Original Article

Outcome of Percutaneous Mechanical Thrombectomy Compare with Catheter Directed Thrombolysis in Acute and Subacute Lower Limb Ischemia Patients

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Background: Catheter based therapy is standard treatment for acute and subacute lower limb ischemia with Rutherford class IIa and IIb. Besides Catheter directed thrombolysis (CDT), Percutaneous mechanical thrombectomy (PMT) is a novel treatment that can remove thrombus faster with less complication. However, no previous study that compare the treatment outcome between PMT and CDT.

Objective: To compare the treatment outcomes between PMT and CDT. Primary outcome is limb salvage rate. Complication, operative time, number of operations, time to lysis, complete clot removal, technical success, length of intensive care unit (ICU) stay and hospital stay were recorded as secondary outcomes.

Materials and Methods: Retrospective chart review of acute and subacute lower limb ischemic patient with severity Rutherford class IIa and IIb from November 2014 to April 2017. We included all of patient treated with PMT and 22 patients treated with CDT based on the similarity of level and severity into our study. This ratio was 1: 2 in line with head-to-head comparison method to empower the result.

Result: Thirty-four patient were enrolled in the present study. 12 patients were allocated to PMT group and 22 patients were allocated to CDT group. There was no significant difference between in demographic data and severity of ischemia, except we found more thrombosis etiology in PMT group (72.7% vs. 33.33%, $p = 0.04$). Limb salvage at perioperative period (0% vs. 4.8%, $p = 0.656$) and at 3-month (80% vs. 80%, $p = 0.751$) were comparable between two groups. There are more technical success rate (100% vs. 85.7%, $p = 0.268$) and complete clot removal (87.1% vs. 57.1%, $p = 0.2$) in PMT group without statistical significance. Only one patient in PMT group need adjunctive CDT resulting in PMT group need less dose of rt-PA (0 vs. 30 mg, $p = 0.001$) and less number of operation (1 vs. 3 times, $p = 0.002$). Only minor bleeding was found in 2 PMT patients. On the other hand, we found 5 patients had minor bleeding and 1 patient had major bleeding in CDT group.

Conclusion: In the present study, we found comparable limb salvage rate between PMT and CDT group. Furthermore, PMT had benefits of reducing the need of thrombolysis, operative time and bleeding complication.

Keywords: Acute limb ischemia, Mechanical thrombectomy, Thrombolysis

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Acute limb ischemia (ALI) is one of major causes of limb loss in aged population. Most common cause of ALI is embolism from cardiac pathology or thrombosis from rupture of atherosclerotic plaque at artery of lower extremity[1,2]. Lower limb is the most common site for ALI and it is a critical condition that caused loss of ability to walk and death rate at 7% and 10% respectively[3]. So it is a life-threatening condition that must require emergency treatment. The delay of treatment may increase risk of amputation due to progression of ischemia that resulted in irreversible ischemia and systemic complication such as acidosis, acute kidney injury or death. The high operative mortality rate is related to re-perfusion injury, systemic complication and non-stabilized concomitant diseases in these patients. Some patients can be presented late after 2 weeks after onset of ischemia due to collateral circulation still preserved. Therefore, limb can be survived but symptoms still persisted and progressed. Removal of these organized thrombus in subacute condition is very challenged.

The mainstay of ALI treatment is open surgery and endovascular treatment[4]. Severity of ischemia is the important factor for choosing mode of treatment. In ALI patients with severity Rutherford I and III, their treatments

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were straight-forward. In contrast, patients with severity Rutherford class II, we need rapid, feasible, efficient and safe revascularization method, however conventional treatment included thromboembolectomy and/or surgical bypass frequently increased morbidity and mortality with suboptimal results of thrombus removal. According to recent clinical practice guideline[5], catheter based therapy is now standard treatment for acute lower limb ischemia with Rutherford class II (threatened limbs). Besides catheter directed thrombolysis (CDT), there was a novel endovascular treatment like percutaneous mechanical thrombectomy (PMT) that can remove thrombus faster with reduction of additional thrombolytic therapy[6]. However, no previous study that compare the treatment outcome between PMT and CDT in acute/subacute limb ischemia patients.

The objective of the present study was to compare treatment outcomes between PMT and CDT in acute/subacute lower limb ischemia patients with severity Rutherford II.

Materials and Methods

The present study has been approved by the Ethics Committee of the Faculty of Medicine Siriraj Hospital, Mahidol University. Its approval number was 507/2560 (EC2). This is retrospective chart review. The medical records of consecutive ALI patients who had undergone endovascular interventions with use of PMT or CDT in Division of Vascular Surgery, Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University from November 2014 to April 2017 were retrospectively reviewed to collect clinical information. We included only acute/subacute limb ischemia patients that caused from thrombosis and embolism, severity Rutherford class IIa and IIb, onset not longer than 3 months. The exclusion criteria are patient who have failed to insert the catheter/guide wire through lesion or patient with contraindication for thrombolytic drug (rt-PA) or patient with ALI at both legs. As we are a national center of vascular surgery care, more than 80% of our patients were referred from remote hospitals, so we have only 3-month surveillance data after intervention.

First, we reviewed sixty-six patients who treated with endovascular therapy for ALI. According to inclusion and exclusion criteria, twenty-seven patients were excluded from this study. Total cases were thirty-nine cases, 12 cases in PMT group and 27 cases in CDT groups. Finally, we have 22 cases in CDT group that was allocated on the similarity of level of occlusion (removed case with aorta/iliac occlusion) and onset (remove case who had onset more than 30 days) in line with head-to-head comparison method to empower the results (Figure 1).

Primary outcomes of this study were limb salvage at perioperative period, 1 month and 3 months. Demographic data, clinical data, operative data, procedural outcome and follow-up data were reviewed from medical records. Additionally, subgroup analysis in Rutherford class IIb patients was done to determine outcome in these group of patients that had more severity and more risk of amputation.

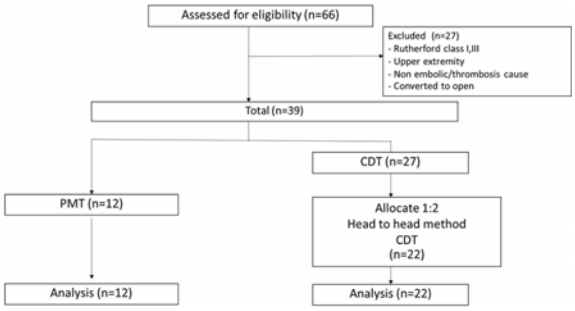

Figure 1. Patient allocation algorithms.

All patients were treated on a routine clinical practice. History taking and physical examination were done for diagnosis, cause finding and assess severity according to Rutherford classification. The demographic data and baseline characteristic were recorded including age, sex, and medical co-morbidities: hypertension, diabetes mellitus, history of tobacco used, hypercholesterolemia, end stage renal disease (ESRD), cancer, chronic obstructive pulmonary disease (COPD), prior coronary artery disease, history of arterial vascular disease, prior acute limb ischemia and prior cerebrovascular disease (CVA) (Table 1). In addition, the clinical data of ALI including cause, side, sites of arterial occlusion, severity, and duration of ALI were collected. Method of treatment were chosen by surgeon on duty case by case. Every patient received preoperative systemic heparin and both anticoagulant and antiplatelet in postoperative period.

Procedural details

The PMT device that used in this study was a wire-guided rotational thrombectomy catheter (Rotarex® catheter/Straub Medical, Wangs, Switzerland). This device can directly fragmentize the thrombus or emboli, detach occlusive materials from the vessels and aspirate fragment of materials into the catheter. Rotation of catheter tip at rate 40,000 to 60,000 rpm cause breakdown of occlusive materials, detach fragment from vessel wall by the strong vortex and generates a negative pressure inside the catheter. The suction performance is approximately 0.66 ml/s (6Fr. Catheter) and 1.5 ml/s (8Fr. Catheter)[5]. In this study, we used only 6Fr. Rotarex® catheter due to vessel size and availability of catheter. Because of this catheter was not warranted to tibial arteries; when there was thrombus extended to tibial arteries, either local thrombolysis or catheter aspiration was warranted as surgeon's decision. After we used PMT, in case of remaining stenosis >30%, percutaneous transluminal angioplasty (PTA) and/or provisional stenting were performed. In case of residual thrombus in treated arteries, local thrombolysis was performed for complete removal of thrombus.

Our center use recombinant tissue plasminogen activator (rt-PA) in every patient underwent CDT. Procedures

Table 1. Demographic characteristics of treated ALI patients

	PMT (n = 12)	CDT (n = 22)	*p*-value
Age (year)	64.36+14.6	59.95+13.64	
Male patient	81.8%	76.2%	1.000
Underlying disease			
Prior Coronary artery disease	36.4%	9.1%	0.146
History of peripheral vascular disease	72.7%	18.2%	0.005
Prior acute limb ischemia	45.5%	13.6%	0.082
Prior CVA	27.3%	13.6%	0.375
Comorbidity			
Cancer	0%	0%	0.000
ESRD	9.1%	0%	0.333
Terminal COPD	9.1%	0%	0.333
Coronary risk factor			
Hypertension	72.7%	63.6%	0.709
Diabetic mellitus	27.3%	18.2%	0.661
History of tobacco use	27.3%	36.4%	0.709
Hypercholesterolemia	63.6%	36.4%	0.163

were performed with placement of infusion catheter in thrombus and then give bolus dose of rt-PA around 5 to 10 mg and then continuous drip in low dose regimens 0.5 to 2 mg per hour for 6 to 16 hours depend on surgeon's preference. After that, we scheduled patients for angiography and adjusted position of catheter every 6 to 24 hours. If the angiogram shown remaining stenosis >30%, percutaneous transluminal angioplasty (PTA) and/or provisional stenting were performed. In case of residual thrombus in treated arteries, local thrombolysis was performed for complete removal of thrombus.

Technical success was defined as complete or near complete restoration of arterial flow[7] on the post-procedural angiogram. Clinical success was defined as either a relief of the acute ischemic symptoms or a reduction of the level of the subsequent surgical intervention or amputation needed[8]. The complication included surgical complication, bleeding complication and cardiopulmonary complication. Major hemorrhage is defined as blood loss that leads to extended or unexpected hospitalization, surgery, or blood transfusion.

Statistical analysis

IBM SPSS Statistics 21.0 software was used for data analyzing. We compare all data and outcomes between PMT group and CDT group by use independent t-test for continuous variables (mean for normal distribution data, median for non-normal distribution data) and Chi-square for categorical variables. If $p<0.05$, it was statistical significance. Limb salvage rate was analyzed using Kaplan-Meier survival analysis

Results

Thirty-four patient were enrolled in the present study. 12 patients were allocated to PMT group and 22 patients were allocated to CDT group. According to table 1, there was no significant difference between two groups in demographic data except we found more history of peripheral arterial disease in PMT group (72.7% vs. 18.2% $p = 0.005$). However, there was a tendency for more coronary artery disease, prior acute limb ischemia and prior stroke in PMT group but not statistical significance. Clinical data in table 2 show more thrombosis cause in PMT group (72.7% vs. 33.33%, $p = 0.04$) and there are no significant difference between severity of ischemia, side and onset.

Table 2. Clinical data

	PMT (n = 12)	CDT (n = 22)	*p*-value
Cause			
Thrombosis	72.70%	33.33%	0.04
Embolism	27.30%	66.70%	
Side			
Right	50%	22.70%	
Left	50%	77.30%	
Severity			
Rutherford IIa	70.00%	45.50%	0.26
Rutherford IIb	30.00%	54.50%	
Onset (days)	7 (1, 30)	10 (0.5, 30)	0.96

As primary outcome, there are no difference in perioperative limb salvage, limb salvage at 1 month, and limb salvage at 3 month between PMT and CDT: (100% vs. 95.2%, $p = 0.656$), (100% vs. 94.7%, $p = 0.65$) and (80% vs. 80%, $p = 0.751$) respectively as shown in Figure 2.

Next, there were more technical success (100% vs. 85.7%, $p = 0.268$) and complete clot removal (87.1% vs. 57.1%, $p = 0.2$) in PMT group compare to CDT but no statistical significance. However, PMT group significantly need less dose of rt-PA (0 vs. 30 mg, $p = 0.001$), number of operation (1 vs. 3 times, $p = 0.002$) and time to lysis (0 vs. 40 hours, $p = 0.001$). However, both PMT and CDT group

required additional procedure as shown in Figure 3.

The complication included surgical complication, bleeding complication and cardiopulmonary complication. In surgical complication we found 2 patients (18.2%) in PMT group and 1 patient (4.8%) in CDT group were developed aneurysm/pseudoaneurysm at puncture site. About bleeding complication, we found only minor bleeding in 2 patients (18.2%) of PMT group without any major bleeding. On the other hand, we found 7 patients of CDT group (31.80%) that had bleeding complication. There was only major bleeding in 2 patients (9.10%) of CDT group. These 2 patients developed groin wound hematoma and bleeding fasciotomy wound that required operation for stop bleeding. Both groups had no cardiopulmonary complication. Additionally, we found more hospital stay in PMT group with no statistically significance (16 vs. 8.5 days, $p = 0.27$).

In subgroup analysis outcome in Rutherford class IIb patients group, we found no statistically significance difference in limb salvage. But we found that not only PMT group had significant lower dose of rt-PA (0 vs. 38 mg, $p = 0.0009$), time to lysis (0 vs. 48 hours, $p = 0.001$) and number of operation (1 vs. 3.5 times, $p = 0.033$) same as before subgroup analysis, but also less in operation time (1.15 vs. 5.85 hours, $p = 0.014$).

Discussion

Previous report about the use of Rotarex® device in peripheral arterial shown technical success rate was 95%, with excellent safety outcome[8]. This device has advantage especially in the patient who have contraindication to thrombolytic drug, because it can complete removal thrombus from vessel without any use of thrombolytic drug in many cases. The same results were found in our study that only 1 case (8%) in PMT group needed adjunct thrombolysis. Moreover, it can provide adjunctive effect in partially successful lytic therapy[9].

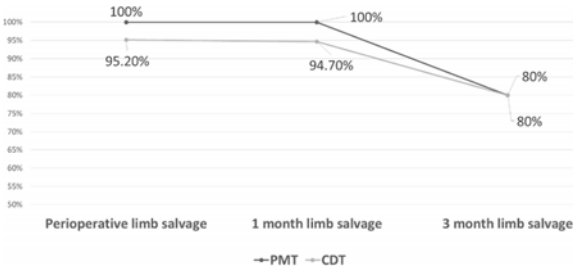

Figure 2. Peri-postoperative limb salvage.

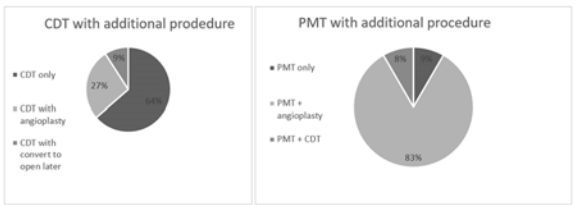

Figure 3. Additional procedure.

The previous randomize control trial (STILE and TOPAS)[10,11] shown that rate of limb salvage after CDT in these patients at 1, 6, and 12 months was 91.5% and 83%, 82.9% and 67%, 82% and 61% respectively. Additionally, previous study of CDT in our center by Wongwanit et al shown that rate of limb salvage at 1, 6, and 12 months was 86.5%, 78.4%, 78.4% respectively[12]. In our study, even we included only more severe patients with limb ischemia severity class II, rate of limb salvage at 1 month was comparable to other studies in both PMT and CDT group.

However, recent study from Heller et al[13] shown excellent outcome of treatment acute limb ischemia patients by use of Rotarex device. Procedural success rate was 90.5% and perioperative limb salvage 98% that comparable to our study. It confirmed that Rotarex® can be used in acute limb ischemia patient effectively.

In our study, PMT was significantly less in time to lysis and rt-PA dose, because we have only one case that need additional thrombolysis for remove remained clot. As a result, it was less in number of operation. It confirmed that PMT can remove thrombus faster than CDT only. In addition, PMT had 100% technical success and more complete thrombus removal. The outcome was correlated with the mechanism of Rotarex® that directly fragmentize the thrombus and aspirate all fragments via tip of catheter that cause immediate restoration of blood flow. Moreover, if angiography after advancing device shown residual thrombus, we can perform this procedure again or add intraoperative thrombolysis for complete thrombus removal unlike CDT only that need time for additional thrombolysis. Therefore, this device can be used effectively in patients with threatened limb ischemia (Rutherford II) that need immediate revascularization.

In previous guideline, there was recommendation to use CDT only for Rutherford I and IIA patients, but in Rutherford IIB patients it still controversy because of the mechanism of CDT that needed time to resolved occlusion[9,14,15]. It may leaded to progression of ischemia. In contrast, PMT can immediate restoration of blood flow. Thus, subgroup analysis outcome in Rutherford class IIb patients was done. We found comparable limb salvage rate in both group, but operative data shown benefit from Rotarex® that not only have significant less dose of rt-PA, time to lysis and number of operation, but also had less operation time.

More benefit of PMT has been shown in Table 4. About one third of case in CDT group was developed bleeding complication compare to only 18.2% in PMT group. There are 2 cases in CDT group was develop major bleeding while there was no major bleeding in PMT group. However, PMT group have more groin pseudoaneurysm that could be explained by bigger size of introducer sheath of PMT than CDT (6 to 8Fr. sheath for PMT and 5 to 6 Fr. sheath for CDT). All pseudoaneurysms can be solved with ultrasound

Table 3. Outcome, procedural details and complications

Outcome	PMT	CDT	*p*-value
Limb salvage			
Perioperative limb salvage	100%	95.20%	1
1-month limb salvage	100%	94.70%	1
3-month limb salvage	80%	80%	1
Perioperative outcome			
Technical success	100.0%	85.7%	0.534
Complete clot removal	81.8%	57.1%	0.287
Time to lysis (hours)	0	40	0.001
rt-PA dose (mg)	0	30	0.001
Number operation	1	3	0.002
Operative time (hours)	4.53	5.73	
Hospital stay (days)	16	8.5	0.27
Complication			
Bleeding	18.20%	31.80%	0.26
Major bleeding	0%	9.10%	0.1
Pseudoaneurysm	18.20%	4.80%	0.1

Table 4. Perioperative outcome in Rutherford IIb patients

	PMT	CDT	*p*-value
Dose (mg)	0	38	0.009
Time to lysis (hours)	0	48	0.01
Number of operation	1	3.5	0.033
Operation time (hours)	1.15	5.85	0.014

guided bovine thrombin injection without any other intervention. Our complication rate was comparable to previous studies[15]. Other complication of PMT from previous studies that not found in this study were arteriovenous fistula, vessel perforation and distal embolization of thrombus. It may be caused from low sample size of this study. We found more hospital stay in PMT group that caused from more co-morbidity in PMT group.

Unfortunately, our study had follow-up results only 3-month limb salvage rate due to lack of good surveillance protocol and more than 80% of patients were referred back to remote hospitals.

There were many limitations in this study. First, it was only retrospective observational study, thus method of treatment was chosen only by surgeon preference and experience. Furthermore, some patient was unable to come back for surveillance, hence there was no mid-term and long-term outcome. Last, small sample size of this study is another limitation. We suggest that good surveillance protocol is needed to record long-term outcome. Moreover, future randomized control trial (RCT) with large number of populations should be establish for more reliable study.

Conclusion

Percutaneous mechanical thrombectomy and catheter directed thrombolysis can be used effectively in acute limb ischemia patients with threatened limb. We found comparable limb salvage rate with more technical success and complete clot removal in PMT group. Furthermore, PMT had benefits of reducing the need of thrombolysis, operative time and bleeding complication.

What is already known in this topic?

Percutaneous mechanical thrombectomy (PMT) is the novel device that can improve outcome of endovascular treatment for acute limb ischemia patient. In previous standard guidelines, PMT can be used as adjunctive therapy for catheter directed thrombolysis that are standard treatment for acute limb ischemia patient.

What this study adds?

This study confirmed that PMT can be used as primary treatment for acute limb ischemia patients and had comparable outcome to catheter directed thrombolysis with less complications and less operations. In PMT group, mostly patients had complete removal of thrombus after first operation.

Potential conflicts of interest

The authors declare no conflicts of interest.

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การศึกษาเปรียบเทียบระหว่างการสอดใส่สายสวนเพื่อสลายลิ่มเลือดด้วยวิธีกลศาสตร์กับการสอดใส่สายสวนเพื่อให้ยาสลายลิ่มเลือดในการรักษาผู้ป่วยที่มีภาวะขาขาดเลือดเฉียบพลันและกึ่งเฉียบพลัน

ณัฐวุฒ พ่วงพันธุ์งาม, ปัณฑ์ธิติ ปลีหจินดา, เฉนียน เรืองเศรษฐกิจ, ชุมพล วองวานิช, ณัฐวุฒิ เสริมสาธนสวัสดิ์, คามิน ชินศักดิ์ชัย, สุธีคณิต หัถพรสวรรค์, เกียรติศักดิ์ หงษ์คู, ประมุข มุทิรางกูร

ภูมิหลัง: การรักษาด้วยการสอดใส่สายสวนเป็นการรักษามาตรฐานสำหรับภาวะขาขาดเลือดเฉียบพลันและกึ่งเฉียบพลันความรุนแรงระดับวิกฤต (ระดับ 2) นอกเหนือจากการสอดใส่สายสวนเพื่อให้ยาละลายลิ่มเลือด, การสอดใส่สายสวนสลายลิ่มเลือดด้วยวิธีทางกลศาสตร์เป็นวิธีการรักษาใหม่ที่สามารถกำจัดลิ่มเลือดได้รวดเร็วกว่า และผลข้างเคียงน้อยกว่า อย่างไรก็ดีไม่มีการศึกษาเพื่อเปรียบเทียบผลการรักษาระหว่างสองวิธีนี้

วัตถุประสงค์: เพื่อเปรียบเทียบผลการรักษาระหว่างการสอดใส่สายสวนสลายลิ่มเลือดด้วยวิธีกลศาสตร์และการสอดใส่สายสวนเพื่อสลายลิ่มเลือดในผู้ป่วยขาขาดเลือดเฉียบพลันและกึ่งเฉียบพลัน โดยผลการรักษาหลักคือ อัตราการตัดขาในช่วงการผ่าตัด และอัตราการเก็บขาได้ที่สามเดือน

วัสดุและวิธีการ: ทบทวนประวัติผู้ป่วยที่เข้ารับการรักษาภาวะขาขาดเลือดเฉียบพลันและกึ่งเฉียบพลันความรุนแรงระดับวิกฤตด้วยวิธีการสอดใส่สายสวนทั้งสองวิธีตั้งแต่เดือนพฤศจิกายน พ.ศ. 2557 ถึง เดือนเมษายน พ.ศ. 2560 โดยรวบรวมผู้ป่วยทุกรายที่รักษาด้วยการสอดใส่สายสวนสลายลิ่มเลือดด้วยวิธีกลศาสตร์ และผู้ป่วยที่รักษาด้วยการสอดใส่สายสวนเพื่อให้ยาสลายลิ่มเลือดอีก 22 ราย โดยเลือกกลุ่มที่ระดับการอุดตันและความรุนแรงใกล้เคียงกัน

ผลการศึกษา: ในการศึกษานี้รวบรวมข้อมูลผู้ป่วยทั้งหมด 34 คน โดยแบ่งเป็น 12 คน ในกลุ่มที่ใช้วิธีสอดใส่สายสวนสลายลิ่มเลือดด้วยวิธีกลศาสตร์ และกลุ่มใช้สายสวนเพื่อให้ยาสลายลิ่มเลือด 22 คน โดยที่ไม่มีความแตกต่างกันในแง่โรคร่วมและความรุนแรงของการขาดเลือด ผลการรักษาพบว่าทั้งสองกลุ่มมีอัตราการตัดขาระหว่างช่วงผ่าตัดและการเก็บขาได้หลังจากผ่านไป 3 เดือนไม่แตกต่างกัน นอกจากนั้นกลุ่มที่ใช้วิธีสอดใส่สายสวนเพื่อสลายลิ่มเลือดด้วยวิธีกลศาสตร์ยังมีอัตราความสำเร็จและการกำจัดลิ่มเลือดที่ดีกว่า รวมถึงมีจำนวนครั้งของการผ่าตัดและปริมาณยาสลายลิ่มเลือดที่ใช้น้อยกว่า ส่งผลให้ผลข้างเคียงเกี่ยวกับเลือดออกน้อยกว่ากลุ่มที่ใช้สายสวนเพื่อให้ยาสลายลิ่มเลือดด้วย

สรุป: จากการศึกษานี้พบว่าการรักษาขาขาดเลือดเฉียบพลันและกึ่งเฉียบพลันทั้งสองวิธีมีประสิทธิภาพในการเก็บขาได้เท่าเทียมกัน โดยที่กลุ่มที่ใช้การสอดใส่สายสวนสลายลิ่มเลือดด้วยวิธีกลศาสตร์มีประโยชน์ในแง่ลดปริมาณยาสลายลิ่มเลือด, ระยะเวลาในการผ่าตัด และผลข้างเคียงด้านเลือดออก