CLINICAL STUDY

Long-Term Outcome of the GORE EXCLUDER AAA Endoprosthesis for Treatment of Infrarenal Aortic Aneurysms

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ABSTRACT

Purpose: To evaluate long-term outcome of GORE EXCLUDER AAA Endoprosthesis (W.L. Gore & Associates, Inc, Flagstaff, Arizona) for elective treatment of infrarenal aortic aneurysms and to evaluate performance of different generations of the device.

Materials and Methods: A retrospective analysis was performed of 248 patients undergoing elective endovascular aneurysm repair with the GORE EXCLUDER between January 2000 and December 2015 in 2 hospitals. Primary endpoint was reintervention-free survival. Secondary endpoints were technical success, overall survival, rupture-free survival, endoleaks, sac diameter change (> 5 mm), limb occlusion, and migration (> 5 mm). Median follow-up time was 26 months (range, 1–190 months).

Results: Assisted primary technical success was 96.8%. Reintervention-free survival for 5 and 10 years was 85.2% and 75.6%, respectively. Independent risk factors for reintervention were technical success ($P < .001$), type I endoleak ($P < .001$), and type II endoleak ($P = .003$). Late adverse events requiring reintervention included rupture (0.4%), limb occlusion (0.4%), and stent migration (0.4%). Type Ia (4.8%), Ib (2.8%), II (35.9%), and V (6.5%) endoleaks were reported throughout follow-up. Sac growth was more prevalent with the original GORE EXCLUDER compared with the low permeability GORE EXCLUDER ($P = .001$) and in the presence of type I, II, and V endoleaks ($P < .05$). Three conversions (1.2%) were performed. Overall survival at 5 and 10 years was 68.4% and 49.0%, with no reported aneurysm-related deaths.

Conclusions: Treatment with the GORE EXCLUDER is effective with acceptable reintervention rates in the long-term and few device-related adverse events or ruptures up to 10 years. Observed late adverse events and new-onset endoleaks emphasize the need for long-term surveillance.

ABBREVIATIONS

AAA = abdominal aortic aneurysm, CI = confidence interval, EVAR = endovascular aneurysm repair, IFU = instructions for use, LFU = lost to follow-up, LP = low permeability GORE EXCLUDER, OP = original permeability GORE EXCLUDER

Endovascular aneurysm repair (EVAR) has become a routinely used procedure for treatment of infrarenal abdominal aortic aneurysms (AAAs). Ongoing improvements in graft design will likely lead to improved long-term outcomes, although long-term data are still scarce. The GORE EXCLUDER (W.L. Gore & Associates, Inc, Flagstaff, Arizona) EVAR device was released in Europe in 1997 and > 250,000 patients have been treated with the device worldwide. Over the course of several years, modifications were made to the original permeability GORE EXCLUDER (OP). In October 2004, the low permeability GORE EXCLUDER (LP) was launched as a response to reported aneurysm enlargement with the OP. The LP has a middle layer with a redesigned polytetrafluoroethylene

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Table 1. Baseline Characteristics of Patients with an Infrarenal Aortic Aneurysm Treated with the GORE EXCLUDER

Variable	Overall (N = 248)	OP (n = 52)	LP (n = 196)	*P* Value
Patient characteristics				
Mean age, y (SD)	71.2 (8.2)	69.5 (6.8)	71.7 (8.5)	.086
Male sex	216 (87.1%)	47 (90.4%)	169 (86.2%)	.426
Risk factors/comorbidities				
Hypertension	172 (69.4%)	36 (69.2%)	136 (69.4%)	.650
Hyperlipidemia	163 (65.7%)	22 (42.3%)	141 (71.9%)	< .001*
Cardiovascular disease				
Coronary artery disease	116 (46.8%)	27 (51.9%)	89 (45.4%)	.403
Cerebrovascular disease	36 (14.5%)	7 (13.5%)	29 (14.8%)	.808
Peripheral artery disease	23 (9.3%)	5 (9.6%)	18 (9.2%)	.924
Diabetes mellitus	37 (14.9%)	7 (13.5%)	30 (15.3%)	.740
Insulin dependent	7 (2.8%)	3 (5.8%)	4 (2.0%)	.149
Severely reduced kidney function/renal dialysis	7 (2.8%)	0 (0.0%)	7 (3.6%)	.167
Lung disease	62 (25.0%)	10 (19.2%)	52 (26.5%)	.280
Currently smoking	73 (29.4%)	17 (32.7%)	56 (28.6%)	.117
Previous vascular surgery	92 (37.1%)	22 (42.3%)	70 (35.7%)	.396
ASA classification				
I–II	144 (58.1%)	30 (57.7%)	114 (58.2%)	.951
III–IV	104 (41.9%)	22 (42.3%)	82 (41.8%)	.951

ASA = American Society of Anesthesiologists; LP = low permeability GORE EXCLUDER; OP = original permeability GORE EXCLUDER.
*Significant difference between OP and LP.

microstructure to decrease graft permeability (1). In 2011, the C3 device delivery system was introduced. This delivery system offers the advantage of repositioning the stent graft, resulting in higher accuracy in positioning relative to the renal arteries and improving ease of cannulation through repositioning. The GORE EXCLUDER has been related to low rates of aneurysm-related death and adverse events, but reports on long-term outcomes are scarce (2–5). The principal aim of the present study was to evaluate the long-term results, particularly the reintervention-free survival, of the GORE EXCLUDER in the elective treatment of infrarenal AAAs. In addition, the outcomes of the different generations of the device were evaluated.

MATERIALS AND METHODS

Study Design

Hospital records from patients who underwent EVAR with the GORE EXCLUDER for the treatment of an infrarenal AAA were retrospectively analyzed. All patients electively treated with the GORE EXCLUDER between January 2000 and December 2015 at 2 hospitals were included. Retrospective "patients' files" research is not within the scope of the Dutch WMO (Wet Mensgebonden Onderzoek [law on research involving human subjects]), and a waiver of the Dutch central ethical board was obtained that their review was not necessary. Anonymity of patients' data was maintained during analysis. The local board approved the study protocol. There were 26 patients excluded because the indication was treatment of a symptomatic or ruptured AAA (n = 15), because no follow-up data were available for at least 1 month (n = 4), and because the device was used as a secondary intervention after previous aortic repair (n = 7).

Baseline Demographics

During the study period, 248 patients were electively treated using the GORE EXCLUDER. In this time interval, 1,643 EVAR procedures were performed at the 2 sites. There were 216 men (87.1%) and 32 women (12.9%) with a mean age of 71.2 years ± 8.2 treated with the GORE EXCLUDER identified and included. Baseline demographics and risk factors are summarized in **Table 1**. Cardiovascular risk factors were present in most of the patients, and 41.9% of the patients had a high operative risk (American Society of Anesthesiologists class III or IV). The mean maximum aneurysm diameter was 59.1 mm ± 9.6 (range, 30–96 mm). Three patients with a saccular aneurysm were treated for an aneurysm diameter < 50 mm. The mean infrarenal aortic neck diameter was 22.9 mm ± 2.4, the mean neck length was 32.3 mm ± 11.9, and the mean infrarenal neck angle (beta angle) was 23.6° ± 21.9. A saccular aneurysm was present in 11 patients (4.4%), and an inflammatory aneurysm was present in 3 patients (1.2%). Besides the infrarenal aneurysm, 25 patients (10%) also had a concomitant common iliac artery aneurysm, and 5 patients (2%) also had an internal iliac artery aneurysm. There were 61 patients (24.6%) treated outside the instructions for use (IFU) of the device, mainly owing to the diameter of the common iliac artery, and 4.8% of the patients had a hostile aortic neck anatomy.