Comparative effectiveness of open surgery versus endovascular repair for hemodynamically stable and unstable ruptured abdominal aortic aneurysm

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Abstract
Several observational studies and randomized trials have compared open surgery (OS) and endovascular aortic repair (EVAR) for ruptured abdominal aortic aneurysm (rAAA). However, none of these studies addressed optimal management of hemodynamically (hd) unstable patients. Our objective was to compare perioperative outcomes in patients undergoing OS vs EVAR for hd-stable and hd-unstable rAAs.

This retrospective study was conducted in West China Hospital from January 2005 to December 2015. Unstable patients were defined as those who have at least 1 of the following: preoperative shock, preoperative transfusion >4 units, preoperative intubation, cardiac arrest, or unconsciousness. Univariable and multivariable logistic regression analyses were performed.

Of the 102 patients, 70.6% underwent OS and 29.4% EVAR. About 46.1% were unstable, and for these patients, OS was performed in 70.2% and EVAR in 29.8%. The 30-day mortality was 23.6% (OS, 25.6%; EVAR, 18.8%; P = .585) for hd-stable patients and was 42.6% (OS, 45.5%; EVAR, 35.7%; P = .537) for hd-unstable patients. Patients with OS had longer operative time and more transfusion. Amongst hd-stable patients, OS subgroup had a higher rate of pneumonia (33.3% vs 6.3%, P = .045), longer intensive care unit (ICU) stay (43.2 vs 15.2 hours, P = .02), and length of stay (11.6 vs 8.6 days, P = .041). Among hd-unstable patients, OS subgroup had a longer ICU stay (194.3 vs 63.9 hours, P = .047). Hospitalization costs of OS group were significantly lower than those of EVAR group, regardless of hemodynamic stability.

Approximately one-third of patients with rAAA were treated by EVAR at our institution. EVAR may be the preferred approach for anatomically suitable rAAs. However, patients treated by EVAR had a similar mortality compared with those treated by OS. In addition, OS is not an independent factor for a higher 30-day mortality, and the costs of OS were much cheaper than those of EVAR. Therefore, OS is difficult to replace, especially in developing countries.

Abbreviations: ACS = abdominal compartment syndrome, BMI = body mass index, COPD = chronic obstructive pulmonary disease, CPR = cardiopulmonary resuscitation, DSA = digital subtraction angiography, EVAR = endovascular aortic repair, rAAA = ruptured abdominal aortic aneurysm.

Keywords: endovascular repair, hemodynamic stability, mortality, open surgery, ruptured abdominal aortic aneurysm

1. Introduction
Elective abdominal aortic aneurysm (AAA) repair is performed in order to prevent future rupture with its accompanying high mortality.[1,2] Several randomized controlled trials (RCTs) comparing open surgery (OS) with endovascular aortic repair (EVAR) for elective AAA repair have demonstrated that patients undergoing EVAR had lower perioperative mortality and morbidity.[3,4] Thus, EVAR has been widely accepted as the primary treatment for elective AAA repair.[4] The minimally invasive nature of EVAR and improved outcomes in the elective patients had led to the use of this technique for the treatment of ruptured abdominal aortic aneurysm (rAAA).[5] Despite advances in emergency process, operative techniques, and intensive care management, rAAA is associated with relatively high mortality.[1,6-9] Therefore, there is still controversy about which operative techniques are more appropriate for patients with rAAA.

The first successful use of EVAR for rAAA was reported in 1994.[10] Subsequent retrospective observational studies revealed that EVAR offered improved mortality and morbidity compared with OS.[1,6-13] However, 3 latest randomized trials demonstrated no differences in the 30-day mortality.[11-13] Regrettably, these current studies did not address the optimal management of hemodynamically (hd) unstable patients with rAAs. Patients under hd-unstable condition have the highest mortality in rAAA patients, and different hemodynamic conditions are important prognostic indicators for them.[14,15] With this evaluation, our study was conducted comparing 30-day outcomes after OS and EVAR for hd-stable and hd-unstable patients, respectively. The
2. Methods

2.1. Patient population

Consecutive patients with rAAA treated in our Vascular Surgery Center from January 2005 to December 2015 were retrospectively reviewed from a prospectively maintained database. This study was approved by the Institutional Review Board, and patient consent was waived for this retrospective research.

Inclusion criteria were ruptured infrarenal AAA. A ruptured aneurysm was defined as presence of blood outside the aorta through imaging data or during operation. Exclusion criteria were thoracoabdominal aneurysms, abdominal aortic dissection, and patients with connective tissue diseases. Patients with known previous repair of AAA were also excluded. We do not have a widely accepted specific definition that identify hemodynamic instability. Through literature review, these patients should meet the following criteria in our study,[14,16] one or more of preoperative shock, preoperative transfusion >4 units, preoperative intubation, cardiac arrest, or unconsciousness. If any patient was suspected of having a rAAA, computerized tomographic angiography (CTA) was performed at the first choice. Patients who are too unstable to undergo a CT scan are transferred directly to hybrid operation. Digital subtraction angiography (DSA) was performed to confirm the aneurysms’ morphology, and we can control the proximal aorta by endovascular balloon occlusion (EBO) at the same time. If the patient had hostile anatomy (proximal aortic neck diameter > 32 mm, aortic neck length < 10 mm), we planned OS as the first choice. When patients had proper anatomy, selection of treatment in each case was made by the vascular surgeon’s experience, patients, and their family members’ opinions.[2,8,17]

2.2. Outcome

Demographic characteristics, vital signs, biochemical data, preoperative comorbidities at presentation, intraoperative, and postoperative parameters were collected. Thirty-day mortality is the most important primary outcomes of our study. Secondary outcomes include transfusion of blood products, length of stay, failure to wean from the ventilator < 48 hours, postoperative complications, hospitalization costs, as well as a number of other postoperative parameters.

2.3. Statistical analysis

Continuous variables were expressed as mean±SD, and were analyzed by t test or F-test. Categorical variables were given as numbers and percentages, and were analyzed by Pearson χ² test or the Fisher exact test. Binary logistic regression was used for performing multivariate analysis, which determines significant risk factors predicting mortality. For multivariable analysis in our study, the inclusion criteria was P < .1. For all statistical evaluation, a P value of < .05 was considered significant. All statistical analyses were performed by using IBM SPSS 19.0 software (IBM Corporation, Armonk, NY).

3. Results

Between 2005 and 2015, a total of 102 patients presenting with rAAA underwent operation in our hospital. Among them, 55 patients (53.9%) were classified as hd-stable, and the rest (46.1%) were hd-unstable. The overall 30-day mortality of our study was 32.4% (OS, 34.7%; EVAR, 26.7%; P = .428). The preoperative demographics, comorbidities, and clinical characteristics are illustrated in Table 1. The intraoperative and postoperative outcomes are detailed in Table 2. In addition, Table 3 summarizes the preoperative and intraoperative data in survivors versus nonsurvivors. Figure 1 illustrates 30-day mortality declined over time, but 30-day mortality between OS and EVAR groups was similar for each year.

3.1. Stable rAAAs

Among the hd-stable patients, 39 (70.9%) underwent OS and 16 (29.1%) underwent EVAR. Patients in the EVAR subgroup were older and had higher BMI than those in OS subgroup (Table 1). There were more patients with coronary heart disease (31.3% vs 5.1%, P = .028), congestive heart failure (25.0% vs 2.6%, P = .035), and diabetes (31.3% vs 5.1%, P = .028) in the EVAR subgroup. The OS subgroup had shorter neck length (P = .02) and larger neck angle (P = .011) than the EVAR subgroup.

During operation, patients in OS subgroup had longer operative time (195.0 vs 130.0 minutes, P < .001), more intraoperative RBC transfusion (3.9 vs 1.4 units, P < .001), and fluid infusion (3000.0 vs 1925.0 mL, P < .001). After operation, the intensive care unit (ICU) length of stay was longer following OS (43.2 vs 15.2 hours, P = .02). EVAR was also associated with shorter hospital length of stay compared with OS (8.6 vs 11.6 days, P = .041). There was no significant difference in the 30-day mortality between the 2 subgroups (25.6% vs 18.8%, P = .585). The rate of pneumonia was 33.3% for OS versus 6.3% for EVAR (P = .045). In addition, the hospitalization costs were lower in the OS subgroup ($8067.0 vs 26,377.5, P < .001). The clinic and morphologic features associated with 30-day mortality were analyzed. Multivariable analyses showed neurologic deficit was associated with a higher risk of 30-day mortality [odds ratio (OR), 11.66; 95% confidence interval (95% CI), 1.04–130.56; P = .046].

3.2. Unstable rAAAs

Among 47 hd-unstable patients, 33 (70.2%) underwent OS and 14 (29.8%) underwent EVAR. Patients in the EVAR subgroup were older and had a higher BMI than those with OS, and neck angle in OS subgroup was larger than that in EVAR subgroup (Table 1).

Patients in OS subgroup had longer operative time (195.0 vs 130.0 minutes, P < .001), more intraoperative RBC transfusion (5.2 vs 2.7 units, P < .001), and fluid infusion (3500.0 vs 2900.0 mL, P < .004). The ICU length of stay was significantly longer for OS (63.8 hours) versus EVAR (134.3 hours, P = .047). There were no significant differences of 30-day mortality and postoperative complications (Table 2). Furthermore, the treatment costs were lower in the OS subgroup ($9655.0 vs 28,424.0, P < .001). Similarly, the clinic and morphologic features, which are associated with 30-day mortality, were analyzed. Multivariable analyses also illustrated that neurologic deficit was associated with a higher risk of 30-day mortality (OR, 14.61; 95% CI, 1.49–143.34; P = .021).

4. Discussion

EVAR is a minimally invasive technique, which has an established status in the elective treatment of AAA.[3] Several
RCTs have illustrated that elective EVAR had an improved morbidity and short-term mortality compared with OS.\(^2,^3\) These perceived benefits of EVAR have led some doctors to produce an “endovascular-first” approach in the treatment of rAAA.\(^1,^1^1\) There has been a yearly increase in the proportion of rAAA treated by EVAR, but the evidence to support EVAR as the primary treatment for rAAA remains controversial.\(^1,^1^6\)

Hinchliffe et al\(^{11}\) carried out the Nottingham Pilot Trial, which is the first single-center RCT of OS compared with EVAR for rAAA. The authors had no conclusions about mortality, because the trial was stopped for its underpowered. Reimerink et al\(^{1^2}\) conducted a randomized comparison of EVAR with OS in patients with rAAA, which found that both groups had similar mortality. However, patients with severe hemodynamic instability were excluded, and 78% of identified patients were refused to join in this trial. The United Kingdom-based IMPROVE trial\(^{1^3}\) included unstable patients (48% of total), but it did not address the differences between stable and unstable patients. In our research, Table 3 summarized that more patients had preoperative shock, coma, stroke with neurologic deficit, preoperative ventilator, and preoperative cardiopulmonary resuscitation (CPR) in the nonsurvivor group. And survivors had higher preoperative hemoglobin and lesser intraoperative pRBC transfusion. These data are indicators for hemodynamic stability. The other preoperative and intraoperative data were similar between survivors and nonsurvivors. It indicated that data associated with hemodynamic stability maybe biases for study. Therefore, the goal of our study was to further evaluate the value of EVAR for rAAA in stable and unstable patients.

Regardless of hemodynamic conditions, we found that patients with EVAR were older and had higher BMI than those with OS. The head-stable patients with EVAR had a higher proportion of preoperative comorbidities than that with OS. Several studies have revealed that patients with EVAR were older and had a higher incidence of comorbidities than those with OS.\(^6,^7,^9,^1^6\) This might due to the less invasiveness of EVAR, so patients with poor general conditions were treated preferentially by EVAR. However, they had similar mortality, fewer complications, and faster recovery compared with patients undergoing OS. Therefore, it can better demonstrate that EVAR may be the preferred approach for rAAA. In addition, the neck length was longer and neck angle was smaller in the EVAR group, which was supported by several literatures.\(^2,^1^6\) It is possible that this morphology of AAA is more suitable for EVAR, introducing selection bias.\(^7\) With the advancements in endograft design, EVARs are now suitable for most patients.\(^7,^1^6\) Our data also showed that

### Table 1

| Variables | Stable rAAA | Unstable rAAA |
|-----------|-------------|---------------|
| **General** | | |
| Age, y | 58.4±10.6 | 71.4±11.6 | <.001 | 59.4±12.4 | 71.1±9.4 | .003 |
| Male | 12 (30.8) | 9 (56.2) | .077 | 16 (48.5) | 10 (71.4) | .148 |
| BMI, kg/m\(^2\) | 22.7±2.0 | 25.3±2.3 | <.001 | 22.9±1.8 | 24.7±3.0 | .011 |
| Hypertension | 26 (66.7) | 12 (75.0) | .544 | 23 (69.7) | 10 (71.4) | .906 |
| Diabetes mellitus | 2 (5.1) | 5 (31.3) | .028 | 3 (9.1) | 3 (21.4) | .496 |
| Chronic renal insufficiency | 4 (10.3) | 2 (12.5) | .57 | 3 (9.1) | 2 (14.3) | .991 |

| Respiratory | | |
| COPD | 12 (30.8) | 10 (62.5) | .029 | 15 (45.5) | 8 (57.1) | .464 |
| Dyspnea | 2 (5.1) | 2 (12.5) | .701 | 3 (9.1) | 2 (14.3) | .991 |
| On ventilator, pre-op | 0 | 0 | – | 12 (36.4) | 5 (35.7) | .966 |

| Cardiac disease | | |
| MII | 2 (5.1) | 5 (31.3) | .028 | 6 (18.2) | 2 (14.3) | .745 |
| Congestive heart failure | 1 (2.6) | 4 (25.0) | .035 | 2 (6.1) | 2 (14.3) | .724 |
| Valvular disease | 2 (5.1) | 2 (12.5) | .701 | 2 (6.1) | 2 (14.3) | .724 |

| Neurologic | | |
| Coma | 0 | 0 | – | 14 (42.4) | 5 (35.7) | .688 |
| Stroke with neurologic deficit | 3 (7.7) | 1 (6.3) | .67 | 2 (6.1%) | 1 (7.1) | .664 |
| Stroke without neurologic deficit | 4 (10.3) | 2 (12.5) | .57 | 3 (9.1) | 2 (14.3) | .991 |

| Circulatory | | |
| Shock | 4 (10.3) | 2 (12.5) | .57 | 26 (78.8) | 9 (64.3) | .297 |
| MAP, mm Hg | 78.9±4.1 | 80.1±5.2 | .366 | 60.6±6.1 | 59.7±6.5 | .636 |
| Preoperative CPR | 0 | 0 | – | 3 (9.1) | 2 (14.3) | .991 |

| Laboratory | | |
| Median creatinine, μmol/L | 78.5 | 79.0 | .897 | 107.0 | 107.0 | .861 |
| Median hemoglobin, g/L | 90.0 | 90.5 | .446 | 68.5 | 67.3 | .449 |

| Morphology | | |
| Neck length, mm | 18.2±9.8 | 24.9±8.1 | .002 | 19.0±7.3 | 22.7±7.8 | .121 |
| Neck diameter, mm | 19.0±2.0 | 20.3±3.1 | .272 | 20.4±2.3 | 21.6±2.6 | .132 |
| Neck angle, mm | 61.4±24.3 | 36.3±27.7 | .01 | 56.0±19.2 | 32.9±22.3 | .001 |
| Aneurysm diameter, mm | 77.4±28.0 | 68.9±15.3 | .155 | 73.2±20.0 | 61.8±13.4 | .056 |

\(\text{BMI} = \text{body mass index}, \text{COPD} = \text{chronic obstructive pulmonary disease}, \text{CPR} = \text{cardiopulmonary resuscitation}, \text{EVAR} = \text{endovascular aortic repair}, \text{MAP} = \text{mean arterial pressure}, \text{MII} = \text{myocardial infarction}, \text{OS} = \text{open surgery}, \text{pRBC} = \text{packed red blood cells}, \text{rAAA} = \text{ruptured abdominal aortic aneurysm}

\(*\) Categorical data are shown as number (%), and continuous data as indicated as mean±standard deviation or median.

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patients with EVAR had a more stable operational process, which had a shorter operational time and lesser blood transfusion. The results had been demonstrated by other clinical reports.\(^7,^{12,16}\) Regardless of hemodynamic status, EVAR can provide a more stable procedure for patient with rAAA. In our study, patients undergoing EVAR had a similar 30-day mortality compared with OS for both hd-stable and hd-unstable cohorts. Several population-based studies have illustrated a mortality rate for rAAA that ranges from 38% to 56% after OS and from 25.9% to 58% after EVAR.\(^{1,6}^{16,8}\) Edwards et al\(^6\) collected data from all United States hospitals about 8 years, and found a 30-day mortality of 33.8% after EVAR in 1126 patients that versus 47.7% for 9872 patients in a comparative OS group\((P<.001)\), which concluded that rAAA patients benefit from EVAR. However, patients in these studies were not classified as hemodynamically stable or unstable cohorts. The Amsterdam Acute Aneurysm Trial\(^{12}\) showed a similar 30-day mortality between EVAR and OS groups in hd-stable patients who met the inclusion criteria. The United Kingdom-based improved trial\(^{13}\) also revealed a 30-day mortality of 36.4% for EVAR and 40.6% for OS\((P=.31)\), which included hemodynamically stable or unstable patients. These RCTs had found similar results compared with us, which demonstrated that these 2 surgical procedures had similar advantages for rAAA patients.

Although these 2 approaches had similar 30-day mortality, our study revealed an advantage of EVAR with regard to rate of respiratory complications and postoperative recovery. Patients with EVAR had a lower rate of pneumonia, bowel obstruction, and faster recovery than that with OS, which are consistent with other clinical reports.\(^7,^{16,16}\) EVAR may be the preferred approach for all patients with ruptured AAA who have a favorable anatomy for EVAR. The IMPROVE trial\(^{13}\) revealed that perioperative costs were similar between these 2 approaches. However, our data demonstrate that OS had significant economic advantages compared with EVAR in the stable and unstable cohorts. There are several possible explanations for the high costs with EVAR, including expensive stent graft and cheap labor for OS. In the developing countries, OS is difficult to replace for most rAAA patients.

In previous studies, factors such as OS, old age, cerebrovascular disease, free rupture, and lower preoperative hemoglobin were found to increase the 30-day mortality.\(^{9,16,18}\) In our study, we found that operational procedures, body mass index (BMI), cardiac diseases, respiratory diseases, and neurologic deficit were predictors of 30-day mortality by univariate analysis, respectively. Nevertheless, neurologic deficit was the only independent factor in multivariate logistic regression for stable and unstable cohorts. Neurologic system has a fatal position in our bodies, which is guarantee preferentiality during emergency situation. The rAAA patients are in life-threatening conditions when they had neurologic deficit. Therefore, these patients may result in poor operative prognosis.

There are obstacles and genuine concerns to accept the EVAR-first procedure for rAAA, in spite of our favorable findings. EVAR for rAAA is a high-risk procedure, which requires appropriate intraoperative imaging, broad selection of available grafts, and experienced call team. Therefore, high-volume vascular centers are more likely to have available endovascular surgeons with greater technical fluency in endovascular therapies.\(^{16}\) The lack of experience or equipment may exacerbate the

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**Table 2**

| Outcomes | Stable rAAA | Unstable rAAA |
|----------|-------------|---------------|
|          | OS (n=39)   | EVAR (n=16)   | P    | OS (n=33)   | EVAR (n=14)   | P    |
| **Intraoperative** | | | | | | |
| Median operative time, minutes | 195.0 | 130.0 | <.001 | 195.0 | 135.0 | <.001 |
| Intraoperative pRBC, units | 3.9±1.7 | 1.4±1.3 | <.001 | 5.2±2.5 | 2.7±1.5 | .001 |
| Median intraoperative fluid, ml | 3000.0 | 1925.0 | <.001 | 3500.0 | 2900.0 | .004 |
| **Postoperative** | | | | | | |
| Mortality | 10 (25.6) | 3 (18.8) | .585 | 15 (45.5) | 5 (35.7) | .537 |
| Failure to extubate at 48h | 16 (41.0) | 2 (12.5) | .041 | 19 (57.6) | 5 (35.7) | .17 |
| ICU stay, h | 43.2±43.9 | 15.2±9.9 | .02 | 134.3±123.2 | 63.8±51.0 | .047 |
| Length of stay, d | 11.6±3.6 | 8.6±3.4 | .014 | 15.6±7.8 | 12.6±3.0 | .27 |
| Pneumonia | 13 (33.3) | 1 (6.3) | .045 | 12 (36.4) | 2 (14.3) | .18 |
| Reintubation | 4 (10.3) | 2 (12.5) | .57 | 9 (27.3) | 2 (14.3) | .46 |
| MI | 2 (5.2) | 1 (6.3) | .652 | 3 (9.1) | 1 (7.1) | .658 |
| Arrhythmia | 3 (7.7) | 0 | .548 | 2 (6.1) | 1 (7.1) | .664 |
| Heart failure | 4 (10.3) | 0 | .311 | 4 (12.1) | 2 (14.3) | 1.0 |
| Stroke | 1 (2.6) | 0 | .709 | 1 (3.0) | 1 (7.1) | .512 |
| Delirium | 4 (10.3) | 1 (6.3) | .544 | 5 (15.2) | 2 (14.3) | .939 |
| Acute renal insufficiency | 7 (17.9) | 2 (12.5) | .924 | 12 (36.4) | 4 (28.6) | .858 |
| Hemodialysis | 0 | 0 | – | 2 (6.1) | 1 (7.1) | .664 |
| Deep venous thrombosis | 3 (7.7) | 1 (6.3) | .67 | 3 (9.1) | 1 (7.1) | .658 |
| Pulmonary embolism | 1 (2.6) | 0 | .709 | 2 (6.1) | 1 (7.1) | .664 |
| Limb ischemia | 3 (7.7) | 1 (6.3) | .852 | 4 (12.1) | 1 (7.1) | .613 |
| Bowel obstruction | 19 (48.7) | 3 (18.8) | .039 | 17 (48.5) | 4 (28.6) | .207 |
| Mesenteric ischemia | 7 (17.9) | 2 (12.5) | .924 | 6 (18.2) | 2 (14.3) | .745 |
| ACS | 1 (2.6) | 1 (6.3) | .501 | 0 | 0 | – |
| Return to operating room | 2 (5.1) | 1 (6.3) | .652 | 1 (3.0) | 0 | .702 |
| Median cost, $ | 8067.0 | 26,377.5 | <.001 | 9655.0 | 28,424.0 | <.001 |

ACS = abdominal compartment syndrome, EVAR = endovascular aortic repair, ICU = intensive care unit, MI = myocardial infarction, OS = open surgery, pRBC = packed red blood cells.

\(^{*}\) Categorical data are shown as number (%), and continuous data as indicated as mean±standard deviation or median.
condition when attempting to urgently treat a patient with rAAA.\cite{11,14} Our center has a hybrid operation room and experienced team. Figure 1 shows 30-day mortality declined over time, except 2010 and 2011. Because younger doctors began operating this procedure independently from 2010, the mortality increased for the moment, and then it decreased subsequently. Although learning curve of these 2 procedures and improved perioperative care may have affected on our results, 30-day mortality between OS and EVAR groups was similar for each year. Therefore, the learning curve effect and improved perioperative care had little influence on our results. None of the literatures had analyzed the effect of learning curve.\cite{15,10,14} In addition, we had performed 100 cases of intact AAA by EVAR and OS previously, and all these cases were performed by 1 skilled surgical team. These strengths had not been found in the other studies.

Our work also had several limitations. This study did not include longer-term mortality or morbidity, which are important indicators of treatment success. Another limitation is that we do not have a recognized definition for the hd-ustable state, so we created a surrogate for instability to conduct this analysis. Although this surrogate definition is not absolute, it creates a relatively ill group in patients with rAAA, which provide us an opportunity to compare EVAR versus OS with a more detailed way. Most of all, this study was not a RCT. The patient groups of OS and EVAR were not surely identical, and it cannot be expected to remove hidden biases.

5. Conclusion

In our vascular center, about one-third of patients with rAAAs were treated by EVAR. Hemodynamically stable patients have more favorable outcomes than unstable patients. Although patients undergoing EVAR had poor general conditions, they had faster recovery. EVAR may be the preferred approach for rAAAs with suitable anatomy. However, patients treated by EVAR had a similar mortality compared with those treated by OS, regardless of the patients’ hemodynamic stability. According to multivariate analysis, procedure is not an independent factor predicting a higher 30-day mortality. Besides, the costs of OS were much cheaper than those of EVAR. Therefore, OS is difficult to replace for most patients with rAAAs in developing countries.

Author contributions

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