

New ideas - Experimental

Percutaneous endoscopic transapical aortic valve implantation:
three experimental transcatheter modelsMichael W.A. Chu^{a,b,1,*}, Volkmar Falk^b, Friedrich W. Mohr^b, Thomas Walther^b^a*Division of Cardiac Surgery, Department of Surgery, University of Western Ontario, London, ON, Canada*^b*Herzzentrum, Klinik für Herzchirurgie, Universität Leipzig, Leipzig, Germany*

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Abstract

We sought to demonstrate the feasibility of an endoscopic approach to transapical aortic valve implantation (AVI), avoiding the morbidity of a thoracotomy incision. Using an experimental pig model, we performed three different approaches to transapical AVI, using a standard minithoracotomy ($n=4$), a robotic approach using the da Vinci telemanipulator ($n=4$) and an endoscopic approach using a port and camera access ($n=4$). The feasibility of the different techniques, exposure of the left ventricular apex, postoperative blood loss and total operative time were evaluated. Left ventricular apical exposure, 'purse-string' suture control and 33-F introducer access were successfully performed and confirmed videoscopically, fluoroscopically and at a post mortem in all 12 animals. The haemodynamics were stable in all animals. Mean intraoperative and postoperative (two-hour) blood losses were 88 and 65 ml with minithoracotomy, and 228 and 138 ml with the robotic and 130 and 43 ml with the endoscopic technique ($P=0.26$, $P=0.14$, respectively). There was no significant change in perioperative haematocrit ($P=0.53$). The mean total operative times were 1.4, 3.9 and 1.1 h ($P=0.06$), respectively. Percutaneous endoscopic and robotic transapical AVI are both feasible and can be performed in a timely manner with reasonable perioperative blood loss. Future research will focus on identifying optimal candidates for surgery based upon preoperative thoracic imaging.

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1. Introduction

Transcatheter valve implantation offers patients innovative, minimally invasive techniques for aortic valve replacement without cardiopulmonary bypass, cardioplegic arrest or sternotomy, with potentially lower morbidity and mortality, quicker recovery and improved patient satisfaction [1–10]. Successful valve implantation relies upon adequate vascular access, traditional surgical and transcatheter wire skills, excellent periprocedural imaging and operator experience.

Two common approaches for transcatheter aortic valve implantation (AVI) include a retrograde, transfemoral approach and an antegrade, transapical (TAP) approach. The transfemoral approach can be performed percutaneously or with a small femoral cutdown, but requires adequate femoral and iliac artery diameters, along with a non-tortuous, atherosclerosis-free arterial tree for a valve prosthesis to travel in a retrograde direction up the aorta, around the aortic arch and to the level of the aortic valve [1, 2, 10]. Challenges with this approach include the following:

(1) crossing the heavily calcified native aortic valve in a retrograde fashion for both balloon valvuloplasty and valve implantation; (2) the long distance between the femoral artery and the aortic valve, which can present challenges in precision and control of the prosthesis during implantation; and (3) most importantly, traversing the aortic arch with a large prosthesis, which may increase the risk of periprocedural stroke because of commonly present aortic atheroma and plaque.

Alternatively, the TAP approach provides a short, direct and co-axial route to the aortic valve, allowing greater operator precision during prosthesis deployment; however, it does require a 5–7 cm left anterolateral thoracotomy incision for access to the left ventricular (LV) apex [3–5, 8]. LV apical access is performed using the Seldinger technique and requires placement of a 26–33-F introducer. Control of the LV apex is achieved with a Rummel tourniquet and two pledgeted purse-string sutures, which are tied down after removal of the introducer. Despite the improved precision and ease of crossing the aortic valve in an antegrade manner, critics of the TAP approach believe that the disadvantages of the chest incision outweigh its benefits.

The ideal transcatheter AVI may be performing the antegrade, TAP approach percutaneously or via port access, hence preserving the ease and precision of the antegrade route while eliminating the deleterious effects of the thoracotomy.

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However, concerns about control of the LV puncture site and haemorrhage remain paramount. A recent report suggested endoscopic LV apical closure with a modified Amplatzer device; however, blood losses were still modest [11]. In addition, these devices are costly, and questions remain about the long-term effectiveness of these devices within a contracting ventricle. A thoracoscopic approach, with or without robotic assistance, may enable safe placement of standard purse-string sutures for control of the LV apex, therefore potentially facilitating a completely percutaneous TAP-AVI.

2. Methods

2.1. Study design

All experiments were conducted under the supervision of a veterinarian and with the approval of the local research Ethics Board and Animal Care Committee. We performed these experiments in 12 pigs with a mean weight of 76 ± 14 kg (range 63–100 kg). The animals were divided into three separate groups: mini-sternotomy ($n=4$), endoscopic ($n=4$) and robotic ($n=4$) technique.

2.2. Surgical technique

All animals underwent general anaesthesia with single-lumen endotracheal tube intubation and monitoring using

a right internal jugular venous line, femoral arterial line, three-lead electrocardiogram, oxygen saturation probe and end-tidal CO_2 monitoring. Contrast left ventriculography was performed, with a pigtail catheter in the left ventricle placed in a retrograde manner via a 6-F femoral artery introducer, both before and after intervention to assess LV function and geometry.

2.2.1. Mini-sternotomy approach

The mini-sternotomy approach served as our control since it closely mimicked the standard open, anterior mini-thoracotomy performed during human cases of TAP-AVI. However, unlike the human anatomy, the apex of the pig heart lies much further towards the midline and is most readily accessed by a limited 8 cm subxiphoid hemisternotomy approach. The pericardium was opened vertically, and pericardial stay sutures were used to suspend the heart. A single running 2-0 Prolene purse-string suture with felt pledgets was placed around the LV apex with a Rummel tourniquet to secure the apical puncture site.

2.2.2. Endoscopic approach

The endoscopic approach (Fig. 1) consisted of a thoracoscopic left lateral approach with one 10 mm camera port in the seventh intercostal space (ICS) in the mid-axillary line, and two 5 mm endoscopic ports in the fifth and ninth

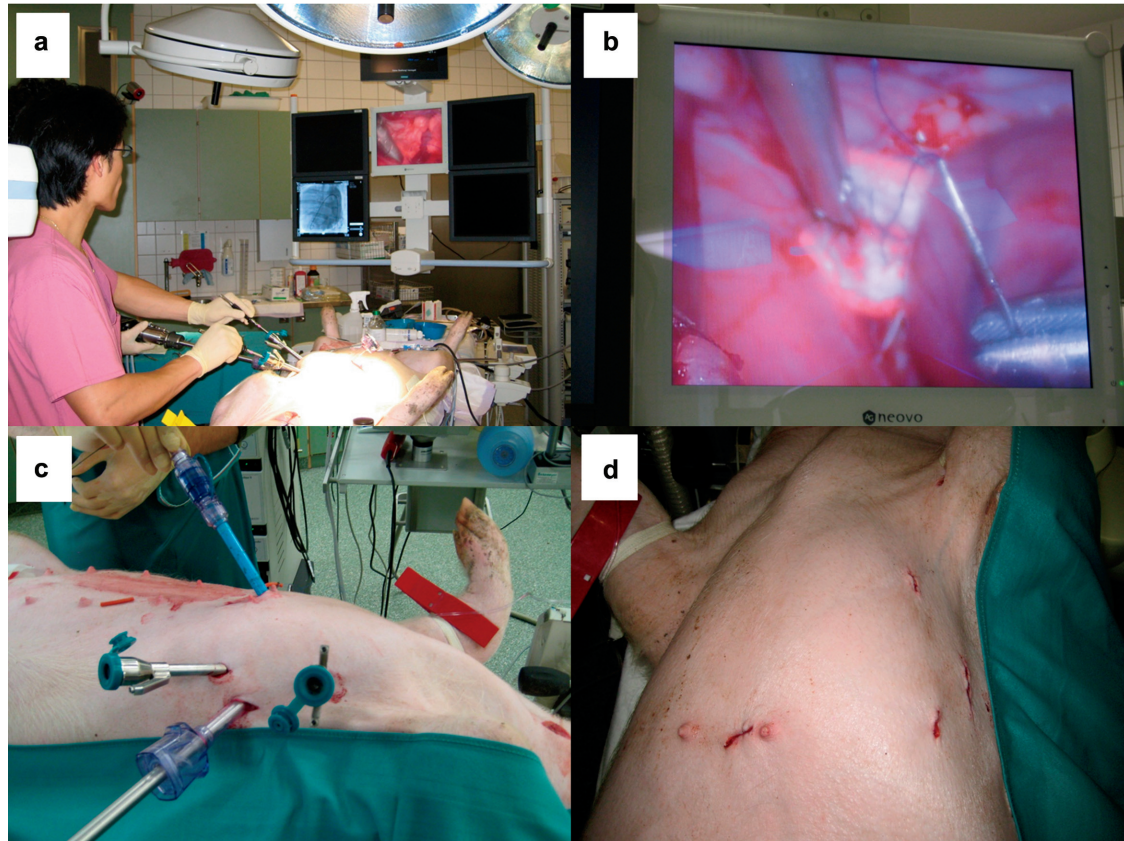


Fig. 1. Endoscopic approach. (a) Endoscopic set-up. (b) Videoscopic view of the left ventricular (LV) apex, felt pledget and suturing of the apical purse-string. (c) Endoscopic port placement and percutaneous cannulation of LV apex with a 33-F introducer sheath. (d) Postoperative thoracoscopic port sites and percutaneous LV puncture site.

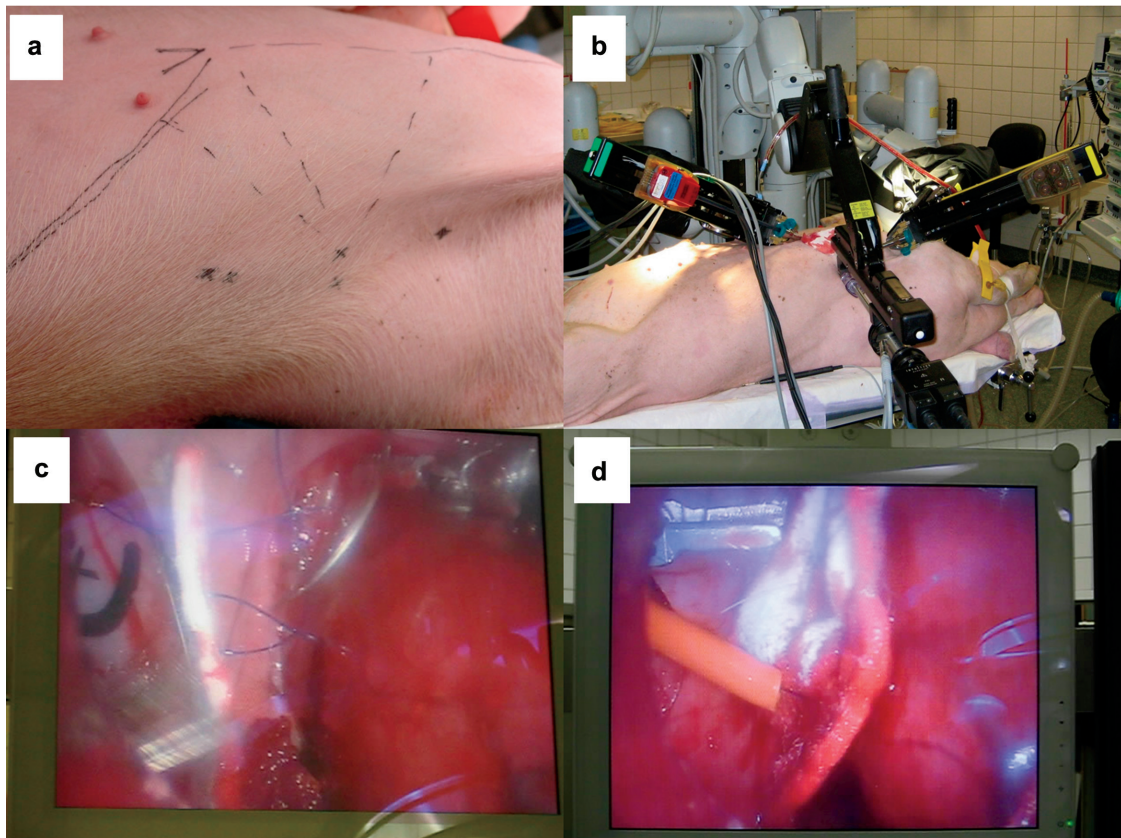


Fig. 2. Robotic approach. (a) Skin markings to plan the optimal robotic port placement for left ventricular (LV) apical exposure. (b) Da Vinci robot set-up. (c) Robotic suturing of the LV apical purse-string. (d) Videoscopic view of securing the LV apical purse-string with a Rummel tourniquet.

ICSs in the anterior axillary line. With assistance from a 0° 10 mm videoscope, the pericardium was opened anterior and parallel to the phrenic nerve, over the LV apex towards the diaphragm. After visual identification of the LV apex, a 3–0 Prolene suture was thoracoscopically placed with long-shafted instruments in the LV apex to create an apical purse-string with two long felt strips. The two suture ends were then brought to the exterior through a separate 10 mm subcostal port incision over the LV apex and secured in place with an external Rummel tourniquet.

2.2.3. Robotic approach

The robotic approach (Fig. 2) employed the da Vinci Surgical System (Intuitive Surgical, Inc, Sunnyvale, CA, USA) to place the same apical purse-string, as with the endoscopic approach. The port locations were similar to those of the endoscopic approach; however, the port sizes were slightly larger because of the obligatory 8 mm ports for each robotic arm and one 12 mm camera port. The purse-string was then secured in a similar fashion with an exteriorized Rummel tourniquet.

All pigs received heparin 5000 U and amiodarone 150 mg intravenously for anticoagulation and arrhythmia prophylaxis, respectively. Using simultaneous videoscopic and fluoroscopic guidance (Fig. 3a–d), the LV apex was punctured with a long 16 gauge spinal needle, and a 0.035 inch Amplatzer superstiff guidewire was passed across the aortic valve and aortic arch and then parked in the

descending thoracic aorta. A 33-F introducer was then advanced into the left ventricle and held in place for 10 min, simulating the time required to perform a TAP-AVI. The introducer was manipulated with guidewires to simulate a valve implantation without actually implanting a transcatheter valve.

Following the removal of the transcatheter introducer sheath from the LV apex, haemostasis was achieved by securing the apical purse-string by tying it either directly (mini-sternotomy) or with a knot-pusher introduced down the apical port site (robotic or endoscopic). A 28-F chest tube was inserted into the mediastinum (mini-sternotomy) or into the left pleural space (robotic and endoscopic techniques) and measured continuously for two hours. Following this observational period, the animals were sacrificed, and post mortem examinations were performed, examining the hearts both in situ and after excision to confirm LV apical puncture, location, and adequacy of the apical purse-string.

2.3. Outcomes measurements

Primary outcomes included technical feasibility of apical exposure and control, apical puncture and postoperative blood losses. Secondary outcomes included procedural length, intraoperative survival and accuracy of apical control and puncture, as determined at the post mortem examination.

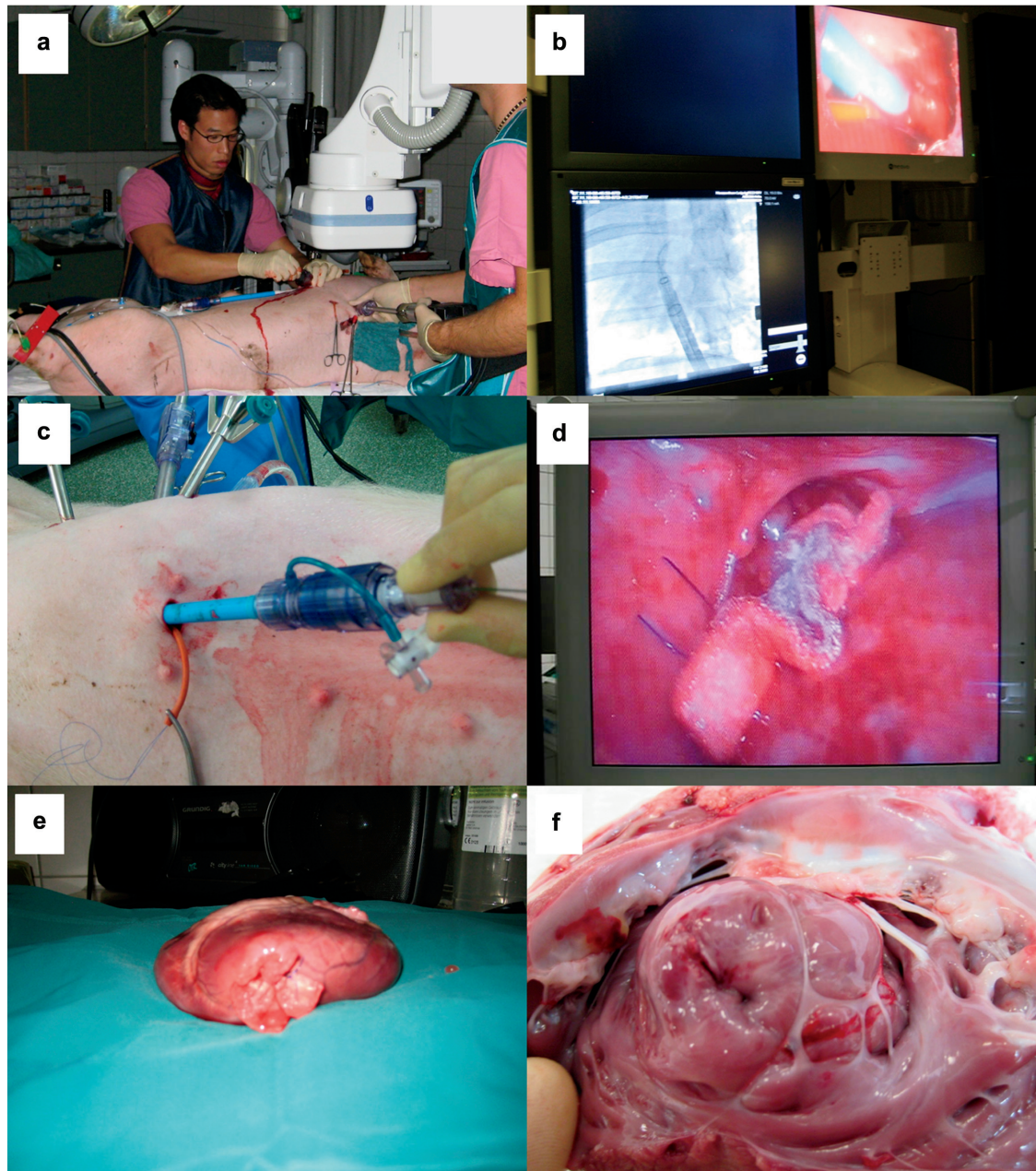


Fig. 3. Procedural steps. (a) Using simultaneous endoscopic and fluoroscopic guidance, the left ventricular (LV) apex was punctured with a spinal needle through the 1 cm stab wound, and a 0.035 inch guidewire was threaded up beyond the left ventricle across the aortic valve. (b) Simultaneous endoscopic and fluoroscopic visualisation to allow safe LV puncture. (c) Photograph of the 33-F cannula advancing through 1 cm stab wound across the apical purse-string into the left ventricle, confirmed endoscopically and fluoroscopically. (d) Endoscopic view of the haemostatic LV apical purse-string after suture tying. (e,f) Pathological confirmation of apical puncture and purse-string placement from externally (e) and internally (f).

2.4. Statistical analysis

Results were expressed as the mean \pm Standard Deviation (S.D.). Statistical analysis was performed using one-way analysis of variance for three independent samples using VassarStats (<http://faculty.vassar.edu/lowry/VassarStats.html>). A *P*-value <0.05 was considered significant.

3. Results

LV apex exposure and identification, purse-string placement and apical puncture were successfully achieved in all 12 pigs,

despite the technically more difficult lateral approach in the endoscopic and robotic groups. Successful apical needle puncture and guidewire insertion were confirmed both videoscopically and fluoroscopically in all animals. There were no procedural mortalities, and all pigs survived through the study period. Only one pig, in the mini-sternotomy group, required transient vasopressor support during the procedure. The most common arrhythmia experienced was premature ventricular contractions, which occurred in two pigs, one each in the robotic and mini-sternotomy groups.

Perioperative and two-hour postoperative haemostasis is demonstrated in Table 1. No animals in any of the three

groups required an additional apical suture for haemostasis. The procedural times are also demonstrated in Table 1. Preoperative and postoperative left ventriculography was performed in all 12 animals, demonstrating preserved LV function and identifying no geometric deformities related to the apical purse-string. Post mortem examination performed in all 12 animals confirmed successful apical puncture and purse-string control in all animals (Fig. 3 e,f). The purse-string was placed centrally over the LV apex in all cases, including in the eight animals who underwent the lateral approach with the endoscopic or robotic technique.

4. Discussion

We demonstrated the feasibility of a percutaneous approach to TAP-AVI with either an endoscopic or a robotic approach. Although it is less straightforward and more difficult to perform than the standard, open approach, we were able to achieve the following goals with both the endoscopic and the robotic approach:

- successful exposure and identification of the LV apex via a left chest port incision;
- safe placement of haemostatically secure purse-string sutures in the LV apex;
- clear visualisation of the LV puncture and introducer cannulation both videoscopically and fluoroscopically.

Losing control of the LV apex is the most feared complication of either the endoscopic or the robotic technique, necessitating emergency thoracotomy to avoid catastrophic haemorrhage. Although our numbers were small, postoperative blood loss and change in haematocrit did not seem unreasonable and were not significantly different between the three groups. In addition, none of our animals required an additional apical suture after removal of the 33-F introducer catheter.

When considering port access approaches to the LV apex, the amount of available working space is important but not well defined. We did not perform any direct measurements but would estimate that at least 3–4 cm of working space would be necessary to facilitate endoscopic or robotic percutaneous TAP-AVI. The working space could be maximised by CO₂ insufflation, instrument miniaturisation and displacement of the LV apex into the left pleural space. Reoperative surgery following a previous left thoracotomy would probably prohibit this thoracoscopic approach to the

LV apex; however, following a previous sternotomy, it could be feasible if pericardial adhesions were manageable.

Transventricular access to the cardiac chambers was first popularised with closed mitral commissurotomies, but has also been used for ventricular septal defect (VSD) repair, LV remodelling procedures and tumour resection. All of these techniques rely upon direct suture closure for haemostatic control. Transventricular introducer access has recently been introduced for hybrid congenital VSD closure with Amplatzer occlusion devices [12, 13]. Recent publications have reported the use of Amplatzer devices to close right ventricular introducer puncture wounds [14, 15]. These have noted good haemostatic control, albeit with much lower right-sided ventricular pressures. Tozzi et al. previously reported using a modified Amplatzer device to close LV apical puncture sites in a pig model [11]. They reported modest haemostatic success, but questions remain about the stability of such a device within the wall of the contracting left ventricle. In addition, these devices are costly and would prohibit LV apical repuncture once deployed, for fear of destabilizing the device. We believe that suture purse-string control of the LV apex provides a simple, reproducible method of haemostatic control that is cheap and effective, as well as allowing LV repuncture, early or late, if additional intervention is required.

Robotic assistance did provide excellent visualization and superior intrathoracic dexterity; however, the significantly prolonged time requirements may prove to be a disadvantage. As seen in any novel and innovative procedure, there was a learning curve to this approach, with the first case lasting 12 h and the last case 3.5 h. However, even with time, it is likely to remain longer than an open TAP-AVI approach. In addition, the same port access results could be achieved with the endoscopic approach, utilizing a 5 mm videoscope and two 5 mm ports for the long-shafted thoracoscopic instruments. Nonetheless, we were able to successfully accomplish our primary outcomes and achieve good results with robotic assistance.

There were several limitations within this feasibility study. First, the study numbers were small, with only four animals in each arm and only eight intervention animals in total. Second, we measured postoperative haemorrhage for only two hours before sacrificing the animals. This was for practical reasons, but we believe that the blood losses during these two hours would still be reflective of the overall effectiveness of the three different surgical approaches and haemostasis.

Table 1. Perioperative haemostasis and operative times

	Mini-sternotomy (n=4)	Endoscopic (n=4)	Robotic (n=4)	Test for equal variances	P-value
Mean blood losses (ml)					
Intraoperative, mean	88 (75)	130 (112)	228 (149)	0.13	0.27
Postoperative – two hours, mean	65 (35)	43 (22)	138 (102)	0.07	0.14
Mean haematocrit (%)					
Preoperative, mean	26.0 (1.3)	27.8 (2.2)	28.4 (1.1)	0.23	0.13
Postoperative – after two hours, mean	27.0 (3.3)	26.4 (1.0)	29.3 (4.4)	0.14	0.44
Delta	1.1 (2.8)	–1.5 (2.8)	0.9 (4.3)	0.36	0.53
Operative times					
Total time, mean (min)	225 (17)	186 (15)	420 (215)	0.12	0.06
Operative time, mean (min)	78 (15)	66 (15)	234 (170)	0.14	0.08

Finally, the translation of this work into a human clinical model is limited by the anatomical and biochemical differences between pigs and humans. Elderly, fragile patients who are selected for transcatheter valve implantation may have LV apices that are too fragile for endoscopic manipulation. Two factors that worked in favour of maintained haemostasis were the relative hypercoagulability of swine blood and perhaps the natural LV hypertrophy of pig hearts, which may also have been haemostatically protective. However, unlike humans, pigs have a triangularly shaped chest, which severely limited the working space available for the thoracoscopic approaches, hence potentially leading to further manipulation and internal bleeding. The natural barrel-shaped chest of a human would provide significantly more working space and perhaps more easily facilitate an endoscopic or robotic approach.

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