Original Article

The Practice of Percutaneous EVAR under Local Anesthesia

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Objectives: Endovascular aortic repair (EVAR) should be performed using a less invasive procedure based on the patient's clinical condition, as many patients who undergo this procedure are elderly and have poor surgical tolerance. We report our experience and results of percutaneous EVAR under local anesthesia in order to practice minimally invasive EVAR at our hospital.

Methods: In August 2019, we started percutaneous EVAR using Perclose ProGlide under local anesthesia. We compared the backgrounds and surgical outcomes of patients who underwent EVAR at our hospital before and after the introduction of percutaneous EVAR under local anesthesia.

Results: We included 148 patients in this study. The age at surgery and prevalence of severe renal dysfunction were significantly higher in percutaneous EVAR under local anesthesia group. The operative time and postoperative hospital stay were significantly shorter in the percutaneous EVAR group under local anesthesia.

Conclusions: The introduction of percutaneous EVAR under local anesthesia enabled minimally invasive EVAR to be performed safely even in high-risk patients. (This is a translation of J Jpn Coll Angiol 2022; 62: 1–5.).

Keywords: percutaneous EVAR, Perclose ProGlide, local anesthesia

Introduction

Endovascular aortic repair (EVAR) is widely performed to treat abdominal aortic aneurysm (AAA). In Japan, because commercially marketed stent grafts were approved for use in 2006, EVAR has been increasingly adopted as a minimally invasive modality, with approximately >60% of AAA cases presently being treated with EVAR.[1] Although EVAR is less invasive than laparotomy, it should preferably be performed in a less invasive manner depending on the patient's condition, considering that EVAR is often selected for elderly patients with low tolerance to surgery. Japan has particularly a super-aging population, with one in two Japanese women living up to 90 years of age.[2] As the society grows older, the complication rate of frailty has increased. Accordingly, the demand for minimally invasive therapeutic options is expected to surge furthermore.

Amid these circumstances, our hospital is aiming to provide even less invasive EVAR operations. We report our efforts at performing minimally invasive EVAR and the results of those efforts, varying from the introduction of percutaneous EVAR to its implementation under local anesthesia.

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Materials and Methods

Low-invasive EVAR methods

Conventionally, surgeons at our hospital performed EVAR under general anesthesia for all patients, following the cut-down approach where both inguinal regions are incised diagonally to expose the common femoral artery. To achieve a less invasive EVAR, we established a new vascular surgery system in August 2019 involving cardiologists, radiologists, and others, and the following initiatives were initiated.

(1) EVAR under local anesthesia

In addition to local anesthesia using lidocaine hydrochloride, we use dexmedetomidine hydrochloride (Precedex) as a loading dose. Although the package insert instructs that the drug should be administered at 6 μg/kg/h and then adjusted at 0.2–0.7 μg/kg/h as necessary 10 min later, we administer it at 4 μg/kg/h and then reduce to 0.4 μg/kg/h 15 min later to facilitate weight-based calculation (when calculated at this dose, a dose of 50 mL/h is reduced to 5 mL/h 15 min later for a patient weighing 50 kg, making it easier to adjust the dose based on the weight).

Table 1 Baseline characteristics

	Percutaneous EVAR group (n = 38)	Conventional EVAR group (n = 110)	P value
Sex (male)	34 (89%)	90 (82%)	0.32
Age (years)	80 ± 7.5	76 ± 7.0	<0.01
BMI	22.7 ± 4.4	22.4 ± 3.2	0.59
Smoking history	18 (47%)	73 (66%)	0.04
Hypertension	30 (79%)	81 (74%)	0.83
Diabetes	8 (21%)	28 (26%)	0.65
Coronary artery disease	17 (45%)	51 (46%)	0.85
Cerebrovascular disease	4 (11%)	21 (19%)	0.32
Pulmonary disease	9 (24%)	23 (21%)	0.82
CKD (eGFR <60)	28 (74%)	52 (47%)	<0.01
Chronic hemodialysis	3 (8%)	4 (4%)	0.38
Cancer	12 (32%)	40 (36%)	0.56
Hgb (g/dl)	12.3 ± 1.9	12.3 ± 2.1	0.91
RBC ($\times 10^3$ μl)	391 ± 62	409 ± 64	0.12
HCT (%)	37 ± 5.5	40 ± 3.0	0.54
Alb (g/dl)	3.7 ± 0.5	3.9 ± 0.5	0.22
Lymp (/μl)	1479 ± 564	1586 ± 647	0.36
Cr (mg/dl)	1.45 ± 1.2	1.30 ± 1.4	0.58
eGFR (ml/min/1.73 m^2)	49 ± 18	61 ± 23	<0.01

We included 148 patients in this study. The age at surgery and prevalence of severe renal dysfunction were significantly higher in percutaneous EVAR under local anesthesia group.

If switching to general anesthesia is necessitated (e.g., in patients for whom excessively prolonging operative duration or intraoperatively maintaining a sedated state is infeasible), a backup system is in place in cooperation with the anesthesiology department.

(2) Percutaneous EVAR by paracentesis

Our hospital has adopted the pre-close method using the Perclose ProGlide (Abbott, Abbott Park, IL, USA), a hemostatic device pertaining to percutaneous access. The pre-close method involves preliminarily attaching two Perclose ProGlide devices before a large-diameter sheath is inserted. A stent graft technique is performed with the suture loosened, and when the large-diameter sheath is removed, the suture is tightened to complete hemostasis.

On the other hand, because percutaneous EVAR is not suitable for patients with poor access in the anterior side of the common femoral artery due to high-level calcification, luminal stenosis, and other conditions, the cut-down approach is selected as the surgical strategy.

(3) Novel contrast imaging approach/concomitant use of intravascular ultrasound (IVUS)

For chronic kidney disease (CKD) patients whose severity is classified as G3b or above (having high-level renal dysfunction), we have adopted techniques such as carbon dioxide contrast imaging and high-contrast transillumination to reduce the risk of contrast nephropathy. Meanwhile, IVUS is concomitantly employed for measuring lesion lengths.

Patients involved

This study involved 148 patients who had undergone elective EVAR at our hospital from June 2012 to April 2021. We comparatively analyzed the patient characteristics, surgical outcomes, and other factors before and after the introduction of minimally invasive EVAR. Emergency cases were excluded. Regarding the aforementioned minimally invasive EVAR approach (3), applicability is judged on a case-by-case basis. Accordingly, the patients satisfying both (1) and (2) were categorized into the minimally invasive EVAR group. The patients who had been operated on before the introduction of minimally invasive EVAR and those who had received surgery that did not satisfy (1) and (2) after August 2019 were categorized into the conventional group.

Statistical analyses

Statistical analysis between the two groups was performed using means ± standard deviation for continuous variables and percentages for categorical variables. Differences in the percentages were evaluated by either the chi-square (χ^2) test or Fisher's exact test. Differences in the means were evaluated by the unpaired Student *t*-test. The significance level was set at a probability value (P value) < 0.05.

Table 2 Procedure details

	Percutaneous EVAR group (n = 38)	Conventional EVAR group (n = 110)
Device details		
Gore® Excluder®	34	90
AFX	4	1
Endurant®	0	4
Zenith®	0	15
Instruction for use (IFU)	79%	88%

The breakdown of devices used for EVAR was shown; 79% for percutaneous EVAR group and 88% for conventional EVAR group were used in IFU.

Table 3 Perioperative outcome

	Percutaneous EVAR group (n = 38)	Conventional EVAR group (n = 110)	P value
Procedure duration (min)	96 ± 31	122 ± 48	<0.01
Hospital stay (days)	4.2 ± 1.2	8.2 ± 15.8	<0.01
Blood transfusion (BARC3 or 5)	0 (0%)	12(11%)	<0.05
Introduction of hemodialysis	1 (3%)	6 (5%)	0.56
Start date of meal (within 12 h after surgery)	37 (97%)	0 (0%)	<0.01
Wound complications	0 (0%)	13 (12%)	<0.05
Endoleak	6 (16%)	25 (23%)	0.44
Type I a/b	0	3	
Type II	3	21	
Type III	3	1	
Type IV	0	0	
Aneurysm related event	1 (3%)	10 (9%)	0.16
Postoperative acute complications	1 (3%) (Aortic dissection)	8 (7%) (Stroke 3, infection 4, pneumothorax 1)	0.34

The procedure duration and postoperative hospital stay were significantly shorter in the percutaneous EVAR group under local anesthesia.

Results

Table 1 lists the patient characteristics in both groups, and **Table 2** describes the details of the devices used in EVAR. Of the 148 patients, 38 were categorized into the minimally invasive EVAR group, whereas 110 were into the conventional group. After August 2019, none of the patients failed to satisfy either approach (1) or (2). All patients were able to receive EVAR under local anesthesia and paracentesis.

Significant differences were noted in the age at the time of surgery, with the minimally invasive EVAR group significantly older (minimally invasive EVAR group: 80 ± 7.5 yr; conventional group: 76 ± 7.0 yr; $P < 0.01$). Of the concurrent diseases, no significant differences were noted in coronary disorders, cerebral infarction, cerebral hemorrhage, respiratory disorders, and malignant tumors. However, the CKD patients who were graded G3a or above (minimally invasive EVAR group: 74%; conventional group: 47%; $P < 0.01$) and the patients with preoperative estimated glomerular filtration rate (eGFR; minimally invasive EVAR group: 49 ± 18 mL/min/1.73 m^2; conventional group: 61 ± 23 mL/min/1.73 m^2; $P < 0.01$) exhibited significant differences. Thus, significantly more patients in the minimally invasive EVAR group had high-level renal dysfunction.

Table 3 lists the surgical outcomes in both groups. The minimally invasive EVAR group experienced significantly shorter operative duration (minimally invasive EVAR group: 96 ± 31 min; conventional group: 122 ± 48 min; $P < 0.01$) and postoperative hospitalization duration (minimally invasive EVAR group: 4.2 ± 1.2 days; conventional group: 8.2 ± 15.8 days, $P < 0.01$). No significant differences were noted in either the incidences of aneurysm-related deaths and aneurysm-related events defined as additional treatment (minimally invasive EVAR group: 3%; conventional group: 9%; $P = 0.16$) or the incidence of endoleaks (minimally invasive EVAR group: 16%; conventional group: 23%; $P = 0.44$).

Discussion

Not involving laparotomy, EVAR is known as a minimally invasive therapeutic option for treating AAA. Nevertheless, a simple modality of EVAR may not be sufficient as a minimally invasive therapy for elderly patients with decreased surgical tolerance. Hence, proper management, encompassing perioperative and long-term control, is considered critical.

We first inferred that avoiding general anesthesia might lead to a less invasive treatment. Japanese medical guidelines on aortic aneurysm and aortic dissection also mention EVAR under local anesthesia.[3] According to overseas registries, this local anesthesia approach was less invasive, had shorter operative/hospitalization duration, and displayed no differences in perioperative mortality compared with the general anesthesia approach.[4,5] However, EVAR under local anesthesia is not currently widely practiced in Japan. This is partially because general anesthesia controlled by anesthesiologists is more conducive to securing the stability of circulatory dynamics, as well as because patients awake under local anesthesia are more liable to mental pressure. Moreover, local anesthesia is highly sensitive to the body movement and respiration of the patient, which may disadvantage the surgeon. However, our study results indicated no significant differences in short-term treatment outcomes and the incidences of aneurysm-related events and postoperative endoleaks between the local anesthesia group and the conventional general anesthesia group. Therefore, the local anesthesia approach was considered just as effective. Furthermore, by circumventing the tracheal intubation procedure associated with general anesthesia, it became possible to resume eating on the same day as the surgery.

As local anesthesia was introduced, the cut-down approach was switched to the paracentesis approach for sheath insertion. Performing EVAR via percutaneous access facilitates early wound healing compared with when the femoral artery needs to be visually secured by the cut-down approach. Besides, there are other advantages, such as shortened operative time, reduced bleeding, alleviated postoperative pain, and shortened hospitalization duration. Clinical data collected both domestically and internationally have proved these benefits.[6–8] Our study also revealed that surgical wound complications significantly decreased. Although 12% of the patients subjected to the cut-down approach experienced surgical wound complications, such as surgical site dehiscence and infection, no such complications were observed in the patients subjected to paracentesis. Moreover, the paracentesis approach is also advantageous in that intraoperative procedures can be performed more comfortably because of the better sheath fixation than that in the cut-down approach.

To accommodate the use of a large-diameter sheath, the use of hemostatic devices is essential. Given that using two Perclose ProGlide devices for a large-diameter sheath (8 Fr or larger) was covered by national insurance in January 2021, instances of percutaneous EVAR are expected to increase further. Reported complications caused by homeostatic devices include poor homeostasis, false lumps, and device-related infections.[9–11] At our hospital, patients receive vascular echography to check for the paracentesis site, and no problems attributed to hemostatic devices have been observed to date. However, to ensure that EVAR is performed not only in a minimally invasive manner but also safely, it is imperative to establish a framework that can rapidly address high-level calcification in the paracentesis site by adopting the cut-down approach and swiftly implement surgical repair in case of any access trouble. Moreover, cardiovascular surgeons who have less opportunity to handle catheters on a daily basis should be required to undergo training for a certain period before using hemostatic devices for a large-scale sheath. Using hemostatic devices haphazardly for a large-scale sheath and then failing to achieve hemostasis may cause serious complications. Hence, surgeons need to practice the procedure using a model, as well as becoming accustomed to handling hemostatic devices for a sheath smaller than 8 Fr.

Patients subjected to EVAR are likely elderly patients with various complications. The results of our study revealed that the conventional EVAR group was older and had a higher incidence of CKD than the local anesthesia percutaneous EVAR group. This may reflect the fact that local anesthesia percutaneous EVAR is less invasive than conventional EVAR and may be applicable to high-risk patients, who have previously been considered unsuitable to surgical treatment owing to intolerance to general anesthesia despite being anatomically compatible.

While many patients have CKD, aggravated renal dysfunction caused especially by contrast agents is also a concern because the use of iodide contrast agents is essential for EVAR. To address this concern, we devised measures to reduce the doses of contrast agents used by introducing carbon dioxide contrast imaging and high-contrast transillumination with the cooperation of radiologists. Carbon dioxide contrast imaging is a safe and effective image diagnostic method, which is also employed in endovascular treatment for obstructive arteriosclerosis, etc. In EVAR, it sometimes occurs that renal artery branches situated dorsally are insufficiently visualized or that evaluating endoleaks is infeasible. Therefore, not all procedures should be done using carbon dioxide gas. Nevertheless, increased doses of contrast agents are an alleged risk of contrast nephropathy,[12] and the concomitant use of carbon dioxide contrast imaging is an effective way to reduce the doses of contrast agents. Although the use of high-contrast transillumination, which enhances the image contrast by adjusting radiation output, increases the radiation dose, it makes it possible to more than halve the dose of a contrast agent used per session. Because the image quality is not compromised compared with that of standard DSA photography, we utilize high-contrast transillumination for final contrast imaging to evaluate endoleaks. The concomitant use of IVUS has made it possible to measure lesion lengths and detect and treat complications such as dissection at an early stage.

It should be noted that this was a single-center study, and the sample size was small because of the introduction of the minimally invasive EVAR approach using local anesthesia and paracentesis. Therefore, the long-term analysis of surgical outcomes and the evaluation of the effects of introducing minimally invasive EVAR compared with the conventional study are not sufficient. To discuss the reliability and validity of the treatment, more case studies and long-term follow-up observations are required.

Conclusion

We devised measures such as using the local anesthesia percutaneous approach and reducing doses of contrast agents. Thus, we could perform less invasive EVAR operations, which were applied safely to higher risk patients. Because the demand for minimally invasive surgical treatment is expected to increase, we hope that the efforts at our hospital will contribute to the popularization of minimally invasive EVAR.

Disclosure Statement

In this study, we do not have any conflicts of interest to disclose, nor have we received any external research funds.

Ethical Statement

This article was approved by the ethics committee of our hospital (approval no.: OR21016).

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