EXPERIMENTAL METHODS IN CLINICAL PRACTICE

Use of the "Shape Memory" Effect of a Titanium Nickelide Spring in a Suturing Device for the Formation of Compression Esophageal Anastomoses

A. N. Robak

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A new method for the formation of a compression esophagointestinal anastomosis is proposed. The compression force in the new device for creation of compression circular anastomoses is created by means of a titanium nickelide spring with a "shape memory" effect. Experimental study showed good prospects of the new device and the advantages of the anastomosis compression suture formed by means of this device in comparison with manual ligature suturing.

Key Words: *gastric cancer; compression apparatus suturing; esophago-intestinal anastomosis; titanium nickelide*

Gastrectomy (total or partial) with the formation of esophagointestinal (EIA) or esophagogastric anastomoses (EGA) remains the main method for radical treatment of stomach cancer up to the present time. Restoration of continuity of the gastrointestinal tract by forming anastomoses with the esophagus or stomach is the most difficult and important stage of surgery. Deep location of the esophagus in the thoracic and abdominal cavities technologically impedes the performance of this stage of the operation, while the absence of a serous coating on the esophagus and the aggressive microflora of the esophagus have a negative impact on the strength of the anastomosis sutures and on the conditions of their healing. Incompetence of EIA formed by traditional manual suturing after gastrectomy develops in 2-10% cases, mortality from this complication is about 45% [9].

Kurgan Regional Clinical Hospital; Department of Clinical Disciplines, Faculty for Upgrading and New Professional Training of Specialists, Tyumen State Medical Academy, the Russian Ministry of Health, Russia. ***Address for correspondence:*** a_robak@mail.ru. A. N. Robak

Introduction of suturing devices (PKS-25, KC-28, AKA-2 and AKA-4, LPK-25) significantly facilitated and standardized the technology of esophageal anastomosis formation and appreciably reduced the incidence of anastomosis suture incompetence [3, 5]. On the other hand, with accumulation of new data, serious flaws intrinsic of these suturing devices were detected [6,7].

The development and use of devices made from titanium nickelide alloys allowing the formation of compression anastomoses [1] is a new approach to the solution of the problem of esophageal anastomosis incompetence.

Titanium nickelide device ("shape memory" implant; SMI) is now used for the formation of EIA and EGA. This device consists of two titanium nickelide coils touching each other by the generatrix. Using this device, an anastomosis is formed, with the 80-85% compression portion, while the other portion is a manual double-row suture [2]. This latter portion of the anastomosis suture leads to development of its incompetence. According to our

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data, EIA incompetence for this reason after gastrectomy with the use of SMI reached 5.4%.

In order to improve the therapeutic results after gastrectomy and proximal subtotal resection of the stomach, we developed a device for the formation of a circular compression suture with the compression zone along the entire perimeter of anastomosis.

MATERIALS AND METHODS

In 2003 surgeons A. N. Robak and V. I. Ruchkin designed a device for the creation of compression circular anastomoses (CCA; patent No. 2208400 of the Russian Federation).

Titanium nickelide alloy (TN-10) was selected as the material creating the compression effect. This alloy is characterized by high strength, plasticity, biological inertness; it is easily deformed if cooled below 4-5°C and restores its initial shape when warmed to just 25°C and more [1]. A spring (9 coils) from 1.2 mm wire was made from TN-10 alloy with an inner diameter of 4 mm; it develops compression force of 900 g.

The CCA device consists of an arch-shaped tubular conductor and a handle, the caudal portion of which is fixed to a tongs traction mechanism, by which the compression device is fixed to the apparatus and is activated (Fig. 1). All details of the system are made from chemically and biologically inert material (titanium) and organic glass.

The compression device consists from two cup-shaped rings connected to each other by a titanium nickelide spring. A preventive cuff is located inside the device. The purse sutures of anastomozed organs are tied on this cuff. Three types of devices of different sizes (20, 22, and 24 mm) are made for use in anastomoses of different diameters (Fig. 2).

Experimental trials were carried out at animal clinic of G. A. Ilizarov's Russian Center of Restorative Traumatology and Orthopedics. Experiments were carried out on mongrel dogs, most often and effectively used for development of new suturing methods in gastrointestinal surgery. Intrapleural EGA was selected as the experimental model. The experiment was carried out in accordance with the regulations of the Helsinki Declaration on Humane Handling of Animals.

All experimental animals were divided into 2 groups, 16 per group. In group 1, EGA was formed by the traditional ligature double-row suture, in group 2 by means of the new CCA device. The results were evaluated on days 1, 3, 7, 14, 21, 30, 45, and 60 after anastomosis creation.

Two of 32 operated animals died during the experiment. In one case (5.9%), death resulted from incompetence of ligature double-row EGA on day 3 postoperation, in the other from open pneumothorax on day 1 postoperation.

Anesthesia was the same in all experiments. Premedication (30 min before the operation): Sol. Dimedroli 1.% (1 mg/kg); Sol. Atropini sulfatis 0.1% (0.05 mg/kg); Sol. Droperidoli 0.25% (0.5 mg/kg); Sol. Rometari 2% (0.1 ml/kg). The operation field was shaven, the operation was performed with consideration for aseptic and antiseptic rules under combined intravenous and inhalation narcosis using forced ventilation device. Narcosis: 2.5% sodium thiopental solution (5 mg/kg) and 2% rometar solution (0.1 ml/kg) or ketamine (5 mg/kg) intravenously. Intravenous injections of sodium thiopental and rometar (ketamine) were repeated every 20-30 min in order to maintain the needed depth of narcosis. Inhalation narcosis (2:1 mixture of nitric oxide and oxygen) was delivered through a Narcon-P device. Forced ventilation of the lungs was carried out manually by a semi-open contour with a respiratory sac. Arduan or pavulone (40 μg/kg) was injected intravenously in order to provide myorelaxation of 45-60 min during forced ventilation of the lungs. In order to prolong myorelaxation, these drugs were injected (i/v) repeatedly.

Esophagogastric anastomosis was formed by manual ligature suturing. After treatment of the operation field by 5% iodine solution, thoracotomy in the 9th right intercostal area was carried out under endotracheal narcosis. The esophagus (2 cm) was mobilized above the diaphragm and sutured directly above the diaphragm by means of the UO-40 device, after which it was crossed. The suture made by means of the device was plunged into a purse suture. Diaphragmotomy in the tendon part was carried out. The fundus of the stomach was brought into the pleural cavity and fixed to the diaphragm. Gastrotomy (2.0 cm) was carried out.

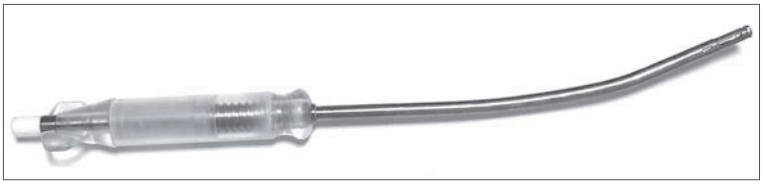

Fig. 1. CCA device.

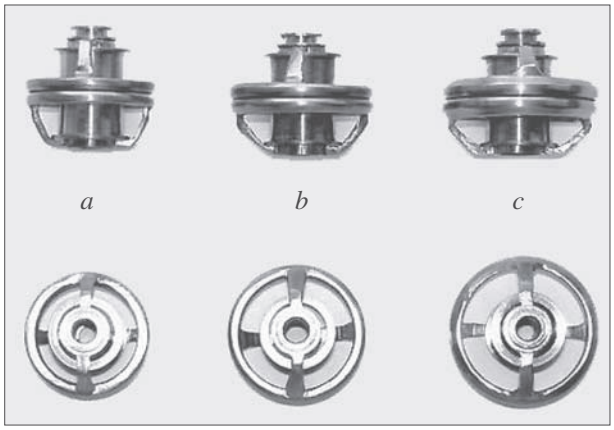

Fig. 2. Compression devices of three types. *a*) 20 mm; *b*) 22 mm; *c*) 24 mm in diameter.

End-to-end EGA between the fundus of the stomach and proximal end of the esophagus was formed using a double-row nodular suture (caproag+ silk). The anastomosis was formed during 45 min. Manual EGA suture and the pleural cavity were examined and samples were collected for bacteriological inoculation. Hemostasis was controlled. The wound was sutured layer by layer; pneumothorax was eliminated; aseptic dressing was applied (glued). The period from the moment of the first to the last suture of the anastomosis was considered as the beginning of anastomosis formation.

Compression EGA was formed by means of CCA device under endotracheal narcosis. After treatment of the operation field by 5% iodine solution, thoracotomy in the 9th left intercostal area was carried out. The esophagus (2 cm) was mobilized above the diaphragm. Diaphragmotomy in the tendon area was carried out. The fundus of the stomach was brought into the pleural cavity and partially attached to the diaphragm. Esophagotomy (1 cm) was carried out. Purse suture was made at the edge of the esophageal opening with an atraumatic monofilament thread (2/0) in a piercing needle. Gastrotomy (1 cm) was carried out. Purse suture was made at the edge of the gastric opening with an atraumatic monofilament thread (2/0) in a piercing needle. Additional gastrotomy was made, the device was inserted, and the cooling device was attached to it and activated. Compression rings of CCA-20 device were inserted into the esophageal and gastric lumen and purse sutures were tied. The device was removed from the lock and the apparatus was removed. The compression suture line was peritonized by rare U-shaped serous/muscular sutures. Additional gastrotomic opening was sutured by double-row nodular suture (caproag+silk). The stomach was completely fixed to the diaphragm. The duration of anastomosis formation was 15 min. The EGA compression suture was examined and specimens for bacteriological inoculation were collected from the suture and pleural cavity. Hemostasis was checked up. The wound was sutured layer-by-layer. Pneumothorax was controled. Aseptic dressing was glued. The period between the moment of purse sutures of the esophageal and gastric opening and the last peritonizing suture of the anastomosis was considered as the beginning of anastomosis formation.

Panorama X-ray imaging of the chest and abdominal cavity were carried out in all animals during the postoperative period in order to monitor the rejection and migration of the device. Mechanical strength of EGA was evaluated by the pneumocompression method [4]. Bacterial contamination of the anastomosis and pleural cavity was evaluated with subsequent inoculation of bacteriological material [8].

RESULTS

X-ray examination showed that the devices were rejected from the anastomosis zones and fell into the stomach on days 4-6. Only in large dogs the devices passed through the pylorus, migrated spontaneously in the gastrointestinal tract, and were eliminated from the body through the natural pathway.

High quality of anastomosis sutures was indirectly shown by studies of their mechanical strength (Fig. 3).

During week 1 postoperation, when the probability of anastomosis suture incompetence was the highest, the strength of compression suture of the anastomosis formed by means of CCA device was

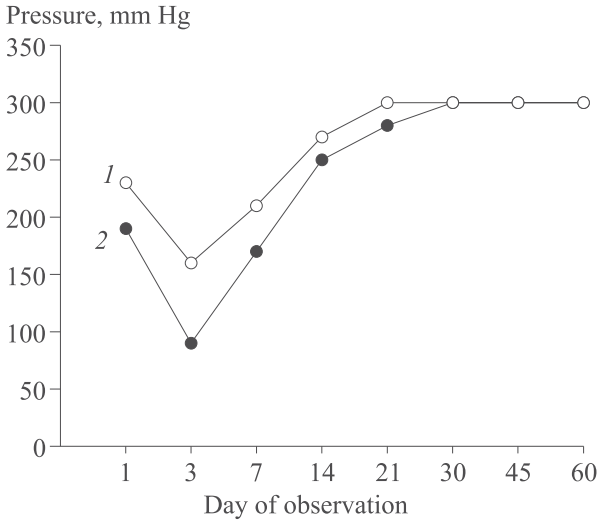

Fig. 3. Mechanical strength of anastomoses. *1*) compression suture; *2*) manual suture.

1.2-1.7 times higher in comparison with manual suture.

Bacterial (biological) permeability is an objective indicator of surgical suture quality. Material for bacteriological analysis was collected from anastomosis surface and from the left pleural cavity directly after anastomosis formation and during euthanasia. *Enterobacter*, *E. coli*, *Proteus*, *Staphylococcus*, *Streptococcus*, and bacteroids were detected in all sutures. The ligature double-row suture was contaminated most of all; enteric microflora growth was detected in it at all stages of the experiment. In the compression suture the microflora was detected only during the first 3 days postoperation and in lesser amounts in comparison with manual double-row suture. The mean bacterial number during the first 3 days postoperation was 0.75×10^2 for compression suture made by the device and 10.75×10^4 for manual ligature suture, this indicating better (14.3 times) hermetic tightness of the compression suture of anastomosis in comparison with manual ligature suture.

Hence, we designed a simple, convenient, and reliable device for creation of compression anastomoses. The device is based on a titanium nickelide spring, generating even compression along the entire perimeter of the created anastomosis, providing high mechanical strength and biological tightness of the resultant anastomosis. The working heads of the device are special pieces of three typical sizes, due to which the optimal size can be selected, with consideration for the diameter of anastomosed organs.

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