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Review Article

Need for restrictive criteria to define symptomatic cholelithiasis to avoid unnecessary cholecystectomies-evidence from the literature review

Naveed Nabi*

Department of General Surgery, SKIMS Medical College Bemina, Srinagar, Jammu and Kashmir, India

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***Correspondence:**
Dr. Naveed Nabi,
E-mail: drnaveednabi58@gmail.com

ABSTRACT

Gall stone disease (GSD) is one among the most common reasons for which patients flock the office of general surgeons and cholecystectomy is one of the most common surgeries performed worldwide. Though majority of the patients are asymptomatic but a considerable number among them are deprived of their vital gall bladder for just or unjust reasons. With the introduction of laparoscopic cholecystectomy, there has been significant escalation in unnecessary cholecystectomies leading to excessive burden on health care system as well as subjecting patients to undue surgical risk. Considering the benign natural history of GSD, a restrictive strategy should be adopted while deciding surgical management for GSD. In this article, the author has given evidence from already published literature to support his views. Preoperative and sincere assessment of each symptom with exclusion of functional disorders and due consideration of patient's life expectancy are paramount in reducing unnecessary cholecystectomies as well as ensuring long tern relief of symptoms post-surgery.

Keywords: GSD, Cholecystectomy, Restrictive criteria, Historical evolution of cholecystectomy

INTRODUCTION

Cholelithiasis contributes significantly to global healthcare burden and is the most prevalent medical abnormality in the pancreatobiliary system.[1,2] It is estimated that gall stones affect 10-15% of population in United States which constitutes around 25 million people. However, its prevalence varies among different populations (Figure 1). Among American adults, the prevalence of gallstone disease is about 10% while in Western Europe, the prevalence ranges from 5.9 to 21.9%. In Asian countries, prevalence ranges from 3.2 to 15.6%.[3]

Gallstone disease (GSD) is a leading cause for hospital admissions related to gastrointestinal problems.[4] In United States it has been estimated that 1.8 million ambulatory care visits each year are because of cholelithiasis. These numbers are likely an underestimate because laparoscopic cholecystectomy is often performed as a day-care procedure and thus not included in hospital statistics that require overnight admission. Cholecystectomy is one among the most common surgeries performed by general surgeons worldwide, hence, contributing substantially to overall health care costs. The direct and indirect cost of gallbladder disease represents a consumption of ~$6.2 billion annually in the U.S, with over 750,000 operations being performed annually.[5] The number of surgical procedures for cholelithiasis has risen markedly in developed countries since 1950.[6] The introduction of laparoscopic cholecystectomy in 1989 further increased the cholecystectomy rate.[6-8] From 1990 to 1993, there was a 28% escalation in the number of cholecystectomies performed.[9] The change in practice resulted from the laparoscopic surgical approach, which represented a less

invasive, more cosmetically acceptable operation while providing a lower surgical risk compared to the then conventional or "open" procedure. This likely resulted in more surgeries being done in patients who were previously thought to be high risk, or in those who had minimal symptoms.

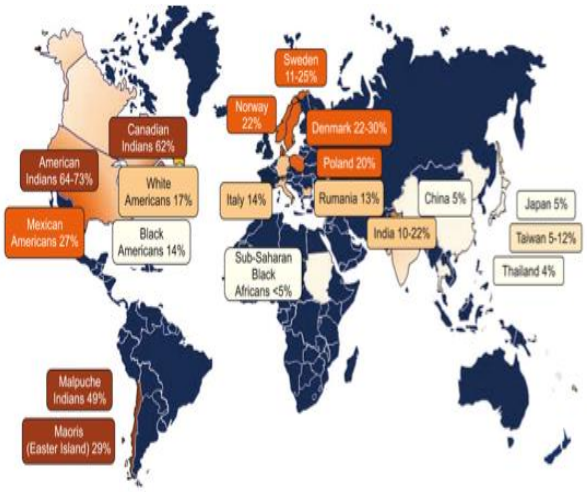

Figure 1: Worldwide prevalence of gallstones in females based on ultrasonographic surveys.[45]

With the adoption of laparoscopic approach, the speculation of inappropriate increase in the rate of cholecystectomies seems justifiable to the author of this article. A thorough literature review was done to support the above hypothesis and hence, give an insight into the need for strict definition of symptomatic cholelithiasis which happens to be absolute indication of Cholecystectomy and most common reason for which cholecystectomies are done.

HISTORICAL EVOLUTION IN SURGICAL MANAGEMENT OF GSD

The first note of gallstones was given in 1420 by a pathologist Antonio Benevieni, in a woman who died with abdominal pain.[10] However, there are reports of Gallstones being found in the gallbladders of Egyptian mummies dating back to 1000 B.C.[11] The first encounter of gallstones with a surgeon dates back to 1687 when Der Wiel, while operating a patient with purulent peritonitis accidentally found gallstones.[12]

Jean-Louis Petit (founder of gall bladder surgery) in 1733, suggested that in a patient with cholelithiasis, gallstones should be removed followed by drainage of the gall bladder, thus creating a fistula, which he successfully performed in 1743.[12] In 1859 Thudichum proposed a two-stage elective cholecystostomy.[13] In the first stage, the inflamed gall bladder was sewed to the anterior abdominal wall through a small incision, which served as a route for the removal of gall stone at a later date. At around the same time, in 1867, Dr John Stough Bobbs, did an incidental cholecystostomy while he was operating on a patient with suspected ovarian cyst. Theodor Kocher performed the first successful cholecystostomy in 1878.[13,14]

It was Carl Johann August Langenbuch who observed that cholecystostomy was only a temporary measure and strived to find a definite management option for the disease.[14] At that time biliary colic was more a medical problem and ordinary surgeons were inadequately exposed to the problem. Langenbuch at the age of 27 developed the technique of cholecystectomy through cadaveric dissection and on July 15, 1882 he successfully removed the gall bladder of a 43-year-old man who was suffering from the disease for 16 years. His initial report appeared in 1882 but was ignored. This new cholecystectomy was debated against the already established cholecystostomy. Langenbuch died on June 9, 1901 of neglected appendicitis but the path showed by him led to further advancement and modification in biliary surgery.

Langenbuch's open cholecystectomy remained the gold standard for symptomatic cholelithiasis for over a century. The only major change was brought by Mirizzi which was the introduction of operative cholangiography for the detection of common bile duct stones.[15] Mouret from France performed the first human laparoscopic cholecystectomy.[16] He performed the procedure successfully and the patient recovered without complications. Finally, in September 1992 a NIH consensus conference held in Bethesda concluded that laparoscopic cholecystectomy was the treatment of choice for gall bladder lithiasis.[17]

INDICATIONS OF CHOLECYSTECTOMY IN CHOLELITHIASIS

Majority of people with cholelithiasis will not develop symptoms: up to 80% will never experience biliary pain or complications such as acute cholecystitis, cholangitis, or pancreatitis.[18] Hence, most gallstones are clinically “silent,” an incidental finding often revealed during abdominal ultrasound being performed for another reason.[19] People with such asymptomatic cholelithiasis, however, eventually may develop symptoms (biliary pain) but this risk is quite low averaging 2 to 3% per year, 10% by 5 years.[20,21] Even lower proportions, 1 to 2% per year, develop major gallstone complications.[22] Therefore, expectant management is an appropriate choice for silent gallstones in the general population.

However, there are some sub groups of patients who need prophylactic cholecystectomy even if asymptomatic: (1) Large gallstones (>3 cm) or gallbladders packed with stones that carry a higher risk of developing gallbladder cancer.[23] (2) Sickle cell disease is associated with the development of pigment gallstones, frequently necessitating cholecystectomy. Prophylactic cholecystectomy should be considered because stone related complications are frequently difficult to

distinguish from a sickle cell crisis or its complications such as infarction of the liver or abdominal viscera.[24] (3) Solid organ transplantation (heart, lung, kidney, pancreas). Gallstones that develop post-solid organ transplantation frequently progress to symptoms and complications like cholecystitis, principally during the first 2 years.[25] Liver transplantation is exempted as the gallbladder is removed at the time of hepatectomy. (4) Morbidly obese patients undergoing bariatric surgery.[26] (5) Porcelain Gallbladder due to increased risk of malignancy. (6) Dysmotile Gallbladder laden with small stones, as has increased risk of pancreatitis.[27] (7) Native Americans because they have higher risk of gallbladder cancer than general population.

Symptomatic GSD causing biliary colic has always remained an uncontroversial and most common indication for cholecystectomy. Though, it is also the only indication which requires thorough deliberation and exclusions to accurately label the symptoms as being gall stone induced.

NEED TO ADOPT RESTRICTIVE CRITERIA FOR ELECTIVE CHOLECYSTECTOMIES

It is essential to define exactly which symptoms are caused by gallstones: true biliary pain and/or complications, versus nonspecific abdominal complaints including dyspepsia.[28-30] Gallstone-associated pain seems to follow a certain pattern in most patients.[31,32] Consensus groups have attempted to establish criteria for biliary pain relative to defined characteristics (e.g., episodic, steady, severe pain located in the upper abdomen and lasting more than 30 minutes) and some accompanying features (e.g., nocturnal onset; nausea and vomiting; radiating through to the back).[33] The importance for clarifying what constitutes true biliary pain is to better predict relief following cholecystectomy.

The accurate diagnosis of true biliary pain is also pivotal in bringing down the rate of unnecessary cholecystectomies as well as preventing a significant proportion of patients from undue surgical risk and health care cost. Currently, cholecystectomy does not relieve biliary pain in 10 to 33% of people with documented gallstones.[34,35] Confusion with other functional gut disorders like irritable bowel syndrome (IBS) and dyspepsia will not provide a favourable outcome from cholecystectomy.[36]

Mertens et al conducted a prospective study to identify the predictors of persisting symptoms post-cholecystectomy.[36] At 6 months after cholecystectomy, merely 47.8% of the patients were symptom free. In addition, 17.9 and 34.0% of the patients reported persistence and emergence of new symptoms, respectively. Hence, it becomes pertinent to mention that preoperative recognition of patients with an increased risk of negative outcome is essential to optimise the management of cholelithiasis. The study also demonstrated that patients with preoperative dyspeptic symptoms only and patients using psychotropic medication are both at risk of persistence of the pre-existing pattern of health complaints after cholecystectomy.

Thistle et al followed their study patients for 12 months post-cholecystectomy to determine the preoperative predictors associated with sustained post-operative relief with respect to upper abdominal pain (UAP). 59% of the patients reported sustained relief from UAP.[37] Factors associated with relief included frequency of UAP ≤1 episode per month, onset ≤1 year preoperatively, usual duration (30 minutes to 24 hours, most often in the evening or night), and severity >5/10. Association of UAP with GERD, IBS like symptoms or somatisation determine the odds for relief of symptoms after cholecystectomy.

A Swedish surgeon Persson conducted a prospective study on expectant management of GSD and followed the study patients for 6 years.[38] After the completion of 6-year follow up only 23 (15%) patients developed acute gall stone related complication, acute cholecystitis (n=18), acute pancreatitis (n=2), and jaundice (n=3). The overall cholecystectomy rate fell from 20 % during the 1st year to about 3% during the 5th year of follow-up. Young age and frequent attacks of true biliary pain episodes predicted the need for gallstone surgery.

Festi et al conducted a multi-centre, population-based cohort study on 11229 subjects. Gall stone patients were followed up for a mean period of 8.7 years. At the end of the follow up, of the asymptomatic subjects, 453 (78.1%) remained asymptomatic; 61 (10.5%) developed mild symptoms and 66 (11.4%) developed severe symptoms.[39] In subjects with mild symptoms, the symptoms disappeared in 55 (58.5%), became severe in 23 (24.5%), remained stable in 16 (17%); in subjects with severe symptoms, the symptoms disappeared in 62 (52.1%), became mild in 20 (16.8%) and remained stable in 37 (31.1%). A total of 189 cholecystectomies were performed: 41.3% on asymptomatic patients, 17.4% on patients with mild symptoms and 41.3% on patients with severe symptoms.

The lancet writes that adopting restrictive selection criteria for decision making significantly reduces the rates of unnecessary cholecystectomies (68% as compared to 75% in usual care group) than operating merely on surgeon's discretion.[40]

DISCUSSION

In this review of literature, significant numbers of studies suggest that cholecystectomy should be a well thought out decision based on predictors of symptom relief, not merely on surgeon's discretion. Though laparoscopic cholecystectomy revolutionised the management of GSD, however, it was accompanied by significantly lowered

threshold for cholecystectomies, resulting in escalation of cholecystectomy rates of the order of 22% reported in some studies.[41] However, the considerable reduction in post-operative morbidity after laparoscopic cholecystectomy must also be appreciated.

The association of true biliary pain with gall stones is paramount in predicting success following a cholecystectomy. Coexistent diseases in patients with cholelithiasis are common and mainly non-biliary like gastro-oesophageal reflux, peptic ulcer, hiatus hernia, gastritis, constipation, IBS, fatty liver disease. Distinction between symptoms caused by coexistent diseases and gallstones is challenging.[42] Misinterpretation of symptoms and suboptimal indication for laparoscopic cholecystectomy will result in persistent symptoms after surgery.[43,44]

CONCLUSION

Laparoscopic cholecystectomy remains the gold standard for treatment of symptomatic gall stone disease. However, it is equally important to mention that avoidance of an unnecessary cholecystectomy becomes critically germane in an era of escalating rates of surgery. Jumping to a cholecystectomy may not always yield good outcomes, although many do still benefit from having a cholecystectomy. There is a need to rigidly define symptomatic cholelithiasis and true biliary pain based on fixed restrictive criteria in order to bring down the rates of unnecessary cholecystectomies and hence, lessen the burden on health care institutions. This will also pave the way for saving considerable amount of health care cost. Besides, it must be insisted that a shared decision making will impart a better understanding to the patient about negative outcomes after a non-essential cholecystectomy.

Hopefully further studies will give an insight to what might cause symptoms and when a cholecystectomy is likely to relieve symptoms.

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