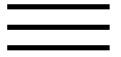


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The American Journal of Surgery

Volume 169, Issue 1, January 1995, Pages 91-97

A multicenter, placebo-controlled, randomized, double-blind, prospective trial of prophylactic ursodiol for the prevention of gallstone formation following gastric-bypass-induced rapid weight loss ***

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[https://doi.org/10.1016/S0002-9610\(99\)80115-9](https://doi.org/10.1016/S0002-9610(99)80115-9)

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Background

Previous studies have documented a high incidence of gallstone formation following gastric-bypass (GBP)-induced rapid weight loss in morbidly obese patients. This study was designed to determine if a 6-month regimen of prophylactic ursodiol might prevent the development of gallstones.

Methods

A multicenter, randomized, double-blind, prospective trial evaluated 3 oral doses of ursodiol: 300, 600, and 1,200 mg versus placebo beginning within 10 days after surgery

and continuing for 6 months or until gallstone development, for patients with a body mass index (BMI) ≥ 40 kg/m². All patients had normal intraoperative gallbladder sonography. Transabdominal sonography was obtained at 2, 4, and 6 months following surgery, or until gallstone formation.

Results

Of 233 patients with at least one postoperative sonogram, 56 were randomized to placebo, 53 to 300 mg ursodiol, 61 to 600 mg ursodiol, and 63 to 1,200 mg ursodiol. Preoperative age, sex, race, weight, BMI, and postoperative weight loss were not significantly different between groups. Gallstone formation occurred at 6 months in 32%, 13%, 2%, and 6% of the patients on the respective doses. Gallstones were significantly ($P < 0.001$) less frequent with ursodiol 600 and 1,200 mg than with placebo.

Conclusion

A daily dose of 600 mg ursodiol is effective prophylaxis for gallstone formation following GBP-induced rapid weight loss.



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This article was supported by grants from the Ciba-Geigy Corporation, Summit, New Jersey.

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