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Is Functional Gallbladder Disease Truly Increasing? Results From The Rochester Epidemiology Project

Mohamed O. Abdelhamid, M.B.B.S.¹, Cornelius A. Thiels, D.O.¹, and Juliane Bingener, M.D.¹

¹Department of Surgery, Mayo Clinic, 200 First Street SW, Rochester, MN 55905, USA

Abstract

INTRODUCTION—Reports from US administrative databases showed an increase in cholecystectomy rate for functional gallbladder disorder (FGBD), a disease is not well recognized elsewhere. We aimed to identify the incidence and cholecystectomy rate for FGBD in an epidemiologically well-defined and prospectively studied population and compare results to published data.

METHODS—After IRB approval, we extracted data from the NIH funded Rochester Epidemiology Project. We used ICD-9 codes (575.8) and (575.9) to identify patients with FGBD from 2000–2014.

RESULTS—Between 2000–2014 we identified 253 patients with specified ICD-9 codes and no stones among a population of 135,000. Based on their medical records, 24 patients had confirmed FGBD, the incidence was 1.77/10,000 and cholecystectomy rate was for these patients was 70%.

CONCLUSION—The incidence of FGBD was much lower than State data with similar cholecystectomy rate. Additional investigation may be needed to understand if cholecystectomy rate is truly increasing.

Graphical abstract

Summary for Table of Contents: The incidence of functional gallbladder disorder, also known as biliary dyskinesia, is reported to be progressively up trending by administrative databases, along with cholecystectomy as the definitive treatment in the United States. This trend is not seen in other Western countries, resulting in concern for unnecessary cholecystectomy in the United States. We found out that the incidence for biliary dyskinesia and operative therapy in the Rochester epidemiology project was much lower than the reported incidence for the administrative data of the State.

Keywords

Functional gallbladder disorder; biliary dyskinesia; laparoscopy; cholecystectomy

Corresponding Author: Juliane Bingener, M.D., Mayo Clinic, 200 First Street SW, Rochester, MN 55905, Phone 507- 293-0767, Fax 507-284-5196, bingenercasey.juliane@mayo.edu.

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INTRODUCTION

Prior to 1970 few investigators speculated on the cause of presumably typical biliary symptoms in the absence of gallstones during surgery. However, with the introduction of scintigraphic methods and the ability to monitor temporal changes of bile excretion, accumulation and ejection from the gallbladder in the setting of symptomatic patients with no apparent gallbladder morphologic abnormality, the diagnosis of functional gallbladder disorder (FGBD) trended up. Within the last decade, publications quoted functional gallbladder disorder to comprise 26 to 38% of all diagnosis leading to cholecystectomy.¹ The reports estimated that 80% of the patients comprised within CPT codes describing not otherwise specified gallbladder disease fall under the diagnosis of FGBD based on a study reported by Preston et al.²

Functional gallbladder disorder, also known as biliary dyskinesia, was defined by various reviews as episodic pain located in the epigastrium or right upper quadrant and triggered by food intake, combined with documented impairment of the gallbladder function as defined by a decreased ejection fraction (EF). ROME III consensus summarized the criteria for functional gallbladder disorder.³ Ejection fraction has been documented using ultrasound, or using gallbladder scintigraphy with values <35% considered abnormal and 35–50% being equivocal.⁴ However, neither is considered gold standard in evaluating gallbladder function.⁵ As the rate of surgery appears to be increasing and neither the veracity of the diagnosis nor the outcome of surgical intervention appears certain, several authors have called for or attempted randomized controlled trials to further evaluate the paradigm.

We aimed to identify the incidence of FGBD and the rate for undergoing cholecystectomy for FGBD in an epidemiologically well-defined population and to compare results to previously published administrative data to better understand whether there is truly an increase of procedures in a well-defined population.

METHODS

Study Design and Patient Selection

After Institutional Review Board approval, we extracted data from the Rochester Epidemiology Project (REP), a unique population-based research infrastructure system that links together nearly all of the medical records of residents of Olmsted County, MN. Olmsted County includes a teaching and a community hospital serving a population base of about 135,000 people.⁶ We used the ICD-9 codes for ‘gallbladder disease not elsewhere specified’ (575.8) and ‘unspecified disorder of gallbladder’ (575.9) to identify all patients with FGBD from 2000 to 2014.

Data Collection

Patients’ demographics, diagnostic testing, additional diagnosis and imaging findings, including HIDA scan and EF measurements, were available for the teaching and community hospitals, using the REP system. We excluded patients whose postoperative pathology reported cholelithiasis.

Statistical Analysis

Descriptive statistics were reported as number (percentage) or mean $\pm$ SD. Differences between the two hospitals were compared using student t-test and Wilcoxon rank sum test for nonparametric variables. Statistical significance was defined as p-value < 0.05 .

RESULTS

Patients Demographics

Over a 15-year period, we identified a total of 607 patient records using the ICD-9 codes for unspecified gallbladder disease. The frequency of patients with unspecified gallbladder disease increased year over year from less than 10 patients per year in 2000–2003 to more than 40 patients/year for the years 2013–2014. (Figure 1) After excluding 354 patients with confirmed cholelithiasis, we reviewed the records of 253 patients in detail. Of those patients, 141 (56%) had ICD-9 code 575.8 and 112 (44%) had ICD-9 code 575.9. Of those 253 patients with no gallstones, 184 patients had a confirmed diagnosis other than FGBD (Table 1) on medical record review. In the teaching hospital setting incidental findings appeared commonly to be leading to the coding of nonspecified gallbladder disease. Sixty-nine patients had confirmed biliary symptoms with no gallstones on ultrasound, 25 patients were seen in a community hospital and 44 patients in a teaching hospital. In the community hospital, 22/25 (88%) of the patients underwent HIDA scan as part of the diagnostic workup compared to 18/44 (41%) in the teaching hospital.

Patients with confirmed biliary dyskinesia

Based on detailed review of their medical records, 24 of the 69 patients with biliary symptoms and no stones on ultrasound had confirmed FGBD as defined by ROME III criteria, 20 women (83%) and 4 men (17%) with a mean age of 38 ± 14 years. The overall incidence of FGBD in Olmsted County was 1.8/10,000 over the 15-year period. Of the patients with ICD-9 code 575.8, 15 (11%) had confirmed FGBD and of the patients with ICD-9 code 575.9, 9 (8%) carried the clinical diagnosis. The frequency of the diagnosis increased five-fold from 2 patients in the first 5-year time period (2000–2004) to 17 confirmed patients over the last 5-year period (2010–2014) (Figure 1). The REP population increased less than 20% during the timeframe. While some of the remainder patients may carry the clinical diagnosis of FGBD, we were unable to confirm the ROME III criteria from the medical record. Based on ROME III criteria, the rate of cholecystectomy for FGBD was 70% in both hospitals.

DISCUSSION

Laparoscopic cholecystectomy is regarded as the gold standard management to alleviate symptoms, but only one small clinical trial compared surgical and medical management.⁷ In the absence of any truly definitive studies, there has been a growing discrepancy between expert consensus and the common practice of cholecystectomy in the absence of stone disease with several authors calling for RCTs.^{8–11}

Recently, several authors have postulated that there is an increase in the incidence and the use of cholecystectomy for functional gallbladder disorder (FGBD) nationwide based on large administrative data sets.

The administrative data sets assume that 80% of patients with the ICD codes 575.8 and 575.9 carry the clinical diagnosis of FGBD.

Administrative data from REP in the current study suggests that the use of coding for nonspecified gallbladder disease has indeed increased 10-fold over the studied time period. The number of patients with confirmed FGBD by ROME III criteria increased 5-fold. However, the detailed medical record review suggests that in this data set 10% of patients had confirmed FGBD by ROME criteria and 70% of patients had another confirmed diagnosis. 26% of the patients in the community hospital with the relevant CPT codes had confirmed FGBD and 5% in the teaching hospital.

The incidence of FGBD in Olmsted County (1.8/10,000) was much lower than the previously published incidence in administrative data for Minnesota (30/10,000).¹¹ Only a small fraction of patients (11%) with the ICD-9 code 575.8 for unspecified gallbladder diagnosis had FGBD compared to the State Inpatient Sample which reported that FGBD accounted for more than 80% of administrative code 575.8. It is unclear if that is a single studies overestimation/practice pattern that has informed a number of large scale data reviews or if this difference is specific to the Rochester Epidemiology Project. Additional non-calculous findings may lead to cholecystectomy due to improve imaging modalities.

Medical practice patterns significantly differed between the teaching and community hospitals in the diagnostic work-up of FGBD. In the teaching hospital, patients would undergo extensive work-up to rule out all possible causes of biliary pain, where in the community hospital a high clinical suspicion of a biliary etiology with a normal ultrasound is a clear indication for cholescintigraphy (HIDA scan). The lack of a gold standard test raises questions about FGBD; this makes the evaluation for FGBD and comparing the surgical or medical management a challenge.

CONCLUSION

The incidence of FGBD in Olmsted County is increasing. However, the rate was much lower than the reported incidence in the state of Minnesota with a slightly lower rate for surgical management. Medical diagnosis patterns differed between teaching and community hospitals; whereas, the cholecystectomy rate was similar and only slightly lower than the previously published rate in a nationwide sample. Additional investigation may be needed to understand what mechanisms are responsible for the increasing rate of cholecystectomy.

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References

1. Bielefeldt K. The rising tide of cholecystectomy for biliary dyskinesia. *Aliment Pharmacol Ther.* 2013; 37:98–106. DOI: 10.1111/apt.12105 [PubMed: 23106129]
2. Preston JF, Diggs BS, Dolan JP, et al. Biliary dyskinesia: a surgical disease rarely found outside the United States. *Am J Surg.* 2015; 209(5):799–803. [PubMed: 25771131]
3. Drossman DA. The functional gastrointestinal disorders and the Rome III process. *Gastroenterology.* 2006; 130:1377–90. [PubMed: 16678553]
4. Cotton PB, Elta GH, Carter CR, et al. Rome IV. Gallbladder and Sphincter of Oddi Disorders. *Gastroenterology.* 2016 Feb 19. pii: S0016-5085(16)00224-9.
5. Lambie H, Cook AM, Scarsbrook AF, et al. Tc99m-hepatobiliary iminodiacetic acid (HIDA) scintigraphy in clinical practice. *Clin Radiol.* 2011; 66(11):1094–1105. [PubMed: 21861996]
6. United States Census Bureau. [Accessed May 5, 2017] 2017. <https://www.census.gov/>
7. Bielefeldt K, Saligram S, Zickmund SL, et al. Cholecystectomy for biliary dyskinesia: how did we get there? *Dig Dis Sci.* 2014; 59(12):2850–2863. [PubMed: 25193389]
8. Bingener J, Richards ML, Schwesinger WH, Sirinek KR. Laparoscopic cholecystectomy for biliary dyskinesia: correlation of preoperative cholecys tokinincholescintigraphy results with postoperative outcome. *Surg Endosc.* 2004 May; 18(5):802–6. Epub 2004 Apr. [PubMed: 15054652]
9. Yap L, Wycherley AG, Morphet AD, Toouli J. Acalculous biliary pain: cholecystectomy alleviates symptoms in patients with abnormal cholescintigraphy. *Gastroenterology.* 1991; 101(3):786–793. [PubMed: 1860640]
10. Thiels CA, Hanson KT, Chawla KS, et al. Functional gallbladder disease: Operative trends and short-term outcomes. *Surgery.* 2016 Jul; 160(1):100–5. [PubMed: 27129932]
11. Bielefeldt K. Regional Differences in Hospitalizations and Cholecystectomies for Biliary Dyskinesia. *Journal of Neurogastroenterology and Motility.* 2013; 19(3):381–389. DOI: 10.5056/jnm.2013.19.3.381 [PubMed: 23875106]

Figure 1.
Number of Rochester Epidemiology Project patients with diagnosis code for unspecified gallbladder disease and confirmed diagnosis by ROME III criteria per year

Table 1

List of Diagnosis under the ICD-9 codes in the Teaching and the Community Hospitals

Etiology	Overall (n=253)	TH (n=200)	CH (n=53)	p-value
Functional Gallbladder Disorder	24	10	14	<.0001 *
Acute Cholecystitis	13	13	0	
Acute Acalculous Cholecystitis	5	5	0	
Acute Suppurative Cholecystitis	1	1	0	
Acute Calculous Cholecystitis	5	5	0	
Acute Gangrenous Cholecystitis	1	1	0	
Acute Hemorrhagic Cholecystitis	1	1	0	
Other Biliary Etiology	13	12	1	0.2712
Adenomyomatosis	5	5	0	
Ampullary Stenosis	1	0	1	
Cholangiocarcinoma	1	1	0	
Gallbladder Cancer	2	2	0	
Gallbladder Duplication	1	1	0	
Primary Biliary Cirrhosis	1	1	0	
Primary Sclerosing Cholangitis	1	1	0	0.1390
Non-Biliary Etiology	52	37	15	
Metastatic Lesion(s)	14	13	1	
Incidental Finding(s)	137	115	22	0.0378 *

n= Number of patients, TH= Teaching Hospital, CH= Community Hospital,

* Statistical significance