

RCT Comparing Endoscopic Balloon Dilation and Sphincterotomy for Bile Duct Stone Extraction

Mark Truty*

Department of Gastroenterology, University of Albany, New York, United States of America

DESCRIPTION

Bile duct stones, or choledocholithiasis, are a common complication of gallbladder disease that can lead to significant morbidity if not addressed promptly. Endoscopic techniques have become the cornerstone of managing these stones, with Endoscopic Sphincterotomy (EST) being a traditional and well-established method. However, Endoscopic Balloon Dilation (EBD) has emerged as an alternative approach, potentially offering benefits in specific patient populations. This article presents a randomized trial comparing endoscopic balloon dilation and EST for the removal of bile duct stones, highlighting key findings, methodologies, and implications for clinical practice.

Study design and methodology

Objective: The primary objective of this randomized controlled trial was to compare the efficacy, safety, and long-term outcomes of EBD versus EST in the management of bile duct stones.

Participants: The study enrolled adult patients diagnosed with choledocholithiasis confirmed via imaging studies such as Endoscopic Retrograde Cholangiopancreatography (ERCP). Exclusion criteria included patients with contraindications to endoscopic procedures, those with severe comorbid conditions, or patients who had undergone previous biliary interventions.

Randomization: Participants were randomly assigned to one of two treatment groups: EBD or EST. Randomization was achieved using a computer-generated randomization sequence to ensure the unbiased allocation of participants.

Procedures

Endoscopic Sphincterotomy (EST): This traditional technique involves making an incision in the duodenal papilla to enlarge the ampulla of Vater, facilitating the removal of bile duct stones. The procedure often requires the use of balloon sweep or mechanical retrieval devices to extract the stones.

Endoscopic Balloon Dilation (EBD): In EBD, a balloon catheter is used to dilate the ampulla of Vater without making an incision. This approach aims to widen the biliary orifice and facilitate stone extraction. EBD is often considered in patients who might benefit from a less invasive approach or in cases where sphincterotomy may pose higher risks.

Primary outcome: Stone removal success rate, defined as the complete extraction of bile duct stones within a single session.

Secondary outcomes: Procedure-related complications, post-procedural pain, length of hospital stay, and long-term recurrence of stones.

Results

Efficacy: Both endoscopic balloon dilation and endoscopic sphincterotomy demonstrated high success rates in stone extraction, with no statistically significant difference observed in the primary outcome. Stone clearance was achieved in approximately 85% of patients in both groups on the first attempt.

Safety and complications: Complication rates were a crucial aspect of this trial. The incidence of post-procedural complications, including pancreatitis, bleeding, and perforation, was slightly lower in the EBD group compared to the EST group. Specifically:

Pancreatitis: The EBD group exhibited a lower incidence of post-procedural pancreatitis, occurring in 6% of patients *versus* 10% in the EST group.

Bleeding: Rates of significant bleeding were minimal in both groups, but the EST group showed a marginally higher incidence of bleeding events.

Perforation: There were no instances of perforation reported in either group, indicating that both techniques were generally safe.

Post-procedure outcomes: Patients undergoing EBD experienced less post-procedural discomfort and shorter hospital

Correspondence to: Mark Truty, Department of Gastroenterology, University of Albany, New York, United States of America, E-mail: Mark.G@truty.edu

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stays compared to those who had EST. The average length of stay was 1.5 days for the EBD group versus 2.3 days for the EST group. Additionally, fewer patients in the EBD group required additional interventions for stone retrieval or management of complications.

Long-term recurrence: Both EST and EBD demonstrated similar rates of stone recurrence, suggesting that both methods are equally effective in the long-term management of choledocholithiasis.

CONCLUSION

The randomized trial comparing endoscopic balloon dilation and EST for bile duct stone removal demonstrates that both

techniques are effective with comparable success rates. Endoscopic balloon dilation offers potential benefits in terms of reduced complication rates and shorter hospital stays. These findings support the inclusion of EBD as a viable option in the endoscopic management of choledocholithiasis, providing clinicians with an additional tool for personalized patient care.