

Anatomical identification of the bile duct by intrinsic illumination in difficult cholecystectomies: Prometheus device

Identificación anatómica de la vía biliar por iluminación intrínseca en colecistectomías difíciles: dispositivo Prometeo

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Abstract

Bile duct injury remains one of the most feared complications after cholecystectomy. The Prometheus device, through intrinsic illumination, facilitates intraoperative anatomical identification of biliary structures. In a case of cholecystitis, it was used during a conventional cholecystectomy, advancing it through Hartmann's pouch to the confluence with the common hepatic duct, illuminating the biliary structures and enhancing critical view of safety. This device proved to be a safe and accessible method, with potential for use in most healthcare centers.

Keywords: Laparoscopic. Cholecystectomy. Cholangiography. Investigational. Indocyanine.

Resumen

La lesión biliar sigue siendo una de las complicaciones más temidas después de una colecistectomía. El dispositivo Prometeo, mediante iluminación intrínseca, facilita la identificación anatómica intraoperatoria de estructuras biliares. En un caso de colecistitis, se utilizó durante una colecistectomía convencional, avanzándolo por la bolsa de Hartmann hasta la confluencia con el hepático común, iluminando las estructuras biliares y mejorando la visión crítica de seguridad. Este dispositivo demostró ser un método seguro y accesible, con potencial para su uso en la mayoría de los centros de salud.

Palabras clave: Colecistectomía. Laparoscopia. Colangiografía. Experimental. Indocianina.

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Introduction

Currently, cholecystectomy is the most common surgical procedure performed by general surgeons and is the standard treatment for gallstone disease^{1,2}. Since the work of Mühe in 1985, followed by that of Mouret, Dubois, and Perissat, laparoscopic cholecystectomy has evolved in terms of precision and safety². Patients undergoing laparoscopic procedures benefit from early recovery, less pain, and a lower risk of surgical site infection³.

One of its most feared complications is bile duct injury, with a rate of 1-2% after laparoscopic cholecystectomy, and its related short- and medium-term complications, with a rate of 9.84%⁴. Epidemiological studies suggest an incidence of 0.4-0.6%, with recent reports indicating an incidence similar to that of open surgery⁵. Bile duct injury increases the risk of all-cause mortality from 8.8% up to 20%⁴, with a sixfold increase in mortality at 1 year⁶. The consequences of bile duct injury not only affect the patient's quality of life but also that of the surgeon. In England, malpractice litigation following bile duct injury accounts for most claims against surgeons, with 16% of bile duct injuries resulting in lawsuits, and in the United States, the rate is 20-30%^{4,7}.

The culture of "safe cholecystectomy" has permeated the daily practice of surgeons worldwide. Various authors have devised methods to reduce this risk based on technical, imaging, and clinical tools, with the most important being the work of Strasberg⁸ and the use of the "critical view of safety," thereby reducing the risk of bile duct injury related to anatomical misidentification, which occurs in approximately 71% up to 97% of cases^{8,9}.

Therefore, anatomical identification of the bile duct is crucial for the success of the procedure. When the critical view of safety cannot be achieved in difficult cholecystectomy cases, the surgeon may rely on imaging and intrinsic methods, such as indocyanine green fluorescence or intraoperative cholangiography. The main disadvantages of these methods are cost, the need for special devices, ionizing radiation, and the required contrast medium⁹⁻¹⁴.

The Prometeo device aims to avoid the main disadvantages of the described methods, as it does not require special equipment (only a light source) or expose the patient to agents that cause associated injuries, such as ionizing radiation and contrast medium, making it possible to use in patients with comorbidities without any additional risks.

Method

A case of acute cholecystitis treated at our center using the experimental Prometeo device is described to evaluate its utility and reliability in identifying biliary anatomy. A review of the current literature was conducted in major digital libraries using the terms "difficult cholecystectomy," "bile duct injury," "laparoscopic cholecystectomy," "intraoperative cholangiography," and "fluorescent cholangiography," considering articles relevant to our research.

A 41-year-old patient with confirmed mild acute cholecystitis TG18 presented to our center. Laparoscopic cholecystectomy was performed upon admission, after obtaining informed consent. Pneumoperitoneum was established at 14 mmHg using a closed technique with a Veress needle. Two 12 mm ports and two 5 mm ports were placed (Fig. 1). Initial dissection of the gallbladder was performed until the infundibulum was exposed, prior to achieving the critical view of safety. At this point, a 3 mm incision was performed on the anterior surface of Hartmann's pouch. The experimental Prometeo device was introduced through the 12 mm port, which was previously connected to an adapter for an external light source (Fig. 2). The tip of the device optical fiber was introduced into the described incision in a distal direction toward the common bile duct, without forcing entry upon encountering resistance (Fig. 3). Once inside, the device light source was activated, and the intensity of the main light source was reduced to achieve adequate contrast (Fig. 4). The optical fiber was gently advanced and retracted until satisfactory visualization of the cystic duct and its confluence with the common bile duct was achieved (Fig. 5). The findings were verified with intraoperative cholangiography (Fig. 6). After confirming successful anatomical identification, the hepatocystic triangle was dissected to achieve the critical view of safety, and the procedure was completed conventionally.

Results

During the postoperative period, the patient did not experience any complications related to the underlying condition or the procedure, and with adequate clinical progress, discharge was decided the day after the surgical event. During the procedure, the entire cystic duct was successfully identified, which was initially the goal when designing the described technique. However, during the introduction of the optical

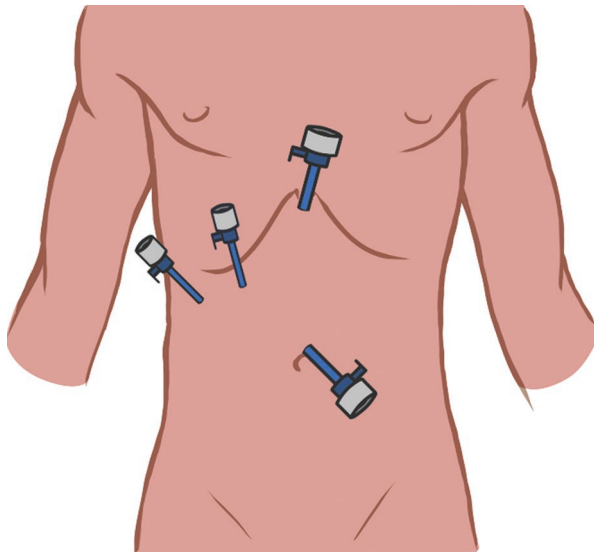


Figure 1. Schematic of port placement.

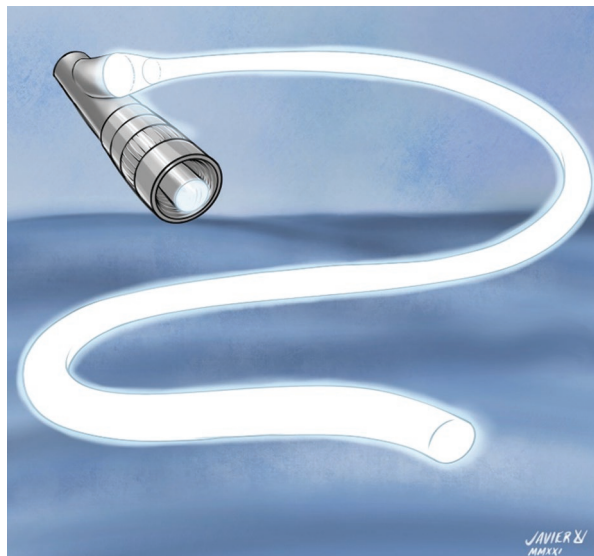


Figure 2. Representation of the initial proposal for the Prometeo device.

fiber into the bile duct, preliminary identification of the confluence of the cystic duct with the common bile duct was achieved (Fig. 5).

Discussion

Identification of the hepatocystic triangle is complex in cases of difficult cholecystectomy. Currently, there are no objective parameters to guide surgeons in using an external method to ensure proper visualization. Nassar et al.¹⁵ attempted to establish an objective method

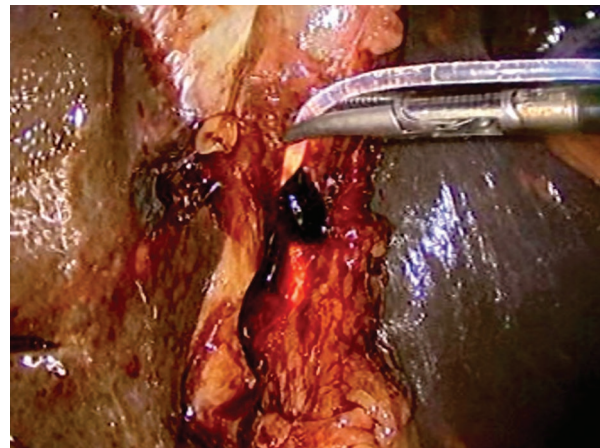


Figure 3. Introduction of the device through the incision performed on the anterior surface of Hartmann's pouch.

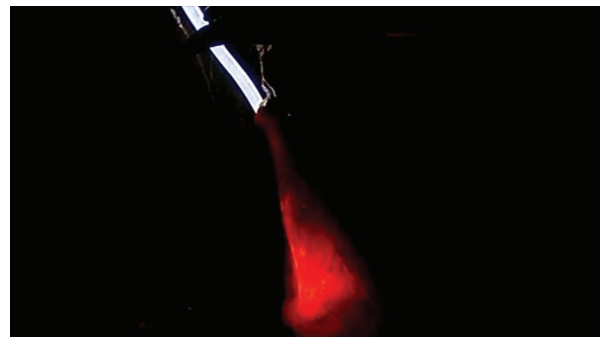


Figure 4. Intrinsic illumination. At this point, the main light source is attenuated to achieve adequate contrast.

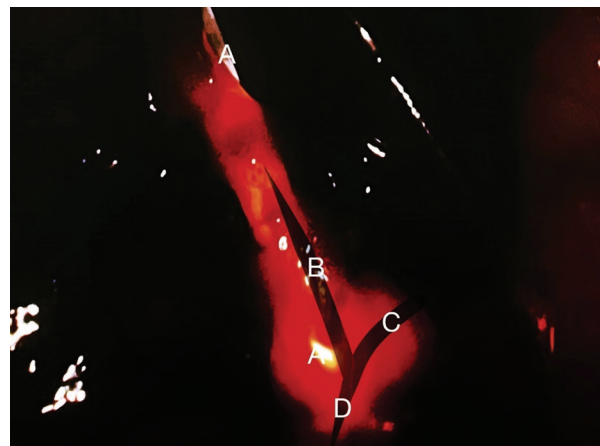


Figure 5. Intraoperative image showing the cystic duct (B), common hepatic duct (C), and common bile duct (D) illuminated by the optical fiber (A).

to define this cutoff point using intraoperative images associated with "difficulty," in which, unlike other intraoperative scores, a high score is related to an increased

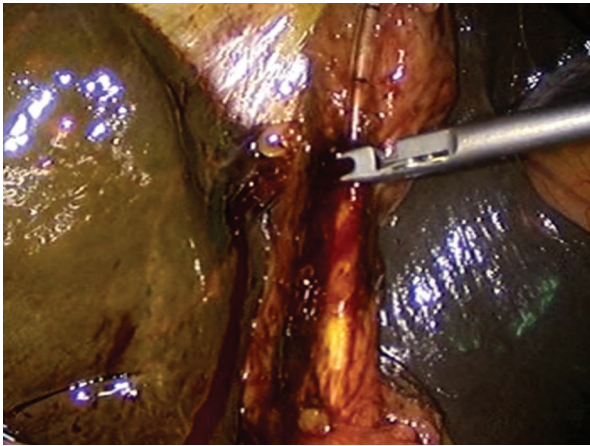


Figure 6. Introduction of the probe to perform intraoperative cholangiography.

complication rate and not solely predictive of conversion to open surgery¹⁶. Preoperative knowledge of a potentially difficult cholecystectomy is essential for proper planning. Factors associated with difficulty can be both intra- and preoperative. Clinical, imaging, and chemical parameters have been studied. Age, male sex, chronic or acute cholecystitis, obesity, cirrhosis, cancer, endoscopic retrograde cholangiopancreatography or previous surgeries, cholecystectomy > 2 weeks after the initial episode of acute pancreatitis¹⁷⁻¹⁹, wall thickening, pericholecystic fluid, and fat stranding on imaging modalities, inflammatory parameters such as elevated C-reactive protein, leukocytosis, fibrinogen²⁰⁻²², and intraoperative factors such as difficulty in gallbladder traction and liver retraction, short or wide cystic duct, adhesions, impacted stones in Hartmann's pouch, gangrene, pyocele, and Mirizzi syndrome, among others^{16,23}, increase the risk of difficult cholecystectomy and failure to achieve the critical view of safety. Other factors, such as procedural volume (high volume: > 50-85 cases per year), experience, and the involvement of a hepatopancreatobiliary surgeon, are related to morbidity and mortality in difficult cholecystectomy²⁴.

Approximately 10-15% of cholecystectomies are classified as difficult. The degree of difficulty is related to failure to achieve the critical view of safety and, consequently, bile duct injury. To avoid this outcome, rescue procedures such as cholecystostomy, a fundus-first approach, subtotal laparoscopic cholecystectomy, and conversion to open surgery can be employed². The use of procedures such as subtotal laparoscopic cholecystectomy has increased in recent years and reduced the conversion rate with changes to training programs and the availability of new technologies²⁵⁻²⁷.

The choice of the safest and most effective procedure depends on the available anatomical identification. Various methods have been studied to achieve this goal. Among the most widely used ones is intraoperative cholangiography, which involves administering contrast medium through a catheter in a safe area of the infundibulum. It has the advantage of direct visualization of the biliary tree, as well as the detection of stones, which are found in 8-15% of cases, with sensitivity and specificity rates of 97% and 99%, respectively²⁸. Its most notable disadvantages include the need to administer a potentially nephrotoxic contrast medium. Additionally, Lehrsokov et al.¹¹ found that in 1 out of 6 patients who underwent intraoperative cholangiography, the cystic duct was not patent.

Fluorescent cholangiography with indocyanine green was first described in 2009 by Ishizawa²⁹ and involves administering a bolus of 0.2 mg/kg of indocyanine green prior to surgery (although the dose and timing are not standardized), which is metabolized in the liver, allowing real-time visualization of biliary anatomy using near-infrared light projection²⁹. The disadvantages include the need for a special device to detect fluorescence and its limited utility in patients with obesity, adhesions, and severe inflammation, as near-infrared light penetration is approximately only 1 cm^{10,12}.

New methods, such as laparoscopic ultrasound, provide more accurate definition of structures (sensitivity of 92-100%), with the added benefit of detecting lithiasis with high sensitivity and specificity (76-100% and 96-100%, respectively), which can be used before dissection, and is quick and harmless; however, it requires special equipment and a steeper learning curve¹³.

The theoretical advantages of anatomical identification by intrinsic illumination include real-time visualization of the cystic duct and its critical junction with the common hepatic duct, and the absence of contrast, ionizing radiation, or medications that may cause adverse reactions, as well as a shorter learning curve and no need for special equipment. In 2020, Vidrio et al.²⁹ described a transillumination method using a 5 mm, 30° lens connected to a light source, which was placed directly in the area to be dissected. In this retrospective study, anatomical structures (not specified) were identified in 2 out of 10 patients; in the remaining ones, prior peritoneal dissection was required, with the risk of bile duct injury. Therefore, the authors concluded that further studies and the search for a different device were required³⁰.

Conclusions

Anatomical identification by intrinsic illumination using the Prometeo device is a safe and efficient, low-cost method that can be used in most centers performing laparoscopic procedures. Randomized, multicenter clinical trials are necessary to evaluate its real cost and its impact on reducing the risk of bile duct injury.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the ethical standards of the responsible human experimentation committee and with the World Medical Association and the Declaration of Helsinki.

Confidentiality, informed consent, and ethical approval. The authors have followed their institution's confidentiality protocols, obtained informed consent from patients, and have the approval of the Ethics Committee. The recommendations of the SAGER guidelines were followed, according to the nature of the study.

Declaration on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing of this manuscript.

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