Current Status of Product for Endoscopic Surgery in Korea

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Abstract

Endoscopic surgeries are popularly performed these days because of the advantages in rehabilitation and cosmetic aspects. But some accompanying disadvantages should not be neglected. For surgeons unfamiliar with the endoscopic surgery techniques, the operation takes more time and dangerous complications may occur more frequently. Most endoscopic surgery techniques, also called minimal invasive surgery techniques, were developed and disseminated from Europe and the U.S. They require specialized equipment and instruments that are expensive, and for this reason the total operation cost compared to conventional open surgery is higher. Despite all the advantages of endoscopic surgery, the high cost due to the of imported specialized instruments is holding back its spread in Korea. The development of self-supporting endoscopic instruments in Korea is mandatory for reducing the expense, and in this regard I have designed trocars of various size, specimen retrieval bags, suction and irrigation tubing sets, gasless laparoscopic surgery sets, scissors of various types, and forceps. Instruments used in suture and ligation which are currently under development will also soon be introduced.

Key Words: Laparoscopic, surgical apparatus

INTRODUCTION

It was Dr. Mouret from France who pioneered the endoscopic surgery technique in performing cholecystectomy, followed by Dr. Reddik from the U.S. who used a laser in performing cholecystectomy. Thereafter, the application of endoscopic surgery technique was expanded to areas including choledochololithotomy, colectomy, splenectomy, adrenalectomy, and gastric surgery. These days, many surgeries once performed in the general surgery department have been replaced by endoscopic surgeries, as well as surgeries performed in the field of thoracics, orthopedics, urology, plastic surgery, neurology, and ophthalmology.

An endoscope with a video camera attached is required, and since the surgeon cannot directly reach the surgical field, specialized instruments are also needed. Specialized valves constitute the trocar sleeve to avoid gas leakage from the body cavity. The very high cost of these specialized tools has prevented the popularization of endoscopic surgeries in Korea. For example, the operation fee for a cholecystectomy reimbursed by health insurance in Korea is about 250 U.S. dollars, whereas the cost of disposable endoscopic instruments used in the operation is about 1,200 U.S. dollars. Health insurance in Korea does not cover any of the additional costs financially-constrained patients find themselves precluded from of endoscopic instruments, therefore endoscopic surgery. To compensate for the high cost, disposable instruments including trocars, graspers, and scissors are resterilized; they are initially soaked in gluteraldehyde solution, cleansed under an ultrasonic sterilizer, and finally cleansed again in saline. Blood clots and tissue fragments cannot be completely washed out from disposable instruments because no irrigation ports are available and the disposable instruments are not designed to be disassembled. As one can easily guess, this resterilization process is far from being effective and safe. Development and manufacturing of endoscopic instruments in Korea is of paramount importance to curtail the high cost. Fortunately, endoscopic instruments are being made in Korea by Sejong Medical Co., (Paju) which is the only company in Korea that produces endoscopic instruments.

TROCARS

The reusable trocar made of stainless steel, with
silicon packing and a metal spring, is popularly used in Europe. It can be disassembled and sterilization of the parts is possible, making it "reusable." Therefore, it can be considered relatively economic. But it is comparatively heavy, so each time the endoscopic instrument is inserted, the trocar has to be manually raised. Also, the metal sleeve prohibits the use of some electrocautery equipment. There is also a need for periodic sharpening of the trocar tip, and because the packing is relatively thick, the sleeve can occasionally be pulled out from the insertion site. In Korea, this type of trocar has been in use for several decades by gynecologists in the performance of sterilization. This might seem economic, but the whole trocar has to be changed each time, even with the loss of the smallest part or with damage to the insulation cover by the sharp edge of the trumpet valve. As a result of these shortcomings, the reusable trocar is losing its popularity. Refinements of these shortcomings have followed; the sleeve has been changed to autoclavable plastic and trumpet valves have been replaced by magnetic ball valves. But concomitantly, the cost has risen to 1,000 U.S. dollars and there is still no automatic safety in the sharp tip, therefore it has not regained popularity. Disposable trocars have been developed, but again the high cost has remained.

A disposable trocar (LapTroc, Sejong Medical, Paju, Korea) was developed in Korea 4 years ago which is relatively low-priced, and its market share has risen up to 40%. It comes in sizes of 2.5 mm, 5 mm, 10 mm, 10/11 mm, and 12 mm. The shape of the puncture needle varies according to the size of the trocar: a simple pyramidal tip needle in 2.5 mm, sharp tube needle with inner safety rod type in 5 mm, a liner-cutting-knife type cutter holder and hemicolumellar rod-type knife cover in 10 mm, 10/11 mm, and 12 mm. All of these trocars have an automatic shutter mechanism for the sake of safety; right after puncturing, the safety system protects body structures from the sharp knife. The valve in the trocar sleeve is composed of 2 magnetic plates, instead of conventional springs, for the prevention of gas leakage. The magnetic plates are tightly attached to each other in case of valve closure; and while the instrument is inserted, the two magnetic plates are far apart and no magnetism is exerted, so manipulation of the inserted instruments is smoothly performed. The trocar has no manual valve opening knob because the instrument-inserting tube is of a pendulum type, opening only at the pendulum, and gas can be removed, making deflation and smoke removal possible. Among all the advantages, the low price is the strongest point of this trocar; its cost is one-quarter of the imported trocar. The low cost and no need for resterilization ensure the future popularization of this made-in-Korea product (Fig. 1).2,4

SPECIMEN RETRIEVAL BAG

The price of the bag used in retrieving the infected gallbladder or a gallstone dropped in the peritoneal cavity is not that expensive, but the bag used in removing the resected spleen or colon segment is imported and it is expensive, costing about 250 U.S. dollars each. No patient is willing to pay about 300,000 won just for retrieving the specimen. Fortunately, specimen retrieval bags are now produced in Korea at one-tenth the price imported products. The Lapbag (Sejong Medical, Paju, Korea) comes in small, medium, large, and X-large sizes. All of them can be inserted in the 10 mm plastic tube, so most of the specimens can be retrieved through the 10 mm trocar sleeve. The bag is made of polyurethane and it is processed by microwave welding, making it strong and durable. When inserted, the oval-shaped spring plate is unfolded and the mouth
of the bag is opened. The bag can be readily identified inside the body cavity, and after the specimen is taken into the bag, it is closed by means of a pursestring. Due to its reasonable price and good quality, the specimen retrieval bag made in Korea is now the most-used product in the field of endoscopic surgery.

OPERATING INSTRUMENTS

As trocars, operating instruments including various types of forceps and scissors can be divided into two types: reusable instruments popular in Europe and disposable instruments used in the U.S. composed of casting steel tips. The working tips of reusable instruments including various types of dissectors, grasping forceps, and scissors are better in terms of quality because they are made by milling machines controlled by computers. The reusable instrument can also be disassembled in pieces and irrigation ports are available, therefore cleaning the inner side of the shaft is possible.

The biggest disadvantage of the reusable instrument is its high cost. In Korea, the reusable instrument costs about 800 to 1,200 U.S. dollars, and the price of the needle holder is even higher. Disposable instruments including dissectors, grasping forceps, and scissors used in cholecystectomy and appendectomy have been in use for about 10 years in the U.S. They are comparatively less exquisite than reusable instruments, but the relative low-cost is the reason for their popularity. Reports on the economic aspects of the endoscopic instruments have concluded that although disposable instruments are about 100 U.S. dollars more expensive than reusable instruments, considering the problems accompanying the sterilization of reusable instruments, disposable instruments provide more advantages. The actual circumstance in Korea is different; disposable instruments are not disposed of after a single usage, but rather they are repeatedly used until their breakdown prohibits functioning. Health insurance does not cover the cost of disposable instruments, and neither can the patient buy the product individually, therefore the cost is added to the operation fee. Also, disposable instruments cannot be completely and perfectly sterilized; the insulated covers and plastic handle are not suitable for autoclave, and blood clots and tissue fragments remaining inside the instrument cannot be sterilized using ethylene oxide, leaving the possibility of disease transmission.

The Sejong Medical Co. produces a 10 mm clip applier, a 7 mm diamond jaw heavy needle holder, and various other 5 mm instruments including curved dissector, grasper, curved scissors, sharp point grasper, tubo-ovarian forceps grasper with teeth, and diamond jaw needle holder. The utilization of autoclavable plastic compared to the weak conventional plastic in their products is noticeable. Shafts are also Teflon resin-covered, which is autoclavable and which has reduced the probability of cross contamination. Operating instruments made in Korea are also gaining popularity in the market.

SUTURING AND LIGATION TOOLS

The imported automatically-reloadable clip applier installs 20 clips. Since only 4 to 6 clips are used in each operation, the applier can be used repeatedly in about 4 to 5 cholecystectomy operations after resterilization. Health insurance covers the cost of up to 10 clips per operation, and this forces surgeons to repeatedly use the clip applier. The shaft of the automatic clip applier is composed of multiple narrow tubes, and by a siphon effect the patient's body fluid can readily regurgitate to the shaft which cannot be washed out; again, the disposable instrument cannot be considered safe. Since the development of the 5 mm-diameter disposable automatic clip applier, the whole process of laparoscopic cholecystectomy can be successfully worked out with only 5 mm-diameter trocar punctures. But despite the simplicity and convenience of the disposable instrument, the importance of sterilization keeping the instrument free of virus can never be overemphasized. In my opinion, rather than the repeated use of the disposable clip applier, the single clip applier should be used after autoclaving. In performing a cholecystectomy using only the 5 mm or 2.5 mm trocar sleeve, the Open Laploop (Sejong Medical, Paju, Korea) can be used with convenience and safety. The cutting stapler used in advanced laparoscopic surgery is produced in various forms by USSC, Ethicon, and Richard Allen Co. The cost of these staplers is not covered by health insurance in Korea. They are not yet manufactured by any Korean companies and their development in the
near future is being encouraged.

Recently, I have designed three easy and safe knot tyings as a means of advanced laparoscopic suturing and ligation; they are general, open, and suture loop. The general loop was initially developed in Europe. It was made of dry cargut ligature in a hangman loop type and it lost its tensile strength too quickly. I designed a loop using the PGA ligature (Samyang Co., Daejeon, Korea) in which the inner core of the string is stiffly processed, there by maintaining the round morphology of the loop and its knot-holding capacity. It is currently manufactured by SJM, Korea (Fig. 2).

The above-mentioned loop can be used in ligating structures such as the vermiform appendix or ovarian cyst, in which only one side is attached to other structures. Structures like the cystic duct, colic vessels, or splenic vessels in which both ends are continuous with adjacent structures cannot be readily ligated using the conventional loop, while making an intra-corporeal knot is very time consuming and usually results in incomplete knot formation. In this case, the open loop that I have designed can be applied with ease. Inside the four half-knots, Teflon tubing is placed to maintain the knot, and the ligature tip is stiffened by a biologic hardener. The ligature tip is revolved around the site of the ligation and pulled out through the same trocar sleeve. It is then inserted into the Teflon guide tube, and after removing the guide tube, the ligature tip is slipped through the plastic knot pusher. Fastening the two ends, ligation with the open loop is successfully completed.

The suture loop is the last type to be introduced. It is basically the same as the open loop, except a suture needle is attached at the end of the ligature tip. Using the general suturing technique, laparoscopic suturing is done, and the ligature tip is removed through the same trocar sleeve. The stiff string right behind the needle is removed and it is converted to an open loop, and the ligation is finally completed (Fig. 3).

Using these three loops, ligation of thickened broad cystic duct, large splenic arteries and veins in spleen weighing more than 1,000 gm was possible. Anterior choledochotomy closure was completed in a shorter operation time and laparoscopic hysterectomy was completed without using staples or clips. Let me introduce the “needle hole cholecystectomy” technique which can be readily performed using the open loop. The 10 mm trocar is inserted around the umbilicus and three other 2.5 mm trocar sites are punctured. All the 2.5 mm trocars are made by SJM and the general laparoscopic cholecystectomy technique is applied. The separated cystic duct and cystic entry are repeatedly ligated repetitively using the 2 mm open loop (ligature diameter: US metric, 2-0). The cystic duct and artery are ligated and the gallbladder is
separated from the liver bed. The laparoscope is removed and a LapBag (Sejon Medical, Paju, Korea) is inserted through the 10 mm trocar. The scope is reinserted through the trocar, the gallbladder is packed into the bag, placed in the peritoneal cavity, and finally it is removed.

OTHER INSTRUMENTS NECESSARY FOR ADVANCED LAPAROSCOPIC SURGERY IN KOREA

Bipolar coagulators and Argon beam coagulators designed for laparoscopic surgery are currently used only in a limited number of hospitals. An ultrasonic coagulator and cutter called a “Harmonic Scalpel” is also a requisite in laparoscopic surgery, and its development in Korea is strongly recommended. The development of the coagulation and cutting device using a high frequency or electric microwave as well as tip temperature-controlled tip coagulation device are also warranted.

GASLESS LAPAROSCOPIC SURGERY APPARATUS

In the early era of laparoscopic surgeries, the gasless technique was used in treating acute cholecystitis, common bile duct exploration, and operating splenectomy. I have designed many gasless laparoscopic surgery accessories such as a balloon-reinforced abdominal wall filter, a right-angle dissector, and continuous suction and irrigation probes. But gasless laparoscopic surgery has its shortcomings in its inability to maintain the operation field and in the development of postoperative pain due to local peritoneal irritation.

CONCLUSION

Ever since its introduction in Korea, endoscopic surgery has been gaining popularity in keeping with the worldwide trend. Unfortunately, the disposable imported instruments are fairly expensive and their cost is not supported by health insurance. To compensate for the high cost, disposable instruments are incompletely resterilized and used repeatedly. Recently, trocars, operation instruments, and specimen retrieval loops have been developed in Korea, and they are being supplied at reasonable cost. With ongoing progress in the development of laparoscopic instruments in Korea, laparoscopic surgery is sure to gain more popularity in the near future.

REFERENCES