Received:
6 November 2014

Revised:
23 April 2015

Accepted:
11 May 2015

doi: 10.1259/bjr.20140735

Cite this article as:

Ioannou CV, Kontopodis N, Kehagias E, Papaioannou A, Kafetzakis A, Papadopoulos G, et al. Endovascular aneurysm repair with the Ovation TriVascular Stent Graft System utilizing a predominantly percutaneous approach under local anaesthesia. *Br J Radiol* 2015; **88**: 20140735.

FULL PAPER

Endovascular aneurysm repair with the Ovation TriVascular Stent Graft System utilizing a predominantly percutaneous approach under local anaesthesia

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Objective: To present our experience with the Ovation Abdominal Stent Graft System (TriVascular Inc., Santa Rosa, CA) during endovascular aneurysm repair (EVAR) and compare results according to the type of anaesthesia.

Methods: We conducted a single-centre retrospective study including patients who underwent EVAR using the Ovation endograft between May 2011 and July 2014. Outcome was evaluated regarding pre-, peri- and immediate postoperative and follow-up measures. Overall results are reported, while additional analysis was performed to compare the outcome between groups of patients undertaking either local or regional/general anaesthesia (LA vs RGA).

Results: 66 patients were included. Median follow-up was 13 months (range, 1–39 months). Median age was 72 years and median abdominal aortic aneurysm diameter was 58 mm (range, 54–100 mm). Technical success was 63 (95%), while there were 2 (3%) conversions to open surgery. A total percutaneous approach was used in 50/66 (76%) cases. Overall, 9/66 (14%) subjects suffered from any kind of morbidity. Median hospitalization was

3 days (range, 1–16 days). Immediate and midterm mortality rate was 0%. No endoleak Type I, III, IV or stent migration was observed. There were 8 (13%) Type II endoleaks. Overall, additional endovascular procedures were required in 6 (9%), while surgery was performed in 4 (6%) patients. 44 (67%) patients underwent LA and 22 (23%) RGA. Differences between groups were significant for procedural time (85 vs 107 min; $p < 0.001$), percutaneous access (91% vs 45%; $p < 0.001$) and systematic complications (2.3% vs 14%; $p = 0.05$).

Conclusion: EVAR with the use of the Ovation endograft shows promising short-term and midterm results regarding safety and effectiveness. Completion of the procedures under LA using a total percutaneous approach seems advantageous and may be used in routine practice.

Advances in knowledge: The Ovation Abdominal Stent Graft System is an ultra-low profile stent graft system that allows percutaneous deployment for EVAR and offers excellent overall efficacy and safety. Totally percutaneous EVAR under LA seems advantageous and may be used as a routine with this specific endograft.

Abdominal aortic aneurysms (AAAs) represent a common cause of morbidity and mortality in the Western societies, becoming more evident with ageing of the population.^{1,2} Endovascular aneurysm repair (EVAR) represents a minimally invasive therapeutic alternative to treat AAAs,³ which is constantly becoming more popular among physicians, currently being the standard of care.^{4,5}

A premise to perform EVAR is a suitable anatomy of the vasculature involved. Subsequently, available devices have evolved continuously from the initial handmade stent grafts manufactured by vascular surgeons to the first commercially available devices released in 1994 and finally

to the fourth generation of endografts currently available.⁶ Continuous evolution and improved redesigning of AAA endografts allows for the inclusion of more complex anatomies in EVAR's indications.^{7–11}

The Ovation Abdominal Stent Graft System (TriVascular Inc., Santa Rosa, CA) is a modular endograft designed for the treatment of AAAs. It is a new device intended to overcome the limitations of currently available stent grafts and to accommodate a broader range of anatomy by addressing the two most important issues in EVAR: access and seal.¹² This is a trimodular endoprosthesis consisting of a 14-Fr outer diameter aortic body and two iliac limbs—the smallest profile

of any currently commercially available stent graft. It uses a unique O-ring sealing mechanism to deal with challenging aortic necks in the same time that it can navigate through complex iliac and femoral access.^{6,12} Currently, with the use of the low-profile delivery catheter of the Ovation stent graft, approximately 90% of males and 70% of females with AAA have access vessel diameters amenable to EVAR, while the fact that it is the only endograft approved to treat proximal necks shorter than 10 mm alone might increase EVAR eligibility by about 10%.¹³ Furthermore, the ultra-low profile delivery system of the Ovation endograft allows for totally percutaneous access and highlights the possibility to perform the procedure under local anaesthesia (LA), which may correlate with fewer systematic complications and reduced procedural times.^{14–16}

In the current study, we aim to present our experience with the Ovation TriVascular Stent Graft system to treat patients with AAA. Moreover, since we have previously applied all anaesthetic techniques [including general/regional (RGA) and LA] to complete procedures, we attempt to compare between RGA on the one hand and LA on the other.

METHODS AND MATERIALS

Study design—patient population

We conducted a single-centre retrospective study that included all AAA patients treated by endovascular means with the Ovation endograft from May 2011 till July 2014.

Indications to treat an AAA were according to current guidelines by the Society for Vascular Surgery (SVS) and the European Society for Vascular Surgery.^{17,18}

- maximum diameter >55 mm
- growth rate >10 mm per year
- symptomatic AAAs
- moreover, AAAs >40 mm were repaired in the presence of concomitant common iliac aneurysms of maximum diameter >30 mm.

Aneurysm diameters were obtained along the centreline axis to acquire precise measurements.¹⁹ Eligible patients to be treated with the specific device were defined according to the manufacturers' anatomic requirements⁶

- a proximal neck length ≥ 7 mm and an inner diameter of between 16 and 30 mm
- a juxtarenal aortic neck angulation $\leq 60^\circ$ if the proximal neck length was ≥ 10 mm or $\leq 45^\circ$ if the proximal neck length was <10 mm
- a distal seal zone of ≥ 10 mm and diameter between 8 and 20 mm.

Device description

The Ovation endograft has a trimodular design consisting of the main body and two iliac limbs. The main body includes a suprarenal nitinol stent with anchors to achieve active fixation to the aortic wall and a low-permeability polytetrafluoroethylene (PTFE) graft, which unlike other devices is not supported by a metallic endoskeleton but contains a network of inflatable channels and sealing rings that are filled during deployment with a low-viscosity, radio-opaque fill polymer. The main body is

80 mm long and designed as one 50-mm long cylinder that splits into two 30-mm long legs. Sealing at the proximal infrarenal aortic neck is performed by a unique mechanism of two inflatable O-rings that cure *in situ* and conform to the patient-specific neck anatomy. The iliac limbs consist of highly flexible nitinol stents encapsulated in low-permeability PTFE. Due to the unique concept of separation of the endografts' fabric and metal portions, delivery is achieved through ultra-low profile delivery system. Moreover, the original sealing mechanism allows sealing in infrarenal necks as short as 7 mm, which makes this the only device that has been approved to treat aneurysms with aortic neck <10 mm.^{6,12}

Procedures/anaesthetic techniques

During initial experience with the Ovation endograft, the procedure was conducted under RGA. All patients were monitored with electrocardiography (ECG) and pulse oximetry, and the left radial artery was cannulated under LA for invasive measurement of the blood pressure.

General anaesthesia was induced with propofol 1 mg kg⁻¹, fentanyl 1–2 µg kg⁻¹ and cis-atracurium to facilitate endotracheal intubation. The patients were intubated, and maintenance of anaesthesia was achieved with propofol infusion and supplemental doses of fentanyl according to patients' needs.

For regional anaesthesia, the combined spinal/epidural technique was preferred using the two-level approach. The epidural space was first located in the standard manner at the L1–2 level with an 18-G Tuohy needle and a 20-G catheter was inserted. After a negative test dose for intrathecal or intravenous placement of the epidural catheter ensuring that the epidural catheter was placed properly, a standard spinal was performed at L3–L4 with 10 mg of levobupivacaine and 20 µg fentanyl.

After accumulating experience with this endograft, completion of the procedure under LA was found to be feasible and well tolerated by the patients. This practice was finally adopted as routine except in cases with relative contraindications as described by Verhoeven et al.²⁰ These mainly were

- patients' anxiety or unwillingness to undergo LA
- need for cut-down to prepare femoral arteries
- previous groin incision
- patient obesity (body mass index >30 kg m⁻²).

If LA was not performed, the choice between regional and general was left to the patients' and anaesthesiologists' preference.

LA protocol included preoperative administration of *per os* bromazepam 1.5–3.0 mg as well as intravenous non-steroidal drugs (usually parecoxib 40 mg) and 75–100 mg of pethidine intramuscularly, administered 30–60 min before the procedure. Furthermore, anaesthetic cream (25 mg lidocaine and 25 mg prilocaine per 1 g of cream) was also locally applied preoperatively at the femoral puncture sites. LA was achieved using infiltration with lidocaine 1% (maximum safe dose 4 mg kg⁻¹) or bupivacaine 0.5% (maximum safe dose 2 mg kg⁻¹). Intravenous sedation was not used. Operative monitoring included continuous ECG, pulse oximetry, and invasive arterial blood pressure measured

through a radial intra-arterial line. A urinary catheter was always used.

Procedures/surgical techniques

Femoral access was generally achieved percutaneously whenever possible (Figure 1). Two Perclose ProGlide (Abbott Vascular, Chicago, IL) vascular closure devices were predeployed after femoral catheterization of each artery to achieve haemostasis upon completion of the procedure. In cases of excessive femoral artery calcification, presence of intramural thrombus or previous groin incision, the common femoral artery was dissected and controlled through a short incision parallel to the inguinal ligament just above the inguinal crease. Following femoral access, the main body and the limbs of the endograft were deployed for use according to the manufacturer's instructions, while the inflatable O-rings were filled with the radio-opaque polymer to achieve proximal sealing (www.trivascular.com/images/files/810-0012-01-01rD_IFU_PMA_Ovation_Prime.pdf).

After accumulating experience with this stent graft, we have previously reported the need to dilate the graft at the ring site with a compliant balloon to dilate and mould the rings and to avoid any inflow stenosis caused by possible inward expansion of the rings (Figure 2).²¹ We now perform this technique on a routine basis. Completion angiography was always performed to evaluate good functioning, patency of renal arteries and the absence of endoleaks (Figure 3).²²

Follow-up protocol

Patients were evaluated during regular follow-up visits, with abdominal X-rays (face/profile) and contrast-enhanced CT scans performed at 1, 6 and 12 months after the intervention (Figure 4). Annual follow-up thereafter was performed using ultrasound scans of the aorta to evaluate sac size and possible intrasac flow. There was a slice thickness of 1 mm to retrieve required accuracy, and all CT scans were reviewed by an interventional radiologist and a vascular surgeon. Migration, endoleaks and AAA dimensions were recorded at that time.

Figure 1. Totally percutaneous access of the 14-Fr stent graft *via* the common femoral arteries utilizing two Perclose ProGlide (Abbott Vascular, Chicago, IL) arterial closure devices.

Figure 2. Dilation of the graft at the ring site with a compliant aortic balloon (35-mm diameter) in order to dilate and mould the rings and to avoid any inflow stenosis caused by possible inward expansion of the rings. This manoeuvre is performed within 20–40 min after inflating the rings with the polymer. Within this time frame, the polymer is pliable and fully stiffens after approximately 40 min.

Outcomes

For the current analysis, 30-day mortality was used as the primary outcome to be evaluated. Secondary outcome measures regarded

- preoperative measures (patients' age, sex, comorbidities, anatomical variables of AAAs)
- perioperative measures (technical success, percutaneous *vs* cut-down femoral access, operative time)
- immediate postoperative information (requirement for intensive care, postoperative systematic and local complications, hospital length of stay)
- follow-up (clinical success, migration, endoleak, increase in AAA size).

Technical success is determined taking into account the SVS Reporting standards for EVAR, which relate the former to periprocedural events that occur from the initiation of the procedure and extend through the first 24-h postoperative period.²³ Primary technical success is defined as successful deployment of

Figure 3. Completion angiography showing good graft patency, without evidence of endoleaks.

the device in the intended location in the absence of surgical conversion or mortality, Type I or III endoleaks or graft limb obstruction, while assisted primary and secondary success refer to endovascular and surgical means, respectively, used to achieve technical success.²³

Operative time is reported as anaesthesia time plus procedural time. Anaesthesia time refers to the time from the beginning of anaesthesia administration (either local, regional or general) till the beginning of the operation and procedural time refers to the time from that point upon completion of the procedure.

For short-term and midterm results, clinical success is evaluated, which requires the absence of mortality as a result of aneurysm-related treatment, Type I or III endoleak, graft infection or thrombosis, aneurysm expansion (diameter >5 mm or volume >5%), aneurysm rupture or conversion to open repair.²³ Moreover, clinical failure is defined as the presence of graft dilatation of 20% or more by diameter, graft migration or a failure of device integrity. Clinical success can be claimed for those cases with a Type II endoleak only in the absence of aneurysm expansion. Assisted primary clinical success is reported when additional endovascular procedures are needed, whereas secondary

clinical success for additional surgical procedures is required to preserve clinical outcome.²³ The following temporal characterization of clinical success is applied according to the reporting standards for EVAR: initial or 30-day clinical success encompasses 30-day data, short-term clinical success includes outcome measures reported within a 30-day to 6-month time frame, midterm clinical success refers to all outcome measures that are statistically significant up to 5 years after endograft implantation and long-term clinical success includes all outcome measures that are statistically significant beyond 5 years.²³

In the current analysis, the abovementioned end points are reported for the whole study cohort. Additionally, patients are divided into RGA and LA groups according to the anaesthesia administered, and outcome is assessed and compared between groups.

RESULTS

Preprocedural data

During a 39-month period (May 2011–July 2014), 66 patients underwent EVAR with the Ovation TriVascular Stent Graft system in our centre. Median follow-up time was 13 months (range, 2–39 months). Median age of patients was 72 years (range, 54–88 years). The great majority of subjects treated were male (65 males and 1 female). Among 66 patients, none had an American Society of Anesthesiologists (ASA) score of 1, 39 subjects had a score of 2, 24 patients presented an ASA score of 3 and finally 3 patients had an ASA score of 4. Median maximum diameter of the AAAs treated was 58 mm (range, 54–100 mm). Anatomical variables of AAAs treated are summarized in Table 1.

Periprocedural data

Median anaesthesia time in our series was 15 min (range, 4–60 min), while median procedural time was 95 min (range, 65–280 min). In

Figure 4. Postoperative CT angiography revealing good graft patency and placement. A, anterior view.

Table 1. Anatomical variables of AAAs in our study population. Median values and range are reported

Anatomical variable (mm)	Median (range)
Neck length	24 (7–55)
Neck angle	24 (0–60)
Neck diameter (lowest renal artery)	23 (11–28)
Neck diameter (lowest renal artery + 13 mm)	24 (15–30)
L1	109 (80–140)
L2	178 (132–240)
L3	178 (120–240)
AAA D_{max}	58 (54–85)
RCIA diameter	13 (7–58)
LCIA diameter	13 (10–100)
REIA diameter	7.5 (5.2–11)
LEIA diameter	7.7 (5.5–12.5)

AAA, abdominal aortic aneurysm; LCIA, left common iliac artery; LEIA, left external iliac artery; RCIA, right common iliac artery; REIA, right external iliac artery.

L1 represents the distance between the origin of the most caudal renal artery and the aortic bifurcation. L2 and L3 are the distances between the lowest renal artery to the right and left internal iliac artery origin, respectively.

50 (76%) patients, a total percutaneous access was achieved, while in 16 (24%) at least one femoral artery was surgically prepared *via* cut-down. RGA was administered in 22 (33%) of patients, while in 44 (67%), the procedure was completed under LA. Technical success (including primary, primary assisted and secondary technical success) was achieved in 63/66 patients (95%). In two patients, catheterization of the contralateral leg of the aortic main body was not possible due to its collapse and/or twisting. In both patients, an additional brachial approach was used in order to facilitate contralateral limb catheterization, which was unsuccessful. The third patient had small-diameter external iliac arteries (of about 4 mm) and extensive angulation, which were preoperatively deemed as passable but it turned out that the passing of the endograft was not feasible. Two of these patients were subjected to conversion to open surgical repair (2/66 patients, 3%). In one patient with bilateral common iliac occlusions that were endovascularly recanalized, a complete left graft limb collapse and occlusion due to a very tight distal aortic lumen (12 mm diameter) complicated the procedure. As previously described, this was managed by inserting an ipsilateral inverted “U” internal to external iliac artery stent graft to insure that a left Type II endoleak *via* the left internal iliac artery would not occur and essentially the graft was converted into an aorto-uni-iliac graft.²⁴ Since the patient had an occluded common iliac artery before the procedure, the arterial perfusion of the left lower limb remained unchanged, and therefore additional surgery was not initially required.

Additional endovascular interventions (primary-assisted technical success) were required in two cases, where a Type Ia endoleak was observed upon completion angiography, which resolved after balloon angioplasty with a compliant aortic balloon (35 mm diameter) at the sealing zone of the inflatable O-rings. Moreover, in one case, thrombosis of the superficial femoral artery (access site)

resulted in acute limb ischaemia that required immediate surgical exploration and thrombectomy (secondary technical success).

Concomitant brachial access was required in two additional cases to achieve contralateral catheterization, which was successful in both instances.²⁵

Postprocedural data and follow-up

AAA-related and all-cause mortality at the immediate post-operative and during the midterm follow-up was 0%. Post-operatively, intensive care unit admission was necessary for one patient receiving regional anaesthesia. Median length of stay in the hospital was 3 days (range, 1–16 days). Systemic complications were encountered in 6% (4/66 patients—one cardiovascular event, one respiratory infection, one renal dysfunction and one case of deep vein thrombosis and pulmonary embolism), and local complications in 9% (6/66 patients—three pseudoaneurysms, one case of wound infection and two cases of lymphorrhea) of subjects treated. In total, 9/66 patients (14%) presented any kind of morbidity (one patient presented both a systemic/respiratory tract infection and a local/lymphorrhea complication). Clinical success was achieved in 62/66 (94%) patients. Clinical failure was attributed to the three cases where successful endograft deployment was not achieved and an additional case of a Type II endoleak in which sac enlargement was observed, but due to comorbidities no further therapeutic actions were taken. In four cases, endovascular procedures were undertaken to correct limb stenosis (primary-assisted clinical success), whereas three patients underwent surgical intervention to maintain good outcome (one surgical debridement due to wound infection, one femoral–femoral bypass due to graft limb occlusion, one resection of a femoral artery pseudoaneurysm: secondary clinical success). In our series, no migration and no Type I or III endoleaks were observed. There were 8/63 (13%) Type II endoleaks, and sac enlargement was observed in one case as already mentioned. Patients’ characteristics and peri- and postprocedural data for our study population are summarized in Table 2.

Local anaesthesia vs regional/general anaesthesia

The abovementioned pre-, peri- and postprocedural variables were compared between groups of LA and RGA. The differences recorded were not significant for any of the variables examined, except anaesthesia and procedural time that both were shorter in the LA group (5 vs 30 min; $p < 0.001$, and 85 vs 107 min; $p < 0.001$, respectively), percutaneous access that was significantly more common in the LA group (91% vs 45%; $p < 0.001$) and systematic complications that were significantly less among patients undergoing LA (2.3% vs 14%; $p = 0.05$). Variables evaluated with regard to type of anaesthesia administered and statistical significance of differences are summarized in Table 3.

DISCUSSION

The constant evolution of devices along with the accumulated experience of physicians are gradually expanding indications of EVAR to include more subjects with complex and challenging anatomies that would otherwise have had to undergo major open surgery accompanied by serious mortality and morbidity.¹¹ The Ovation TriVascular Stent Graft system is intended to overcome limitations of previous endografts by embracing an innovative

Table 2. Overall patients' characteristics and peri- and postprocedural data are reported. Additional surgical and endovascular procedures include those that were performed both immediately after endovascular aneurysm repair but also during follow-up. Conversion to open surgery is recorded separately

Variable	Overall (n = 66)
Age (years) (range)	72 (54–88)
Gender (male:female)	65:1
American Society of Anesthesiologists 3,4	27 (41%)
D _{max} (mm) (range)	58 (55–100)
Anaesthesia time (min) (range)	15 (4–60)
Procedural time (min) (range)	95 (65–280)
Percutaneous access	50 (76%)
Technical success	63 (95%)
Conversion to open surgical repair	2 (3%)
Intensive care unit	1 (1.5%)
Length of stay (days)	3 (1–16)
Morbidity	9 (14%)
Systemic complications	4 (6%)
Local complications	6 (9%)
Clinical success	62 (94%)
Additional endovascular procedures	6 (9%)
Additional surgical procedures	4 (6%)

EVAR, endovascular aneurysm repair.

design and introducing some unique concepts in EVAR philosophy. The technical revolution that this device brings is the idea to uncouple the stages of stent graft fixation and seal during the procedure. Subsequently, during deployment, stent and fabric are not competing within the delivery system and an ultralow profile delivery of 14 Fr can be achieved.¹² This platform acquires fixation exploiting a suprarenal nitinol stent (35 mm), with integrally formed anchors that are delivered in a staged way, allowing precise placement. After fixation has been accomplished, seal is achieved by inflating the two O-rings located at the proximal infrarenal aortic neck, which are filled with a low-viscosity, radio-opaque fill polymer and cure *in situ* to form a custom moulded ring seal at the margin of the aneurysm. Furthermore, the polymer-filled O-rings do not exert the kind of chronic outward force on the aorta that is observed with other stent graft systems using oversized, self-expanding stents to achieve proximal seal.^{24–29} The distinct advantages of these originalities result in the Ovation system being the only endograft approved for the treatment of AAAs with proximal aortic necks <10 mm and access vessels as small as 4.7 mm.²²

Following FDA approval and introduction of the Ovation endograft in clinical practice, studies to evaluate its safety and effectiveness were conducted. The pivotal study recently published was a prospective analysis that included 161 patients and reported a favourable outcome of patients treated with this

device. Specifically, these authors report a technical success rate of 100%, while the 30-day major adverse event rate was 2.5%. At 1 year, AAA-related and all-cause mortality were 0.6% and 2.5%, respectively, whereas major adverse event rates were 6.2%. The 1-year treatment success rate was achieved in 99.3% of patients, while there were no cases with a stent graft migration or Types I, III or IV endoleaks. Type II endoleaks were identified in 34% of patients, and AAA enlargement was identified in one patient (0.7%). No AAA rupture or conversion to open surgery was reported, and secondary procedures were required in 10 patients (6.2%) for endoleak, main body stenosis and iliac limb stenosis or occlusion.³⁰

Recently, a single-centre experience with Ovation stent graft has been reported by Mangialardi *et al*¹⁴ including 35 patients with a technical success rate of 97.1%. One case of Type I endoleak was identified, while at a mean follow-up of 10 months (range, 1–24 months), there was no mortality, no Types II, III or IV endoleak, no migration, no AAA enlargement, no AAA rupture, or conversion to open surgery. Additionally, the authors reported two complications (5.7%) where monolateral iliac limb occlusion was treated by endovascular means. Moreover, Nano *et al* in a recent retrospective analysis reported a primary success rate of 89.2% (33/37). They did not observe any deaths or major complications during the procedure or in follow-up. No Type I, III or IV endoleak, AAA enlargement, AAA rupture, stent fracture, migration, or endovascular or surgical reintervention were reported during the follow-up period.³¹

These results are comparable to ours (all-cause and AAA-related mortality 0%, technical success rate 95%, midterm clinical success rate 94%, no Type I, III, IV endoleak, no migration, open conversion required in 3% of patients), indicating overall promising results, with excellent demonstrated safety and effectiveness in patients with AAA. The two cases that needed conversion to open surgery were performed with the first-generation Ovation device and looking retrospectively back it is our belief that in at least one of these patients cannulation would have been feasible with the second-generation Ovation Prime™, in which the limbs are attached at the distal end to facilitate easier catheterization of the contralateral limb. According to the definition of major adverse events used in the pivotal study by Mehta *et al*³⁰ (death, myocardial infarction, stroke, renal failure, respiratory failure, paraplegia, bowel ischaemia or procedural blood loss >1000 ml), we report 1/66 (1.5%) such events during the initial postoperative period and midterm follow-up (one case of myocardial infarction from which the patient fully recovered).

A total percutaneous approach and also completion of procedures under LA was more common in our study population compared to the results reported in the pivotal study of the Ovation endograft. Specifically, 76% of our patients had percutaneous access compared to 43% reported by Mehta *et al*, while 66% of procedures were performed under LA in the current study compared to 34% in the pivotal study. The percutaneous approach and the acquisition of adequate experience resulted in the reduction of the procedure duration, and patients who underwent EVAR under LA reported minimal discomfort.

The haemodynamic and respiratory effects of the LA protocol were minimal, enabling a trained nurse to provide monitored care and the demand for the presence of an anaesthesiologist during the procedure decreased. We were therefore able to increase the number of patients undergoing EVAR and decrease the waiting times without increasing the workload of the anaesthesiology department. Taking into account the shortage of anaesthesia providers in Greece, similar to that seen in low- and middle-income countries, the advantages of such a management become apparent.^{32,33} Moreover, the additional analysis of our data with reference to the type of anaesthesia indicate that LA is advantageous compared to RGA in terms of procedural time, percutaneous access and more importantly systematic complication rate, resulting in significantly fewer complications. In the same time, completion of procedures under LA did not produce inferior results with regard to any of the other variables tested. This is in accordance with previous studies including large number of patients and procedures which postulate that LA is an effective alternative to perform EVAR and suggest that the adaption of a minimally invasive approach with the use of LA and percutaneous access may be used as a routine during the treatment of AAAs with the Ovation endograft.^{15,16} Furthermore, taking into account the significantly less systemic complication rate in the LA group that we and others have found and given the fact that previous research indicates a high estimated cost of such complications (*i.e.* nosocomial pneumonias), we may postulate that this approach will reduce medical costs and contribute to a judicious management of economic resources.¹⁶

This could be an important factor to achieve a larger amount of interventions to take place given the current economic environment in a regional hospital in Greece.

Study limitations

The present findings should be evaluated with the perspective that they have arisen from a retrospective analysis. Such a design is well known to be susceptible to confounding factors due to the lack of randomization between groups. A percutaneous approach was our preferred method to gain vascular access in every patient, regardless of the anaesthetic technique used. The comparisons between LA and RGA groups may have a selection bias since during initial experience with the Ovation system, general and regional anaesthetic techniques were mainly applied, while LA was adapted as routine after having accumulated considerable experience with the use of this device. Therefore, the increased familiarity of the treating physicians may have contributed to the observed results of reduced procedural time and increased proportion of patients undergoing a total percutaneous approach in the latter group. Moreover, recall bias is a well-known factor that may limit reliability of obtained results in a retrospective study.

CONCLUSION

EVAR with the Ovation TriVascular Stent Graft system shows promising short-term and midterm results regarding safety and effectiveness outcomes. Completion of the procedures under LA using a total percutaneous approach may be used as a routine with the exception of specific relative contraindications. Such

Table 3. Outcomes with regard to anaesthetic technique used and statistical significance of differences. Median and range values are reported

Variable	LA (<i>n</i> = 44)	RGA (<i>n</i> = 22)	<i>p</i> -value
Age (years)	71	74	0.51
American Society of Anesthesiologists 3,4	18 (41%)	9 (41%)	1
<i>D</i> _{max} (mm)	57	58	0.41
Anaesthesia time (min) (range)	5 (3–7)	30 (20–60)	>0.001
Procedural time (min) (range)	85 (65–260)	107 (85–280)	>0.001
Fluoroscopy time (min) (range)	13.3 (11.5–17.3)	13.9 (11.4–19.1)	0.2
Contrast used (ml) (range)	126 (80–250)	169 (80–350)	0.15
Percutaneous access	40 (91%)	10 (45%)	>0.001
Technical success	42 (95%)	21 (95%)	1
Conversion to open surgical repair	1 (2.3%)	1 (4.5%)	1
Intensive care unit	0 (0%)	1 (4.5%)	0.34
Length of stay (days)	3	3	0.11
Morbidity	4 (9%)	5 (23%)	0.25
Systemic complications	1 (2.3%)	3 (14%)	0.05
Local complications	4 (9%)	2 (10%)	1
Clinical success	42 (95%)	20 (91%)	0.6
Additional endovascular procedures	5 (11%)	1 (4.5%)	0.6
Additional surgical procedures	2 (4.5%)	2 (9%)	0.6

LA, local anaesthesia; RGA, regional/general anaesthesia.

The groups were not randomly selected and the outcomes may be subject to other variables.

a practice may be advantageous resulting in a reduced complication rate and conforming to a beneficial management of economic resources.

CONFLICTS OF INTEREST

Dr D Tsetis has a consulting agreement with TriVascular to prepare and deliver presentations.

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