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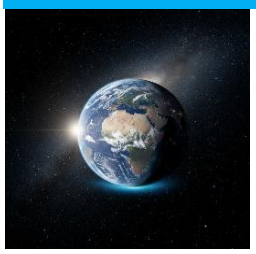

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Use of Ursodeoxycholic Acid (UDCA) in the Prevention of Gallstone Disease After Bariatric Surgery – A Literature Review

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Abstract

The aim of this study was to evaluate the efficacy of ursodeoxycholic acid (UDCA) in the prevention of gallstone disease in patients after bariatric surgery. The review covered scientific literature from 2016 to 2024, including four randomized controlled trials, two meta-analyses, and one retrospective study, examining the use of UDCA following procedures such as sleeve gastrectomy (SG), Roux-en-Y gastric bypass (RYGB), and one-anastomosis gastric bypass (OAGB). A standard dose of 500–600 mg/day was used, most commonly for six months postoperatively. The results demonstrated a significant reduction in the incidence of gallstone disease, particularly after SG, with a decrease from 25–37% in control groups to 7–12% in UDCA-treated groups. The studies confirmed good drug tolerance and a low incidence of adverse effects, with the main issue being non-adherence to recommendations at higher doses. The findings clearly indicate that UDCA is an effective and safe method for the prophylaxis of gallstone disease after bariatric surgery, with an optimal duration of administration of six months.

Keywords: ursodeoxycholic acid, UDCA, gallstone disease, cholelithiasis, bariatric surgery, gallstone prophylaxis

1. Introduction

Cholelithiasis is a disease characterized by the formation of gallstones within the biliary tract and the gallbladder. It is one of the most frequently diagnosed diseases of the gastrointestinal system among Europeans and is associated with numerous serious complications, including acute cholecystitis, cholangitis, and pancreatitis. The continuously increasing incidence of the

disease is attributed to the growing prevalence of risk factors such as obesity, low levels of physical activity, diabetes mellitus, low high-density lipoprotein (HDL) cholesterol concentrations, and hypertriglyceridemia. [1] It is also well established that a significant risk factor for the development of cholelithiasis is rapid weight loss, which also occurs in patients undergoing bariatric surgery for the treatment of obesity. Studies indicate that the incidence of gallstone disease following bariatric surgery may reach as high as 28%. [6]

2. Material and Methods

This study is a narrative review and was developed based on the available scientific literature concerning the use of ursodeoxycholic acid (UDCA) in the prevention of cholelithiasis in patients after bariatric surgery.

The literature review was conducted over the period from 2016 to 2024 using the following databases: PubMed/MEDLINE, PubMed Central, and ScienceDirect, as well as publishing platforms of scientific journals (including Frontiers and the American Physiological Society). Selected Polish clinical sources, such as *Medycyna Praktyczna* and *Interna Szczeklika*, were also included.

Due to the limited number of high-quality clinical studies addressing the use of UDCA after bariatric surgery, a total of seven publications evaluating the efficacy of UDCA were included in the analysis: four randomized controlled trials, two meta-analyses, and one retrospective study. This approach enabled a comprehensive assessment of treatment effects across experimental, synthetic, and observational study designs.

3. Mechanism of Cholelithiasis in Patients after Bariatric Surgery

The mechanism underlying the development of cholelithiasis in patients after bariatric procedures—such as Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG)—is most likely associated with the formation of so-called lithogenic bile, characterized by a high cholesterol content. Although this mechanism has not yet been fully elucidated, it is presumed that in such cases there is an increased concentration of calcium and mucin in the bile, which leads to the formation of supersaturated or lithogenic bile. This bile subsequently undergoes crystallization, resulting in the formation of cholesterol gallstones within the gallbladder. [8]

Studies indicate that symptomatic gallbladder cholelithiasis develops in up to 25% of patients following bariatric surgery. In addition, the onset of symptoms may occur in patients with previously asymptomatic gallbladder stones. [11]

4. Symptoms and General Management of Cholelithiasis

The primary manifestation of cholelithiasis is the so-called biliary colic, characterized by colicky pain in the right upper quadrant or epigastric region, typically lasting 15–30 minutes. However, in most cases, gallstones remain asymptomatic. [1]

Gallstones can be classified into cholesterol stones and pigment stones. Cholesterol stones consist of 50–100% cholesterol and form primarily within the gallbladder. Cholesterol is eliminated from the body via bile production. Through aggregation with bile salts and lecithin, it becomes soluble in water. However, when its concentration exceeds the solubilizing capacity, cholesterol precipitates as crystals. [2]

Management of cholelithiasis includes analgesics and antispasmodic medications. In all patients with symptomatic gallstones, surgical intervention is additionally recommended. The method of choice is laparoscopic cholecystectomy. [1]

Recent research has focused on the use of ursodeoxycholic acid (UDCA) in the management of gallstone disease. It has been demonstrated that UDCA can dissolve small, poorly calcified stones. Nevertheless, UDCA is currently not recommended as a treatment modality due to the high recurrence rate and is primarily used for the prevention of gallstones in specific cases, such as post-bariatric surgery. [14]

Additionally, studies indicate that UDCA is recommended for the treatment of primary biliary cholangitis (PBC) and intrahepatic cholestasis of pregnancy (ICP). It is also applied in other conditions, such as non-alcoholic fatty liver disease (NAFLD) and inflammatory bowel disease (IBD). [5] UDCA has been shown to exert neuroprotective effects in neurodegenerative diseases, including Alzheimer's disease and Huntington's disease. [3]

5. Characteristics of Ursodeoxycholic Acid

Ursodeoxycholic acid (UDCA) is a highly hydrophilic secondary bile acid with low toxicity, exhibiting choleretic, anti-inflammatory, and cytoprotective properties. Primary bile acids (PBAs), mainly chenodeoxycholic acid (CDCA) and cholic acid (CA), are synthesized de novo in the liver through the actions of two key enzymes: sterol 27-hydroxylase (Cyp27a1) and cholesterol 7-alpha-hydroxylase (Cyp7a1). Bile acids are secreted into the biliary tract conjugated with taurine and glycine. Subsequently, through the interaction with the gut microbiome, PBAs are converted into secondary bile acids—including UDCA, which is derived from CDCA. [3,4]

Individual bile acids differ in their physicochemical and biological properties. UDCA is the 7β-epimer of chenodeoxycholic acid (CDCA); the main structural difference is the orientation of the hydroxyl group at the 7β position, which renders UDCA more hydrophilic. The chemical composition of UDCA was determined by Iwasaki in 1936, marking the beginning of its use as a hepatoprotective agent.

Under physiological conditions, UDCA constitutes only a small fraction of human bile. Orally administered UDCA is in crystalline form and is insoluble in acidic environments. It is only in the intestines, at a pH of 7.8–8, that UDCA is solubilized and absorbed into the systemic circulation. Approximately 60% of systemically circulating UDCA is metabolized in the liver and conjugated with glycine or, less frequently, taurine. The conjugated form is then reabsorbed from the intestines into the circulation, while the majority of the remaining unabsorbed fraction is excreted unchanged in the feces. [7]

Cytoprotective Effects

One of the key functions of UDCA is its cytoprotective activity. Although the precise cytoprotective mechanisms are still under investigation, numerous studies attribute this effect to UDCA's ability to reduce apoptosis in cells. Within the cell nucleus, UDCA modulates apoptotic pathways, including the E2F-1/p53/Bax signaling pathway. Furthermore, UDCA influences the mitochondrial pathway by affecting reactive oxygen species (ROS) formation, cytochrome c release, and caspase-3 activation. [3]

Anti-inflammatory Effects

UDCA also exhibits anti-inflammatory properties. It is postulated that UDCA reduces the accumulation of immune cells in the intestinal mucosa in inflammatory bowel disease (IBD), as assessed by myeloperoxidase activity. In addition, UDCA decreases the levels of pro-inflammatory cytokines, including TNF-α, IL-6, and IL-1β. [5]

Effects on Lipid Metabolism

UDCA lowers cholesterol concentration in bile, likely by influencing cholesterol absorption and promoting its conversion into bile acids. UDCA stimulates the secretion of bile acids and bilirubin. Moreover, it affects bile acid secretion by modulating the activity of transport proteins responsible for moving bile acids from hepatocytes into the gallbladder. [7]

6. Use of UDCA in the Prevention of Gallstone Disease after Bariatric Surgery – Review of Published Studies

One of the strategies for preventing gallstone disease is performing a prophylactic concomitant laparoscopic cholecystectomy during bariatric surgery. However, this approach is often technically challenging in bariatric patients and is associated with additional potential complications and adverse events. To avoid the risks associated with gallbladder removal while simultaneously preventing gallstone formation, the use of UDCA has been proposed as a prophylactic measure for gallstone disease following bariatric procedures, particularly after sleeve gastrectomy. [8] After other surgical procedures, such as Roux-en-Y gastric bypass (RYGB), the reduction in gallstone incidence with UDCA use has not always reached statistical significance. [12]

In one retrospective study, patients who underwent laparoscopic sleeve gastrectomy at the General Surgery Department of the University Hospital in Mansoura, as well as at three private hospitals in Mansoura, Egypt, were analyzed. The study included patients with a BMI > 40 kg/m² or BMI > 35 kg/m² with at least one comorbidity. Patients under 18 or over 60 years of age, as well as those with a history of cholecystectomy or prior bariatric surgery, were excluded. Patients were divided into two groups. The first group consisted of patients operated on between January 2010 and March 2012, who did not receive UDCA for gallstone prophylaxis. The second group included patients operated on between April 2012 and May 2015, who received 600 mg of UDCA daily for six months postoperatively as a prophylactic measure. In this study, none of the patients in the UDCA group developed gallstone disease by the end of the follow-up period. However, the study emphasized that routine use of UDCA after bariatric surgery is still not recommended due to challenges in identifying risk factors and potential adverse effects of UDCA administration. The overall incidence of gallstone disease in the group that did not receive prophylactic UDCA ranged from 2% to 5%. [8]

In a subsequent study, which was a meta-analysis based on randomized controlled trials, the efficacy of UDCA in preventing gallstone formation after bariatric surgery was evaluated. Eleven randomized controlled trials were included, encompassing a total of 2,363 patients randomized to UDCA treatment and 2,217 patients, with 1,415 patients in the control group and 1,257 in the UDCA group. In all selected studies, patients received UDCA for six months at a dose of 500–600 mg/day. The meta-analysis demonstrated that UDCA significantly reduced the incidence of gallstone disease following bariatric surgery. [9]

In a 2019 randomized controlled trial conducted at the Surgical Clinic of the Medical Research Institute Hospital and the main University Hospital of Alexandria University in Egypt, from March 2013 to April 2018, the efficacy of UDCA in the prevention of gallstone disease after bariatric surgery was once again confirmed. A total of 1,530 patients with morbid obesity were enrolled in the study. Surgical procedures included one-anastomosis gastric bypass (OAGB), sleeve gastrectomy (SG), or greater curvature plication (GCP). Patients were assigned to two groups: one receiving UDCA and the other receiving a placebo. Sixty patients were excluded from the analysis. Additionally, 23 patients from the experimental group and 15 patients from the control group were lost to follow-up, resulting in 1,432 patients who completed the control ultrasonography (USG) evaluations. Compared to previous studies, the follow-up period in this trial ranged from 12 to 36 months. Ultrasound assessments were performed at 6 and 12 months postoperatively. Importantly, no significant differences were observed between patients who developed gallstones during the follow-up period with respect to age, sex, or preoperative body mass index (BMI). The study estimated that patients who did not receive UDCA were 3.4 times more likely to develop gallstone disease than those receiving the medication. [10]

Another meta-analysis of randomized controlled trials additionally demonstrated a dose–response relationship for UDCA. According to this study, doses higher than the standard 500–600 mg/day did not confer greater efficacy and were associated with a higher incidence of adverse effects and reduced adherence to therapy. The analysis once again confirmed the effectiveness of UDCA in the prevention of gallbladder stone formation after bariatric surgery. Moreover, the study compared the incidence of gallstones following specific surgical procedures, yielding the following results: in patients undergoing sleeve gastrectomy (SG), gallstone incidence was 11.8% in the UDCA-treated group versus 37% in the control group; in patients undergoing gastric bypass procedures, 8.6% of UDCA recipients developed gallstones compared with 25.7% in the control group; and in patients undergoing vertical banded gastroplasty (VBG), gallstones occurred in 14% of the UDCA group versus 29.3% of controls. [11]

A subsequent multicenter, randomized, double-blind, placebo-controlled study in Israel further confirmed the efficacy of UDCA. The study evaluated a six-month course of Ursolit (UDCA) treatment and was conducted between 2015 and 2018 at the following centers: Emek Medical Center (Afula), Galilee Medical Center (Nahariya), and Rambam Health Care Campus (Haifa). Patients assigned to the UDCA group received 600 mg/day divided into two doses of 300 mg. The study population included individuals aged 18–65 years. Exclusion criteria included previous cholecystectomy, pregnancy, existing gallstone disease, or gallbladder wall thickening. Patients were monitored monthly via telephone to assess adverse effects and adherence to the regimen. Additionally, in-person ambulatory follow-ups were performed preoperatively, 10 days postoperatively, and at 3, 6, and 12 months after surgery. A total of 92 patients participated, undergoing SG or OAGB/RYGB procedures. Interestingly, although both surgical groups showed a reduction in gallstone formation, statistically significant prevention was observed only in the SG group. [12]

A prospective controlled study included 322 patients scheduled for sleeve gastrectomy (SG) between June 2017 and June 2019. Patients with previously diagnosed gallstone disease, abnormal liver function tests, or a history of cholecystectomy were excluded. Patients assigned to the intervention group received 500 mg of UDCA daily for 12 months. The control group did not receive a placebo and was managed with routine postoperative follow-up. During the study, 71 patients were lost to follow-up—33 from the UDCA group and 38 from the control group. Weight loss was significantly greater in the control group. A significantly higher proportion of patients in the control group developed gallstones. Overall, 20% of patients

included in the study developed cholelithiasis. The study also found that traditional risk factors for gallstone disease are not predictive in the context of post-bariatric surgery cholelithiasis; rapid weight loss was identified as the most significant risk factor. [13]

In another study, the role of UDCA was evaluated in patients undergoing one-anastomosis gastric bypass (OAGB). This was a prospective, randomized study in which patients were allocated to two groups: one receiving oral UDCA and a control group not receiving UDCA. UDCA was administered at a dose of 600 mg/day for six months immediately postoperatively. A total of 190 patients were included, with 95 patients in each group. Ultrasound assessments were performed at 3, 6, and 12 months postoperatively. After 12 months of follow-up, gallstone disease was observed in 4 patients (4.2%) in the UDCA group and 24 patients (25.2%) in the control group. This study concluded that UDCA administration during the first six months after OAGB significantly reduces the incidence of gallstone formation. [15]

7. Conclusions

The analyzed studies—including retrospective analyses, randomized controlled trials, and meta-analyses—consistently indicate that UDCA administration significantly reduces the risk of gallstone formation following bariatric surgery. In many studies, the risk reduction is particularly pronounced, with gallstone incidence decreasing from 25–37% in control groups to 7–12% in UDCA-treated groups. [11] The effect is especially strong after sleeve gastrectomy (SG) [12], while efficacy is also observed after RYGB or OAGB, although in some studies the reduction did not always reach statistical significance. [12]

In most studies, the standard UDCA dose was 500–600 mg/day [8,9,12,13,15], usually administered as a single daily dose or divided into two doses. One meta-analysis demonstrated that higher doses do not provide additional benefit and may be associated with increased adverse effects, leading to reduced patient adherence. [11]

In the majority of analyzed studies, UDCA was administered for six months, which appears to be the period providing the most reliable prophylactic effect. In one study, UDCA was administered for 12 months [10], also showing a significant reduction in gallstone risk, but without an advantage over the six-month protocol. Based on these findings, a six-month course can be considered the minimal, sufficient, and optimally studied duration for prophylaxis, although one study questioned this timeframe because the peak incidence of gallstones occurred 16 months postoperatively. [13]

The greatest efficacy of UDCA was observed after SG, as confirmed by both RCTs and meta-analyses. After OAGB and RYGB procedures, a reduction in gallstone formation was also observed, although in some analyses the effect was weaker or did not reach full statistical significance.

Across all referenced studies, UDCA was well tolerated, and the incidence of adverse events was low. The main issue was not drug toxicity, but rather non-adherence to the regimen, particularly with higher doses.

DISCLOSURE

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