Endovascular Aneurysm Sealing System for Treating Abdominal Aortic Aneurysms: Early Outcomes from a Single Center

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Background: *Evidences reveal relative benefits of Endovascular aneurysm repair (EVAR) has declined over time, largely due to higher rates of re-intervention. Endovascular aneurysm sealing system (EVAS) has been proposed as a novel treatment for abdominal aortic aneurysms by excluding the sac with sealing at both the proximal and distal landing zones. Global experience with this novel treatment is limited. Therefore, there is a need to examine clinical outcomes after EVAS to provide appropriate treatment of abdominal aortic aneurysm.*
Objective: *To present the feasibility for treatment of abdominal aortic aneurysm by EVAS.*
Material and Method: *Eight patients with abdominal aortic aneurysm were treated with EVAS between January 2016 and November 2016. Data of demographics-, aneurysm morphology-, early outcomes-, endoleaks and other complications were included and analyzed. Computed tomographic angiography was used for postoperative imaging.*
Results: *The mean age of the participating patients was 71±6 years and 75% were male. Aneurysm neck length of <10 mm was 25% (n = 2), neck angulation was 44.26±22.5°, aneurysm diameter was 63.2±22.2 mm. There was one death within 30 days. The incidence of Type 1 endoleak within 30 days was one case. There were no Type 2 or Type 3 endoleaks.*
Conclusion: *The use of EVAS treating abdominal aortic aneurysm is feasible with acceptable early outcomes. EVAS may be applicable to a broader range of morphology compared with conventional EVAR. Eventually EVAS needs long-term follow-up.*

Keywords: *Abdominal aortic aneurysm, endovascular aneurysm sealing system, endobags, endoleak, chimney, endovascular aneurysm repair*

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Endovascular aneurysm repair[1] (EVAR) has become the first line of therapy for abdominal aortic aneurysms (AAA), especially in high-risk patients. The majority of devices currently used in EVAR are based on a 2-piece bifurcated design that consists of a main body/unilateral limb and a separate contralateral limb. However, previous published studies presented high rates of reintervention[2].

Endovascular aneurysm sealing system (EVAS) is a new alternative of EVAR (Fig. 1) by excluding the sac with sealing at both the proximal and distal landing zones and fixing the device at either the proximal attachment site or utilizing anatomic fixation at the bifurcation by sealing the aneurysm sac completely using a biostable polymer filling.

EVAS is able to resist both the caudal and lateral displacement forces by virtue of the device fixation throughout aorta in which it is implanted, as well as obliterate the aneurysm sac lumen. The European trials, presented good outcomes with short and midterm follow-up[3,4]. EVAS is the alternative therapy and also used in the treatment of post-EVAR complications[5].

The superior of EVAS over conventional EVAR is the lower incidence of type II endoleak with occlusion of visceral branch by endobags.

This study described perioperative complications, procedural details, and treatment of early endograft-related complications.

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Material and Method

Study population

All patients with infrarenal abdominal aortic aneurysm treated with EVAS between January 1, 2016 and November 30, 2016 were included. Data including demographics data, aneurysm morphology, procedural details, and early outcomes were recorded retrospectively. The study protocol was approved by the ethics committee of the Faculty of Medicine Khon Kaen University.

Endovascular aneurysm sealing

Bilateral common femoral arteries could be accessed by percutaneous puncture and Proglide (Abbott Vascular, Abbott Park, IL, USA) closure devices deployed[5].

Under fluoroscopy, the Nellix delivery systems were inserted bilaterally and positioned at the desired location with respected to the renal arteries (Fig. 2).

Retracting the sheaths, the stents were then exposed. The stents were expanded with simultaneous inflation of the balloons (Fig. 3). Both endobags were then currently filled with saline while the endobag pressure was monitored in order to determine the quantity of polymer that would fill the aneurysm sac. Aortogram was performed to confirm the absence of endoleak. The endobags were then deflated and a similar volume of polymer was injected under fluoroscopy with pressure control (Fig. 4). The stent-graft positioning must be maintained. The endobag filling pressure was 180±10 mmHg.

All cases a secondary fill were performed to fill up any persistent sac filling space after the first cure. After the polymer had cured, the delivery catheters were removed from the patient and a final aortogram was obtained. The arteries were closed with percutaneous techniques.

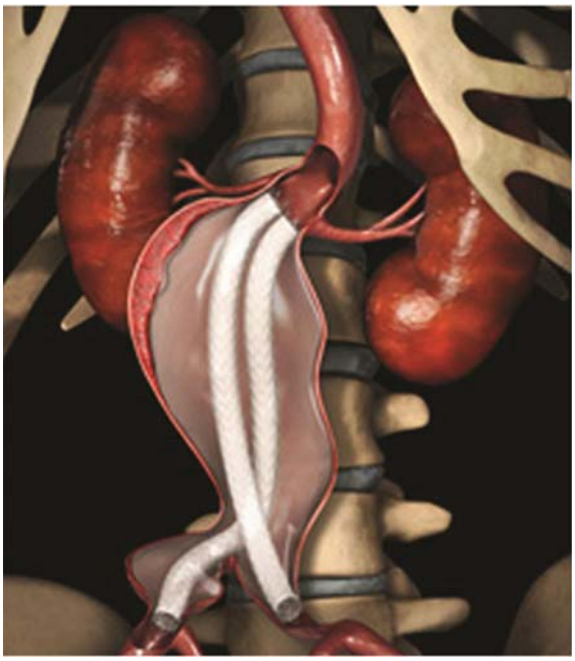

Fig. 1 Endovascular aneurysm sealing system (Courtesy of ENDOLOGIX, Inc.).

Results

A total of eight patients underwent EVAS with the Nellix device for infrarenal non-ruptured AAA between January 1, 2016 and November 30, 2016. The mean age of the patients was 71±6 years. In all, 75% were males and the American Society of Anesthesiologists (ASA) class 3. Five of the patients

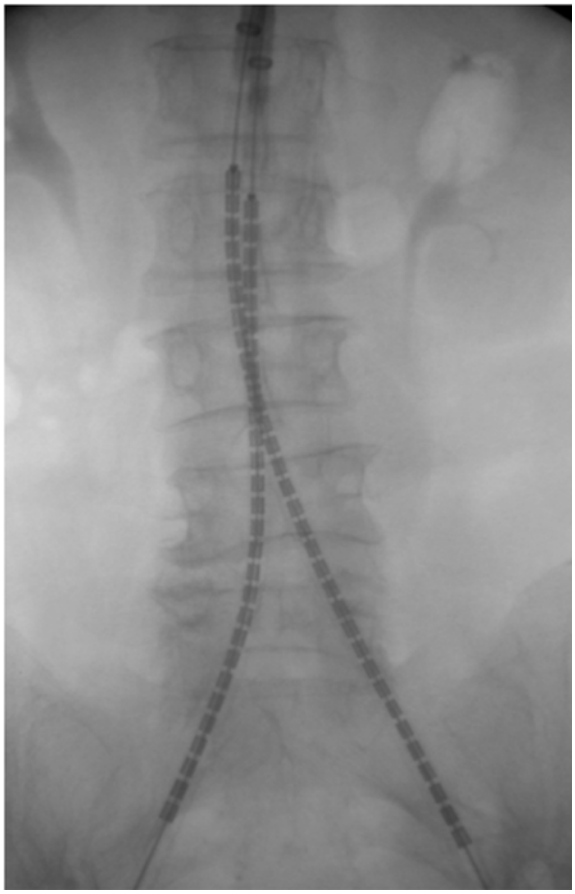

Fig. 2 Nellix delivery systems are inserted bilaterally and positioned at the desired location (Srinagarind Hospital, 2016).

(62.5%) had hypertension and three patients (37.5%) had dyslipidemia. Half of the patients were treated for symptomatic aneurysms. Two patients had challenging proximal neck anatomy, in which unsuitable for the conventional bifurcated graft. One case (12.5%) had saccular aneurysm with aorto-iliac aneurysm and two cases (25%) were juxtarenal AAA.

The mean aneurysm diameter was 63.2±22.2 mm (28.2 to 91.3 mm) , mean proximal neck diameter 22.16±4.8 mm (16.9 to 32.6mm), distal neck diameter 21.76±5.1 mm (13.7 to 30.2 mm) neck length 17.75±7.7 mm (6 to 27 mm) and neck angulation 44.26±22.5° (12.7 to 79°). Right common iliac artery diameter was 17.18±4.1 mm (11.1 to 22.8 mm) and left common iliac artery was 17.81±5.4 mm (11.4 to 25.6 mm).

The mean operative time was 139.25±71 minutes (79 to 305 minutes), fluoroscopic time 27.13±22.9 minutes (9.6 to 80.1 minutes), and contrast media (1:1 dilution) was 116.12±35.8 ml (70 to 175). One patient with 6-mm neck length was treated with Chimney EVAS, and another case with very narrow abdominal aorta (13.7mm) was treated with EVAS Aorto-Uni-Iliac (AUI) technique. Endobags intentionally occluded left internal iliac artery was founded in one (12.5%) case.

All cases were treated successfully during primary procedure with a final angiogram showed no endoleak. No significant change of renal function was observed between pre-operative and on discharge (serum creatinine 1.44±0.8 versus 1.38±0.3 mg/dl). The mean intensive care uinit (ICU) stay was 1.88±1.5 days (1 to 5 days) and hospital stay was 13.13±7.6 days (7 to 27 days), one case had thoraco-abdomial aortic aneurysm and had been treated with thoracic endovascular aortic repair (TEVAR) before EVAS.

There was one death on day eight following EVAS dued to aspiration pneumonia. Type Ia endoleak was found in one case due to short and severe angulation of aortic neck. Neither aortic nor endovascular graft related complications were observed.

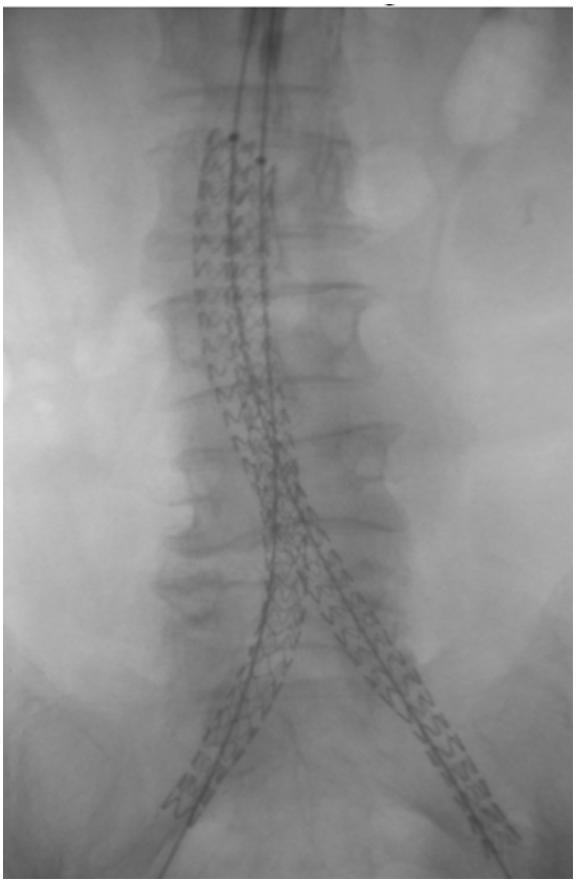

Fig. 3 Balloon insufflation of the balloon-expandable stents (Srinagarind Hospital, 2016).

Discussion

Recent studies reported the increased incidence of secondary intervention and complications

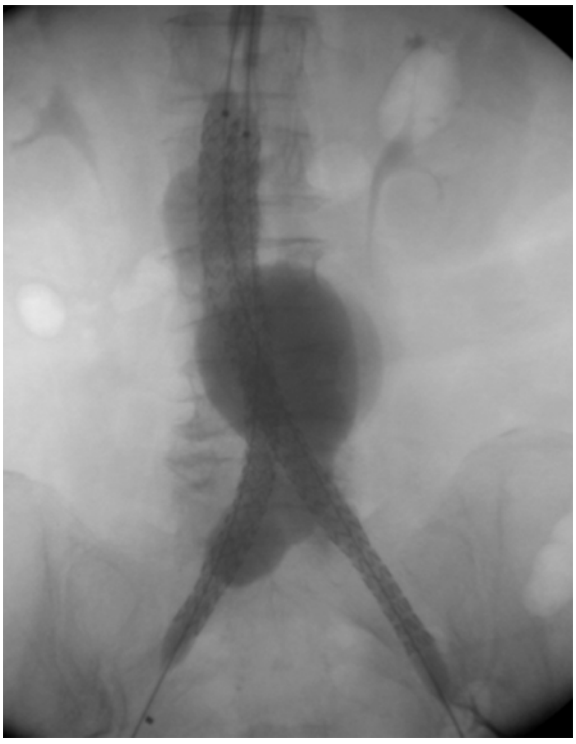

Fig. 4 Endobags are filled with saline mixed with contrast media (Srinagarind Hospital, 2016).

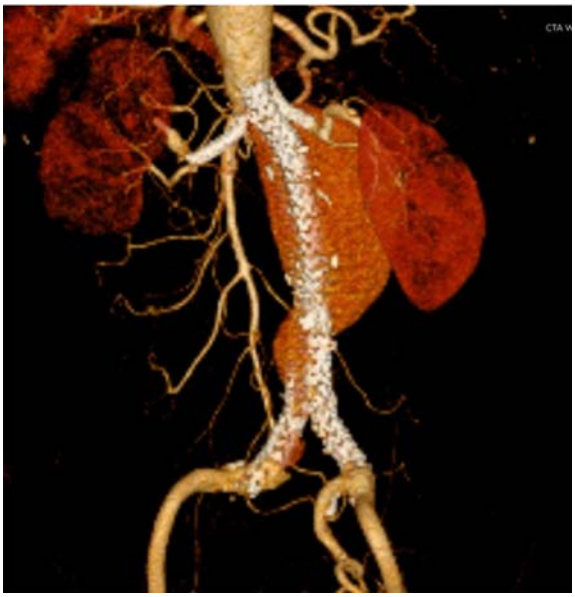

Fig. 5 Chimney EVAS (Srinagarind Hospital, 2016).

Table 1. Demographic data

	n = 8
Age, years	71± 6
Males, n (%)	6 (75)
CAD, n (%)	1 (12.5)
Smoking, n (%)	1 (12.5)
COPD, n (%)	1 (12.5)
HTN, n (%)	5 (62.5)
Dyslipidemia, n (%)	3 (37.5)
ASA class 3, n (%)	6 (75)
Serum Creatinine, mg/dl	1.44±0.8

(CAD = Coronary Artery Disease, COPD = Chronic Ob structive Pulmonary Disease,HTN = Hypertension, ASA = American Society of Anesthesiologists)

Table 2. Aneurysm morphology

Maximal diameter, mm	63.2±22.2
Neck length, mm	17.75±7.7 (6-27)
Proximal neck diameter, mm	22.16±4.8 (16.9-32.6)
Distal neck diameter, mm	21.76±5.1 (13.7-30.2)
Neck angulation	44.26±22.5° (12.7-79°)
RCIA diameter, mm	17.18±4.1 (11.1-22.8)
LCIA diameter, mm	17.81±5.4 (11.4-25.6)

(RCIA = Right Common Iliac Artery, LCIA = Left Common Iliac Artery.)

with EVAR. DREAM (Dutch Randomized Endovascular Aneurysm Management) trial demonstrated a significant lower rate of freedom from secondary interventions 70.4% for EVAR versus 81.9% for open surgery[8]. Cause of re-intervention mostly related to endograft complication such as endoleaks.

Type I and II endoleak leads to treatment failure with EVAR[2]. Investigator developed novel treatment for AAA by reducing incidence of type I and II endoleak[7]. By obliterating the aneurysm sac and providing stent-graft fixation, EVAS may reduce the occurrence of Type I, II, and III endoleaks. Reduced endoleak rates may also decreased secondary intervention and complications.

Global experience with this novel treatment was limited. Eight patients presented early experience of this novel treatment for improving outcomes with EVAS in single center. EVAS evolved new technical aspects and procedures. This present study showed success of primary procedure with no secondary intervention, also with short operative time. This benefited scheduled operations, which went on with more comfort. Filling endobags with polymer could occupy aneurysmal space and provided anatomical fixation in the aneurysm sac as well as a proximal and distal seal[7]. Collateral arteries such as lumbar artery or internal iliac artery are occluded for prevention of type II endoleak. Endobags also stabilize endograft, reducing migration, graft displacement, and structural failure[7]. However, there is still potential for aortic rupture as endobags are inflated. Even the aneurismal neck is very short and angulation less than 60°, endobags can be filled in aortic neck for prevention of type Ia endoleak effectively.

In this present study one case was found with type Ia endoleak related to shortened infra-renal neck and angulation more than 60°, causing insufficient proximal sealing zone and then leading to blood leakage to aneurysm sac.

Chimney EVAS was performed in one case in this present study, this may reduce the risk of type Ia endoleak from gutter formation between standard EVAR stent and chimney graft by endobags filling up the space between stents and chimney graft. This conformable polymer-filled endobag may provide a good and durable seal around stents, chimney grafts and aortic wall.

EVAS can be applied to patients with conical necks as endobags could be filled the entire length of the conical neck, thus elongating the optimal sealing zone.

Limitations

The limitations of this present study included sample size and retrospective analysis of the data with early outcomes from a single center. Further studies on mid-term and long-term outcomes may provide further evidences.

Conclusion

The use of EVAS for treating abdominal aortic aneurysm is feasible with acceptable early outcomes. EVAS can be applicable to a broader range of morphology and with lower incidence of peri-operative type I and II endoleak compared with conventional EVAR. Therefore, long-term follow-ups of EVAS are required.

What is already known on this topic?

EVAR has become the first line of therapy for AAA, especially in high-risk patients. The majority of devices currently used in EVAR are based on a 2-piece bifurcated design that consists of a main body/unilateral limb and a separate contralateral limb.

What this study adds?

EVAS is a new alternative of EVAR by excluding the sac with sealing at both the proximal and distal landing zones and fixing the device at either the proximal attachment site or utilizing anatomic fixation at the bifurcation by sealing the aneurysm sac completely using a biostable polymer filling. The use of EVAS treating abdominal aortic aneurysm is feasible with acceptable early outcomes. EVAS may be applicable to a broader range of morphology compared with conventional EVAR.

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Potential conflicts of interest

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ผลการรักษาระยะสั้นของโรคหลอดเลือดแดงโป่งพองในช่องท้องโดยวิธีการผ่าตัดสอดสายสวนและอุดหลอดเลือดโป่งพองด้วยสารสังเคราะห์

ฐิติ จันทร์เมฆา, อนุชา อาสุยา, ชลัช มิตรประชาปราณี, ชวลิต วงศ์พุทธะ, สมภพ พระธานี, ชูศักดิ์ คุปตานนท์

ภูมิหลัง: วิธีการผ่าตัดสอดสายสวนและอุดหลอดเลือดโป่งพองด้วยสารสังเคราะห์ (Endovascular Aneurysm Sealing System, EVAS) เป็นวิธีการใหม่ โดยใส่สารสังเคราะห์สามารถคงรูปตามหลอดเลือดแดงใหญ่แต่ยังมีข้อมูลเกี่ยวกับการรักษาด้วยวิธีนี้น้อย จึงทำงานวิจัยนี้ขึ้นเพื่ออธิบายผลการรักษาระยะสั้นของโรคหลอดเลือดโป่งพองในช่องท้อง โดยวิธีการผ่าตัดสอดสายสวนและอุดหลอดเลือดโป่งพองด้วยสารสังเคราะห์ (EVAS)

วัตถุประสงค์: เพื่ออธิบายการรักษาโรคหลอดเลือดโป่งพองในช่องท้องโดยวิธีการผ่าตัดสอดสายสวนและอุดหลอดเลือดโป่งพองด้วยสารสังเคราะห์ (EVAS)

วัสดุและวิธีการ: การศึกษาย้อนหลังเชิงพรรณนาในผู้ป่วยจำนวน 8 รายที่เข้ารับการรักษาโรคหลอดเลือดแดงโป่งพอง ในช่องท้องโดยวิธีการผ่าตัดสอดสายสวนและอุดหลอดเลือดแดงโป่งพองด้วยสารสังเคราะห์ที่โรงพยาบาลศรีนครินทร์ และศูนย์หัวใจสิริกิติ์ภาคตะวันออกเฉียงเหนือ คณะแพทยศาสตร์ มหาวิทยาลัยขอนแก่น โดยการทบทวนวรรณกรรมที่เกี่ยวข้องใช้เวลาศึกษา 1 ปีเก็บรวบรวมข้อมูลเป็นเวลา 11 เดือน (เดือนมกราคม พ.ศ. 2559 ถึงเดือนพฤศจิกายน พ.ศ. 2559) โดยรวบรวมข้อมูลเรื่องเพศ, การวินิจฉัย, วิธีการผ่าตัด, Endoleak, ภาวะแทรกซ้อนหลังจากการผ่าตัด

ผลการศึกษา: พบว่าอายุเฉลี่ย 71±6 ปี โดยเป็นเพศชายร้อยละ 75 ความยาวหลอดเลือดแดงส่วนคอที่น้อยกว่า 10 มม. เป็นจำนวน 25% มุมของหลอดเลือดแดงเฉลี่ย 44.26±22.5 องศา ความกว้างของหลอดเลือดโป่งพอง 63.2±22.2 มม. มีผู้ป่วยหนึ่งรายเสียชีวิตภายในเวลา 30 วันหลังการรักษาและหนึ่งรายมี endoleak ชนิดที่ 1 แต่ไม่มี endoleak ชนิดที่ 2 หรือ 3 เกิดขึ้นหลังการรักษาในผู้ป่วยทุกราย

สรุป: การรักษาโรคหลอดเลือดแดงโป่งพองในช่องท้องโดยการผ่าตัดสอดสายสวนและอุดหลอดเลือดแดงโป่งพอง ด้วยสารสังเคราะห์สามารถรักษาได้ผลดีและปลอดภัยในระยะสั้น มีข้อบ่งชี้ใช้รักษาโรคหลอดเลือดแดงโป่งพองในช่องท้องมากขึ้นกว่าการผ่าตัดสอดสายสวนแบบทั่วไป สามารถประยุกต์ใช้ให้เหมาะสมแก่พยาธิสภาพที่จำกัดของโรคหลอดเลือดแดงโป่งพองได้มากขึ้น และจำเป็นต้องมีการศึกษาวิจัยเพิ่มเติมในอนาคต