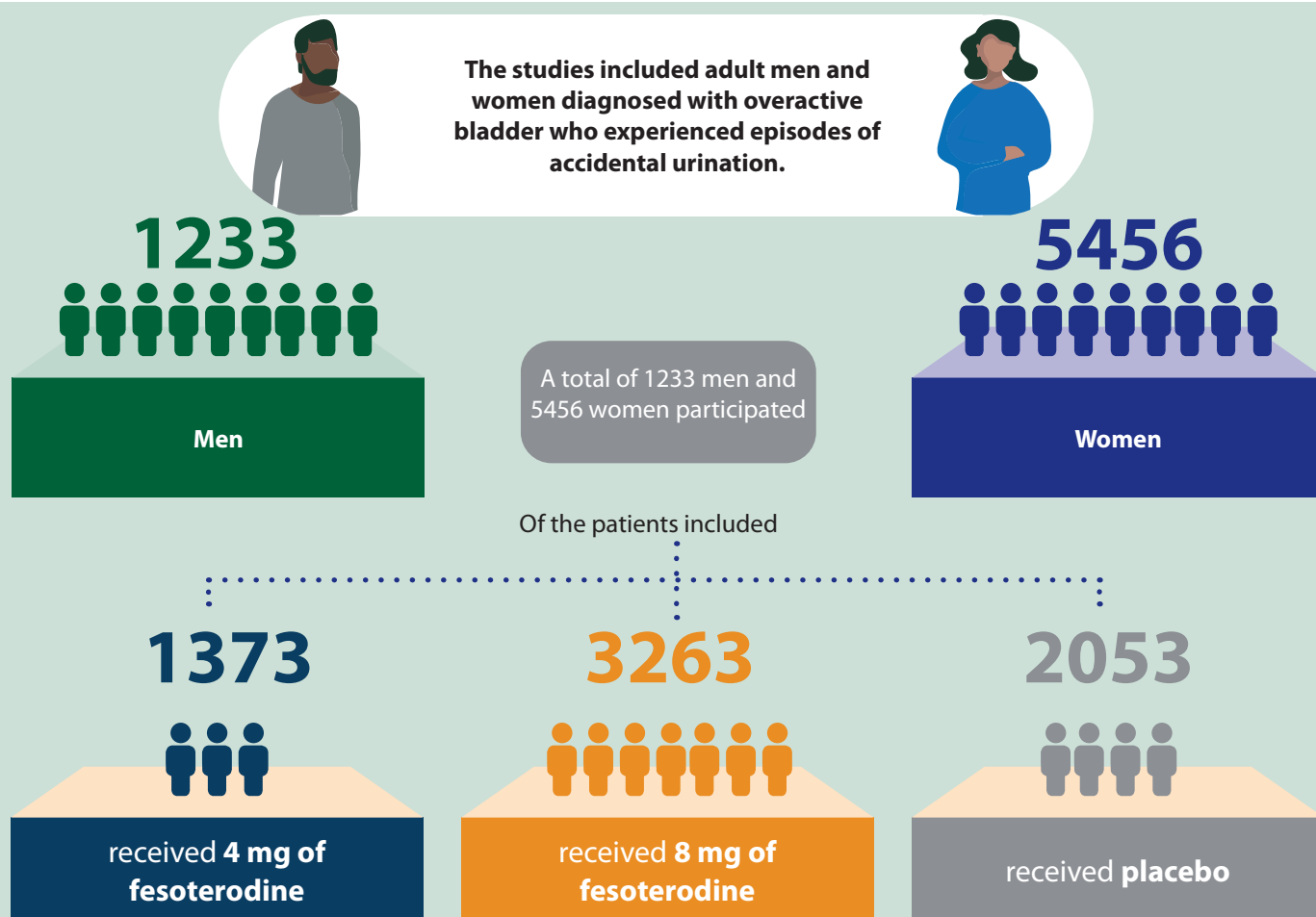
In this study, researchers analyzed the combined results of **6 previous studies** of patients using 4 mg or 8 mg of fesoterodine for 12 weeks to treat overactive bladder. The results were compared with those of patients who received placebo.



A **placebo** is a pill that contains no active medicine

Researchers used this information to answer the following 6 main questions:





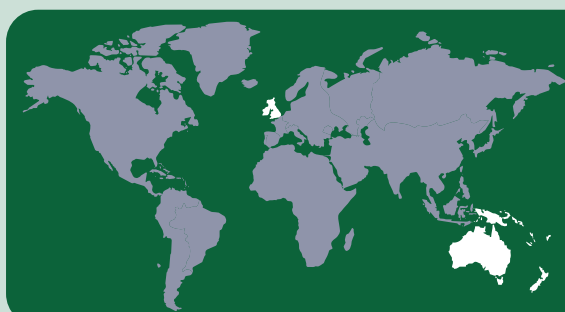
The average age of the patients in the study was 58 years, but the study included patients 18 to 95 years old.

Before taking fesoterodine, patients had a daily average of about 10 episodes of an urgent need to urinate and about 3 episodes of accidental urination. They urinated about 10 times during the day and twice during the night.



When did this study take place?

The 6 studies that were used to perform this new analysis took place between 2003 and 2012.



Where did this study take place?

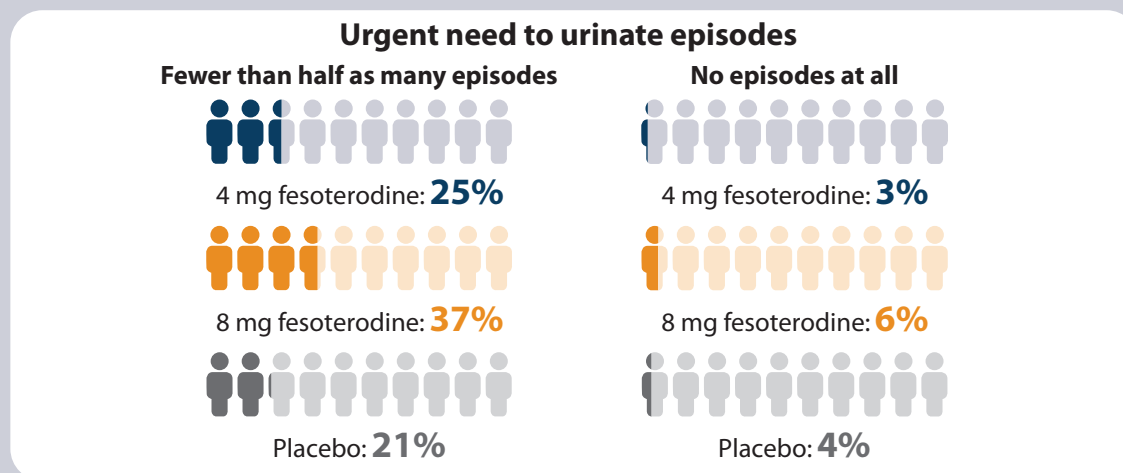
The studies included in this analysis took place at more than 200 sites worldwide, including North America, South America, Europe, Africa and Asia.

What were the results of the study?

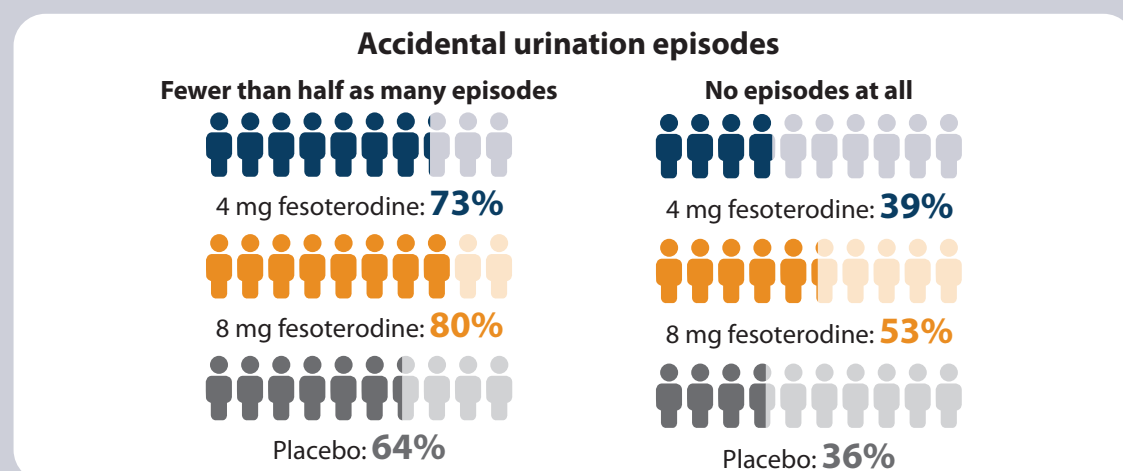
1

What effect did fesoterodine have on overactive bladder symptoms?

- After 12 weeks of using **4 mg** or **8 mg** of fesoterodine:
 - **25%** to **37%** of patients had fewer than half as many episodes of the urgent need to urinate, and **3%** to **6%** of patients had no episodes at all.



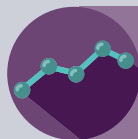
- **73%** to **80%** of patients had fewer than half as many episodes of accidental urination, and **39%** to **53%** of patients had none at all.



- **42%** of patients treated with 4 mg fesoterodine and **55%** of patients treated with 8 mg fesoterodine were urinating fewer than 8 times during the day, and about a third of patients treated with either fesoterodine dose did not need to urinate during the night.
- Up to **5%** of patients treated with 4 mg or 8 mg fesoterodine no longer had any overactive bladder symptoms at all.
- In general, patients receiving 4 mg or 8 mg of fesoterodine had a greater response to treatment than those who received placebo.
- The likelihood of having fewer episodes of accidental urination was generally similar regardless of age, but other symptoms were less responsive to treatment in patients older than 75 years compared with younger adults.
- For all symptoms, the likelihood of improvement was generally similar for men and women.

2

What effect did fesoterodine have on quality of life?



After 12 weeks of treatment, patients who reported an improvement in quality of life also reported having an improvement in accidental urination.

For patients who had an improvement in quality of life, **82%** who received 4 mg of fesoterodine and **88%** who received 8 mg of fesoterodine also reported having half as many episodes of accidental urination.



Accidental urination stopped completely in **48%** of patients who received 4 mg fesoterodine and in **63%** of patients who received 8 mg fesoterodine.

3

Was fesoterodine safe?

An adverse event is a health problem that occurs during or after treatment and may or may not be caused by the treatment.



An adverse event is considered serious when it is life-threatening, needs hospital care, or causes lasting problems.

Adverse events and serious adverse events were reported by patients within each of the study groups

Adverse events



4 mg fesoterodine: **45%** (612 out of 1373)



8 mg fesoterodine: **50%** (1632 out of 3263)



Placebo: **34%** (707 out of 2053)

Serious adverse events



4 mg fesoterodine: **2%** (30 out of 1373)



8 mg fesoterodine: **2%** (58 out of 3263)



Placebo: **2%** (47 out of 2053)



Of the 1223 men included in the studies

Of the 5456 women included in the studies



39%	Reported at least one adverse event	45%
3%	Experienced serious adverse events	2%
5%	Discontinued treatment	4%
1%	Temporarily stopped treatment	1%

What were the main conclusions reported by the study authors?

1

Although complete resolution of all symptoms was rare with fesoterodine treatment, a **resolution of accidental urination was more common**, which is the most important treatment goal for many patients.

2

After taking fesoterodine, episodes of **accidental urination** were **more likely to be reduced or completely absent** than episodes of an urgent need to urinate.

3

These results can help patients **understand their own chances of treatment success with fesoterodine** and can help doctors support their patients on what to expect regarding their specific symptoms and concerns.

Who sponsored this study?

The statistical analysis performed in this study was supported by Pfizer Inc (New York, NY, USA).

Where can I find more information?

The full title of the original article is: 'What are the chances of improvement or cure from overactive bladder? A pooled responder analysis of efficacy and treatment emergent adverse events following treatment with fesoterodine'.

You can read the article at: <https://onlinelibrary.wiley.com/doi/epdf/10.1002/nau.24706>

The full citation of the original article is: Wagg AS, Herschorn S, Carlsson M, Fernet M, Oelke M. What are the chances of improvement or cure from overactive bladder? A pooled responder analysis of efficacy and treatment emergent adverse events following treatment with fesoterodine. *Neurourol. Urodyn.* 40(6), 1559–1568 (2021). doi:10.1002/nau.24706

Trial registration sites

You can read more about the studies analyzed here on the www.ClinicalTrials.gov website. Once on the website type the clinical trial identifiers listed below into the 'Other terms' search box and click 'Search'

Clinical trial identifiers: NCT01302054, NCT01302067, NCT00444925, NCT00611026, NCT00220363, and NCT00138723

<https://clinicaltrials.gov/ct2/show/NCT01302054>

<https://clinicaltrials.gov/ct2/show/NCT00611026>

<https://clinicaltrials.gov/ct2/show/NCT01302067>

<https://clinicaltrials.gov/ct2/show/NCT00220363>

<https://clinicaltrials.gov/ct2/show/NCT00444925>

<https://clinicaltrials.gov/ct2/show/NCT00138723>

Educational resources

For more information on overactive bladder or fesoterodine, please visit the following websites:

<https://www.yourpelvicfloor.org/conditions/overactive-bladder/>

<https://patients.uroweb.org/videos/oab-overactive-bladder-syndrome/>

<https://www.urologyhealth.org/educational-resources/overactive-bladder>

https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022030s007lbl.pdf

https://www.ema.europa.eu/en/documents/product-information/toviaz-epar-product-information_en.pdf

Financial & competing interests disclosure

Adrian Wagg reports personal fees from Astellas Pharma, grants from Essity Health & Hygiene AB, grants and personal fees from Pfizer Corp, personal fees from Pierre Fabre Medicaments, personal fees from Sanofi, outside the submitted work; his spouse is an employee of Pfizer. Sender Herschorn reports personal fees from Pfizer, grants and personal fees from Astellas, grants from Urovant, outside the submitted work. Martin Carlsson and Mireille Fernet are employees of Pfizer and may own stock or stock options; Matthias Oelke reports nonfinancial support and others from Apogepha Arzneimittel, personal fees, nonfinancial support and other from Astellas, personal fees, nonfinancial support and other from Pfizer, personal fees, nonfinancial support and other from Pierre Fabre, outside the submitted work.

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