

CHOLANGIOGRAPHY CATHETER APPARATUS AND METHOD

BACKGROUND

1. Field of the Invention

This invention relates to laparoscopic surgical techniques for laparoscopic cholecystectomy and, more particularly, to a novel cholangiography catheter apparatus and method for introducing a liquid contrast medium or dye into the cystic duct during a laparoscopic cholecystectomy.

2. Disclosure Document

This patent application is based, in part, on the subject matter disclosed in Disclosure Document No. 294,219 filed 15 Oct. 1991.

3. The Prior Art

Gallbladder disease is indicated by the presence of gall stones which are caused by the concentration of bile into stones. Bile, constituted primarily of bile salts, is secreted by the liver through ducts into the intestine where it aids in the digestion of fats. Bile is stored and concentrated in the gallbladder where it is available when the digestive processes require additional bile. The common bile duct is formed by the junction of the cystic duct and the hepatic ducts draining from the liver. The bile passing through the bile duct empties into the duodenum adjacent the outlet of the stomach.

It is presently unclear as to what causes gall stones to form, but it has been postulated that infection or a chemical disturbance in the gall bladder may cause gall stones to precipitate from the bile. These gall stones create obstructions to the passage of bile through the ducts and into the intestinal tract. A stone blocking the cystic duct may cause acute inflammation of the gall bladder leading to poor filling and emptying and even loss of function of the gall bladder.

The standard treatment of cholelithiasis (presence of stones in the gallbladder or bile ducts) in the United States is surgical removal of the gallbladder. Historically, this was considered as a major surgical procedure involving a lengthy stay in the hospital and was, therefore, a major economic impact on the patient due to the major surgery, lengthy hospitalization, and absence from work for several weeks.

Cholelithotomy, the surgical incision of the common bile duct, should be made if gall stones are present in the duct. Cholangiography aids in identifying the presence of stones and related problems. Also cholangiography may avoid an unnecessary cholelithotomy since both the surgical incision of the common duct and the presence of unlocated stone particles may cause post-cholecystectomy morbidity. These unlocated stone particles may become the nucleus of new stones, requiring subsequent surgical intervention. Cholangiography, therefore, aids in the X-ray identification and location of stone particles for their immediate removal.

More than a half million patients underwent total cholecystectomy in 1988, and with the increasing number of elderly patients, this number is expected to increase. Laparoscopic cholecystectomy was developed in an attempt to reduce the morbidity and cost of gallbladder disease by providing a minimally invasive approach to the surgical removal of the gallbladder. The first laparoscopic cholecystectomy was performed in France in 1987 by a gynecologist. By the Fall of 1988 this procedure was being performed clinically. Subsequently, the introduction of and pioneering techniques

for laparoscopic cholecystectomy were being performed by Dr. Eddie Joe Reddick and Dr. Douglas Ole Olsen in the United States, and the results thereof are widely reported in the scientific literature. They reported that their techniques allowed for the same day or next day discharge of the patient from the hospital coupled with an expeditious return to full working schedule. As an added benefit, there is minimal scarring from the procedure, making it desirable from a cosmetic standpoint.

Patient acceptance, in fact, demand, for laparoscopic cholecystectomy has been phenomenal with the result that it has become the procedure of choice in treating gallbladder disease. There are many reasons for its popularity. Cosmetically, the four small incisions required for the procedure are preferred to the large, right subcostal incision of traditional surgery. Pain is minimal. The new procedure allows the patient to be discharged the same day of surgery instead of a several day hospitalization. Most patients can return to work and resume vigorous activity by one week instead of six weeks. Time lost from work and other activities is minimized. Therefore, the economic benefits are two fold: (1) lower hospitalization costs, and (2) reduced loss of employment.

However, with the advent of laparoscopic cholecystectomy, the ability to perform cholangiography has been rendered difficult due to the techniques and equipment employed for the laparoscopic procedure. One currently used prior art technique involves a rigid, stainless steel catheter having an angled tip that is passed through a trocar sleeve in the abdominal wall which is the access port used by the surgeon for instrument access. The angled tip is inserted into the cystic duct and secured with a clip. A syringe containing saline solution is attached to the proximal end of the catheter and is used to flush saline into the common bile duct, possibly indicating whether the common duct is open or blocked. The saline syringe is then replaced with a syringe containing dye or, rather, a contrast medium. The contrast medium is injected into the duct system and an X-ray is taken to identify the presence and location of any stones.

This prior art technique is fraught with a number of problems such as the risk of cystic duct tearing by the rigid catheter, air entry when the syringes are changed, and obscuration of details by the non-radiolucent nature of the stainless steel. An even further problem is that the catheter is inserted through the instrument port so that this port is unavailable to the surgeon for other instrumentation while the catheter is in place. The alternative would be to create a separate access port for the catheter, but this is unacceptable since it represents another incision that requires attention and adds to the healing burden of the patient.

Another prior art technique was to use a ureteral catheter cut immediately behind the side ports. This catheter had the advantages of being flexible and radiolucent. However, it has no Luer fitting for securing the saline and dye syringes and the sharp edge resulting from its fenestrated tip being cut off is a cause for concern. There is still the risk of air entering the catheter when the syringes are changed. Also, there is no way for telling how far the catheter has been inserted into the cystic duct. The softness of the catheter may also allow it to become occluded when the clip is applied to secure the catheter to the cystic duct.