Evaluation of an Aortic Stapler for an open aortic anastomosis

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Introduction

Open repair of abdominal aortic aneurysms (AAA) requires cross clamping of the aorta at the level of renal arteries or just below them. One of the significant predictors of the outcome following aortic aneurysm repair is the total aortic clamp time .

The complication rate of aneurysm repair results, in part, from pathophysiologic disturbances that occur during aortic cross-clamping and unclamping of the aorta. With increasing duration of the clamping time systemic vascular resistance increases and cardiac output decreases. Release and accumulation of vasoactive substances also may play a role in the time-dependent changes during ischemia and reperfusion , including decrease in systemic vascular resistance.

Nearly a decade has passed since the original report of Parodi, Palmaz and Barone of the successful clinical use of endovascular (EV) stented grafts to treat an AAA was published. The main advantage of the EV repair is not only the reduced access trauma but equally important the avoidance of ischemia and reperfusion injury. In spite of the significant progress in the design and performance of endografts in many countries open surgical repair is still the "gold standard" for patients with AAA who are fit for surgery.

Although the basic principle may be consistent among various devices, it seems that different and new techniques will be required for each future developed device. So far, conventional open repair of AAA is still the "gold standard" for most patients with AAA who are fit for surgery (5-10).

Stapling devices are routinely used in gastrointestinal surgery and have replaced to a large extent conventional suturing. Reports have been published showing that clips placed using a stapling device are more reliable than manual suturing causing less leakage related problems (1-3). However, experimental reports describing automatic anastomotic devices (including staplers) for the aorta are extremely rare.

A mechanical vascular anastomosis must not compromise quality or patency rates of the anastomosis, and have at least the same results as those obtained with standard suturing techniques. The device should reduce ischemia time and in the end it should result in a reduction of ischemia related complications.

(Clinical Trial Number: NCT00319475)

Material and Methods:

A single-center, intention to treat safety and feasibility study was performed. Data were prospectively collected and retrospectively analyzed. The study protocol was approved by the institutional review board and from all patients informed consent was obtained. Patients with infrarenal abdominal aortic aneurysms and aorto-iliac occlusive disease who were suitable for elective, open aortic repair were included. According to the protocol in aneurysm patients a neck below the renal arteries of 1.5 cm was required. Patients with suprarenal clamping or thoracoabdominal aneurysms were at this point of the safety and feasibility trial excluded.

In all cases the proximal anastomosis had to be performed in and end – end fashion. The primary endpoint was the time to complete the anastomosis (defined as the time required to achieve anastomotic integrity and hemostasis) . Time to complete each anastomosis was recorded as well as any additional sutures and re-clamping. Cross clamping time was documented by both the investigator and by the anesthesiologist. Time to complete the proximal anastomosis was measured by the anesthesiologist using a stopwatch, in precision of one minute. Starting time for the stapled anastomosis was defined as the moment of insertion of the stapler with the graft into the neck of the aneurysm. Completion time for the stapled anastomoses was defined as the moment when declamping was performed. Cross clamping time was defined as the time from aortic clamping to final aortic de-clamping and was measured in precision of one minute.

Secondary endpoints were patency and anastomotic complications (pseudoaneurysm, hematoma, fistula) as diagnosed by duplex evaluation and CT scan at one month follow-up

Technical details and device description:

The Aortic Stapler is comprised of applier and implantable clips (staples) and also includes specially designed clamps and a Graft Placing Guide.

The Aortic Stapler applier consist of two parts: the head and the handle. The head of the Aortic Stapler applier contains a round cassette that is pre-loaded with 10 stainless steel (316 LVM) staples. Two specially designed Clamps are used with the Aortic Stapler:

Graft Fixation Clamp- for fixation of the graft on the stapler before introducing it into the Aorta. The Operating Clamp- for external "gripping" of the aorta, graft and stapler together and for proper deployment of the clips while stapling.

The infrarenal abdominal aorta was exposed, using a conventional transperitoneal approach. Infrarenal aortic clamping was performed and the aorta was incised. Intraluminal thrombus was evacuated in aneurysm patients. A Dacron Graft of appropriate diameter (proximal neck: 14, 16, 18, or 20 mm) was mounted over the tip of the Aortic Stapler, through a transverse incision in the graft, about 3-5 cm proximal to the distal edge.

The graft was attached to the stapler by using a Graft Fixation Clamp of appropriate size. After fixation, the Graft Fixation Clamp was released and the stapler with the graft mounted on it was inserted into the aorta or into the neck of the aortic aneurysm. A special clamp serving as an anvil was placed 2 – 3 mm directly below the aortic clamp matching the size of the stapler. The staples were fired against the branches of this clamp through the aortic wall and the prosthesis.The graft was stapled to the aortic wall by squeezing the handle of the Stapler. The stapler was removed and the graft was clamped distal to the anastomosis. De-clamping of the aorta confirmed the integrity of the stapled anastomosis. The distal anastomosis was performed using a continous 3-0 Prolene suture. In patients with AAA the graft was covered by the aneurysmal sac and the retroperitoneum was sutured separately.

Results:

Between January 2005 and May 2006, ten (10) patients were enrolled in the study. Preoperative diagnosis was an abdominal aortic aneurysm (AAA) in 3 cases and LeRiche Syndrome with aortic occlusion or a combination of aneurysmal and occlusive disease in 7 cases. All patients were scheduled for a conventional tube graft repair or an Aorto-Iliac/Femoral bypass procedures (AI/FB). None of the patients was withdrawn from the study. Mean values and range are given to summarize the characteristics of the study population and the results . A consecutive number of 10 patients who fulfilled the inclusion criteria was included into the study. The procedure was performed in 7 males (70%) and 3 female patients (30%). Mean patients' age was 66.4 years (53.0 - 78.0) . The demographic data of the patients including risk factors, diagnosis and the procedure performed are summarized in **Table 1.**

Open Aortic Staplers of 14, 16, and 18 mm diameters were used in the procedures. Either woven Dacron Tube grafts or a bifurcated prosthesis were mounted on the staplers. In all cases only the proximal anastomosis was performed using the Open Aortic Stapler. The distal anastomosis was sutured in a conventional manner using a continuous Prolene suture.

There were no stapler related deaths or anastomotic complications observed **(Table 2).**The Aortic Stapler was successfully used in all cases. The mean time to complete the stapled proximal anastomosis was 10.2 min (7 – 18). The mean number of additional sutures required with the Aortic Stapler was 1.20 (0 -6) **(Table 3).** Mean Total aortic clamping time was 50.1 min (22 – 66). Duplex and CT Imaging obtained at one-month confirmed the integrity of the proximal anastomosis as well as the patency of the vascular grafts.

DISCUSSION

There has been enormous progress in vascular surgery since Alex Carrel in 1902 first described his technique for a vascular anastomosis.

Increasing interest in minimally invasive vascular surgical procedures has generated a renewed interest in facilitated methods to create vascular anastomosis. These devices, in order to be viable, must perform equally or better than sutures. The creation of a facilitated mechanical vascular anastomosis should not compromise quality or patency rates and produce at least the same results as those obtained with standard suturing techniques. In the past decades almost 60 proposals for vascular anastomotic devices have been described in the patent literature. Most ideas are anastomotic devices using micro-mechanical fastening techniques. Other devices are supposed to facilitate the construction of an anastomosis using laser-assisted technique or adhesive bonding of donor and recipient vessel.

Although vascular closure staples were originally designed for microvascular surgery, their use has been broadened and tested in multiple laboratory and clinical settings to evaluate tissue reaction, pull out force and anastomotic integrity. The conclusion of these studies was always that with a stapled anastomosis there is less vessel trauma and a reduced inflammatory reaction.

Advancements in technology have resulted in the development of titanium vascular closure staples, which allow vessel approximation in a rapid and accurate fashion. The sutureless technique, described by Kirsch (4) consisted of a vascular anastomosis with nonpenetrating titanium arcuate-legged clips which are now primarily used for creation of AV fistulas.

Although vascular closure staples were originally introduced for microvascular surgery, the development of larger sizes has widened their applicability. Currently these clips are used in transplant, cardiac, and trauma vascular surgery (4,5) In addition to the original three sizes of vascular staples, a larger clip (extra large 3mm) has been developed for an aorto iliac anastomosis . In all studies the main advantage of vascular staples was better intimal healing and a reduced period of time to perform the anastomosis compared to standard suturing techniques. Yet our data also show that there is a learning curve for the stapling devices described. We assume that it takes about three to four cases until the stapler can be used in a short period of time and with a minimum number of additional sutures. Average clamping time was still relatively long in our series. This is to a large extent due to the fact that most patients in our series required a bifurcated graft with two limbs of the graft anastomosed with the iliac bifurcation. This was not intended when the study was initiated.

The clinical study, described in this report, was intended to further demonstrate the safety and performance of the Aortic Stapler. In the study, in a single arm treatment patient group, the proximal anastomosis was stapled with the Aortic Stapler in AAA and Leriche Syndrome patients. The proximal anastomosis is considered as technically more complicated to be performed and the one requiring longer procedural time than the distal part. Moreover, since the distal aorta is often calcified and not all patients are suitable for tube graft repair (in cases of aorto-iliac/femoral repair) the proximal anastomosis alone was chosen to be stapled with the investigational device.

The performance of vascular staples in atherosclerotic vessels is currently limited, and their use in chronically diseased vessels needs further investigation. In our own limited experience the plaque was crushed between the stapler and the external anvil a technique used in conventional surgery with the help of a hemostat clamp or an aortic De Bakey clamp.
The properties of the aortic wall, the difficulty of handling the automatic anastomotic device within the operative field, and the inability to invert an anastomosis were for a long time considered as obstacles for the development of such devices for an aortic anastomosis. With the devices now available clamping time can be shortened in procedures where the anastomosis has to be performed in deep, narrow operative fields or under pneumoperitoneum. Widespread applications of totally laparoscopic aortic reconstructions have been limited by the long cross-clamp time required to suture the aortic anastomosis laparoscopically despite improvement in instrumentation; an automatic stapling device allows performance of a graft-to-aorta anastomosis through a minimally invasive approach with shorter clamping time than a videoscopic suturing technique (6-10).

There have been reports concerning automatic anastomotic devices for blood vessels since 1894; Zeebregts has reviewed these in detail in Reference (11). Several automatic anastomotic devices are under experimental and clinical evaluation for myocardial revascularization (12 - 15). In contrast to cardiac surgery an aortic anastomotic device has not yet been introduced into the market. For too long the main focus of all developments was on an anastomosis accomplished by an inverted suture. The drawbacks here are stenosis and thrombosis at the anastomotic site because the intima of the aorta—a large, elastic artery—is turned over to create an annular segment. These considerations have limited the use of an automatic anastomotic device for the aorta. Recently, however, a device for coronary anastomotic stapling was developed based on an inverted suture line (15) In another report by Stephane et al. a commercially available circular stapling device was used. The histological results showed the integrity of the anastomosis (16). Although specimens of the anastomotic site in this study were harvested during immediately after the procedure the inverted anastomotic site was histologically in a satisfactory condition. Since the aorta has a larger diameter than the coronary artery, an inverted anastomosis can probably be performed with an acceptable clinical result.

There are a number of issues concerning the future use of circular stapling devices in aortic surgery. When the circular stapler was pulled out after firing from the anastomotic site, a certain resistance was felt. This resistance was due to the difference in geometry between the slightly smaller anastomotic site compared to the anvil and the relative lack of flexibility of the Dacron graft (17). This could perhaps be accomplished with an external anvil which has thinner thickness and an improved configuration.

CONCLUSION

The construction of a geometrically perfect, uniform and standardized anastomosis that will not depend on the skills of the surgeon, is one of the principles lying behind the design of the Open Aortic Stapler. This safety and feasibility trial showed that we now have the technology to use aortic stapling in a clinical setting. The Aortic Stapler can create a uniform staple line between a vascular prosthesis and the aortic wall. It is a simple, safe, rapid and reliable technique to perform a sutureless, end-to-end anastomosis in patients with aortic aneurysms or occlusive disease. However, a larger number of patients and a longer follow-up is required before a wider clinical application.

References

1. Takeyoshi S, Ohwada T, Ogawa Y et al. Esophageal anastomosis following gastrectomy for gastric cancer. Hepatogastroenterology, 2000; 47:1026–1029.

2. Hori T, Ochiai Y, Gunji H et al. A prospective randomized trial of hand-sutured versus mechanically stapled anastomoses for gastroduodenostomy after distal gastrectomy. Gastric Cancer, 2004; 7:24–30.

3. Yoshida K et al. Experimental study of aortic anastomosis using a circular stapling device in the porcine model. Eur J Vasc Endovasc Surg, May-2006.

4. Kirsch W et al. A new method for microvacular anastomosis. Am Surg, 1992, 58:722-727.

5. Deb S, Martin B, Sun L et al. Comparison of Titanium vascular closure staples with suture repair of the thoracic aorta in swine. Chest, 2000;118:1762-1768.

6. Edoga JK et al. Laproscopic surgery for abdominal aortic aneurysms: technical elements of the procedure and a preliminary report of the first 22 patients, Surg Endosc 12 (1998), pp. 1064–1072.

7.Kolvenbach R, Puerschel A, Fajer S, Lin J, Wassiljew S, Schwierz E, Pinter L.

Total laparoscopic aortic surgery versus minimal access techniques: review of more than 600 patients. Vascular. 2006 Jul-Aug;14(4):186-92.

8.Wassiljew S, Kolvenbach R, Puerschel A, Schwierz E.

Total laparoscopic iliac artery aneurysm repair using endoscopic techniques and endovascular balloon occlusion.
Eur J Vasc Endovasc Surg. 2006 Sep;32(3):270-2. Epub 2006 Jun 6.

9.Kolvenbach R.

Total laparoscopic aortic aneurysm surgery.
Acta Chir Belg. 2006 Jan-Feb;106(1):36-9.

10. Jobe BA, Duncan W, and Swanstrom LL. Totally laparoscopic abdominal aortic aneurysm repair. Surg Endosc, 1999; 13:77–79.

11. Zeebregts CJ et al. Non-suture methods of vascular anastomosis. Br J Surg, 2003; 90: 261–271.

12. Eckstein FS et al. Minimizing aortic manipulation during OPCAB using the symmetry aortic connector system for proximal vein graft anastomoses. Ann Thor Surg, 2001; 72:S995–S998.

13. Eckstein FS et al First clinical result with a new mechanical connector for distal coronary artery anastomosis in CABG. Circulation, 2002; 106:Suppl I, I/1–I/4.

14. Mack MJ et al. Initial experience with proximal anastomoses performed with a mechanical connector. Ann Thorac Surg, 2003; 75:1866–1871.

15. Suyker WJL et al. Stapled coronary anastomosis with minimal intraluminal artifact: the S2 anastomotic system in the off-pump porcine model. J Thorac Cardiovasc Surg, 2004; 127:498–503.

16. Elkouri S et al Stapled aortic anastomoses: a minimally invasive, feasible alternative to videoscopic aortic suturing? Vasc Endovasc Surg, 2004; 38:321–330.

17.Shifrin EG, Moore WS, Bell PR, Kolvenbach R, Daniline EI
Intravascular stapler for "open" aortic surgery: preliminary results.
Eur J Vasc Endovasc Surg. 2007 Apr;33(4):408-11.