

High Prevalence and Underdiagnosis of Gastroparesis Symptoms Among Patients with Type 1 and Type 2 Diabetes Mellitus

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Oral presentation at Digestive Disease Week

May 20, 2013

Orlando, FL



Background

- Gastroparesis is an often debilitating complication of diabetes, interfering with normal daily activities, productivity, and quality of life of affected patients
- Current therapies adequately control symptoms in only a minority of patients, sparking a search for new and more effective alternatives
- There are few available epidemiological determinations of prevalence of diabetic gastroparesis (DGP) in the U.S.
 - Results have been variable, with estimates ranging from 100,000 to >5,000,000 patients nationally
 - Primary focus has been on type 1 diabetes, thought to account for the majority of patients with diabetic GP

Aims

- To develop and validate a survey instrument for assessing symptoms of diabetic gastroparesis
- To determine the prevalence of GP symptoms and rates of GP diagnosis among U.S. patients with diabetes mellitus

Methods: Development of Survey Instrument

- **Structured interviews**

- 41 patients with scintigraphy-confirmed diabetic gastroparesis
- Used focus groups to define common symptoms, severity and impact
- Cognitive interviews to guide development and refinement of survey questionnaire, which was designed to be compliant with 2009 FDA guidelines for patient-reported outcomes

- **Key findings from interviews**

- Nausea, vomiting, bloating and abdominal pain/discomfort among most bothersome GP symptoms
- Approximately half of participants also reported constipation as bothersome (not traditionally considered a hallmark of GP)

Methods: Population Survey

- **Administered to a national sample of 911 patients with diabetes mellitus (DM)**
 - 408 with type 1 DM
 - 511 with type 2 DM
- **Administered online questionnaire**
 - Patient demographics, diabetes history and current and previous medication use
 - Specific GP symptoms and their severity during the previous 24 hours and 7 days, including:
 - Bloating, abdominal pain, nausea, vomiting, post-prandial fullness
 - Constipation not assessed
 - Whether care was sought for these symptoms
 - Specialty of treating physician
 - Diagnostic tests performed
 - Diagnosis communicated to patient

Definitions (by patient self-report)

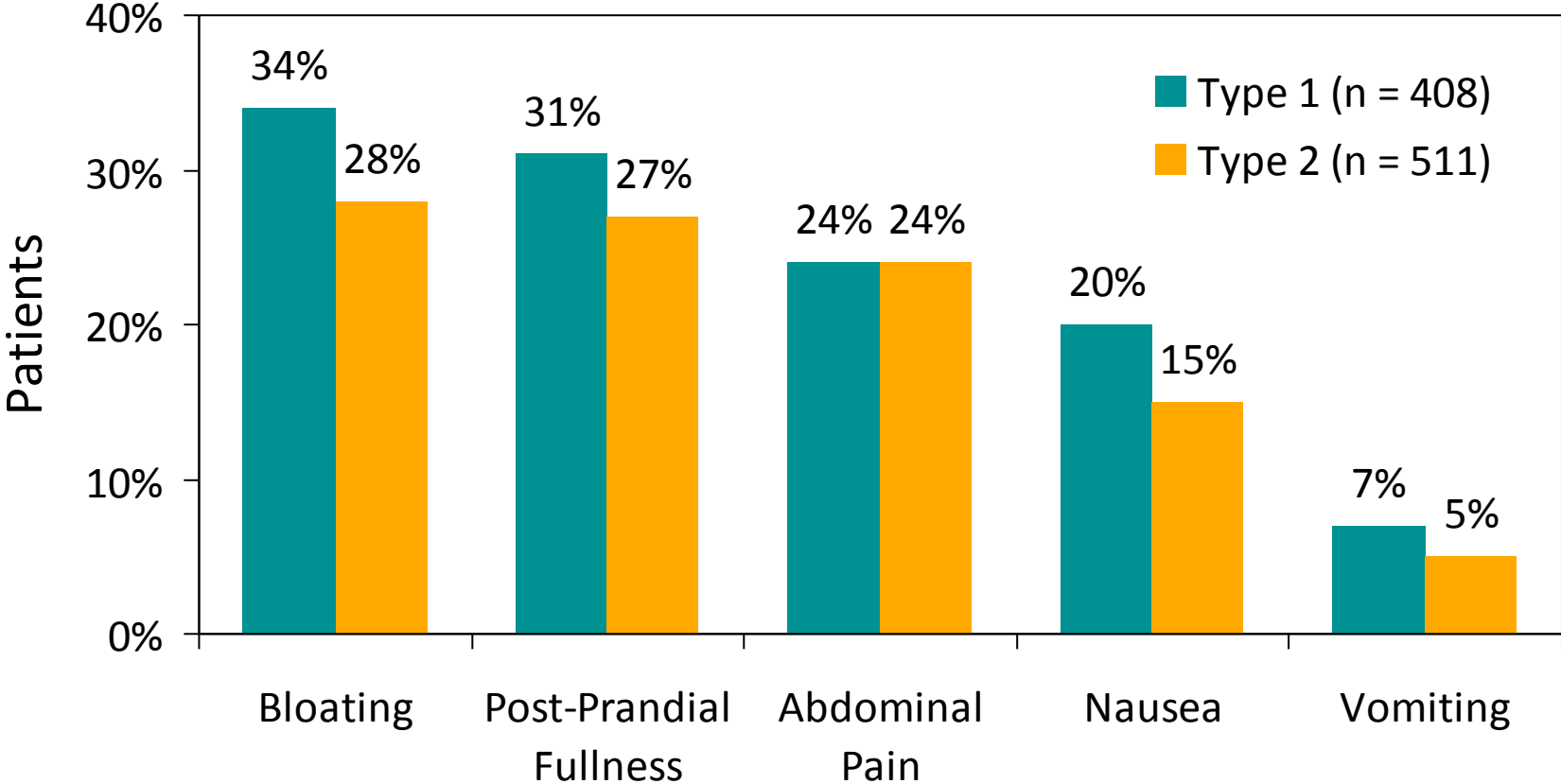
- **GP Symptoms**
 - Report of one or more GP symptoms (from among bloating, abdominal pain, nausea, vomiting, and increased post-prandial fullness) during the previous 7 days
- **Severity**
 - Semantic scale: mild, moderate, severe
 - Analog scale: 0 (none) to 10 (worst possible)
- **Moderate-Severe GP Symptoms**
 - Report of one or more moderate-severe GP symptoms during the previous 7 days

Definitions (by patient self-report)

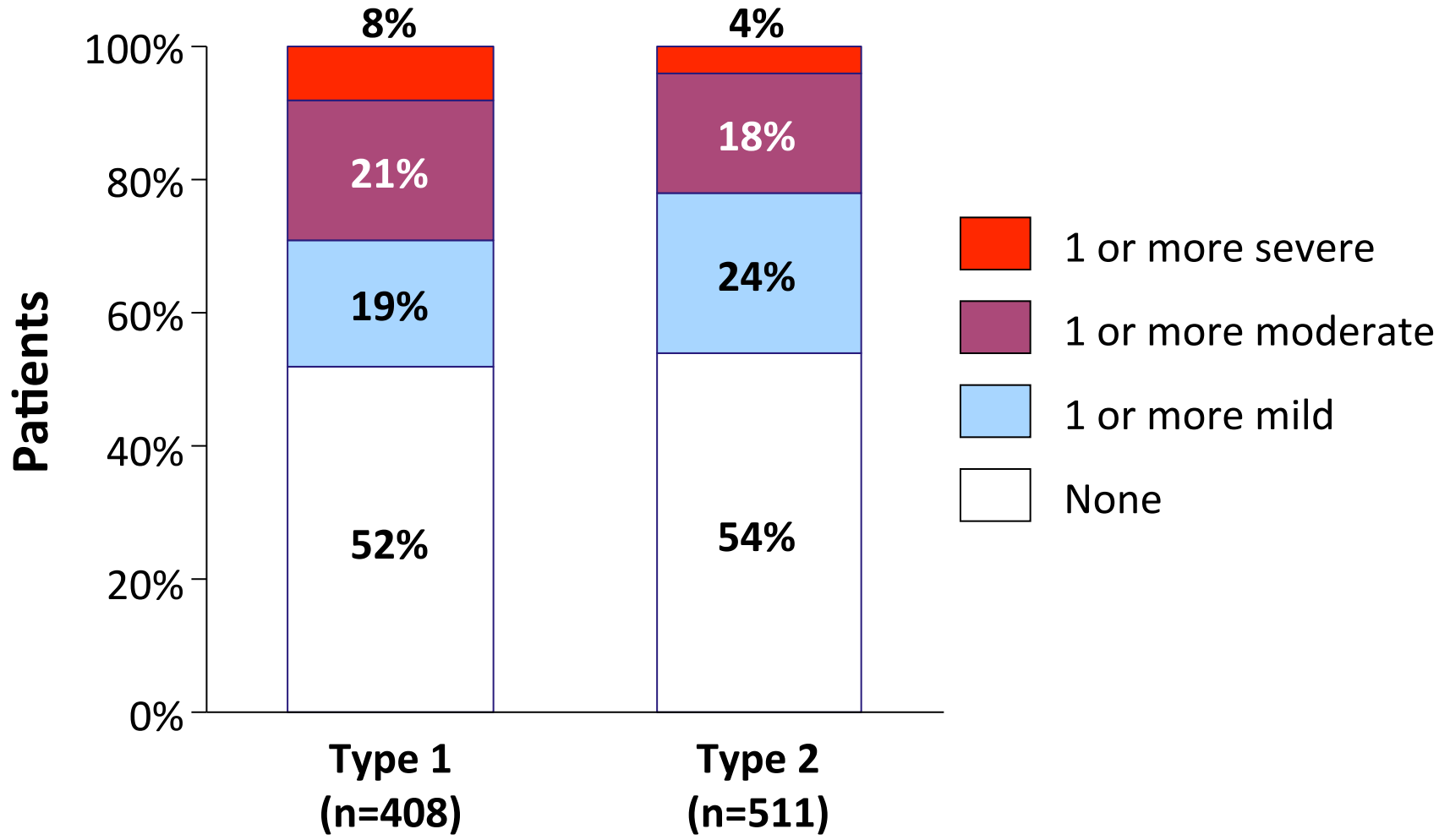
- **Care Seeking**
 - Saw a physician for assessment of reported GP symptoms within the previous 12 months or intends to see a physician within the next 12 months
- **Diagnosis**
 - Recollection of being told by a physician that he or she has GP

GP Symptoms Common Among Type 1 and Type 2 Diabetics

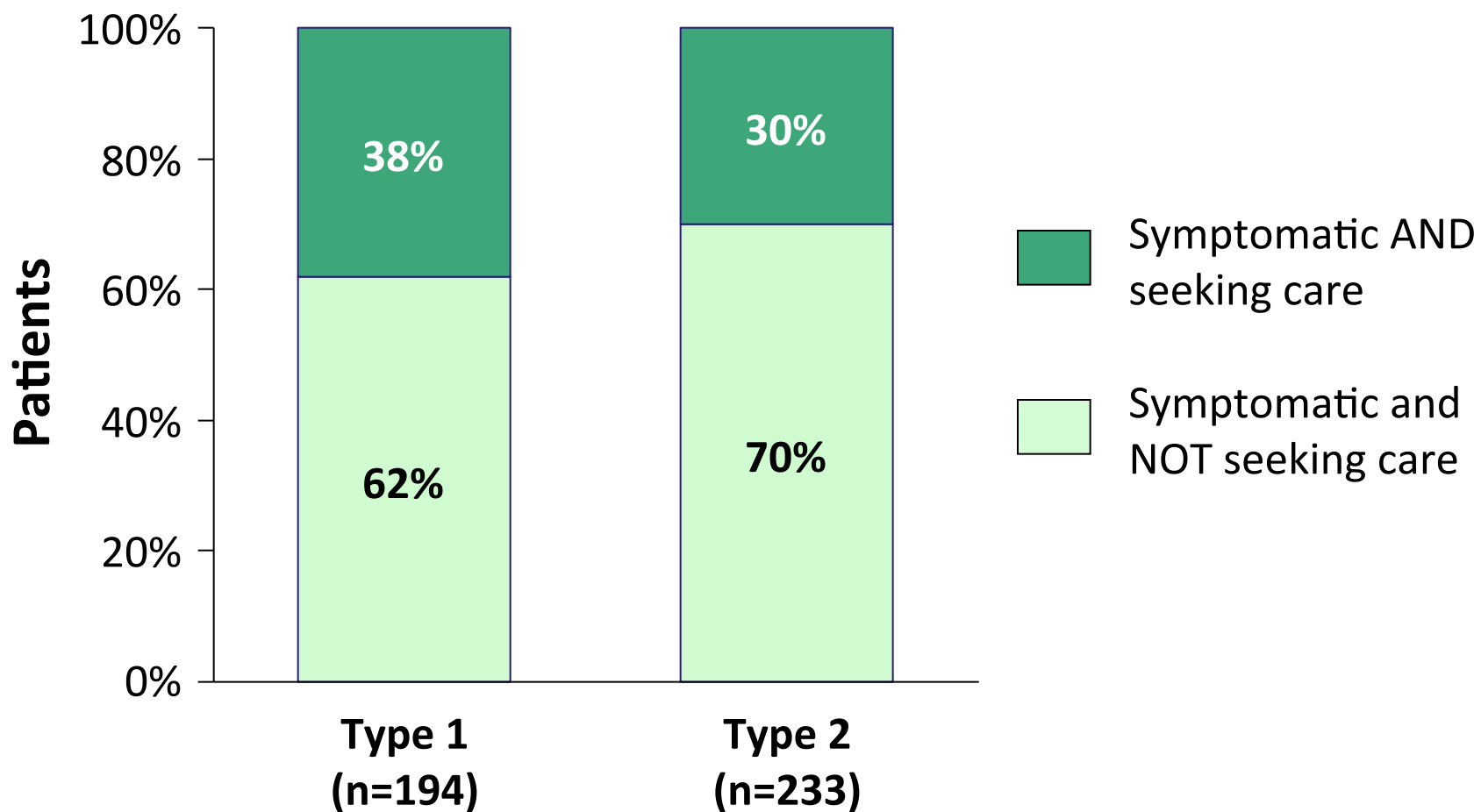
Reported Symptoms within Previous 7 Days



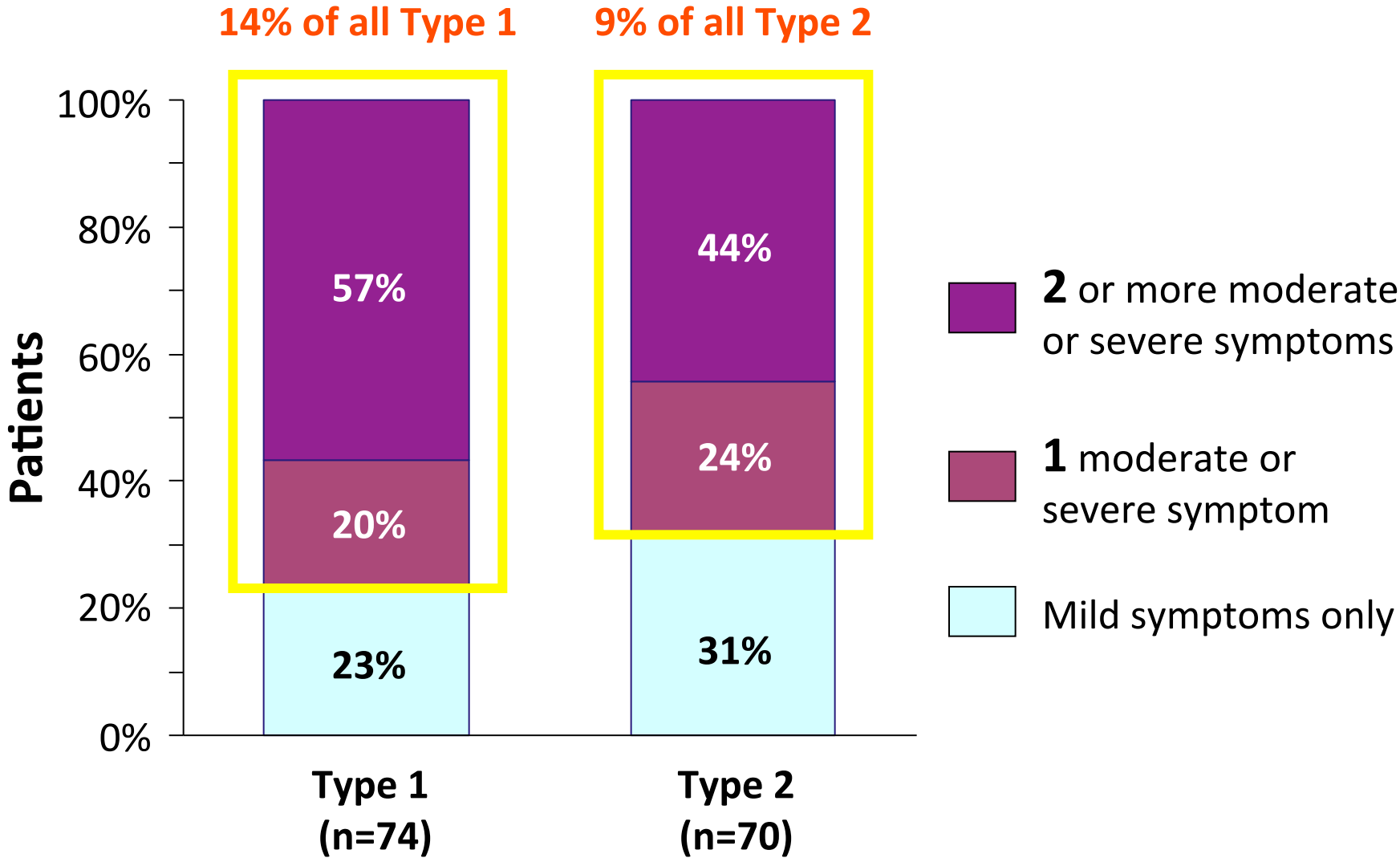
Severity of Reported GP Symptoms



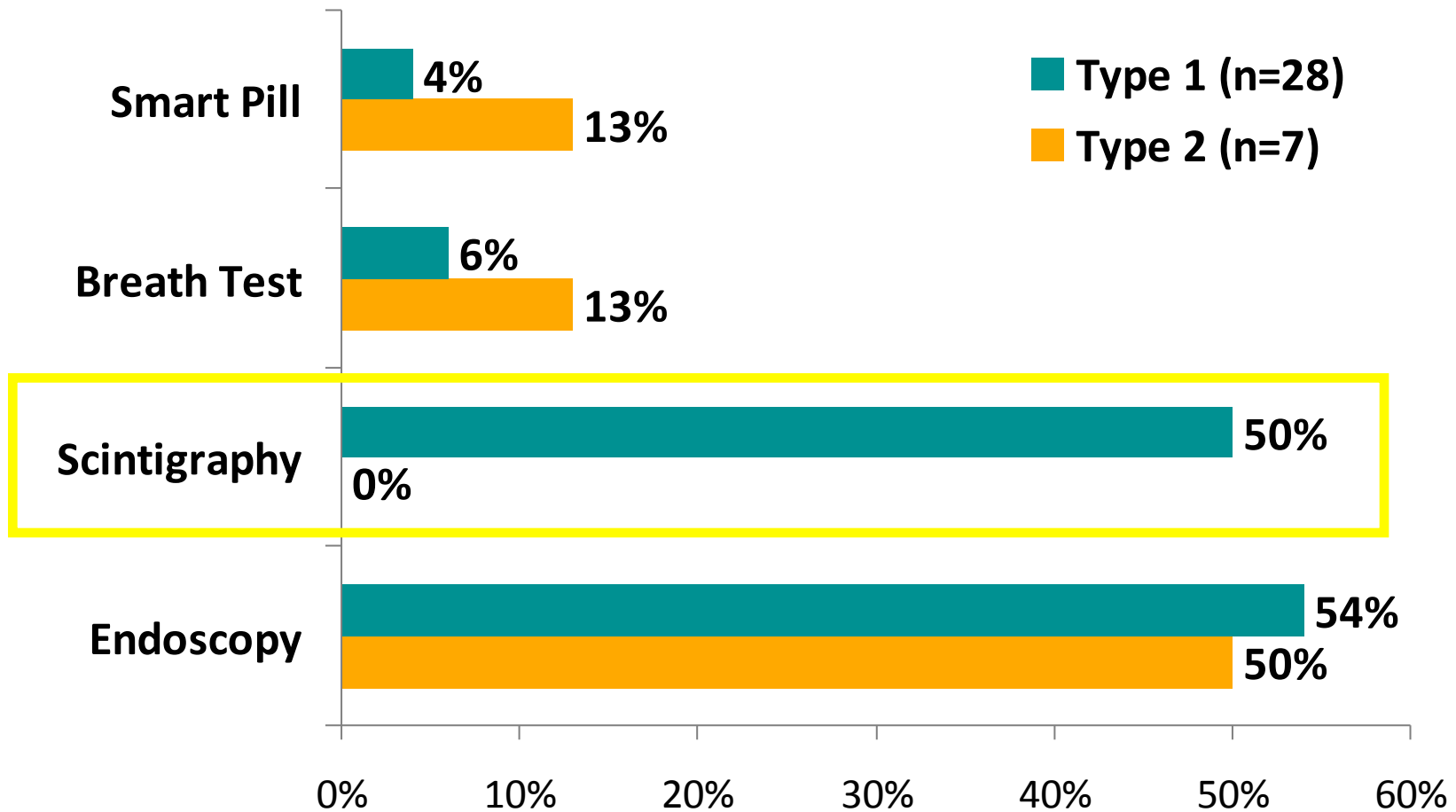
Seeking Care Common for Patients with GP Symptoms



Seeking Care Associated with More Severe Symptoms

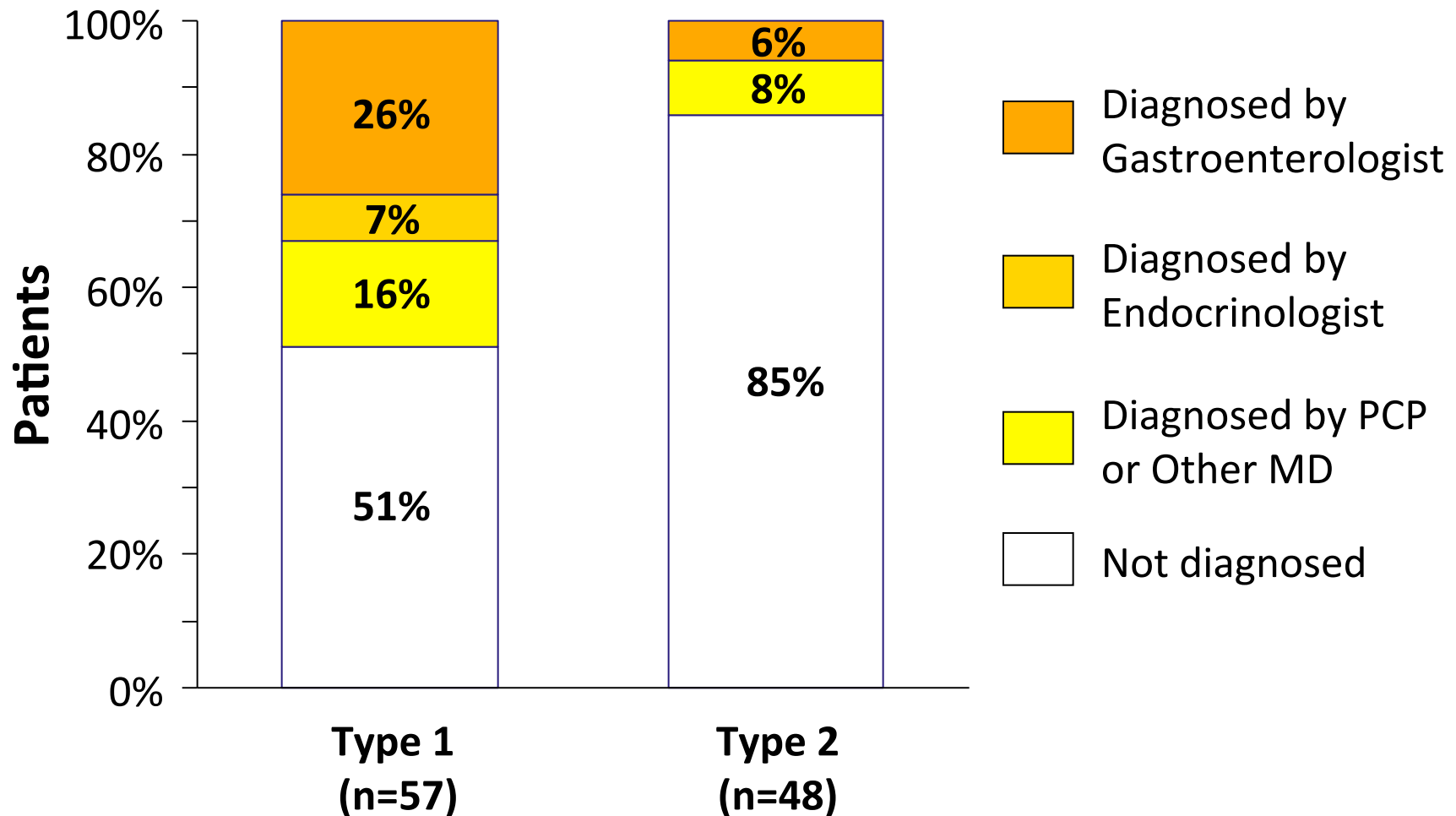


Scintigraphic Evaluation Rare Among T2DM Patients Diagnosed with GP

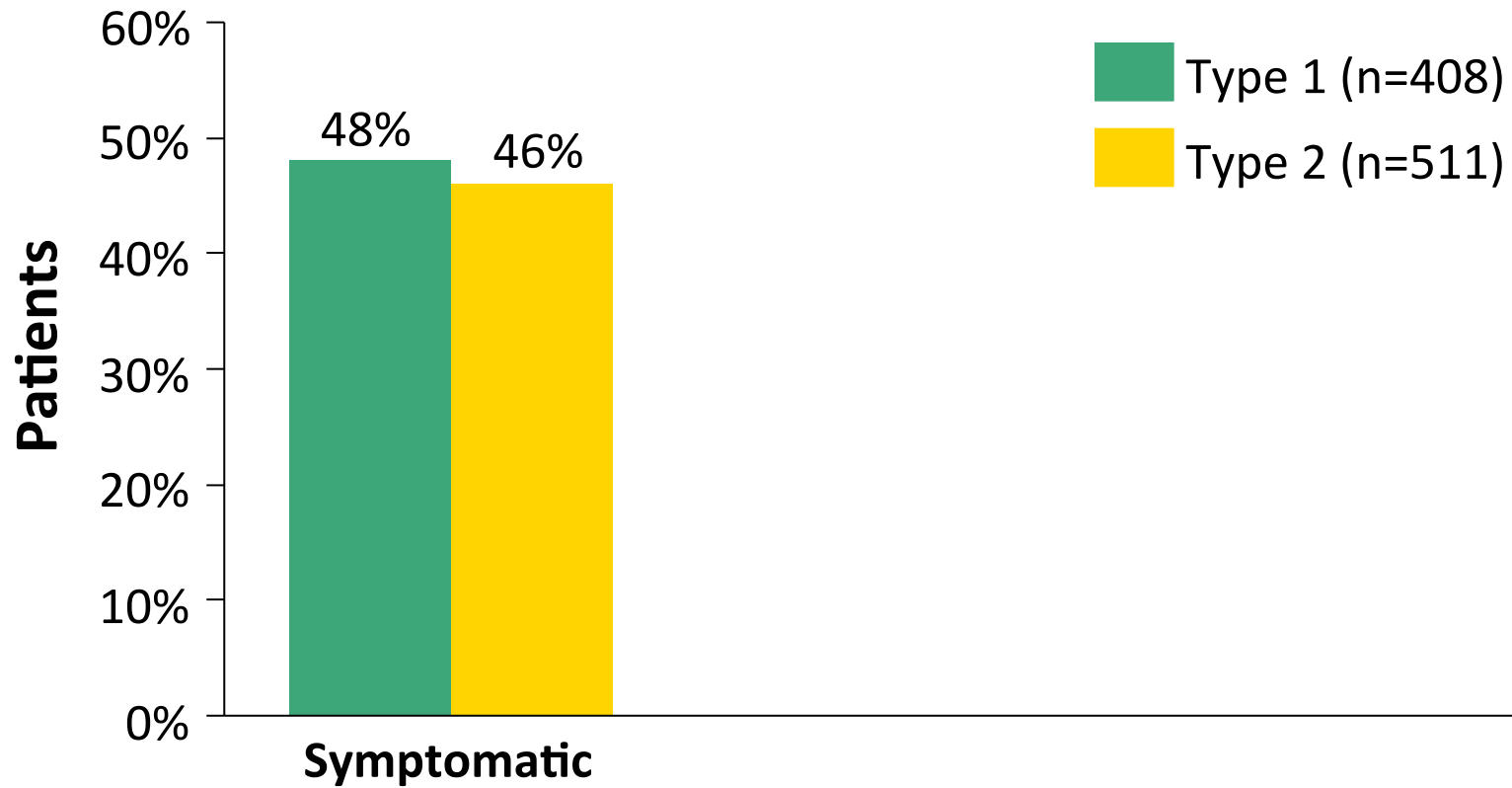


GP Diagnosis Rare in Patients with Type 2 Diabetes

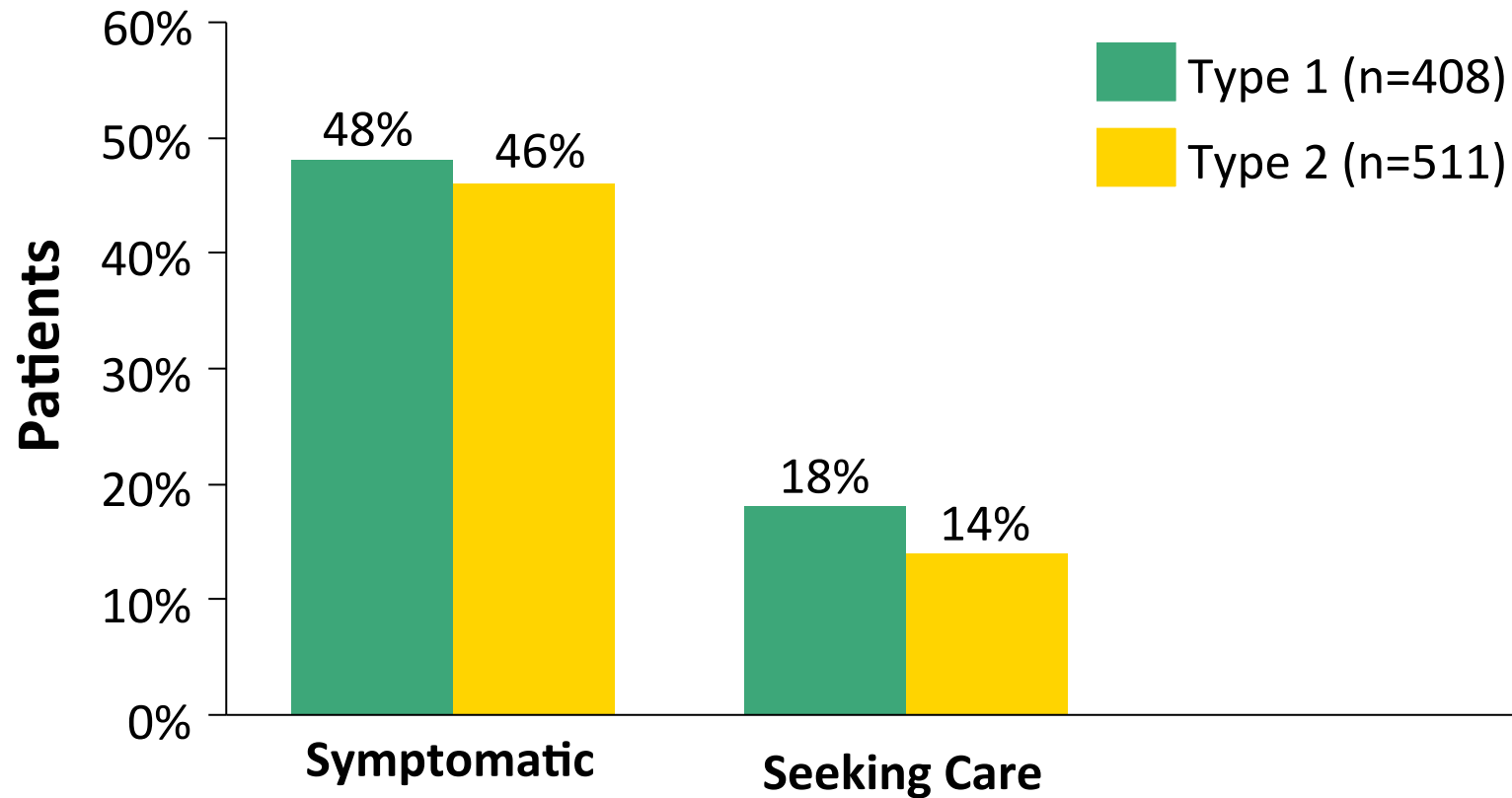
Patients with Moderate-Severe Symptoms During Previous 7 Days



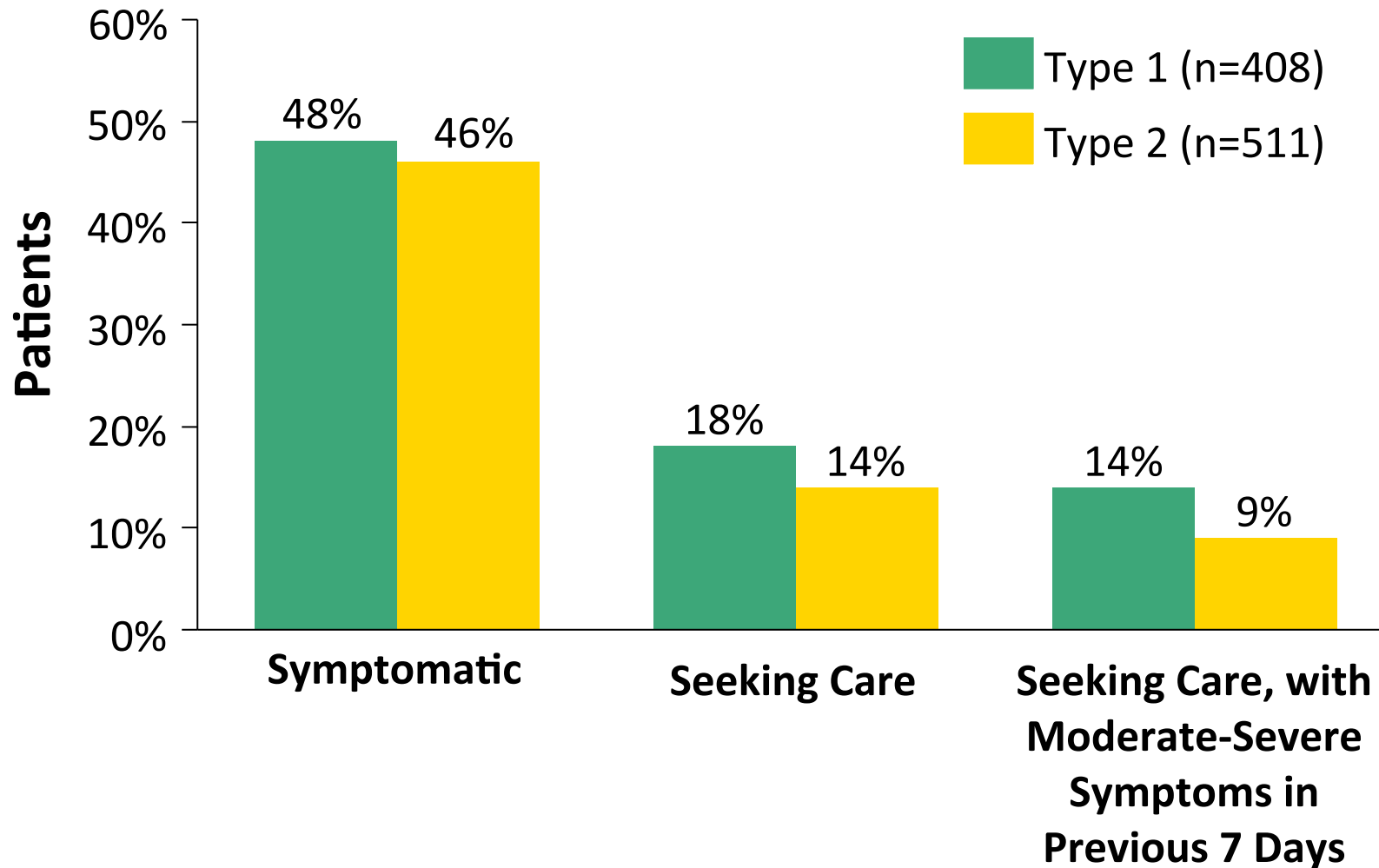
Symptoms of GP Are Common in Patients with Type 1 and Type 2 Diabetes



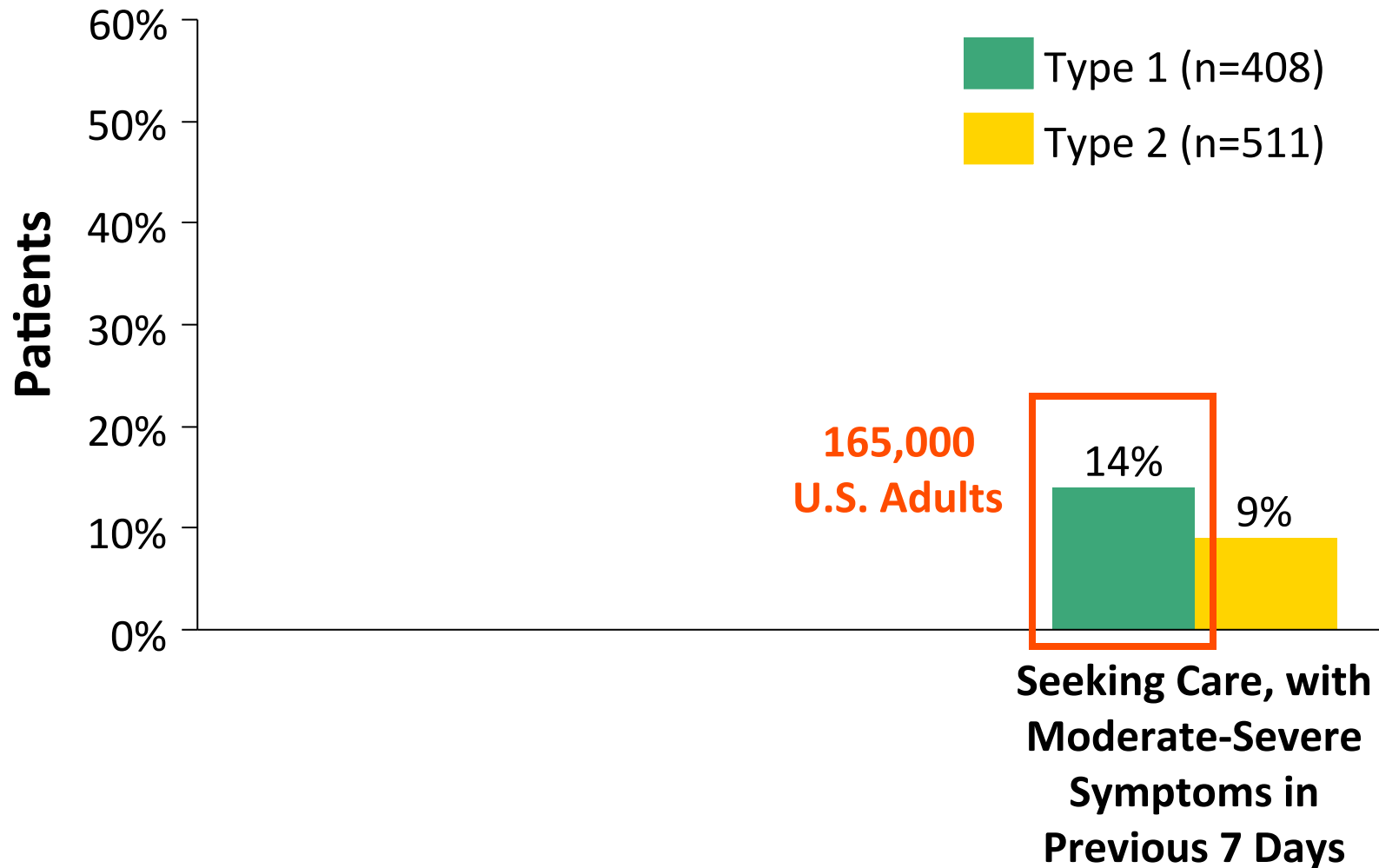
A Substantial Number of Patients with Both Type 1 and Type 2 Diabetes Seek Care for GP Symptoms



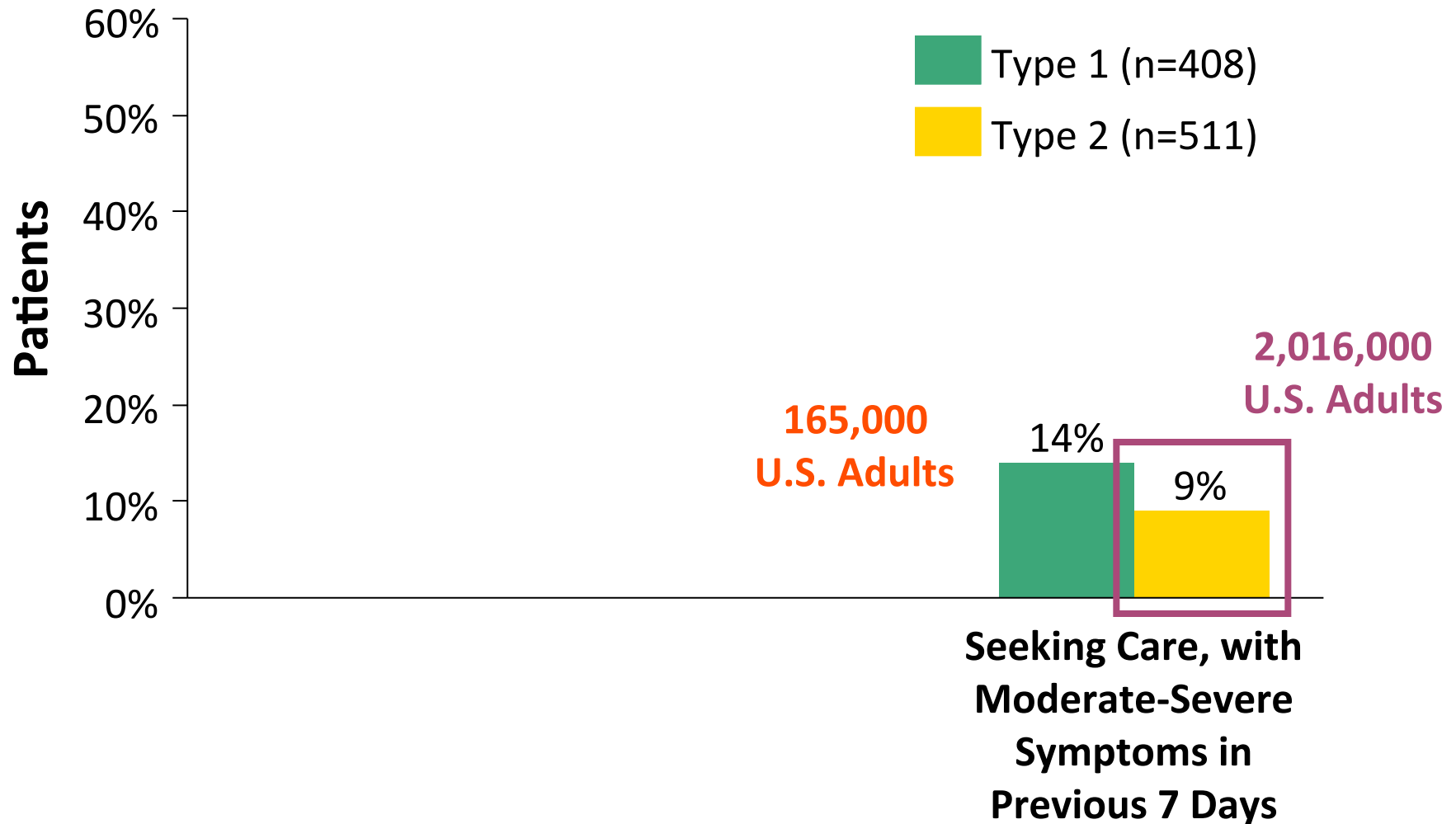
A Substantial Population of Patients with Diabetes Seek Care for Ongoing Moderate-Severe GP Symptoms



Within this Group, **Type 1** Diabetes is Likely a Substantial Cause of Symptomatic GP ... but...



By the Same Criteria, **Type 2** Diabetes is Likely the Predominant Cause of Symptomatic GP in the US



Summary

- Using focus group discussions and structured interviews, we developed a novel web-based survey tool for assessing symptoms of GP that is compliant with FDA guidelines for patient-reported outcomes
- A population-based assessment with this tool reveals that GP symptoms are substantially more prevalent than previously reported
- Patients with type 2 diabetes report GP symptoms at more than 80% of the rate of those with type 1 disease and report **moderate-severe** symptoms at 75% of the rate of those with type 1 diabetes
- Because of the substantially higher prevalence of type 2 diabetes, patients with this disorder are likely to account for the vast majority of GP overall
 - >2,000,000 type 2 diabetics in the U.S. seek care for moderate-severe symptoms
 - 165,000 type 1 diabetics meeting the same criteria

Summary

- Patients with type 2 diabetes seek care for symptoms of GP at approximately 75% the rate of those with type 1 disease
- Despite similar (or even higher) rates of GI evaluation, symptomatic patients with type 2 diabetes are substantially less likely to undergo specific (e.g., scintigraphic) assessment for GP
- Among diabetic patients with ongoing, moderate-severe symptoms of GP, those with type 2 diabetes are diagnosed with GP less than one-third as often as those with type 1 disease
- The basis for these differences in evaluation and diagnosis is not clear, but may include:
 - Different sites of care (type 2 diabetes more commonly treated by PCPs)
 - Difference in GI symptoms in type 2 diabetics (not detected by the assessment tool) that trigger an alternate GI evaluation
 - Underappreciation of the risk of GP in type 2 diabetics

Conclusions and Implications

- GP is likely underdiagnosed in patients with type 2 diabetes by a large margin
- Given the high prevalence of type 2 diabetes, these observations highlight the need for greater awareness of GP in this population and for more targeted and vigorous evaluation for this disorder
- The rising incidence of type 2 diabetes and its onset earlier in life predict a growing burden of GP, underscoring the need for improved diagnostic and treatment strategies for this disorder

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