Outcomes of Asymptomatic Abdominal Aortic Aneurysm as Compared between Open Aortic Repair and Endovascular Aneurysm Repair

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Background: *Endovascular aneurysm repair (EVAR) is less invasive than open aortic repair for treatment of abdominal aortic aneurysm (AAA).*
Objective: *To investigate the outcomes of EVAR and open aortic repair among patients with asymptomatic AAA.*
Material and Method: *We retrospectively reviewed consecutive, asymptomatic, AAA patients who have undergone either a conventional open aortic repair procedure or an EVAR from January 2007 to December 2011. The primary endpoint of our investigation was perioperative mortality. Secondary endpoints included procedural details, perioperative adverse events, intensive care unit (ICU) stays, hospital stays, re-intervention and survival rate during five years of follow-up.*
Results: *Among 147 patients, 77 patients were treated with the open aortic repair method and 70 patients were treated with an EVAR. Mean age of the EVAR group (75.21±7.7 years) was higher than the open aortic repair group (69.14±8.7 years), ($p<0.01$). In addition, the EVAR group was made up of more unfit patients (58.4%) than the open aortic repair group (34.3%), $p = 0.07$. The perioperative mortality rate for the open aortic repair group was 2.9% as compared to 0% in the EVAR group ($p = 0.225$). Patients in the EVAR group experienced statistical advantages in the reduction of operative time, blood loss and blood replacement as compared with the open aortic repair group ($p<0.01$). In addition, EVAR patients also experienced a decrease in ICU and hospital stays as compared to open aortic repair patients ($p<0.01$). There were minimal statistical differences between the two groups in terms of perioperative complications (EVAR 40.3% vs. open repair 30.4%, $p = 0.265$), perioperative re-intervention (EVAR 7.8% vs. open repair 2.9%, $p = 0.28$) and late re-intervention (EVAR 10.4% vs. open aortic repair 4.3%, $p = 0.28$). However, as for the cumulative survival rate at five years, the EVAR group was 54% as compared with 80% in the open aortic repair group ($p<0.05$).*
Conclusion: *Endovascular treatment (EVAR) for asymptomatic AAA has a decrease in operative details as well as ICU and hospital stays as compared with an open aortic repair procedure. In spite of the fact that the EVAR group included more unfit patients than open aortic repair group, our reviewed data showed minimal statistical significance in terms of perioperative mortality and re-intervention rates as compared with the open aortic repair group.*

Keywords: *Asymptomatic abdominal aortic aneurysm, Open aortic repair, Endovascular aneurysm repair*

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An *elective* open aortic repair procedure, so as to prevent an aortic rupture and death is the primary goal in the treatment of abdominal aortic aneurysms (AAA). However, the mortality rate of an *elective* open aortic repair procedure is 5.6%, as compared with 49.8% in cases of an *emergency* open aortic repair, to a ruptured aortic condition[1]. Since 1991 Parodi JC, et al has been reporting notable successes in the treatment of AAA with endovascular aneurysm repair (EVAR)[2]. Moreover, opting for EVAR has rapidly expanded worldwide in recent years as a significantly more effective and alternative means to the open aortic repair option. This factor was especially evident in unfit patients with higher risks in treatment success and recovery.

There are several reports which demonstrate the positive outcomes of an EVAR as compared to an open aortic repair procedure. The EVAR 1 study and OVER trials revealed that the EVAR method is associated with fewer complications and better short-term outcomes over the open aortic repair method for the treatment of AAA - though no difference in mid-

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and long-term mortality was evident[3-6]. However, some reports demonstrated that the 30-day mortality rate is not statistically significant between EVAR and open aortic repair[7,8].

The purpose of this study is to examine the early and long-term outcomes of an EVAR procedure and an open aortic repair procedure in Thai patients diagnosed with asymptomatic AAA.

Material and Method

After receiving the certificate of approval from Siriraj Hospital's review board, the authors conducted a retrospective review of the prospective abdominal aortic aneurysm database of the Vascular Surgery Division, Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Thailand, to identify patients who have undergone elective, conventional, open aortic repair procedures and endovascular aneurysm repairs (EVAR) between January, 2007 and December, 2011. Patient cases which were evaluated, met the following inclusion criteria: AAA-maximal diameter ≥55 mm, maximal diameter ≥45 mm with rapid enlargement and saccular morphology or iliac aneurysm diameter ≥30 mm. Also, patients who have had previous AAA repairs were excluded from this study. Aneurysm morphology and diameter were confirmed with computed tomography angiography (CTA), MRI or Duplex ultrasonography. The process for determining AAA type of repair, planning-sizing and particular device for each EVAR was performed by the vascular surgeon in each case. All cases using open aortic repair methods were performed via a trans-peritoneal route. All demographic data, preoperative co-morbidities, investigations and operative details were obtained from the Siriraj Hospital database and supplemented from the medical record system and chart review. The criterion of fit and unfit classification was originally addressed by Brown LC, et al[9]. Postoperative CTA or Duplex scan evaluations were conducted at one, six and twelve months and annually. We prospectively collected data regarding re-intervention and survival status until December 31, 2013. Additional survival data was obtained by follow-up visits and telephone contact at the end of the study. The primary outcome measurement was perioperative mortality. This was defined as any cause of death within 30 days after operation. The secondary outcomes included procedural details, perioperative adverse events, length of ICU and hospital stays, re-intervention after 30 days, one-year and two-year mortality and overall survival at five-year follow-up.

Statistical methods

All statistical analyses were conducted using SPSS software (SPSS Inc, Chicago, III version 18). Patient demographical data, procedural details, perioperative adverse events and outcomes were compared between open aortic repair and EVAR methods. The Pearson's Chi-square test and Fisher exact test was used for categorical variables reported as numerical values and percentages. For continuous data, the results are reported as mean and standard deviation, which are analyzed by two-tailed means. One, as in T' test for parametric data and the other by Mann-Whitney U' test for non-parametric data. The value of $p<0.05$ was considered as statistical significance. Kaplan–Meier life table analysis techniques were used to estimate survival during follow-up.

Results

Between January 2007 and December 2011, 147 patients with asymptomatic AAA were treated with endovascular and, or open aortic repair. According to inclusion and exclusion criteria, 77 patients were treated by Endovascular aneurysm repair (EVAR) with the remaining 70 patients being treated with the open aortic repair method.

Demographics and clinical characteristics of the two groups are shown in Table 1. The EVAR group had a statistical difference in older age (75.21±7.7 vs. 69.14±8.7, $p<0.001$) as well as a more unfit proportion (58.4% vs. 34.3%, $p = 0.003$) as compared with the open aortic repair group. The co-morbidity rate in terms of diabetes mellitus was higher in the EVAR group (24.7% vs. 10%, $p = 0.02$); however, the EVAR group had a lower proportion of current smoking habits as compared with the open aortic repair group (7.8% vs. 24.3%, $p = 0.006$). As for AAA morphology, there was no statistical significance between the two study groups.

It can be summarized from the data in Table 2 that the EVAR method demonstrated substantial advantages with respect to reductions in operative time, blood loss and blood replacement, duration of postoperative mechanical ventilation, use of an intensive care unit (ICU), and length of hospital stay as compared with the open aortic repair method. In addition, the EVAR method was associated with a decrease in 30-day mortality, although this difference was not statistically significant. There were no perioperative deaths in EVAR group, whereas two deaths (2.9%) occurred in the open aortic repair group. One death resulted from acute massive pulmonary embolism and the second from acute ischemic stroke

Table 1. Demographics and clinical characteristics of AAA patients who underwent EVAR or open repair

Variables	Type of operation		*p*-value
	EVAR (n = 77)	Open (n = 70)	
Age, year (mean±SD)	75.21±7.7	69.14±8.7	< 0.001
Male gender, n (%)	58 (75.3)	56 (80)	0.497
Unfit, n (%)	45 (58.4)	24 (34.3)	0.003
ASA classification, n (%)			
Class 1	0 (0)	2 (2.9)	0.225
Class 2	22 (28.6)	28 (40)	0.144
Class 3	55 (71.4)	40 (57.1)	0.07
Pre-op comorbidities, n (%)			
CAD*	24 (31.2)	14 (20)	0.122
COPD**	16 (20.8)	8 (11.4)	0.126
Current smoking	6 (7.8)	17 (24.3)	0.006
Hypertension	64 (83.1)	53 (75.7)	0.266
Hyperlipidemia	29 (37.7)	34 (48.6)	0.182
Renal insufficiency	8 (10.4)	6 (8.6)	0.708
Diabetes mellitus	19 (24.7)	7 (10)	0.020
Previous stroke	7 (9.1)	7 (10)	0.851
PVD***	0 (0)	7 (10)	0.004
Carotid-artery disease	1 (1.3)	2 (2.9)	0.500
Current medication, n (%)			
Statins	41 (53.2)	35 (50)	0.694
B-blocker	41 (53.2)	39 (55.7)	0.764
Anti-platelet agent	27 (35.1)	23 (32.9)	0.778
Anticoagulant	3 (3.9)	2 (2.9)	1.000
Max. AP diameter, mm, (mean ± SD)	59.29±11	63.13 ±14	0.081
Type of AAA morphology, n (%)			
Abdominal aorta	45 (58.4)	39 (55.7)	0.739
Aorto-iliac	28 (36.4)	30 (42.9)	0.421
Common iliac	4 (5.2)	1 (1.4)	0.208

* CAD = coronary arterial disease, ** COPD = chronic obstructive pulmonary disease, ***PVD = peripheral vascular disease

and acute respiratory distress syndrome. Regarding early and late re-intervention, no significant differences were found between the two groups.

Table 3 compared the results obtained from systemic complications which were comparable without statistical significance between the two groups (EVAR 40.3% vs. open 31.4%, $p = 0.265$). Regarding local or vascular issues, there were no significant differences between the two groups in terms of thromboembolic complications and surgical wound infection.

Late complications were defined as "complications after a 30-day postoperative term with required readmission" and are chronicled in Table 4. Patients who have undergone EVAR were more likely to be readmitted (11.7% vs. 5.7%, $p = 0.2$) and and performed re-intervention (10.4% vs. 4.3%, $p = 0.16$) as opposed to patients who have undergone the open aortic repair procedure. However, the variance was not statistically significant (Table 2). Following the admittance of four patients (5.7%) being prescribed an open aortic repair procedure for treatment of complications including aorto-iliac graft infection, incisional hernia, and aortoenteric fistula, post intervention was administered for three of four patients (4.3%). As for the EVAR group and following their prescribed procedures, there were nine patients (11.7%) who had developed late complications. Two of these nine patients were diagnosed with endoleak type Ib and required an iliac limb extension. Four patients presented type II endoleak, of whom three needed coil embolization of the inferior mesenteric artery (IMA) and the lumbar artery. The fourth was treated

Table 2. Operative details and post-operative outcomes of AAA patients who underwent EVAR or open repair

Variable	Type of operation		*p*-value
	EVAR (n = 77)	Open (n = 70)	
Operative time, min (mean ± SD)	227.8±95	318.4±82.3	<0.001
Blood loss, ml (mean ± SD)	331.3±270	1,988.6±2,027	<0.001
Blood replacement, units (mean ± SD)	0.45±0.9	3±2.3	<0.001
Postoperative mechanical ventilation, day (mean ± SD)	0.14±0.4	1.17±2.2	<0.001
ICU stay, day (mean ± SD)	2.47±7.58	3±3.4	<0.001
Length of hospital stay, day (mean ± SD)	14.13±18.2	15.7±8	<0.001
30-day mortality, n (%)	0 (0)	2 (2.9)	0.225
30-day complication, n (%)	31 (40.3)	22 (31.4)	0.265
Re-intervention ≤30 days, n (%)	6 (7.8)	2 (2.9)	0.280
Re-intervention >30 days, n (%)	8 (10.4)	3 (4.3)	0.160

Table 3. Complications of AAA patients who underwent EVAR or open repair.

Variable	Type of operation		*p*-value
	EVAR (n = 77)	Open (n = 70)	
Systemic complication, n (%)	31 (40.3)	22 (31.4)	0.265
Pneumonia	6 (7.8)	6 (8.6)	0.863
Stroke	0	1 (1.4)	1.000
Congestive heart failure	3 (3.9)	1 (1.4)	0.112
Cardiac arrhythmia	2 (2.6)	0	0.622
Atelectasis	2 (2.6)	3 (4.3)	0.498
Renal failure	4 (5.2)	4 (5.7)	0.669
Urinary tract infection	3 (3.9)	1 (1.4)	0.622
Septicemia	5 (6.5)	4 (5.7)	1.000
Local or vascular complication, n (%)			
Thrombo-embolic complication	3 (3.9)	2 (2.9)	1.00
Wound infection	3 (3.9)	3 (4.3)	1.00

conservatively. Two patients developed groin seroma and were treated with aspiration and explored groin with drainage. The ninth patient developed stenosis of femoro-femoral bypass graft and required crossover femoral ring graft to superficial femoral artery bypass graft.

In the survival analysis (Fig. 1), the mean follow-up was 33±20 months and the median follow-up was 24 months (range, 24-72 months). During five year follow-up, the survival rate of the open aortic repair group was significantly higher than the EVAR group (80% vs. 54%, $p<0.005$).

Discussion

In the present study, the authors investigated the clinical outcomes after open aortic repair procedures and EVAR procedures in patients diagnosed with asymptomatic AAA. EVAR for management of asymptomatic AAA suggested an advantage in the decrease of perioperative mortality as compared with open aortic repair[3,4,10-12]. However, most reports showed no positive effect of EVAR in long-term survival rate[5,6,11]. In this present study; however, there is no statistical significance in perioperative mortality between the two groups. In contrast to previous studies, the open aortic repair group showed significantly better results in cumulative survival rates than in the EVAR group after the five- year follow-up.

The primary endpoint of this study did not show any significant difference in perioperative mortality between groups of open and endovascular repair procedures (2.9% vs. 0%; $p = 0.225$). This finding

Table 4. Complications after 30 days post-operation that required readmission of AAA patients who underwent EVAR or open repair

Complications that require readmission	Number (%)	Time of event (months)	Intervention
Open (n = 70)	4 (5.7)		
Graft infection	1 (1.4)	1.5	Antibiotic treatment
Incisional hernia	2 (2.8)	6, 53	Hernioplasty with mesh graft
Aortoenteric fistula	1 (1.4)	67	EVAR with femorofemoral crossover
EVAR (n = 77)	9 (11.7)		
Endoleak type Ib	2 (2.6)	5, 7	Endovascular graft (iliac limb extension)
Persistent endoleak type II	4 (5.2)	8, 25, 26, 30	Follow-up, IMA* and/or lumbar artery embolization
Groin seroma	2 (2.6)	2, 9	Aspiration or groin exploration with drainage
F-F crossover anastomosis stenosis	1 (1.3)		Femoral crossover to SFA** bypass

IMA* = Inferior mesenteric artery, SFA** = Superficial femoral artery

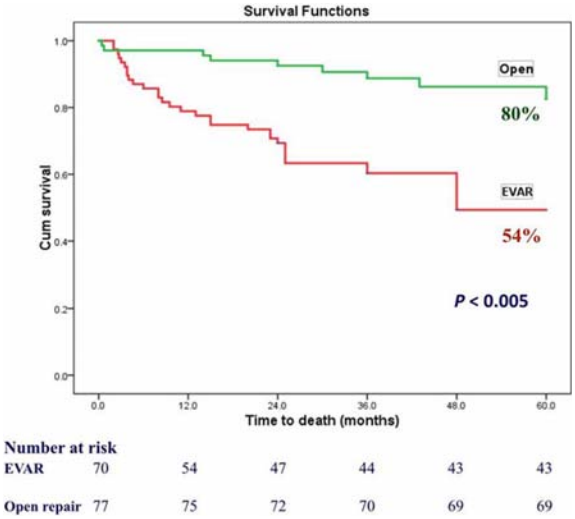

Fig. 1 Kaplan–Meier estimates of survival among patients in open repair group and EVAR group.

is consistent with those of Becquemin JP, et al[8] who similarly found that there was no statistical significance in 30-day mortality between open and endovascular repair procedures (0.6% vs. 1.3%; p = 1.0). Likewise, Prinssen M, et al[7] showed the same outcome of perioperative mortality between open and endovascular repair procedures (4.6% vs. 1.2%; p = 0.10). In contrast to other articles, the perioperative mortality in the EVAR group is better than that in the open aortic repair group[3,4,12-14]. The result of the current study may be explained by the fact that a small sample size was involved and that it enrolled fit and unfit patients within both groups of study.

In terms of operative details in this study, the EVAR method provided substantial advantages with respect to reductions in operative time and blood loss and blood replacement as compared with the open aortic repair method. The present findings seem to be consistent with other research which found similar results using this data[4,7,15]. It seems possible that these positive results reflected in EVAR are due to the minimally invasive nature of this procedure. It is, therefore, likely that EVAR decreases not only operative details but also the length of postoperative mechanical ventilation, ICU stays and hospital stays[7,13,14].

The present study was designed to determine the effects of various conditions, complications and related procedures described herein on both systemic and local levels. The result of this study indicates that there is no significant difference between the complications in both groups. These findings support the previous research and results which are not significantly different in systemic and local complications between the two groups[8]. In contrast, some articles found that the cardiac and pulmonary complications are higher in the open aortic repair group as compared to the EVAR group[13].

This study set out with the aim of assessing the late outcomes between open and endovascular repair procedures. In terms of late re-intervention, there is no statistical difference between the two study groups. The most common, late complication in the open aortic repair group is incisional hernia whereas endoleak is a common complication in the EVAR group. However, the findings of the current study do not

support the previous research which showed that EVAR had a significant increase in late re-intervention as compared with open aortic repair[5,8,14]. This data must be interpreted with caution due to the small sample size in this present study.

On the question of the mortality rate at five year terms, this study found that the cumulative survival rate at five years within the open aortic repair group was significantly higher than that of the EVAR group (80% vs. 54%, $p<0.005$). A possible explanation for this may be that the EVAR group, in this current study, included a significantly higher number of unfit patients as compared to the open aortic repair group. This finding is in contrast to earlier findings; however, there was no statistical difference between the two groups in the rate of long-term survival[5,8,12,14,16].

The present study was limited by its small sample size and lack of randomization within the two study groups. In future studies, larger sample sizes should be utilized, with randomization and all patients should be monitored in long-term outcomes.

In conclusion, the present study was designed to determine the outcomes of open and endovascular repair in asymptomatic AAA. This study has found that EVAR treatment for asymptomatic AAA has a decrease in operative details, ICU and hospital stays as compared with open aortic repair treatment. In spite of the EVAR group having more unfit participants than in the open aortic repair group, it showed no statistical significance in terms of perioperative mortality and re-intervention rates as compared with the open aortic repair group.

What is already known on this topic?

Elective open repair of AAA is the gold standard to preventing an aortic rupture of this magnitude. However, EVAR has rapidly expanded worldwide in the last decade as an alternative to open aortic repair, especially in high risk patients. Several reports reveal the contrasting outcomes between EVAR and open aortic repair procedures. The EVAR 1 study and OVER trials suggest that the EVAR is associated with fewer complications and better short-term outcomes over an open aortic repair for treatment of AAA, though with no difference in mid- and long-term mortality. However, DREAM and ACE trials demonstrated that the 30-day mortality rate is not statistically significant between EVAR and open aortic repair procedures. Therefore, the aim of this study is to analyze early and late outcomes of EVAR and open aortic repair in Thai patients diagnosed with asymptomatic AAA and to compile current and past data so as to fortify accurate and most effective intervention decisions

What is this study adds?

In the present study, the authors investigated the post, clinical outcomes of EVAR and open aortic repair in asymptomatic AAA. It can be seen in this present study that there is no statistical significance in perioperative mortality between the two groups. In *contrast* to the previous studies, the open aortic repair group showed significantly *better* in cumulative survival rate than the EVAR group during the five- year follow-up.

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Potential conflicts of interest

None.

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ผลลัพธ์ของการรักษาโรคหลอดเลือดแดงใหญ่โป่งพองในช่องท้องชนิดที่ไม่มีอาการระหว่างการผ่าตัดแบบเปิดช่องท้องและแบบใส่สายสวนผ่านทางหลอดเลือด

คามิน ชินศักดิ์ชัย, วรรณภา เพชรพูนพิพัฒน์, เฉนียน เรืองเศรษฐกิจ, ชุมพล ว่องวานิช, ประมุข มุทิรางกูร, ณัฐวุฒิ เสริมสาธนสวัสดิ์, เกียรติศักดิ์ หงษ์คู, สุธีคณิต หัลพรสวรรค์

ภูมิหลัง: *การรักษาโรคหลอดเลือดแดงใหญ่โป่งพองในช่องท้องแบบใส่สายสวนผ่านทางหลอดเลือดมีความรุนแรงน้อยกว่าแบบเปิดช่องท้องผู้นิพนธ์ต้องการศึกษาผลลัพธ์การรักษาในโรคระหว่างการผ่าตัดทั้ง 2 วิธี*

วัตถุประสงค์: *เพื่อศึกษาเปรียบเทียบผลลัพธ์ของการรักษาโรคหลอดเลือดแดงใหญ่โป่งพองในช่องท้องชนิดที่ไม่มีอาการระหว่างการผ่าตัดแบบเปิดช่องท้องและแบบใส่สายสวนผ่านทางหลอดเลือด*

วัสดุและวิธีการ: *การศึกษาย้อนหลังในผู้ป่วยที่มีภาวะหลอดเลือดแดงใหญ่โป่งพองในช่องท้องแบบไม่มีอาการที่รักษา แบบเปิดท้องและใส่สายสวนผ่านทางหลอดเลือดตั้งแต่ปี พ.ศ. 2550 ถึง พ.ศ. 2554 เป้าหมายหลักของงานวิจัยคืออัตราการเสียชีวิตภายใน 30 วัน หลังผ่าตัด เป้าหมายรองได้แก่รายละเอียดของการผ่าตัด, ภาวะแทรกซ้อนภายใน 30 วัน หลังผ่าตัด, การผ่าตัดซ้ำและอัตราการมีชีวิตรอดหลังผ่าตัด*

ผลการศึกษา: *จำนวนผู้ป่วยทั้งสิ้น 147 คนแบ่งเป็นผ่าตัดแบบเปิดท้อง 77 คนและผ่าตัดแบบใส่สายสวนทางหลอดเลือด 70 คน อายุเฉลี่ยของการผ่าตัดแบบใส่สายสวน = 75.21±7.7 ปี ซึ่งมีค่าสูงกว่าผ่าตัดแบบเปิดท้องซึ่ง = 69.14±8.7 ปี, p<0.001 และผู้ป่วยที่ไม่แข็งแรงจะมีในกลุ่มผ่าตัดแบบใส่สายสวน (59.4%) ซึ่งมากกว่าการผ่าตัดแบบเปิดท้อง (34.3%), p = 0.003 อัตราการเสียชีวิตภายใน 30 วันหลังผ่าตัดของการผ่าตัดแบบเปิดท้อง = 2.9% เทียบกับการผ่าตัดแบบใส่สายสวนคือ 0% (p = 0.225) กลุ่มการรักษาแบบใส่สายสวนจะได้ประโยชน์ในการลดระยะเวลาการผ่าตัดและการเสียเลือดระหว่างผ่าตัดตลอดจนระยะเวลาการรักษาตัวที่โรงพยาบาลเมื่อเปรียบเทียบกับการผ่าตัดเปิดท้อง (p<0.001) อย่างไรก็ตามเมื่อเปรียบเทียบในแง่ของภาวะแทรกซ้อนภายใน 30 วันหลังผ่าตัดการรักษาซ้ำหลังผ่าตัด พบว่าไม่มีความแตกต่างกันระหว่าง 2 กลุ่มสำหรับอัตราการมีชีวิตรอดที่ 5 ปีหลังผ่าตัดพบว่าการรักษาแบบเปิดท้องมีอัตราที่สูงกว่าการผ่าตัดแบบใส่สายสวนคือ 80% และ 54% ตามลำดับ (p<0.005)*

สรุป: *การรักษาแบบใส่สายสวนเพื่อรักษาภาวะหลอดเลือดแดงใหญ่โป่งพองในช่องท้องนั้นสามารถลดระยะเวลา การผ่าตัดการเสียเลือด ระหว่างผ่าตัดและระยะเวลาการอยู่โรงพยาบาลเมื่อเทียบกับการรักษาแบบเปิดท้อง แม้ว่าการรักษาแบบใส่สายสวนจะมีผู้ป่วยที่ไม่แข็งแรงมากกว่าแบบเปิดช่องท้องแต่อัตราการเสียชีวิตภายใน 30 วัน หลังผ่าตัดและอัตราการผ่าตัดซ้ำหลังผ่าตัดพบว่าทั้ง 2 วิธีไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ*