

The Safety Sphincterotome: The Device, the Technique and Preliminary Results

D. F. Martin, R. England, O. Martin

Department of Radiology, South Manchester University Hospitals NHS Trust, Manchester, UK

Background and Study Aims: Endoscopic sphincterotomy is a widely used and safe procedure for the management of common bile duct stones, but little attention has been paid to the design of the sphincterotome and its influence upon risk of sphincterotomy. This study was undertaken to evaluate a sphincterotome, designed to incorporate known and original aspects which may contribute to safety.

Patients and Methods: 144 patients with bile duct stones were evaluated in an open prospective study of the use of the sphincterotome in performing endoscopic sphincterotomy. Evaluation included post-sphincterotomy compli-

cations, 30-day morbidity and mortality and effective duct clearance.

Results: Only one complication (0.7%) occurred in the group of 144 patients. Duct clearance of stones was ultimately achieved in 94%.

Conclusions: Whilst more experience is necessary using the sphincterotome in the manner described, the absence of significant complications in all but one patient appears to support the philosophy behind the design of the sphincterotome.

Introduction

Although there is conflicting evidence, identifiable risk factors for complications after endoscopic sphincterotomy (ES) include the size of the sphincterotomy (1,2) impacted stone at the ampulla (3), periampullary diverticulum (3), papillary stenosis (4) and needle knife papillotomy (3,5). Since the earliest description of ES (6), relatively little attention has been paid to the influence of the design of the sphincterotome itself on the risk of complication, although modified devices (7) have been described in an effort to simplify the procedure.

We have designed a modified sphincterotome, each feature of which is specifically incorporated to facilitate low risk sphincterotomy. This paper describes the sphincterotome, the author's sphincterotomy technique using the device and preliminary results.

Materials and Methods

The device is a 6 Fr, double lumen, wire-guided sphincterotome with a 3 cm monofilament diathermy cutting wire (Figure 1). The guide wire and cutting wire are entirely separated. The proximal 1.5 cm of the cutting wire is insulated. The insulation is bonded to the cutting wire and is made of perfluoroalkoxy (PFA), a PTFE-like polymer which has good electrical insulating properties, is heat resistant and can be autoclaved. The insulated section is coloured to minimise iris closure when using a videoscope and contrasts with the silver colour of the cutting wire for easy visibility. Colour coded distance markers are incorporated into the shaft of the catheter alongside the cutting wire. Distally there is a 3 cm tapered nose with a radio opaque marker incorporated in its tip.

Wire Guidance

The simplest, and most efficient, device for deep bile duct cannulation is an endoscopic retrograde cholangiopancreatography (ERCP) cannula. Once deep cannulation has been achieved with a cannula, wire-guided exchange guarantees successful placement, avoiding the risk of the occasional failure of sphincterotomy, as well as the risk of inadvertent pancreatic duct cannulation with the sphincterotome. The device is designed to take a 0.035 inch guide wire, but any

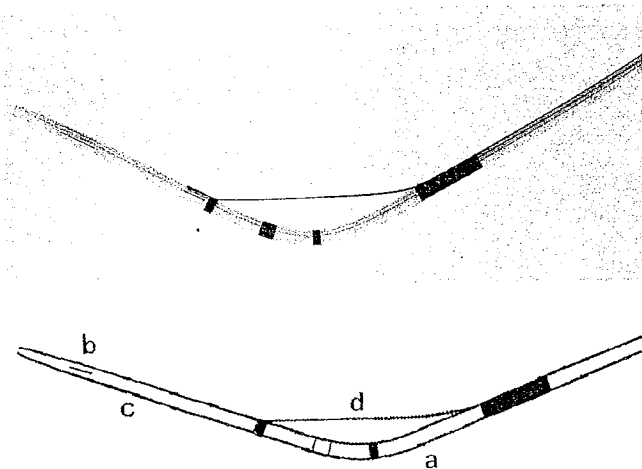


Figure 1: a Double lumen for 0.035 inch wire guidance. b Tapered tip with metal marker. c 3 cm leading nose. d 3 cm cutting wire (1.5 cm insulated).

wire of lesser diameter can be used. Contrast medium can be injected through the guide wire channel using a side arm valve with the guide wire in place.

Tapered Tip and Metal Tip Marker

The tip facilitates introduction through the papilla, with minimum trauma and minimum risk of dislodgement of the guide wire. The metal marker provides additional reassurance to check that the sphincterotome is properly positioned within the bile duct.

3 cm Nose

As the device is wire-guided, the presence of a long nose has no disadvantage. The long nose allows the guide wire to be removed completely during sphincterotomy in order not to inhibit bowing of the cutting wire. The guide wire can be replaced after cutting if necessary. Additionally the nose allows virtually all the cutting wire to be withdrawn from the papilla prior to diathermy without risk of withdrawing the device completely from the duct. This allows a very short segment of contact between the papilla and the cutting wire, maintaining high current density and precise control of the cut, avoiding the risk of a zipper sphincterotomy. The nose also assists the orientation of the sphincterotome in the line of the duct. The sphincterotome can be groomed (8,9) if required.

3 cm Cutting Wire

A long cutting wire is used, not in order to allow a large sphincterotomy, but to maintain the axial orientation of the sphincterotome during bowing. Short wire sphincterotomes tend to twist when bowed (3).

Proximal Cutting Wire Insulation

The proximal part of the wire is not used for cutting. Insulation is provided to avoid contact with the endoscope, but more importantly, to avoid contact with the medial wall of the duodenum anterior to the papilla and to avoid inadvertent cutting of a low-lying duodenal fold or of the roof of a periampullary diverticulum. Proximal insulation also encourages the endoscopist to use only the distal portion of the wire for cutting, thereby maximising current density.

Technique

After deep bile duct cannulation, contrast medium is flushed from the cannula with saline, a guide wire is passed through the cannula into the duct and the cannula is removed. The sphincterotome is loaded onto the guide wire, passed down the endoscope and introduced into the papilla by advancement of the sphincterotome, lifting the forceps elevator and upward angulation of the endoscope. After the papilla is deeply cannulated with the sphincterotome, the guide wire is removed. Once a stable position of the endoscope is achieved, the sphincterotome is withdrawn until only 1 or 2 mm of the cutting wire remains within the papilla. An assistant bows the sphincterotome slightly and the endoscopist applies short (less than 1 second) bursts of diathermy current whilst lifting the forceps elevator or angling the endoscope upwards in order to drive the tip of the diathermy wire up the infundibulum of the papilla. Pure cutting current or a mixture of cutting and coagulating current can be used. Our preference is for blended current (Olympus PSD10 diathermy unit) at a setting of 4.5 (50 watts) output. If repositioning is necessary during cutting, the assistant unbows the wire and the endoscopist pushes the sphincterotome up the duct by upward endoscope angulation. The endoscope can be withdrawn slightly and the positioning of the sphincterotome repeated in order to complete the cut. The cut is extended only to the apex of the infundibulum of the papilla, never beyond. After completion of sphincterotomy, the sphincterotome is withdrawn in order to remove stones with a balloon or basket. A guide wire can be re-introduced prior to removal of the sphincterotome if necessary.

Clinical Experience

Sphincterotomy was performed by supervised trainees or by experienced endoscopists. Results were prospectively evaluated and patients followed up by questionnaire to referring practitioners. Complications were defined according to agreed criteria (10). The complications of haemorrhage, retroperitoneal perforation and acute pancreatitis were specifically sought. All patients were either in-patients in our hospital or attended on day-case transfer from other hospitals. All patients remained under hospital supervision for 18–24 hours after sphincterotomy and were discharged only when considered medically fit. Questionnaires relating to 30-day morbidity and mortality following sphincterotomy were administered by a research assistant who

achieved 100% compliance with the questionnaire by diligent follow-up. In cases of uncertainty regarding follow-up, patients' notes were retrieved and reviewed. Additionally, patients' primary physicians were contacted where necessary.

Results

We have so far used this device in the manner described in 144 patients, aged between 29 and 94 years, with bile duct stones. Sphincterotomy was successfully completed in every case. Immediate stone extraction was always attempted using a standard stone extraction basket. Mechanical lithotripsy was used when appropriate. 7 Fr double Pig-tail stents were placed when duct clearance failed. We have seen no complicating cholangitis and no clinical pancreatitis. Two patients had bleeding sufficient to obscure the endoscopic view temporarily and one of these required further therapy (transfusion only). There was no retroperitoneal perforation. Complete duct clearance was ultimately achieved in 94%.

Discussion

Complications that are directly related to endoscopic sphincterotomy include acute pancreatitis, haemorrhage and retroperitoneal perforation. Although acute cholangitis is commonly considered a complication of ES, it is in fact a complication of inadequate bile duct drainage (11). Factors that predispose to complication after sphincterotomy either may be present in the patient (coagulation disorder, papillary stenosis, diverticulum) or may be a consequence of technique (12). Mechanical or thermal trauma to the papilla may result in acute pancreatitis; a rapid uncontrolled and extensive sphincterotomy leads to haemorrhage and a misdirected or extensive cut leads to retroperitoneal perforation (13). The sphincterotome described here was designed specifically with these aspects of risk in mind. Whilst cannulation of the bile duct is possible using a slightly bowed sphincterotome, deep cannulation is most easily and atraumatically achieved using an ERCP cannula. Use of a wire-guided sphincterotome after placement of a wire through a cannula ensures deep cannulation of the duct with the sphincterotome and minimises trauma to the papilla during re-insertion.

Many endoscopists find the use of a sphincterotome with a long leading nose awkward because of difficulty in cannulation, but the use of wire guidance removes this difficulty. The advantages of a long nose are that orientation of the sphincterotome in the line of the bile duct is maintained, the guide wire can be removed without risk of the sphincterotome slipping out of the duct, and also that the endoscopist can remove virtually all the cutting wire from the duct prior to performing sphincterotomy, without risking complete displacement of the sphincterotome. Occasionally deep cannulation is thwarted by an impacted stone at the ampulla and access for any sphincterotome may be limited. Needle knife papillotomy usually resolves this problem and allows

deep access (5). It is our belief, as well as that of others (13) that sphincterotomy is most safely and precisely achieved when only a short segment of cutting wire is in contact with the papilla. High current density is maintained over a very short segment of tissue, allowing sphincterotomy to be performed under precise visual control and thereby minimising total electrical energy requirement for sphincterotomy.

Whilst many of these features described are already available in standard production sphincterotomes, all are incorporated in our sphincterotome for specific safety reasons. Additionally we have incorporated a 3 cm cutting wire in order to maintain axial stability of the device. The disadvantage of a longer cutting wire is that when withdrawn from the papilla in order to use only the distal tip of the wire for cutting, the endoscopist has less control over the proximal part of the wire. This has therefore been insulated in order to give the endoscopist the confidence that no damage will occur from inadvertent contact of the proximal part of the wire with endoscope or duodenum. The proximal insulation has two other advantages. It allows sphincterotomy within a diverticulum with less risk of contact between the cutting wire and the diverticular roof. Additionally, the insulated segment obliges the endoscopist to use only the distal portion of the wire for cutting. It may be that insulation of a greater proportion of the cutting wire may enhance this benefit further.

An integral component of the use of the sphincterotome is limitation of the extent of the sphincterotomy. In our practice this is taken only to the visible junction of the apex of the infundibulum of the papilla, with the duodenal wall (12). Anecdotally, some endoscopists feel that use of external landmarks is difficult and may lead to incomplete sphincterotomy but in fact this technique is rarely difficult with experience. Complete transection of the choledochal sphincter is not necessary for successful duct clearance (14). Whilst larger stones are less easily removed after such a sphincterotomy (15), lithotripsy techniques (16) can deal successfully with large stones, avoiding the need for sphincterotomy size to be tailored to stone size. Limitation of sphincterotomy size must reduce the risk of complication. Naturally, experienced endoscopists have their individual views regarding their favoured design of sphincterotome but our design is popular with our trainees who find its features gave them confidence when performing sphincterotomy and they have eschewed all other sphincterotomes in its favour. Although our experience with the sphincterotome is as yet limited, we have experienced only one significant complication (10) in 144 patients (0.7%). Clearly we should be circumspect whilst gaining further experience, but preliminary results suggest that this sphincterotome, used in the manner described, can achieve the aim of certain, safe biliary sphincterotomy.

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Corresponding Author

D. F. Martin, F.R.C.P., F.R.C.R.
 Consultant Gastrointestinal Radiologist
 Department of Radiology
 South Manchester University Hospitals NHS Trust
 Withington Hospital, West Didsbury
 Manchester M202LR
 UK
 Fax: +441614481688

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