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Temporal Analysis of the Incidence, Mortality and Disability-Adjusted Life Years of Benign Gallbladder and Biliary Diseases in High-Income Nations, 1990–2019

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Objective: The aim of this observational study was to analyze trends in the incidence, mortality, and disability-adjusted life years (DALYs) of benign gallbladder and biliary diseases across high-income countries between 1990 and 2019.

Background: Benign gallbladder and biliary diseases place a substantial burden on healthcare systems in high-income countries. Accurate characterization of the disease burden may help optimize healthcare policy and resource distribution.

Materials and methods: Age-standardized incidence rates (ASIRs), age-standardized mortality rates (ASMRs), and DALYs data for gallbladder and biliary diseases in males and females were extracted from the 2019 Global Burden of Disease (GBD) study. A mortality-incidence index (MII) was also calculated. Joinpoint regression analysis was performed.

Results: The median ASIRs across the European Union 15+ countries in 2019 were 758/100,000 for females and 282/100,000 for males. Between 1990 and 2019 the median percentage change in ASIR was +2.49% for females and +1.07% for males. The median ASMRs in 2019 were 1.22/100,000 for females and 1.49/100,000 for males with a median percentage change over the observation period of −21.93% and −23.01%, respectively. In 2019, the median DALYs was 65/100,000 for females and 37/100,000 among males, with comparable percentage decreases over the observation period of −21.27% and −19.23%, respectively.

Conclusions: International variation in lifestyle factors, diagnostic and management strategies likely account for national and sex disparities. This study highlights the importance of ongoing clinical efforts to optimize treatment pathways for gallbladder and biliary diseases, particularly in the provision of emergency surgical services and efforts to address population risk factors.

Keywords: biliary disease, gallbladder disease, incidence, mortality, trends

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The corresponding dataset for this study may be found in the supplemental digital content.

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INTRODUCTION

Benign gallbladder and biliary diseases pose serious challenges to global healthcare systems. Cholelithiasis, choledocolithiasis, cholangitis, and associated cholecystitis affect 20–25 million adults in the United States alone, while ultrasound, survey and necropsy studies from Europe have demonstrated a prevalence of 6–21%.[1–3] Global mortality estimates remain low at approximately 0.6% despite clinically relevant morbidity.[4,5] This heterogeneous group of diseases is associated with close anatomical relations and a shared profile of risk factors, including increasing age, obesity, diabetes, hyperlipidemia, and metabolic syndrome.[2,6,7] With rising intervention rates reported in high-income nations and >700,000 cholecystectomies performed in the United States per annum at a cost of $6.5 billion,[4,8] this group of diseases is also of substantial interest to policymakers.

The Global Burden of Disease (GBD) dataset has previously been used to investigate worldwide epidemiological trends in gallbladder and biliary diseases, and trends in individual low- and middle-income nations.[9–11] However, incidence data has not been reported, and there are no studies with a focus on high-income countries, where the burden of disease is greatest. The broad scope of existing GBD literature also severely limits the specificity of epidemiological insights, and epidemiological data from other sources are often confined to individual nations.[1,8,12–15] As a result, it is likely our current understanding of the complex burden of disease across high-income countries is suboptimal. Therefore, the aim of this study was to characterize and compare trends in the incidence, mortality, mortality-incidence index, and DALYs of benign gallbladder and biliary diseases across high-income countries between 1990 and 2019, to inform the ongoing development of prevention, screening, and treatment strategies.

MATERIALS AND METHODS

Data Source

Data were extracted from the GBD database. The GBD study is a publicly accessible source of mortality and disability data (deaths, death rates, years of life lost due to premature mortality, incidence, and prevalence) for 369 diseases/injuries compiled from 204 contributing nations.[16] Commissioned by the World Health Organization, the study collates data from multiple sources (inpatient and outpatient hospital encounter data, systematic reviews, disease registries, and claims data) relating to various diseases, risk factors and procedures based on the 10th iteration of the International Classification of Disease (ICD-10) coding system. Codes K80–K83 correspond to gallbladder and biliary diseases: gallbladder and biliary calculi, cholecystitis, cholangitis, and other diseases of the gallbladder and biliary tract (Table 1). Malignant diagnoses are grouped and coded separately in the GBD dataset, and the majority of benign gallbladder and biliary diseases relate to acute presentations of cholecystitis and cholangitis. Population estimates and confidence intervals for disease death rates, prevalence, incidence, and disability-adjusted life years (DALYs) are generated using Bayesian statistical methods, which are made available online via the GBD results tool (http://ghdx.healthdata.org/gbd-results-tool).

Mortality estimates for gallbladder and biliary diseases were derived from vital registration data from the cause of death database modeled alongside location level covariates (body mass index, socio-demographic index, education years per capita, log lag distributed income, liters of alcohol consumption per capita, healthcare access and quality index, and exposure variable for low polyunsaturated fatty acids). A standard cause of death ensemble model (CODEm) was used to produce sex-specific mortality estimates.

TABLE 1.

ICD-10 Code Specification for Gallbladder and Biliary Diseases

ICD-10 Code	Corresponding Pathology
K80.0	Calculus of gallbladder with acute cholecystitis
K80.1	Calculus of gallbladder with other cholecystitis
K80.2	Calculus of gallbladder without cholecystitis
K80.3	Calculus of bile duct with cholangitis
K80.4	Calculus of bile duct with cholecystitis
K80.5	Calculus of bile duct without cholangitis or cholecystitis
K80.8	Other cholelithiasis
K81.0	Acute cholecystitis
K81.1	Chronic cholecystitis
K81.8	Other cholecystitis
K81.9	Cholecystitis, unspecified
K82.0	Obstruction of gallbladder
K82.1	Hydrops of gallbladder
K82.2	Perforation of gallbladder
K82.3	Fistula of gallbladder
K82.4	Cholesterolosis of gallbladder
K82.8	Other specified diseases of gallbladder
K82.9	Disease of gallbladder, unspecified
K83.0	Cholangitis
K83.1	Obstruction of bile duct
K83.2	Perforation of bile duct
K83.3	Fistula of bile duct
K83.4	Spasm of sphincter of Oddi
K83.5	Biliary cyst
K83.8	Other specified diseases of biliary tract
K83.9	Disease of biliary tract, unspecified

Incidence estimates were produced from clinical administrative data (claims and inpatient hospital data) and a systematic literature review of prevalence data, with meta-regression and logit-transformation methods being used to produce nonreference incidence data. Hospital discharge data were adjusted using correction factors producing an estimate of the number of cases to adjust for repeat presentations. A DisMod-MR 2.1 model for both symptomatic and asymptomatic cases of gallbladder and biliary disease was used to produce outcome estimates by age, sex, year, and country.

DALYs for gallbladder and biliary disease are calculated as the sum of years lived with disability (YLD) and years of life lost (YLL). YLDs were calculated from DisMod-MR 2.1 model symptomatic case estimates divided according to the severity distributions derived from Medical Expenditure Panel Survey data (ie, mild, moderate, or severe)[17] and adjusted via a microsimulation process. YLL is calculated by multiplying the standard life expectancy at the age of death by the estimated number of deaths from gallbladder and biliary disease. The full GBD methodology with detailed descriptions of data sources and statistical analysis has previously been published.[16]

GBD data reliability is evaluated using a 5-star scale based on availability and completeness. A 5-star rating was awarded to 10 countries included in this analysis denoting greater than 85% data completeness (Australia, Austria, Canada, Finland, Ireland, Italy, Norway, Sweden, UK, and the United States). The remaining nine countries received a 4-star rating denoting greater than 65% data completeness (Belgium, Denmark, France, Germany, Greece, Luxembourg, Netherlands, Portugal, and Spain).

Data Handling

Age-standardized incidence rates (ASIRs), age-standardized mortality rates (ASMRs), and DALYs per 100,000 population for gallbladder and biliary diseases were extracted by sex for each year available in the GBD dataset (1990–2019). A prolonged observation period was selected to facilitate a comprehensive assessment of epidemiological trends in light of recent medical developments. Incidence data was selected over prevalence data due to the acute nature of most coded diseases. Data were extracted for each of the EU15+ countries (Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, UK, and the United States), a set of high-income nations grouped on account of comparable levels of healthcare expenditure. United Nations Population Division's World Population Prospects data is used to perform age standardization of GBD data.[18] A standard population estimate is calculated based on a nonweighted average of a percentage of the population of all countries in 5 yearly age brackets from 2010 to 2035.

Sex-specific absolute and relative changes in ASIRs, ASMRs, and DALYs were calculated for each nation based on the difference between rates at the start and end of the observation period (ie, 1990 and 2019). The annual mortality-to-incidence index (MII) was calculated per sex in each country by dividing the ASMR by the ASIR and multiplying by 1000 to provide a representation of individual case fatality rates. This study has been reported in line with Strengthening The Reporting Of Cohort Studies in Surgery (STROCCS) guidelines.[19]

Statistical Analysis

Joinpoint software developed by the United States National Cancer Institute Surveillance Program (Joinpoint Command Line V4.9.1.0, National Cancer Institute, USA) was used to perform a joinpoint regression analysis to evaluate temporal trends in the disease burden of the gallbladder and biliary diseases.[20]

The analysis fits the simplest statistical model to a particular dataset by connecting different line segments on a logarithmic scale. These line segments are known as joinpoints, with the simplest model being an uninterrupted line (ie, zero joinpoints). Joinpoints are added to the model using a Monte Carlo permutation method. The software calculates the estimated annual percentage changes (EAPC) for each Joinpoint with 95% confidence intervals to establish if there is a difference from the null hypothesis that no annual change occurs. The estimated annual percentage changes allow the assessment of changing trends at a constant percentage per year. Each Joinpoint in the final model represents an increasing or decreasing trend (*P* value <0.05).

RESULTS

The analysis included data from 19 high-income countries across 30 years. Over the observation period, significant changes were observed in the ASIRs, ASMRs, and DALYs for gallbladder and biliary diseases in all 19 countries. Sex-specific ASIRs, ASMRs, and DALYs per 100,000 and MII per country between 1990 and 2019 are displayed in Supplemental File 1, http://links.lww.com/AOSO/A361. Sex-specific joinpoint regression analyses for gallbladder and biliary disease ASIRs, ASMRs, DALYs, and MIIs between 1990 and 2019 are presented in Supplemental File 2, http://links.lww.com/AOSO/A362.

Incidence

Overall, increasing ASIRs were observed in 13 of 19 countries for females and 11 of 19 countries for males (Figure 1). Generally, the greatest rate of increase was observed during the 2000s. In 2019, the median ASIR across EU15+ nations was 758/100,000 among females and 282/100,000 among males. In the same year, the highest ASIRs were observed in the UK, Italy, and Norway for females (2,222/100,000, 2,035/100,000, and 1,458/100,000, respectively) and Italy, UK, and Norway for males (1,407/100,000, 963/100,000, and 934/100,000, respectively). The lowest ASIRs were observed in Portugal, Spain, and France for females (303/100,000, 443/100,000, and 466/100,000, respectively) and Portugal, Spain, and Belgium for males (127/100,000, 161/100,000, and 220/100,000, respectively). The median percentage change over the observation period was +2.49% for females and +1.07% for males. The greatest percentage decrease in ASIR was observed in the USA for females, and in France for males (−16.63% and −32.40%, respectively).

Mortality

Overall, a decrease in ASMR was observed in 16 of 19 countries for females and 15 of 19 countries for males between 1990 and 2019 (Fig. 2), despite increasing ASMRs in certain countries during the 2000s (Germany, Greece, Ireland, Italy, Netherlands, Portugal, Spain, UK, USA). In 2019, the median ASMR across EU15+ nations was 1.22/100,000 among females and 1.49/100,000 among males. In the same year, the highest ASMRs among females were observed in Spain, UK, and Belgium (2.02/100,000, 1.98/100,000, and 1.60/100,000, respectively) and in Spain, UK, and Portugal among males (2.49/100,000, 2.00/100,000, and 1.91/100,000, respectively). The lowest ASMRs among females were observed in Austria, the United States, and Canada (0.77/100,000, 0.99/100,00, and 1.03/100,000, respectively) and the lowest among males in Austria, Australia, and Ireland (0.98/100,000, 1.21/100,000, and 1.24/100,000, respectively). The median percentage change over the observation period was −21.93% among females and −23.01% among males. The greatest overall decrease in ASMRs were observed in Austria for both females and males (−51.55% and −47.07%, respectively) and the greatest increase in ASMRs were observed in the UK for both females and males (+52.44% and +45.41%, respectively).

Mortality-to Incidence Index

Overall, decreasing individual case mortality was observed in 16 of 19 nations for females and 15 of 19 nations for males (Fig. 3), despite an initial increase in MIIs in certain countries during the first half of the observation period (Denmark, France, Portugal, Spain, UK, and the United States). In 2019, the median MIIs across EU15+ nations were 1.72 and 5.04 for females and males, respectively. In the same year, the highest MIIs among females were observed in Portugal, Spain, and Belgium among females (5.02, 4.56, and 2.80, respectively) and in Spain, Portugal, and Belgium among males (15.46, 15.04, and 7.62, respectively). The lowest MIIs were observed in Italy, Austria, and Norway among both females (0.60, 0.71, and 0.86, respectively) and males (1.13, 1.95, and 1.62, respectively). The median percentage change in MII over the observation period was −31.81% for females and −22.66% for males, with the greatest overall decrease among females observed in Finland (−46.65%) and among males in Norway (−40.53%). The greatest overall increase in MII was observed in Denmark for both females and males (+34.34% and +30.60%, respectively).

DALYs

Overall, a decrease in DALYs was observed in 16 of 19 nations for both females and males (Fig. 4). In 2019, the median DALYs across EU15+ nations were 65/100,000 for females and 37/100,000 among males. In the same year, the highest DALYs among females were observed in the UK, Italy, and Norway (222/100,000, 152/100,000, and 121/100,000, respectively) and the highest among males in Italy, UK, and Norway (115/100,000, 106/100,000, and 84/100,000, respectively). The lowest DALYs among females were observed in Portugal, France, and Spain (41/100,000, 45/100,000, 53/100,000, respectively) and among males in Ireland, Sweden, and Luxembourg (33/100,000, 34/100,000, and 34/100,000, respectively). Over the observation period, the median percentage change in DALYs was −21.27% among females and −19.23% among males. The greatest overall decrease was observed in France for both females and males (−34.62% and −40.24%, respectively).

DISCUSSION

In this observational study of gallbladder and biliary disease trends in high-income nations over 30 years, overall decreases in mortality, mortality-to-incidence index, and DALYs were noted in the majority of EU15+ nations. Contrastingly, incidence trends were more variable, with 11 of 19 nations reporting an increase in ASIR over the observation period. The most notable increases in ASIR occurred during the 2000s. More broadly, observed sex disparities include higher ASIRs and DALYs among females but poorer individual case mortality among males (MII), in keeping with wider epidemiological data. It is likely that a complex interaction of contributory factors drives these temporal trends, primarily related to international variation in diagnostic and management strategies and risk factor epidemiology.

First, it seems likely that developments in medical imaging technology contribute to the increasing ASIRs and declining ASMRs/MIIs observed in certain nations over the observation period. Specifically, this relates to the more widespread utilization of magnetic resonance cholangiopancreatography (MRCP) and dual energy computed tomography in the diagnosis of gallbladder and biliary disease since the 1990s.[21,22] While

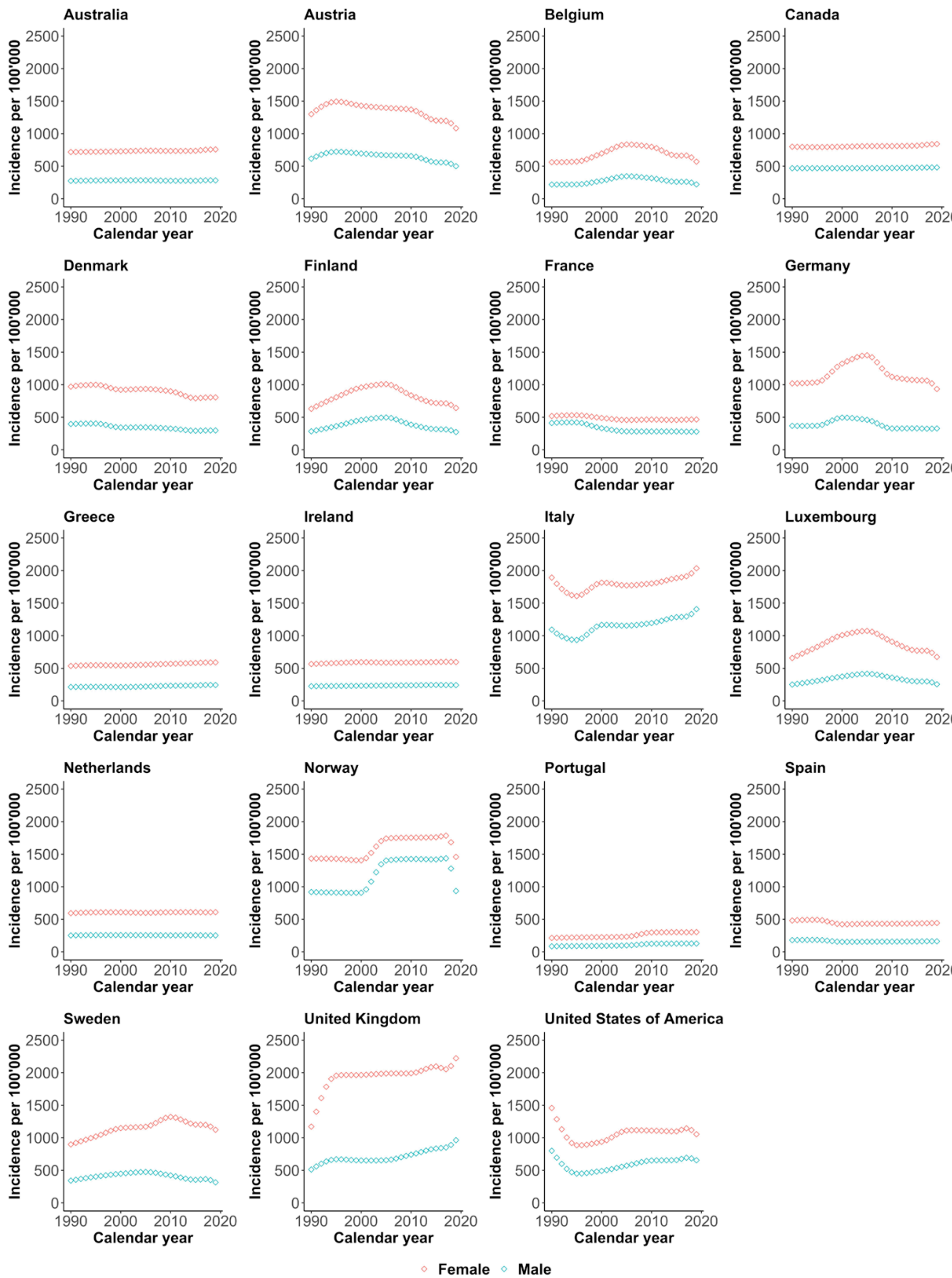

FIGURE 1. Incidence trends for males and females in EU15+ countries. Symbols represent raw data, age-standardized incidence rates (ASIR) per 100,000. Blue lines represent males and red lines females.

conventional trans-abdominal ultrasonography has reported sensitivity as high as 94–97%, MRCP provides greater diagnostic specificity in cases of biliary obstruction, facilitating rapid treatment implementation.[23,24] The specificity of computed tomography imaging has also increased in recent decades with the evolution of helical imaging technology. It remains a particularly useful tool in the evaluation of the postoperative patient, with a reported sensitivity of 95% for the detection of intra-abdominal biliary collections.[23]

Second, developments in endoscopic and laparoscopic techniques may account for the declining ASMRs, MIIs, and DALYs observed over the past 3 decades. Endoscopic retrograde

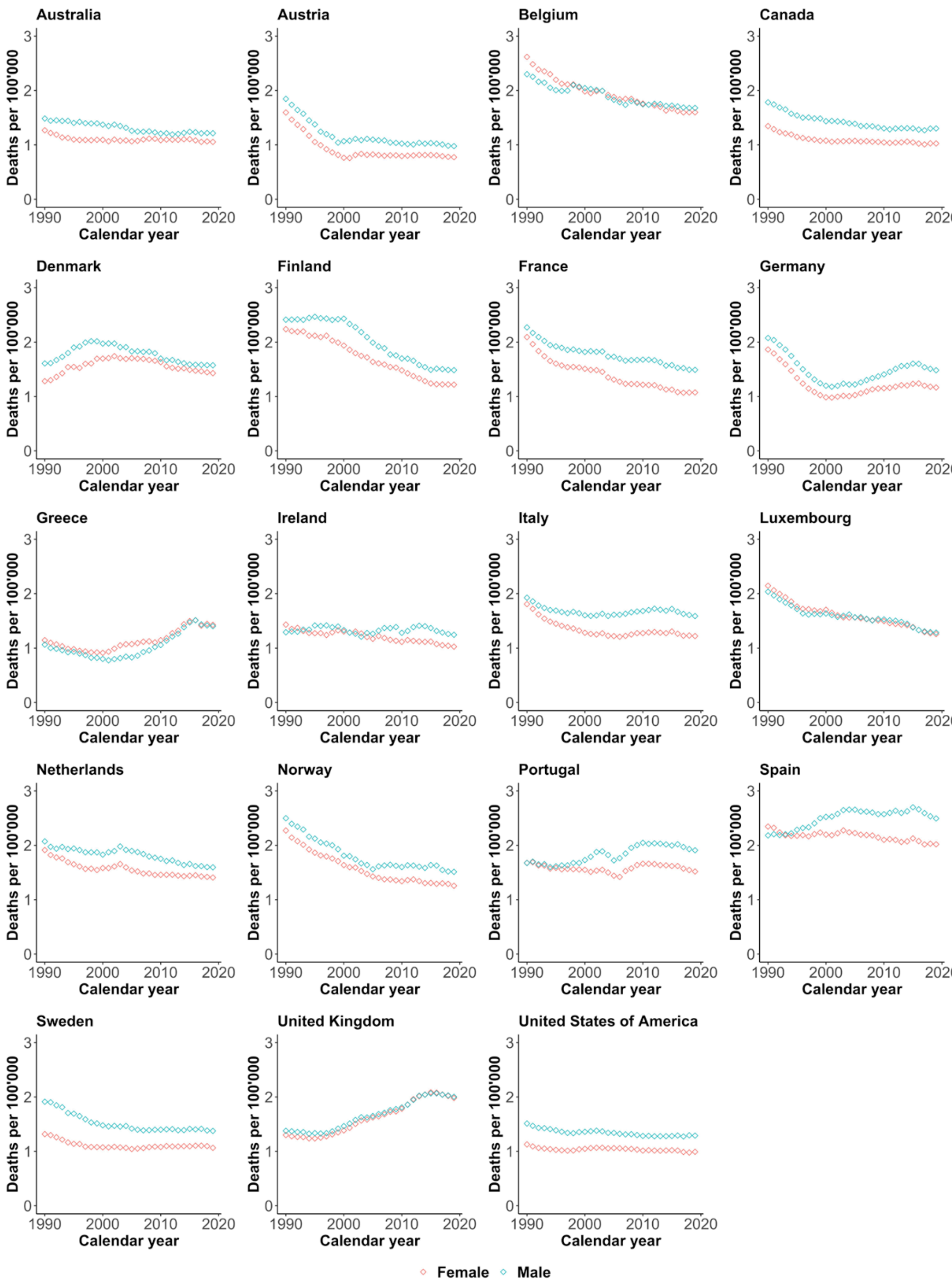

FIGURE 2. Mortality trends for males and females in EU15+ countries. Symbols represent raw data, age-standardized mortality rates (ASMR) per 100,000. Blue lines represent males and red lines females.

cholangiopancreatography (ERCP) usage steadily increased over the first 2 decades of the observation period, changing from an exclusively diagnostic to a therapeutic modality.[14] While ERCP mortality is generally comparable to laparoscopic cholecystectomy in gallstone disease,[25] US data suggest that a decline in unsuccessful ERCP has been associated with reduced mortality in this patient population. This may, in part, account for the decreasing ASMR and MII trends, which is particularly significant given that comorbidity has increased over time. Additionally, robotic surgical techniques have been increasingly used over the past decade with data reporting lower rates of conversion to open cholecystectomy and safe application in patients with anatomical

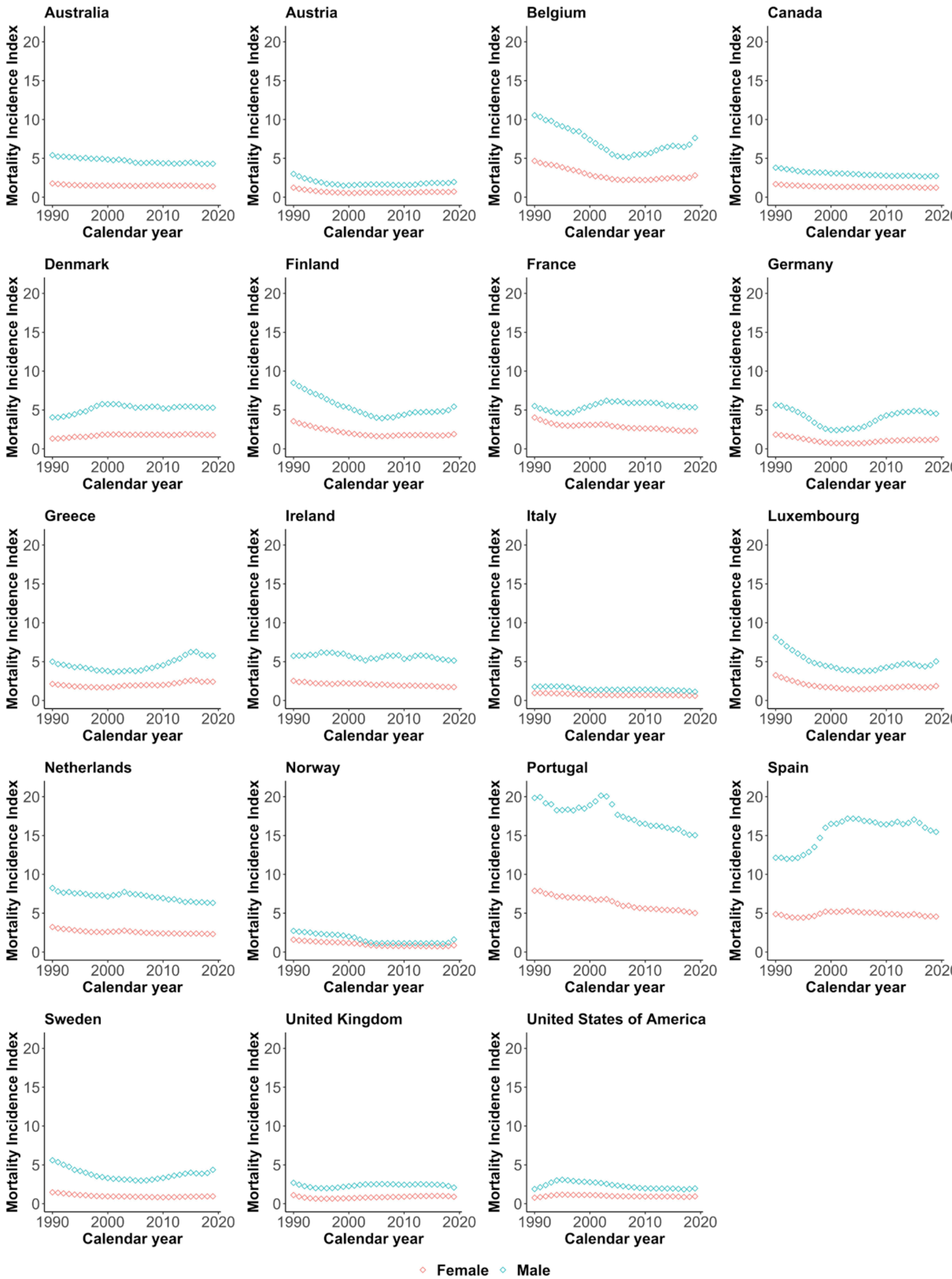

FIGURE 3. Mortality-to-incidence index trends for males and females in EU15+ countries. Symbols represent raw data, age-standardized incidence rates (ASIR) per 100,000. Blue lines represent males and red lines females.

variation and complex viscus pathology.[26–30] This may contribute in a minor sense to the declining DALY trends observed in the latter section of the observation period, such as the United States where much of this research has been conducted.

Also relevant is the transition from open to laparoscopic cholecystectomy and a corresponding increase in the number of cholecystectomies performed over the observation period, as reported in the UK and US data.[15,31] Numerous studies have demonstrated improved morbidity and a shorter length of inpatient stay associated with laparoscopic compared to open cholecystectomy, which may account for the decreased DALYs observed.[32,33] Several studies have also demonstrated fewer

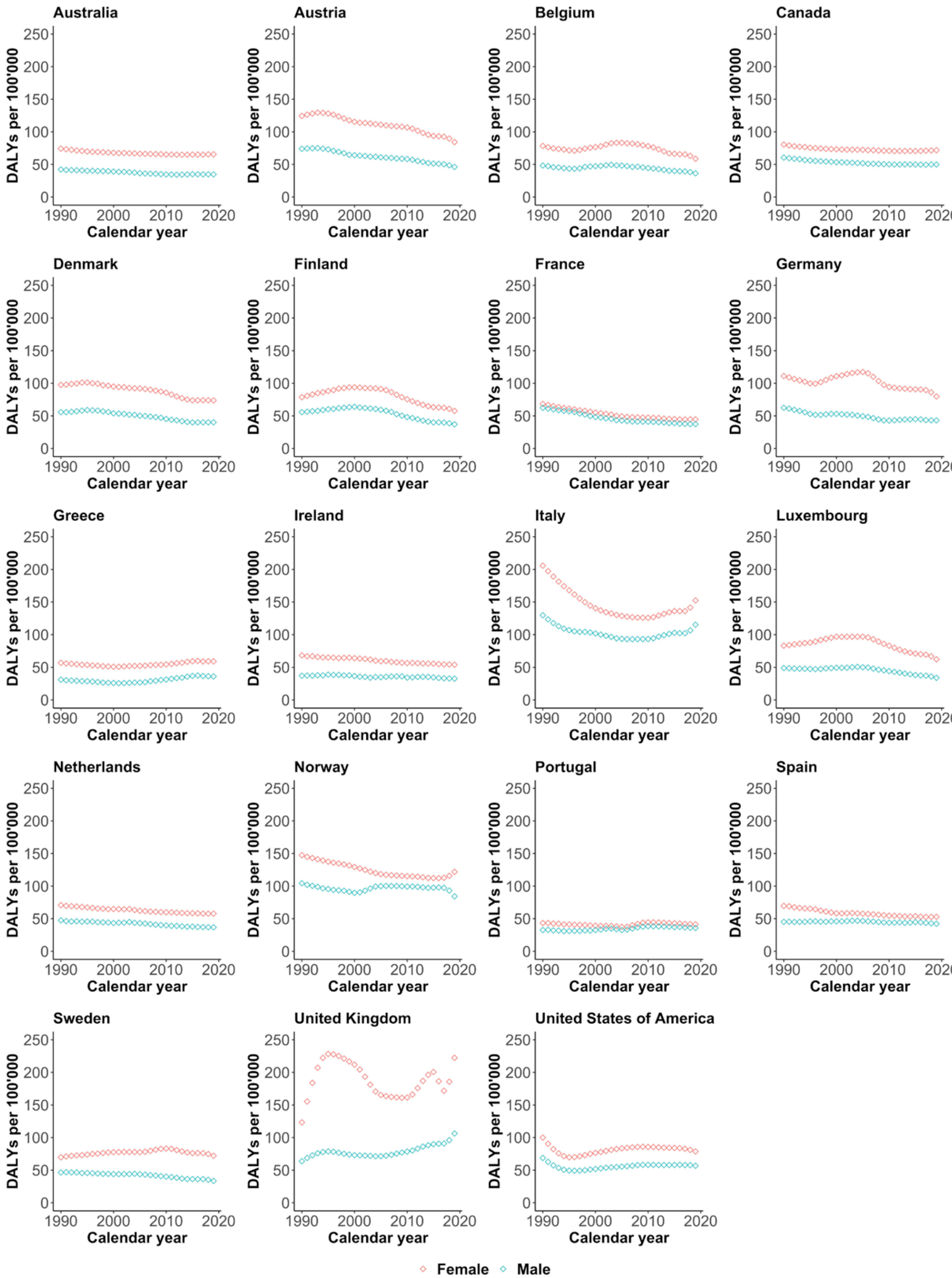

FIGURE 4. Disability-adjusted life years (DALYs) trends for males and females in EU15+ countries. Symbols represent raw data, age-standardized incidence rates (ASIR) per 100,000. Blue lines represent males and red lines females.

complications, fewer work days lost, and reduced hospital costs associated with early compared to delayed laparoscopic cholecystectomy for gallstone disease.[34] Despite early intervention being recommended by the UK National Institute for Health and Care Excellence in 2014,[35] UK practice of this approach has remained relatively poor, which may contribute to the higher ASMRs and DALYs observed compared to other nations such as the United States.[36–38]

Third, changes to modifiable risk factor epidemiology may contribute to the ASIR trends observed. The comparatively low ASIRs observed in Greece, Portugal, and Spain may be partially accounted for by the Mediterranean diet, with preliminary data suggesting the diet may be associated with a reduced risk of symptomatic gallstone disease and the need for cholecystectomy.[39,40] Other explanations may include shared lifestyle habits (smoking and physical activity, etc.) and genetic traits. Interestingly, these 3 nations report comparatively high MII, which may result from a latent shift from curative to preventative healthcare policy in the Mediterranean region, as highlighted in recent Spanish reports.[41,42] Conversely, certain Northern European nations (Austria, Denmark, Germany, Norway, Sweden, and the UK) with high rates of metabolic syndrome report higher ASIRs in keeping with the risk factor profile of this group of diseases.[43] Italy represents an outlier in the Mediterranean region, but the observed trends may result from higher rates of asymptomatic disease detected on population screening, which would correspond to the very low MIIs observed.[44] Alternatively, the specific clusters of metabolic syndrome components prevalent in certain regions of Italy are in keeping with Northern European nations, which may also contribute.[43]

The reported data offer current insights into the epidemiological trends of gallbladder and biliary diseases in high-income nations, illustrating geographical variation and disparities. This information may assist policymakers in developing therapeutic pathways to address the increasing incidence of disease. Specifically, this may include plans to increase MRCP and ERCP capacity, increase emergency surgery capacity through the implementation of services to facilitate early cholecystectomy (such as 'hot gallbladder' clinics), and develop public health measures to mitigate the impact of metabolic syndrome.[45] There is also a need to improve the quality and coverage of gallbladder and biliary disease registries to guide treatment policies and programs in the wake of increasing incidence rates. Presently, most registry data relates to cancer, with benign gallbladder and biliary disease registries few in number.[46] Future studies may perform interval evaluation of epidemiological trends in the wake of more widespread use of newer treatment modalities, including endoscopic ultrasound-guided interventional procedures including lumen-apposing metal stents.[47] Alternatively, future research may further investigate individual trends and/or factors in a subset of these countries, such as the decreasing ASIRs observed in certain nations.

Strengths and Limitations

The data in this analysis offer comprehensive and current insights into trends in gallbladder and biliary diseases across high-income nations, illustrating various disparities. Data are standardized and of relatively high quality due to garbage code correction processes performed by the GBD investigators.[48] Highlighting these data trends may assist policymakers in the development and adaptation of prevention, screening, and treatment pathways. The limitations, common to all registry and observational studies, include an inability to establish causal inference secondary to the probable existence of confounding factors, and differences in data collection practices and coding systems. In the case of gallbladder and biliary disease, these may relate to local variation in treatment protocol and the underdiagnosis or misclassification of pathology. It is also beyond the scope of this analysis to account for every country-specific epidemiological variation due to the large number of probable underlying factors; hence, the most widely applicable factors are prioritized.

CONCLUSIONS

Overall increases in ASIRs and decreases in ASMRs, MIIs, and DALYs for gallbladder and biliary diseases were observed across most EU15+ countries between 1990 and 2019. ASIRs were higher among females and mortality and DALYs among males. Variations in lifestyle factors and diagnostic and management strategies likely account for national and sex disparities. This study highlights the importance of ongoing clinical efforts to optimize treatment pathways for gallbladder and biliary diseases, particularly in the provision of emergency surgical services and efforts to address population risk factors such as metabolic syndrome.

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