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Heru Angkoso

Training program in Surgery, Department of Surgery, Faculty of Medicine, Universitas Indonesia,
heruangkoso@gmail.com

Dedy Pratama

Division of Vascular Surgery, Department of Surgery, Faculty of Medicine, Universitas Indonesia,
dedygpratama@yahoo.com

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Review: Conventional Thrombectomy with Intraoperative Fluoroscopy in Acute Limb Ischemia Rutherford IIb

Heru Angkoso,¹ Dedy Pratama.² 

1) Training Program in Surgery, 2) Division of Vascular and Endovascular Surgery, Department of Surgery, Faculty of Medicine Universitas Indonesia.

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Abstract

Introduction. Acute limb ischemia (ALI) is a severe condition affecting the extremities and the patient's survival that requires immediate treatment. It can be treated with either surgical or endovascular revascularization or both (hybrid procedure). It is crucial to evaluate the defect using intraoperative fluoroscopy or angiography in each case. The review aimed to find out the outcomes of the thrombectomy with intraoperative fluoroscopy for ALI Rutherford IIb.

Method. According to the PRISMA protocol, the literature search proceeded in online databases, i.e., Cochrane, Scopus, PubMed, and EBSCOhost, with no year limitation on the publication. All articles were screened and critically appraised. Five eligible articles enrolled in this study with 269 patients ALI Rutherford IIb. All selected articles are cohort studies, including prospective and retrospective.

Results. The endovascular intervention (with intraoperative fluoroscopy assistance) showed lower mortality and morbidity than open thrombectomy – however, no difference between open and hybrid thrombectomy in mortality rate. In addition, morbidities such as amputation and limb salvage showed no difference significantly between these interventions. Open thrombectomy has a high risk of mortality and amputation. Meanwhile, the endovascular intervention likely showed a risk of reocclusion, thus, requiring a conversion to open thrombectomy.

Conclusion. Intraoperative angiography during open thrombectomy may reduce complications of postintervention reocclusion.

Key words: acute limb ischemia, fluoroscopy, intraoperative, Rutherford IIb, thrombectomy

Introduction

Acute limb ischemia (ALI) not solely adversely affects the extremities but is also life-threatening. It is a severe condition requiring immediate treatment. The treatment includes surgically, with endovascular revascularization, or a hybrid procedure. It is important to evaluate the lesion using fluoroscopy or additional imaging in each case. Considering the survival and prognosis, if complications occur, a procedure of amputation may have proceeded.¹ The main goal of ALI management is to limb–save and maintain its function. Revascularization is the first step to preserving limb viability. However, the procedure is not possible in some cases.¹

The ALI Rutherford IIb case is common in Indonesia that requires an immediate operative procedure to save the limb and avoid amputation. The Data National Hospital Discharge Survey in 1988-2007 showed 1.76 million cases of arterial thromboembolism in the lower extremities. The incidence was 42.4 per 100,000 in 1988-1997 and 23.3 per 100,000 in 1998-2007, with a mortality rate of 8.28% in 1988-1997 and decreasing to 6.34% in 1998-2007.^{2,3} To date, the incidence of ALI is increasing and approaching 1.5 cases per 10,000 per year.⁴ Risk of the sacrificed limb was 5-30%, and the mortality was 11-18%.⁵

Some urgent revascularization is needed in managing these cases, one of which is a thrombectomy. Fukuda et al. reported the success rate of revascularization with the conventional endovascular procedures without thrombolytic agents in 64 treated limbs. Success in 20 patients with this kind of treatment was 95.5%, while in 42 patients treated with surgical revascularization was 92.9%.⁶ Another study by Argyriou et al.

reported that the success rate of hybrid revascularization in 31 patients was 100%.⁷

The typical thrombectomy procedure applied at our tertiary hospital (CMGH) was conventionally using a Fogarty catheter. The treatment proceeded without intraoperative fluoroscopy. Unfortunately, some complications or repetition after the initial thrombectomy; thus, amputation risk increased from 10 to 40%. In addition, Zaraca et al. found reocclusion after thrombectomy. Those treated without intraoperative angiography were 10% higher than those treated with routine intraoperative angiography.⁸ The review focused on the necessity of intraoperative fluoroscopy assistance during conventional thrombectomy for ALI Rutherford IIb.

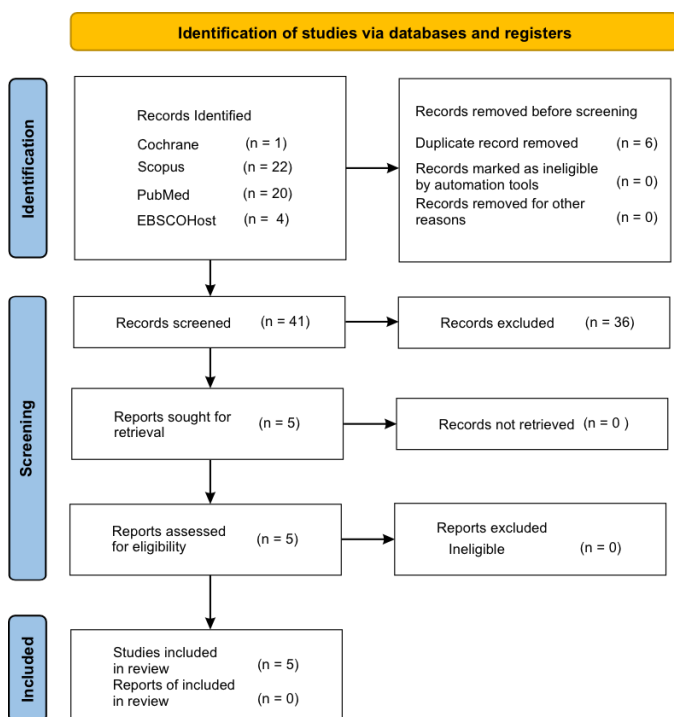
Methods

In this review, a literature search proceeded in four online databases. i.e., Cochrane, Scopus, PubMed, and EBSCOhost. The keywords used was: ((acute limb ischemia)) AND ((Rutherford IIB) OR (Rutherford 2B)) AND ((fluoroscopy) OR (angiography) OR (hybrid) OR (thrombectomy) OR (thromboembolism) OR (embolectomy)). These include (1) meta-analysis, systematic review, randomized controlled trial, or cohort study; (2) the subject is ALI Rutherford IIb that were treated with thrombectomy and intraoperative fluoroscopy; (3) no limitation of publication year. Excluded articles were: (1) correspondence, editorial, or commentary, (2) no full text, and (3) subjects with thrombectomy or previous catheter-directed thrombolysis (CDT).

These articles were screened based on title and abstract and then appraised for validity, importance, and applicability. The appraised articles were further critically appraised using specific tools: (1) meta-analysis, a systematic review from RCT, and RCT were appraised using the University of Oxford Centre for Evidence-based Medicine (Oxford CEBM critical appraisal worksheet) for Systematic Reviews and Randomized Clinical Trials; and (2) the cohort, case series, and case report were each appraised using Joanna Briggs Institute, Faculty of Health and Medical Sciences, University of Adelaide, South Australia, Checklist for Cohort, Case Series, and Case Reports Studies (critical appraisal tools). Finally, the level of evidence was determined according to the Oxford CEBM level of evidence 2011. The literature search proceeded according to the PRISMA (Figure 1).

Results

Five articles were included in this study through a literature search, as shown in the flowcharts presented in figure 1 comprised a cohort study, including prospective and retrospective. In addition, a critical appraisal worksheet was drawn in a table in the appendix. A study by Poursina et al. proceeded with an endovascular intervention only. In contrast, Jungi et al. performed an open thrombectomy. These two studies did not fit the eligibility criteria since there were no comparative analyses, but the subject's measures remain eligible. Poursina et al. reported no conversion to open thrombectomy in two subjects,⁹ and consistently, Jungi et al. reported the outcome of open thrombectomy only.¹⁰ To date, the published comparative studies that focused on endovascular and open thrombectomy outcomes remain minimal. Thus, should these two studies be excluded, the review will not reach the baseline outcome of each procedure. Therefore, the scope and discussion will be limited. For this reason, the authors decided to include these two studies.



The PRISMA 2020 Flow. <http://www.prisma-statement.org/>

Figure 1. Literature search in accordance to PRISMA protocol found 5 eligible studies.

Table 1. Characteristic of study

No	Author, year	Subjects	Study Design	Intervention	Outcomes	Level of evidence	Results	Notes
1	Genovese, 2016 ¹	158 patients of ALL Rutherford IIb	Retrospective cohort	1. open thrombectomy = 128 patients. 2. endovascular intervention = 30 patients.	1. Mortality at five years 2. Amputation at five years	2	1. Mortality at 5 years = 5.4% (65% open thrombectomy and 36% endovascular intervention; p < 0.001). 2. Hazard ratio of mortality at 5 years (controlling for clinical presentation only) = 4.80 (95%CI: 1.30—17.87; p = 0.019). 3. Hazard ratio of mortality at 5 years (controlling for clinical presentation and adverse event) = 3.99 (95%CI: 1.10—14.40; p = 0.035). 4. Amputation at 5 years = 28% (18% open thrombectomy and 17% endovascular; p = 0.042).	Long-term mortality and amputation frequency were higher in patients treated with open thrombectomy.
2	de Athayde, 2019 ²	30 patients of ALL Rutherford IIb	Retrospective cohort	1. open thrombectomy (group 1) = 24 patients. 2. endovascular intervention (group 2) = 6 patients.	1. limb salvage 2. overall survival in 30 days 3. overall mortality in 30 days	2	1. limb salvage in group 1 vs group 2 = 79.2% vs 90.6% (p = 0.27) 2. overall survival in group 1 vs group 2 = 53% vs 60.8% (p = 0.45) 3. overall mortality in 30 days = 10.1%, higher in group 1 = 13.0% (p = 0.03) 4. Factors related to limb salvage rate, based on Rutherford's classification in univariate analysis, hazard ratio = 6.0 (95%CI: 0.128-2.767; p = 0.068). In multivariate analysis, hazard ratio = 7.0 (95%CI: 0.226-10.060; p = 0.880)	Open thrombectomy is recommended in Rutherford IIb because of the need to restore blood flow immediately.

Discussion

Frequently, the choice of intervention in ALI Rutherford IIb patients is mostly open thrombectomy. Genovese et al. reported their study on managing ALI Rutherford IIb. Of 128 patients who underwent open thrombectomy, only 30 patients proceeded with endovascular intervention.¹¹ Likewise, de Athayde al. reported that thirteen patients underwent open thrombectomy, and only four proceeded with endovascular intervention (p = 0.003).¹² The non-open thrombectomy is increasing. The treatment in managing ALI Rutherford IIb is not solely open thrombectomy. Poursina et al. showed that endovascular intervention might replace the open surgery as the first line in various Rutherford categories, even though Rutherford III, which was previously considered, could be revascularized solely with an open thrombectomy.⁹

Consideration in choosing an intervention is determined based on the etiology of ALI. Should it be caused by thrombus, endovascular intervention (arteriogram with thrombolysis, mechanical thrombectomy, balloon angioplasty, and stent) is preferred in 50% of cases. Only 20% required an open thrombectomy (open simple), and 11% had an open complex. Should ALI be caused by embolism, 80% of subjects proceeded with an open thrombectomy, and 20% proceeded with endovascular intervention.¹³ Reports showed that hybrid interventions remain infrequently carried out, merely in 11% of cases. However, this intervention has been more frequent recently. This procedure allows the patient to proceed with both endovascular and open thrombectomy.¹⁴ The requirement for providing hybrid intervention was the availability of operating room facilities and competent surgeons to perform open thrombectomy should the non-open intervention fail. Recently, there has been an increasing demand for a closed technique. However, it should note that some cases require an open thrombectomy or open revascularization. For instance, a local thrombus or embolism of the common femoral artery should be treated with simple exposure and thromboendarterectomy. In addition, in cases of ALI Rutherford IIb, a fasciotomy is often required. This case preferred an open thrombectomy and avoided the use of thrombolytic agents.^{9,14}

The above studies show that the endovascular and hybrid were the most chosen without leaving the role of open thrombectomy. However, open thrombectomy remains the most common choice in some centers to avoid an unfavorable outcome. This ALI with Rutherford IIb requires an immediately restored blood flow, so an endovascular intervention is less recommended.⁹⁻¹⁴ The most performed endovascular intervention was the catheter-directed thrombolysis (CDT) type. Meanwhile, open thrombectomy was more preferred in an open procedure. However, the lack of single endovascular thrombectomy procedures without thrombolysis remains unknown. Therefore, it is necessary to discuss the outcome of each procedure let the surgeon may have a reasonable consideration to choosing the best intervention for their patients.

Regarding the outcomes, i.e., mortality and morbidity, many studies have assessed outcomes based on overall survival, thirty days to one-year survival rate, the major amputations prevalence, limb salvage, and length of hospital stays. Regardless of the choice of intervention, Hemingway et al.,¹³ showed that the mortality rate was 2%.¹³ However, Poursina et al.⁹ reported increasing mortality to 23.1% in those who proceeded with endovascular intervention. Somehow the increased mortality was thought to be influenced by the embolic-type ALI.⁹ So far, some studies have shown that open thrombectomy had higher long-term mortality and amputation than endovascular intervention.¹¹ A comparative study reported a higher overall survival rate in the endovascular group and higher thirty-day mortality in the open thrombectomy group.¹² Meanwhile, the survival rate in the hybrid

Table 1. Characteristic of study (continued)

No	Author, year	Subjects	Study Design	Intervention	Outcomes	Level of evidence	Results	Notes
3	Jungi, 2018 ¹⁰	20 patients of ALI Rutherford IIb	Retrospective cohort	Open surgical revascularization 1. Intraoperative thrombolysis = seven patients Rutherford IIb. 2. Without intraoperative thrombolysis = 13 patients Rutherford IIb.	1. mortality in 30 days 2. major amputation in 30 days 3. limb salvage	2	1. mortality in 30 days = 4% (n = 2). 2. major amputation in 30 days = 4 patients, overall rate 16% (8/51, 95%CI: 7.0–28.6). 3. A total of 18 (90%) patients of ALI Rutherford IIb successfully performed limb salvage.	
4	Hemingway, 2019 ¹³	48 patients of ALI Rutherford IIb	Retrospective cohort	It is not known the type of intervention carried out among the following five interventions: 1. open simple 2. open complex 3. endovascular 4. hybrid 5. primary amputation	1. limb salvage 2. in-hospital mortality 3. 30-days mortality 4. discharge disposition	3	1. There were 38 patients (79.2%) who successfully performed limb salvage. Meanwhile, ten subjects (20.8%) were amputated. 2. In-hospital mortality and 30-days mortality were not significantly different. 3. Mortality in ALI Rutherford IIb = 2% 4. Discharge disposition did not significantly different. Rutherford IIb = 67% vs. 31% between being discharged home and referred to an expert care facility.	
5	Poursina, 2020 ⁹	13 patients of ALI Rutherford IIb	Retrospective cohort	Thirteen subjects with Rutherford IIb have an unknown type of intervention (endovascular first approach).	Mortality	3	1. Mortality rate = 3 patients (23.1%) 2. Rutherford category as a predictor of amputation-free survival, unadjusted hazard ratio = 1.7 (95%CI: 1.01–2.70; p = 0.02).	

procedure was reasonable.⁷ de Athayde et al.,¹² who compared the open thrombectomy group vs. the endovascular group, found a higher limb salvage in the open thrombectomy group.¹² While as, Jungi et al.,¹⁰ found the long-term outcomes of limb salvage better if immediate revascularization proceeded with an open thrombectomy, especially in ALI Rutherford IIb.

Severe cases categorized as Rutherford III may be treated with revascularization, although those in the borderline between category IIb or III should be subjectively selected.¹⁰ Cases with ALI of Rutherford IIb could be treated by hybrid revascularization. The endovascular access is proximally or distally to the open thrombectomy site. With this treatment, the six-month overall patency and limb salvage were reasonable.⁷ Hemingway et al.,¹³ found that primary amputation and limb salvage were not associated with the intervention chosen. Open, closed, or hybrid interventions showed a higher successful limb salvage in Rutherford IIb. Of 21% failed and had proceeded with amputation. Primary amputation is associated with ischemia due to thrombotic occlusion but not embolic. Morbidity is also seen in the difference in hospital discharge between ALI Rutherford IIb patients discharged compared to those referred to a skilled care facility.¹³

All the above studies showed that the outcome of ALI Rutherford IIb was reasonable. Endovascular intervention is superior in the mortality and morbidity rate. Although de Athayde et al.,¹² Jungi et al.,¹⁰ Davis et al.,¹⁴ and Argyriou et al.,⁷ showed that open thrombectomy is superior for limb salvage. However, Hemingway et al.¹³ reported no difference in outcomes between open, hybrid, and endovascular thrombectomy in amputation rates and limb salvage.^{7,10,12-14} However, endovascular intervention with intraoperative angiography is the first-line approach. Operators and resources should also be prepared to convert into an open thrombectomy procedure when the endovascular intervention fails. The need for a hybrid operating room (which can perform both endovascular and open thrombectomy assisted by intraoperative angiography) was an issue that deserves consideration.

Regarding intraoperative fluoroscopy or angiography, Poursina et al. reported intraoperative imaging and ultrasonography (USG) that guides the catheter. Ultrasound is sufficient to assess the thrombus, leading the surgeon to decide.⁹ Intraoperative angiography was beneficial in determining the reduced patency flow in the blood vessels, which may lead immediately to a primary major amputation.¹⁰ Intraoperative angiography helps assess the success of revascularization based on vessel runoff. When the test results did not reveal a patent vessel runoff with bypass flow to the leg only through collaterals, this situation indicated unsuccessful revascularization.¹⁰

The reocclusion within 24 months after thrombectomy or embolectomy is lower in those who proceeded with routine intraoperative angiography than in selective intraoperative angiography. However, there was no difference in amputation and mortality rates between the two types of angiographies. However, there was no difference in amputation and mortality rates between the two types of angiographies. Should it be compared to selective angiography, a routine angiography known to increase intraoperative reintervention (53.4% vs. 29.9%). Intraoperative angiography was associated with an increase in the procedure's duration to remove residual lesions.⁸ In upper limb ALI, routine angiography decreased the reocclusion rate 24 months after embolectomy. However, the mortality between routine and selective intraoperative angiography was not significantly different. The rate of intraoperative reintervention was also higher at routine angiography, reaching 26%.¹⁵ A complete angiogram should be performed before the patient is discharged from the operating room. It helped detect incomplete procedures that require reintervention. Regardless of the occlusion site, failure to identify and treat the thrombus can lead to incomplete revascularization and recurrent

thrombosis. Patients who underwent selective angiography had a reocclusion hazard ratio 5.44 times higher than patients who underwent routine intraoperative angiography.^{8,15}

Complete angiography helped identify residual thrombus and identify incomplete recanalization of the proximal artery because of adherence of the remaining thrombus to the arterial wall. In addition, it detected the occurrence of steno-occlusive lesions after clot removal.^{16,17} European Society for Vascular Surgery (ESVS) 2020 recommends complete angiography (1C recommendation) in the treatment of open and endovascular thrombectomy.¹⁸

Parson firstly introduced the use of intraoperative angiography or fluoroscopy in 1996. Parson was the first who performed a combination of surgical and endovascular techniques as a treatment for ALI patients. Intraoperative angiography helped minimize arterial damage and blood loss during clot clearance, increase the accuracy of site identification, and manage arterial occlusion lesions. Since then, the recommendation for routine post-thromboembolectomy angiography has been increasingly adopted. Interestingly, intraoperative angiography plays an important role in hybrid intervention. It served as additional guidance in endovascular technique. However, to date, intraoperative angiography in clinical practice remains infrequent.¹⁶

The contrast used in angiographic procedures was iodine which was nephrotoxic. Thus, postoperatively, patients should be proceeded with dialysis and have renal function monitoring. There were successful case reports of using carbon dioxide as a substitution for iodine contrast. The advantages of carbon dioxide were safety and non-nephrotoxicity. It provides both diagnostic and therapeutic modalities, but its application has not been common in clinical settings recently. The use of carbon dioxide contrast might be considered in ALI patients with borderline renal function to reduce the risk of short-term and long-term dialysis.¹⁹ This idea was later supported by the study of Kawasaki et al., who performed angiographic-guided endovascular intervention. That study compared the effects of carbon dioxide contrast and iodine contrast in ALI patients. As a result, both contrasts were successful without any major complications. Arteriograms using carbon dioxide were cheap, easy, and safe for ALI patients with CKD who will undergo endovascular intervention.²⁰

All studies discussed showed evidence that intraoperative fluoroscopy or angiography implementation should be more intense. It is preferable to perform it in a hybrid operating room or an operating room with a C-arm to optimize ALI patients' management. We advise this procedure led by a team of clinicians who are ready and able to perform an endovascular intervention, even a conversion to open thrombectomy if needed.¹⁸

Conclusions

Mortality and morbidity were lower in ALI Rutherford IIb treated with endovascular intervention with intraoperative fluoroscopy assistance than open thrombectomy. However, the mortality rate was not different between open and hybrid thrombectomy. In addition, morbidities such as amputation and limb salvage were not significantly different between the type of intervention performed.

Open thrombectomy has a high risk of mortality and amputation. Meanwhile, the endovascular intervention risks reocclusion, so conversion to open thrombectomy is required. The role of intraoperative angiography in open thrombectomy provides a better outcome in ALI Rutherford IIb patients. Open thrombectomy with intraoperative angiography can also reduce complications of post-intervention reocclusion.

Disclosure

Authors declare no conflict of interest

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