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Urologic Diseases in America

ANNUAL DATA REPORT

Fournier's Gangrene

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Note

This document is one of the seven that collectively comprise the 2024 *Urologic Diseases in America: Annual Data Report (ADR)*. This document reports and discusses findings on Fournier's Gangrene (FG). Other topics in the 2024 ADR are Introduction and Methods; Benign Prostatic Hyperplasia and Associated Lower Urinary Tract Symptoms (BPH/LUTS); Urinary Stone Disease (USD); Urinary Incontinence (UI); Urologic Chronic Pelvic Pain Syndrome (UCPPS); and Healthcare Expenditures of Urologic Diseases. These analyses are available as separate documents on the UDA website. Additional details on the methodology and data sources are provided in Appendices A and B, respectively, in the Introduction and Methods document.

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Fournier's Gangrene

Main Takeaways

- The overall claims-based annual prevalence of Fournier's gangrene (FG) ranged between 3 and 7 per 100,000 persons from 2012 to 2021. Prevalence was higher for patients aged 65 to 69 compared to other age groups above 65.
- The overall claims-based annual incidence of FG ranged between 3 and 7 per 100,000 persons from 2015 to 2021. Incidence was higher for patients aged 65 to 69 compared to other age groups above 65.
- FG often co-occurred with diabetes. In 2021, 66% of patients age 65 and older with FG also had diabetes.
- In 2021, 13% of patients aged 65 years and older with FG filled a prescription for sodium-glucose cotransporter-2 inhibitors (SGLT2i) or glucagon-like peptide 1 (GLP-1) agonists.
- Mortality was high for patients with FG. Among patients aged 65 and older with incident FG in 2015, 70% died within 5 years.

1 Overview

Fournier's gangrene (FG) is a rare, but life-threatening urologic disease characterized by acute necrotic infection of the perineal, anal, scrotal, and genital regions. FG falls under necrotizing soft tissue infections, a group of infections occurring from inoculation of the pathogen into the subcutaneous tissue. Infection of the perineum or genitals leading to FG can be caused by trauma, urinary tract infections or stones, Bartholin gland abscesses, and surgery or other instrumentation.[1] FG disproportionately affects men compared to women and is most commonly seen among older adults, especially those with diabetes and obesity.[2] The risk of FG may also be heightened with use of specific prescription drugs, including sodium-glucose cotransporter-2 inhibitors (SGLT2i).[3] Pharmacological classes used in the analysis are shown in Table 1 below. FG is also noted for its high mortality rates.

Section 2 illustrates results on prevalence, incidence, co-occurrence of diabetes, prescription drugs filled, and mortality. Section 3 discusses these results relative to the peer-reviewed literature on FG.

Table 1. Pharmacological classes considered for FG analysis

SGLT2 Inhibitors	GLP-1 Agonists
• Canagliflozin • Canagliflozin/metformin hydrochloride • Dapagliflozin propanediol • Dapagliflozin propanediol/metformin hydrochloride • Dapagliflozin propanediol/saxagliptin • Empagliflozin • Empagliflozin/linagliptin • Empagliflozin/linagliptin/metformin • Empagliflozin/metformin hydrochloride • Ertugliflozin • Ertugliflozin/metformin hydrochloride • Ertugliflozin/sitagliptin	• Dulaglutide • Exenatide extended release • Exenatide • Semaglutide • Liraglutide • Lixisenatide

2 Results

➔ Study population

Table 2 shows the total number of patients with FG as well as the total population in the cohort aged 65 and older (in Medicare fee-for-service) in 2021.

Table 2. Total number of patients with FG, 2021

Population	Medicare FFS Age 65+		
Gender	Overall	Male	Female
Total	24,473,919	10,779,115	13,694,802
Patients with FG	831	570	261

➔ Prevalence

The overall claims-based annual prevalence of FG from 2012 to 2021 ranged between 3 and 7 per 100,000 persons among patients aged 65 and older (Figure 1a). The prevalence of FG was between 6 and 7 per 100,000 persons from 2012 to 2015 and was between 3 and 4 per 100,000 persons from 2016 to 2021 (Figure 1a). In 2021, there were 831 patients with prevalent FG (Table 2). The prevalence was higher for men compared to women (Figure 1a). Patients aged 65 to 69 were found to have the highest prevalence of FG compared to older age groups (Figure 1b). Trends in prevalence for all age groups across the study period were similar, with the percentage decreasing between 2015 and 2016 and remaining relatively stable from 2016 to 2021 (Figure 1b).

Figure 1a. Claims-based prevalence of FG, by year and gender (2012-2021)

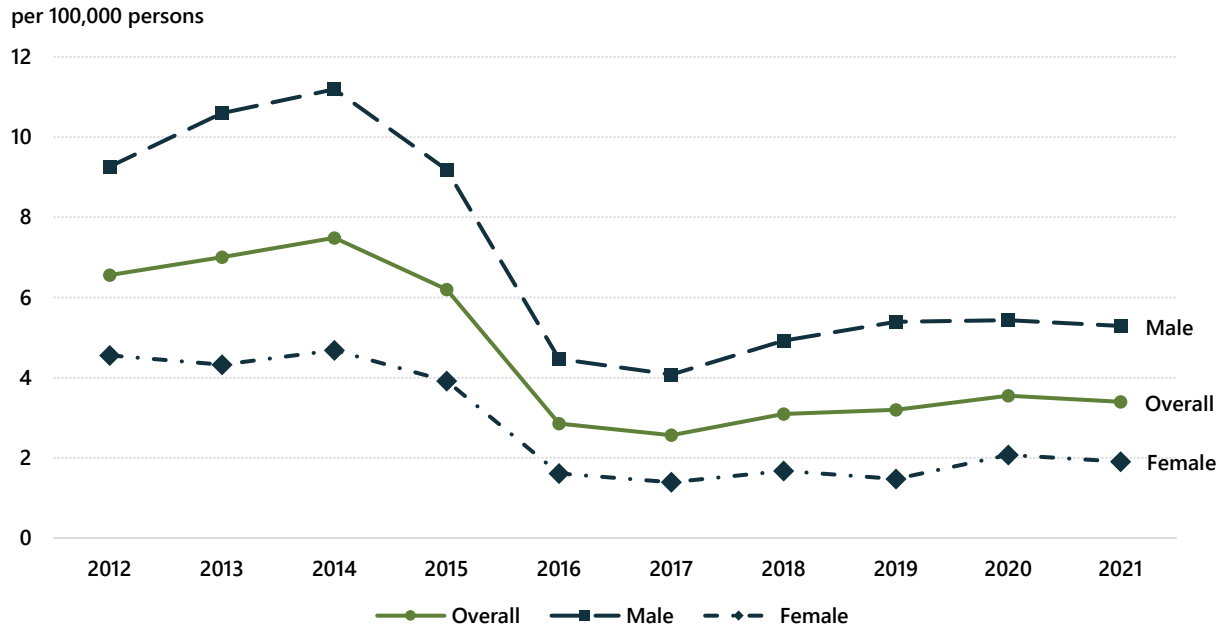
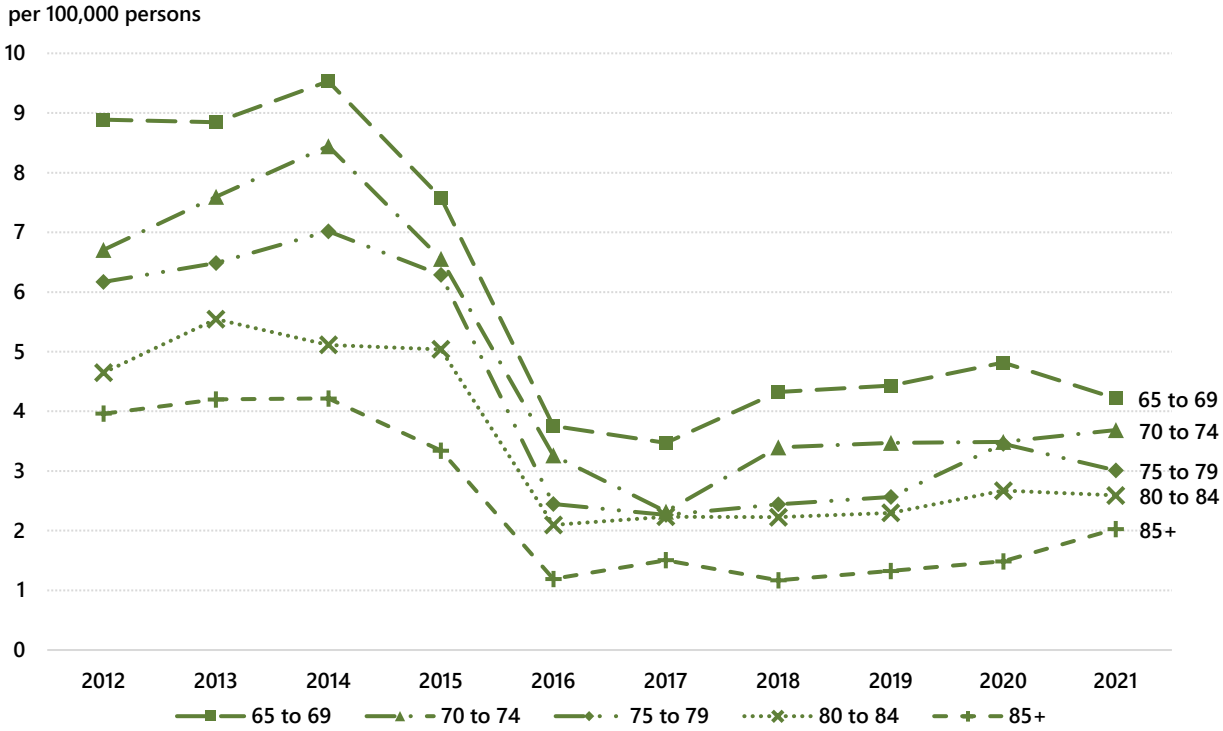


Figure 1b. Claims-based prevalence of FG, by year and age (2012-2021)

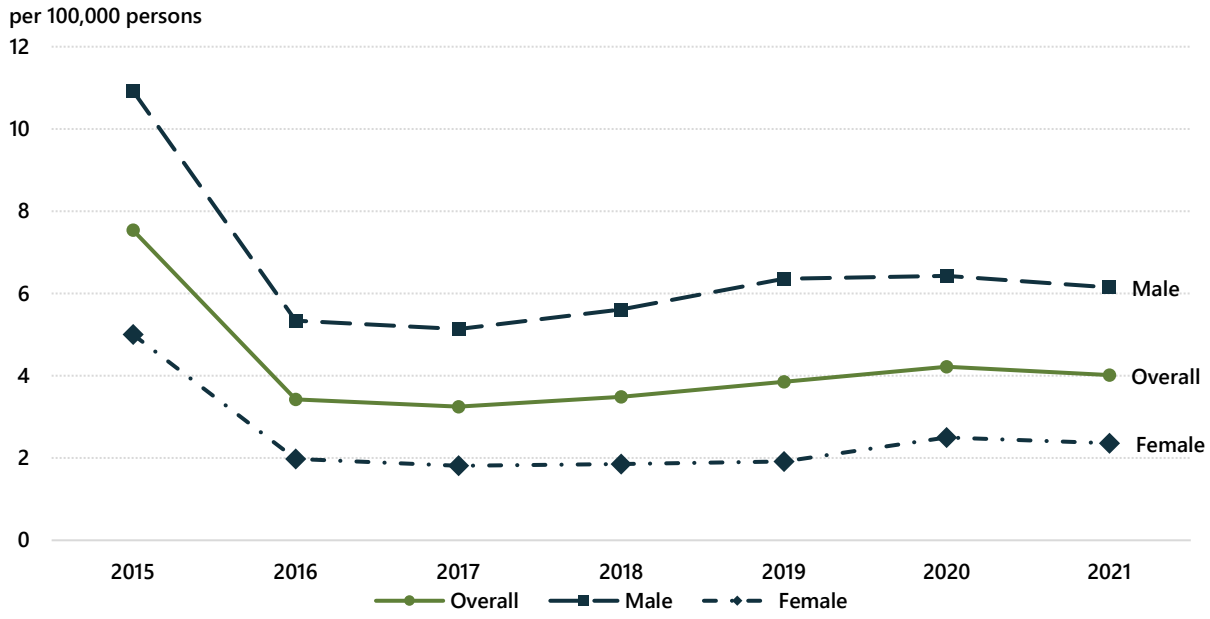


Notes: The numerator denotes the number of patients with FG aged 65 and older in each year, by gender (panel a) or age (panel b). The denominator denotes the total number of persons in each age cohort, by gender (panel a) or age (panel b).

➔ Incidence

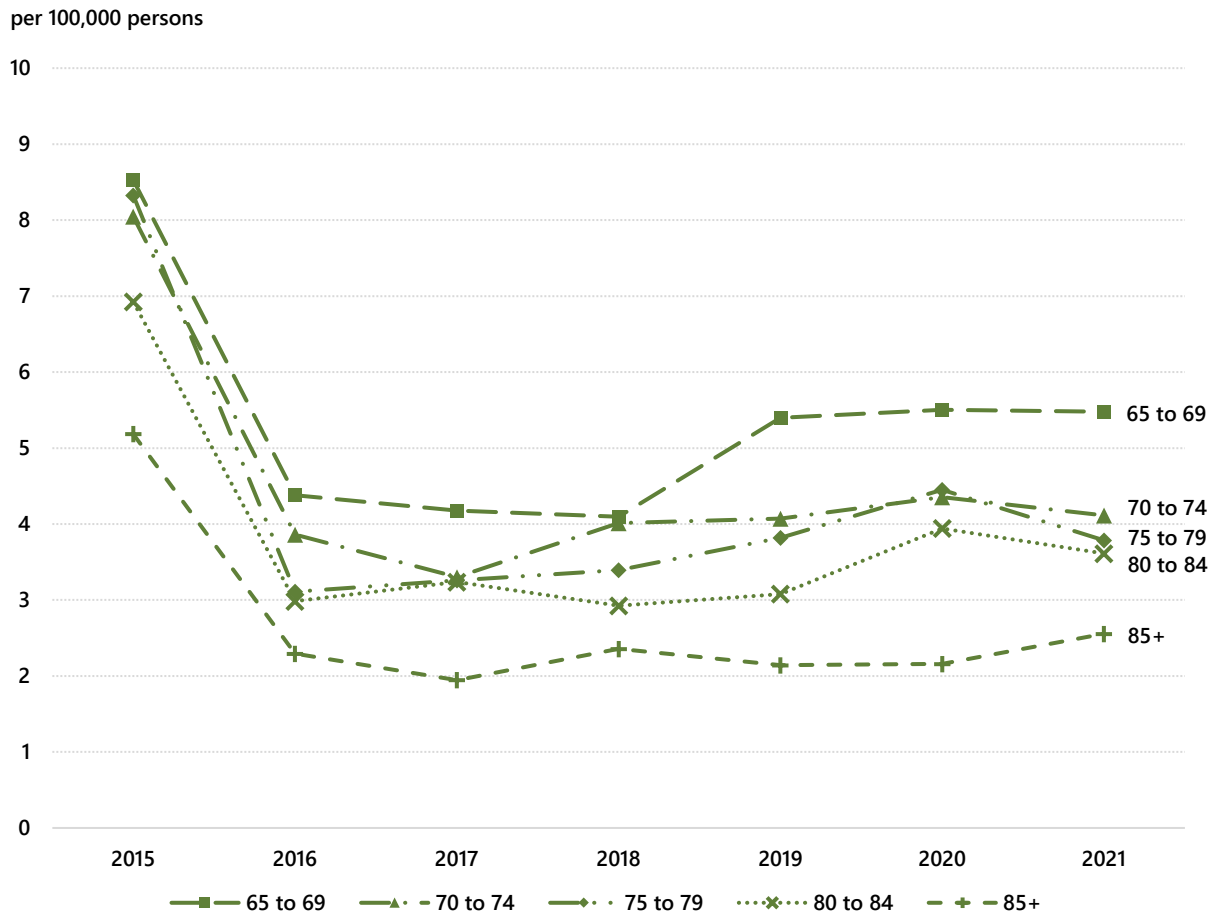
The overall claims-based annual incidence of FG for patients aged 65 and older was 8 per 100,000 persons in 2015 and approximately 4 per 100,000 persons after 2015 (Figure 2a). In 2021, there were 920 incident cases of FG. Similar to prevalence, incidence was higher for men compared to women and for those aged 65 to 69 compared to older age groups (Figures 2a and 2b). Across all age subgroups, incidence remained relatively constant from 2016 to 2021, and was lower than that during 2015 to 2016 (Figures 2b).

Figure 2a. Claims-based incidence of FG, by year and gender (2015-2021)



Notes: The numerator denotes the number of patients with incident FG aged 65 and older in each year, by gender. The denominator denotes the total number of persons aged 65 and older each year-group.

Figure 2b. Claims-based incidence of FG, by year and age (2015-2021)

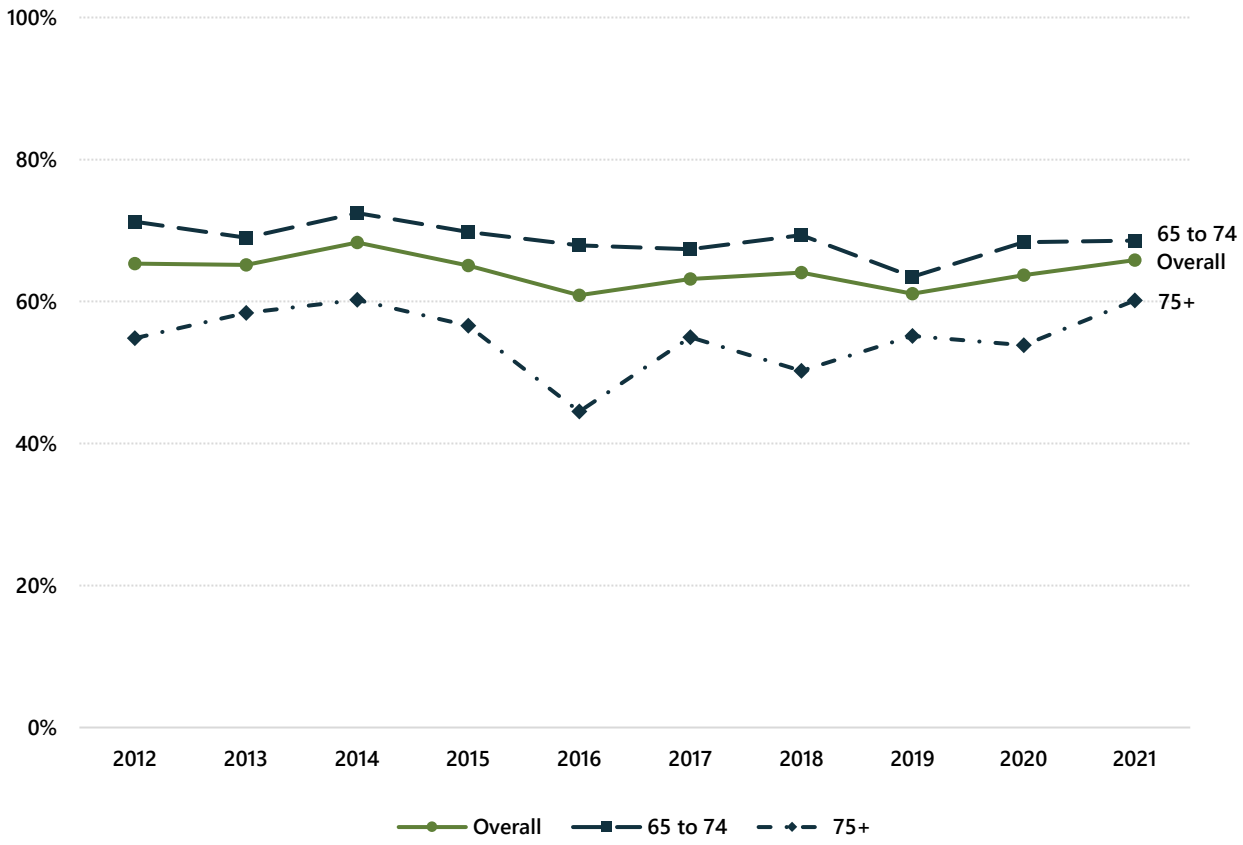


Notes: The numerator denotes the number of patients with incident FG aged 65 and older in each year, by age. The denominator denotes the total number of persons in each age cohort in each year.

➔ Comorbidity (diabetes)

In 2021, the percentage of patients with FG who also had diabetes was 66% (Figure 3). The rate of diabetes for patients with FG remained stable from 2012 to 2021. The percentage of patients with FG aged 65 to 74 who also had diabetes was 69%, compared to 60% for patients with FG aged 75 and older in 2021.

Figure 3. Rate of diabetes among patients with FG, by year and age (2012-2021)

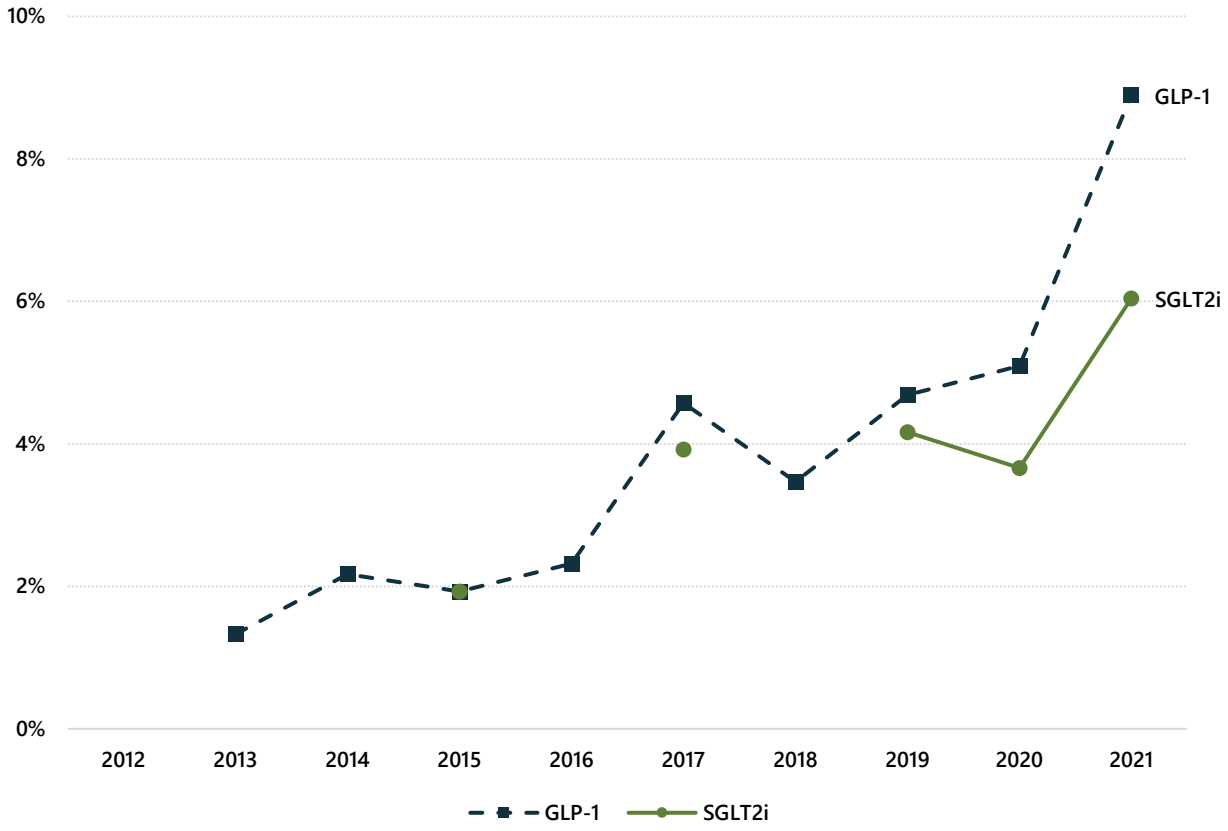


Notes: The numerator denotes the number of patients with FG aged 65 and older who were also identified with diabetes in each year. The denominator denotes the total number of patients with FG in each year, overall and by age.

➔ Prescription drugs

Overall, the percentage of patients aged 65 and older with FG who filled SGLT2i or GLP-1 agonist drug prescriptions was 13% in 2021. Among these patients, 9% had a prescription filled for GLP-1 agonists, and 6% had an SGLT2i prescription filled in 2021 (Figure 4). Both of these drugs experienced an increase in rate of prescription filled from 2012 to 2021 (Figure 4).

Figure 4. Prescription drugs filled, by year and type (2012-2021)



Notes: The numerator denotes the number of patients with FG aged 65 and older who filled the prescription referenced in each year. The denominator denotes the total number of patients aged 65 and older with FG and continuous Part D enrollment in each year. Values for some years have been suppressed due to small number of observations (observations < 12).

➔ Mortality

The 5-year all-cause mortality among the 2015 incident FG beneficiaries was 70%. Cumulative mortality within the first week of diagnosis was 7%. Cumulative mortality within 2 and 4 weeks was 13% and 19%, respectively. Among patients who died, 50% of all deaths occurred within 20 weeks of the incident diagnosis, and 64% of all deaths occurred within the first year of the incident diagnosis.

3 Discussion

This analysis yielded several key findings. First, the claims-based prevalence of FG among patients aged 65 and older ranged between 3 and 7 per 100,000 persons from 2012 to 2021. Second, the claims-based incidence of FG was similar to its prevalence. Third, FG frequently co-occurred with diabetes. Fourth, 13% of patients diagnosed with FG filled an SGLT2i or GLP-1 agonist prescription in 2021. Lastly, 5-year all-cause mortality for the incident cohort was 70 percent, and most of the deaths occurred within a year of the incident diagnosis.

There is limited literature on prevalence and incidence of FG, but the overall incidence rate has been reported as 1.6 cases per 100,000 men per year, with the incidence of FG among men aged 50+ being 3.3 per 100,000.[4] Another study reported an average of 97 cases per year from 1989 to 1998.[5] These rates are lower than our reported annual incidence of 4 per 100,000 in 2021, and may be attributed to differences in population size, diagnostic criteria, or different study periods.

The prevalence and incidence of FG experienced a noticeable decrease between 2015 and 2016, and this trend is present across all subgroups. This may be due to the implementation of the International Classification of Diseases (ICD) 10th Edition codes. Transitioning from ICD-9 to ICD-10 resulted in much higher specificity of diagnosis and procedure codes, potentially impacting the number of beneficiaries identified with FG.

Diabetes was a common comorbidity among patients with FG, which aligns with other studies that explore outcomes and prognosis of FG. The rate of diabetes among patients with FG reported in the literature ranged from 32% to 77%,[6] while the rate of diabetes in the present study was 66% in 2021.

Overall, prescription drug filled for SGLT2i and GLP-1 agonists increased over time, with 13% of patients with FG enrolled full-time in Medicare Part D filling the studied drugs in 2021. Among these patients, 6% filled a prescription for SGLT2i and 9% filled a prescription for GLP-1 agonists in 2021. Given the increase in prescription filled for SGLT2i and the findings of association of FG with these drugs,[7] the timing of the onset of SGLT2i drugs use and the diagnosis of FG is worth further exploration.

The 5-year mortality for the incident cohort was 70%. In prior studies, mortality rates have been reported as high as 88%.[8] These differences in the results could be due to differences in the length of follow-up period after incident FG. Also, some of the published mortality rates are based on case studies, which may show larger variance in mortality rates due to small number of cases. A more detailed study on the timing as well as the location of mortality would shed more light on the differences in estimates between the literature and this analysis. Future analysis comparing FG mortality with mortality of other beneficiaries aged 65 and older would provide additional perspectives on the high mortality of FG patients.

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