Animal Model of Bile Duct Dilatation Created with Minimally Invasive Surgery[1]

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Rationale and Objectives. The purpose of the study was to evaluate a method of producing obstruction of the common bile duct and concomitant biliary duct dilatation in an animal model.

Materials and Methods. Laparoscopic placement of a double-balloon occlusion device was used to produce common bile duct obstruction and bile duct dilatation in pigs.

Results. One week after the procedure, common bile duct obstruction and dilatation of the biliary tree were demonstrated with either percutaneous transhepatic cholangiography or percutaneous cholecystography.

Conclusion. The use of this method is technically feasible and provides a useful subacute and chronic animal model of common bile duct obstruction and dilatation of the biliary tree for percutaneous interventional training and research purposes.

Key Words. Bile ducts, stenosis or obstruction; laparoscopic surgery; model, anatomical.

Research continues on methods and new devices for the minimally invasive management of biliary obstruction. In animal studies, the method of choice for the placement of biliary endoprostheses has been surgical access to the gallbladder (1–3). This approach has been used primarily because the percutaneous approach is hampered by the presence of a nonobstructed, undilated biliary system. Improved percutaneous access to the biliary system in an animal model has been suggested by fixing the gallbladder to the abdominal wall (4). However, this access route differs substantially from the traditional percutaneous transhepatic approach, and it does not exactly replicate the clinical situation.

The purpose of this study was to test a method to cause obstruction of the common bile duct with concomitant biliary duct dilatation in a swine model that uses laparoscopic surgery. The final objective was to facilitate research and training in the interventional management of biliary obstructive diseases.

MATERIALS AND METHODS

Double-Balloon Occlusion Device

The device used in this study was a modified version of a previously described occlusion balloon (5). The modified device consisted of two latex balloons, each one connected to a segment of soft plastic (Silastic; Dow Corning, Midland, Mich) tubing (Fig 1). The balloons were manufactured in-house by dipping a 2.8-mm-diameter stainless steel rod into liquid latex (PVVM latex; Chematex, Malmo, Sweden). Before it was dipped, the rod was coated with mineral oil and baby powder to facilitate removal of the latex from the rod. The rod was allowed to dry on a plastic (Plexiglas) stand at room temperature for 12 hours. The dipping process was repeated seven to eight times until the outside diameter of the la-

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tex-coated rod reached 4 mm. The latex was then pulled off the stainless steel rod and cut to a length of 3 cm. A 4-mm long segment of a 23-gauge needle was cut and placed inside a piece of soft plastic tubing (0.51 mm in inner diameter and 0.94 mm in outer diameter). The needle-supported end of the tubing was then inserted into the free end of the balloon, and a ligature was placed around the balloon. The proximal ends of the balloons had been tied together before placement into the animal. The soft plastic tubing used in this experiment was 30 cm long, and its free end was used to inflate the balloon from a distance with diluted contrast medium. All balloons were checked for leakage or damage by injecting 1.5 mL of saline before they were used.

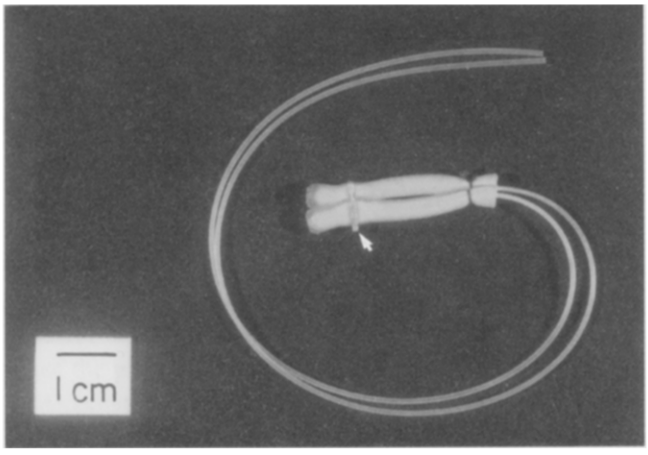

Figure 1. After being placed around the common bile duct, the balloons are tied together by placing a metal clip (arrow) over the free end of both balloons laparoscopically.

Technique

Laparoscopic placement of the double-balloon occlusion device was performed in three young domestic pigs (two female, one male), aged 6–9 weeks and weighing 20–29 kg. The study was carried out in compliance with the Guide for the Care and Use of Laboratory Animals (National Research Council, 1996). The animals were intubated and anesthetized by the intravenous injection of diazepam (0.15 mg/kg) and ketamine hydrochloride (10 mg/kg). Halothane 2% inhalant was also administered. Immediately before placement of the occlusion device, baseline cholangiography was performed with fluoroscopic quidance through a percutaneous gallbladder puncture with a 23-gauge Chiba needle. Contrast material was injected until the common bile duct, common hepatic duct, and intrahepatic ducts were visible.

While under sterile conditions, a pneumoperitoneum was created by introducing CO_2 through a Verres needle (United States Surgical Corp, Norwalk, Conn) inserted into the peritoneal cavity 3 cm below the xiphoid process. Four trocars measuring 5 mm in inner diameter were placed in the abdomen, 6 cm from the midline on both sides, and used to establish access into the peritoneal cavity for laparoscopic instrument insertion. By using laparoscopic guidance, the common bile duct was exposed. After the common bile duct was dissected from the adjacent tissues, the double-balloon occlusion device was introduced into the peritoneal cavity and placed around the distal common bile duct. The balloons were then joined by placing a metal clip over their free ends. The balloons were inflated by injecting diluted contrast medium through the soft plastic tubing until satisfactory common bile duct occlusion was observed laparoscopically. The free end of the tubing was then ligated with 3-0 silk suture. The average amount of contrast medium used to achieve sufficient balloon inflation was approximately 1 mL.

As soon as sufficient distention of the 10 × 12-mm balloon was achieved, the laparoscopic instruments and trocars were removed and the soft plastic tubing was buried subcutaneously. All incisions on the abdominal wall were sutured in layers. The free end of the soft plastic tubing was secured on the skin by a suture through a nearby sutured incision, facilitating subsequent balloon deflation with a syringe. No more than 2 mm of tubing was allowed to protrude above the skin surface, to prevent the pig from scratching or clawing the tube out after the procedure. One week after the procedure, follow-up percutaneous transhepatic cholangiography (n = 1) or percutaneous cholecystography (n = 2) was performed to demonstrate the common bile duct obstruction.

RESULTS

Placement of the double-balloon device with use of laparoscopic surgery was successfully accomplished in three animals without any technical difficulty or complications. The inflated balloons remained the same size 1 week after placement, as assessed radiographically. The procedure took an average of 30 minutes to perform. One week after the procedure, marked dilatation of the extrahepatic bile duct was demonstrated by cholecystography, with a 120% increase in diameter of both the right and left hepatic ducts. The intrahepatic biliary tree was dilated with an average of 50% increase in diameter; however, the dilatation appeared to be less prominent than

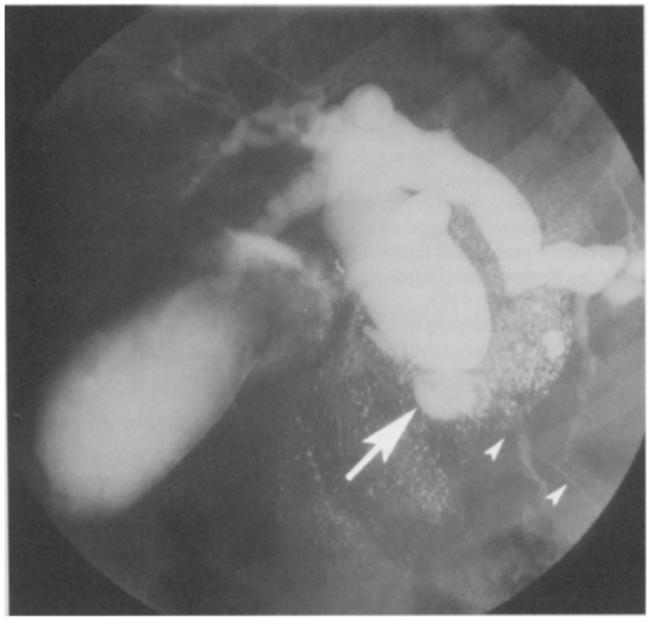

Figure 2. One week after placement of the double-balloon occlusion device (arrow), the bile ducts appear to be severely dilated because of the occluded distal common bile duct. Note the soft plastic tubing (arrowheads) that connects the balloons.

that in the extrahepatic bile ducts (Fig 2). The gallbladders were noted to be moderately distended in all pigs. After the balloons were deflated, contrast medium entered the duodenum and the biliary system remained dilated.

DISCUSSION

This study was designed to develop an animal model of biliary duct dilatation by means of laparoscopic surgery. This model is needed for testing of new devices and for learning biliary interventional procedures. The method is simple and creates an adequate biliary duct dilatation model. Our study showed that (*a*) the procedure is simple and can be used to create one or many experimental subjects within a short period of time for training purposes, (*b*) the technique is less traumatic than the conventional open surgical procedure, (*c*) the procedure eliminates the possible complications of surgical procedures that cause anatomic or physiologic changes, and (*d*) the model is expected to be predictable and reproducible. In reports of previous studies (5), complete occlusion of the common bile duct invariably resulted in marked duct dilatation 3 days after the occlusion was performed. It is, however, difficult to cross the obstruction when the balloons are still inflated. Therefore, with the guide wire in the bile duct above the obstruction, the balloon should be partially deflated to allow the wire to pass into the duodenum (A. Lunderquist, written communication, October 1998).

Previous experience has shown that the degree of duct dilatation is associated with the length of occlusion time: The longer the balloons stay inflated, the more dilated the bile ducts may become (6). In addition, since the common bile duct stricture or occlusion is produced by the extrinsic compression of the latex balloons, it is expected that the stenosis will respond to metallic stent placement.

The technique does have some limitations. The most notable limitation is that the intrahepatic biliary tree does not dilate as much as the extrahepatic bile ducts do. This may make percutaneous transhepatic biliary access difficult. The lack of marked dilatation of the intrahepatic bile ducts may be the result of the buffer effect provided by gallbladder distention in the face of increased bile duct pressure, since in these circumstances the gallbladder acts as a reservoir by increasing its volume. In addition, the extrahepatic ducts tend to dilate substantially more in cases of distal biliary obstruction than do the intrahepatic ducts (7). This preferential dilatation can be explained by Laplace's law, in which the expanding force under a given pressure is directly proportional to the diameter of the cylinder (8). On the basis of these mechanisms, a longer duration of occlusion or the placement of the occlusion device on the common hepatic duct may augment intrahepatic biliary duct dilatation.

An alternative solution in cases in which minimally dilated intrahepatic biliary radicles are present is to perform a percutaneous gallbladder puncture to opacify the bile ducts. Once the intrahepatic radicles are delineated, puncture of a suitable dilated duct can be easily accomplished with fluoroscopic guidance.

The technique described in this report is by no means practical for all institutions. The technique will be feasible only for those institutions where laparoscopic instrumentation is available for experimental applications.

The study demonstrated the feasibility of creating an animal model of bile duct dilatation and common bile duct obstruction by using laparoscopic techniques. This model can be used as an alternative to direct gallbladder puncture during laparotomy for placement of a biliary stent. The model may be further improved by ligation of the cystic duct, eliminating the buffer effect by gallbladder distention to achieve maximal intrahepatic duct dilatation. If an acute model is desired for training purposes, this model can also be used to produce acute common

bile duct obstruction on the day the model is to be used by inflating the balloon through the soft plastic tubing.

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