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CRITICAL LOWER LIMB ISCHEMIA DUE TO INFRAGENICULAR LESIONS BYPASS SURGERY VERSUS ENDOVASCULAR THERAPY

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Abstract
Background: Critical limb ischemia (CLI) is a severe form of peripheral arterial disease (PAD) characterized by clinical findings of lower extremity ischemic pain at rest.The study aimed to discuss the better management of patients with critical lower limb ischemia. Patients and methods: A randomized control trails study was included 24 participants diagnosed with critical lower limb ischemia (CLI) due to Infragenicular lesions with mean age of 69.01±7.11 years and conducted at Vascular Surgery Department at Zagazig university Hospitals. Patients were divided equally into the endovascular therapy (EVT) group and the bypass surgical group. Follow up was done by the Rutherford recommended standards for reports dealing with lower extremity ischemia by using the life table and Kaplan-Meier survival curve. Results: The study revealed that the arteries that underwent dilatation were 7 anterior tibial arteries, 5 posterior tibial artery, 7 distal popliteal artery and 8 peroneal arteries. There was a significant difference of hemodynamic success among the studied groups. Additionally, there was no significant association of technical success between the studied groups. There were significant differences in limb salvage between the studied groups. The probability of artery patency in endovascular therapy group is higher than in bypass treatment in the 1st month, 2nd month and 4th month. Conclusion: Endovascular techniques are a viable treatment approach for limb salvage in patients with infrageniculate critical limb ischemia, and can be considered as a first-line approach in patients presenting with diabetes and/or tissue loss.
Keywords: Bypass Surgery; Endovascular Therapy; Critical Lower Limb Ischemia

INTRODUCTION

Critical Limb Ischemia (CLI) refers to severe ischemia of the limb manifested by rest pain and or tissue loss. Such cases belong to stages 4 through 6 of Rutherford classification and stages 3 and 4 of the Fontaine classification. Estimated annual incidence of CLI is 220-3500 cases per 1 million persons with a prevalence of 1-2%. The incidence of CLI is rising worldwide because of the aging population, increasing rates of metabolic syndrome, and continuing high rates of smoking **(1).**

Natural history of claudicants over 5 years includes worsening of claudication in 20% patients and development of CLI in 5-10%; 5-10% of patients will die because of cardiovascular problems. In CLI patients, however, 30% end up with amputation, 20% die and only 40% patients will be alive with both limbs intact at 1 year **(2).**

Revascularization to restore perfusion of the extremity with rest pain and/or tissue loss is the mainstay of therapy **(3)**. No medical therapy has been shown to be effective in salvage of the affected limb itself. However, lifestyle modifications such as smoking cessation as well as lipid-lowering and cardioprotective medications have been shown to reduce the risk of cardiovascular events and mortality in patients with CLI and to increase the patency of both open and endovascular revascularization **(4)**.

To ensure limb salvage, long-term supply of a large volume of blood to the defective tissue region is necessary, and below-the-knee-ankle joint bypass has been considered as the gold standard revascularization for CLI complicated by below-the-knee lesions **(5)**.

Therefore, the aim of the present study was to investigate the type of patient for who bypass surgery (Bypass First) is appropriate. And to compare the complications of a bypass-first versus endovascular-first strategy for revascularization in patients with CLI due to infrageniculate arterial disease.

PATIENTS AND METHODS:

A randomized control trails study was included 24 participants diagnosed with critical lower limb ischemia (CLI) due to Infragenicular lesions with mean age of 69.01±7.11 years and conducted at Vascular Surgery Department at Zagazig university Hospitals. Patients were divided equally into group (1) who undergoing the endovascular therapy (EVT); group (2) who undergoing the Bypass surgical therapy.

Inclusion and exclusion criteria:

Patients with CLI (rest pain, or non healing ulcer or gangrene), the foot was salvegable and the ulcer of gangrene was not affecting very deep. Their infragenicular arterial tree has several tibial or tibio-peroneal lesions. The diseased segment at the arteri es were occlusion (long > 5 cm or short <5 cm) or stenosis (significant >50% or tight >75%) or both . While, Patients with claudications only, patients with combined supragenicular or iliac arterial lesions and patients with renal impairment (S.Cr >1, 8) were excluded from this study.

Operating Design:

Full history taking, Clinical examination, Radiological evaluation and Laboratory Investigations were done for all patients.

Surgical Procedure and Assessment:

1. Endovascular Group:

The procedure was done under local anesthesia in a vascular surgery room with a mobile C-arm with vascular imaging capabilities. Obtaining of intraarterial access through antegrade ipsilateral CFA through pulse palpation or under fluoroscopy in cases of severe calcification is by using cutting sheath 6 Fr. A wire with a diameter of 0.014” was used to cross the lesion. The selected vessel was punctured under fluoroscopic guidance or sonar guidance with a 21-G micropuncture kit. Dilatation was done through long tibial balloons and high pressure **(Figure 1)**.

2. Bypass surgery group:

No patient received a prosthetic bypass graft. The proximal anastomosis was placed on the popliteal artery, below the knee, on the basis of the appearance of the popliteal artery pulsation and angiography. The distal anastomosis was placed on the posterior tibial artery in 7 bypasses, anterior tibial artery in 5 cases. Intra-operative completion angiography was performed in all patients to assess the technical adequacy of the distal anastomosis. Local wounds debridement was done to all the patients **(Figure 2)**.

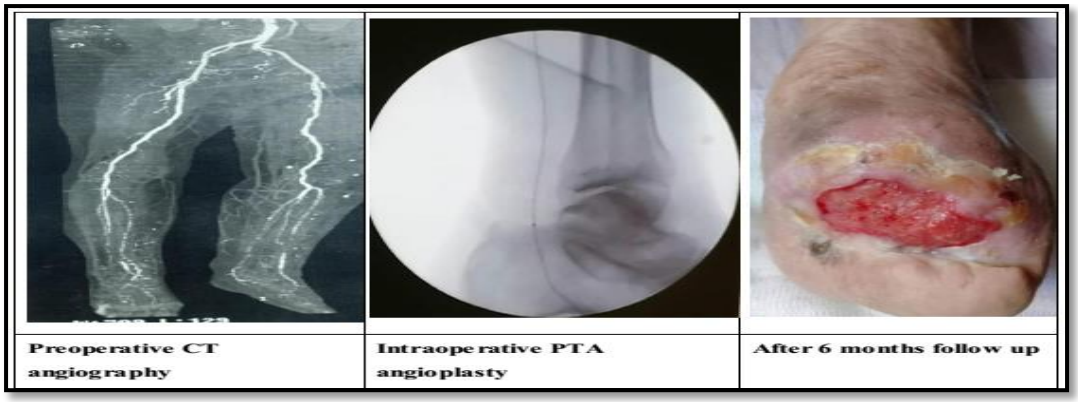

Figure (1): A case (67 years) old male, known case of diabetis melliates type II, hypertensive, presented with infected ischemic wet gangrene in left foot, no palpable distal pulse at the ankle level but the popliteal pulse was palpable, arterial doplex revealed monophasic waves on pedal vessels and ABI was 0.4 at posterior tibial artery. Post operative: patient had good general condition, foot warm by examination with good signals on posterior tibial artery, ABI post operative is 0.6.

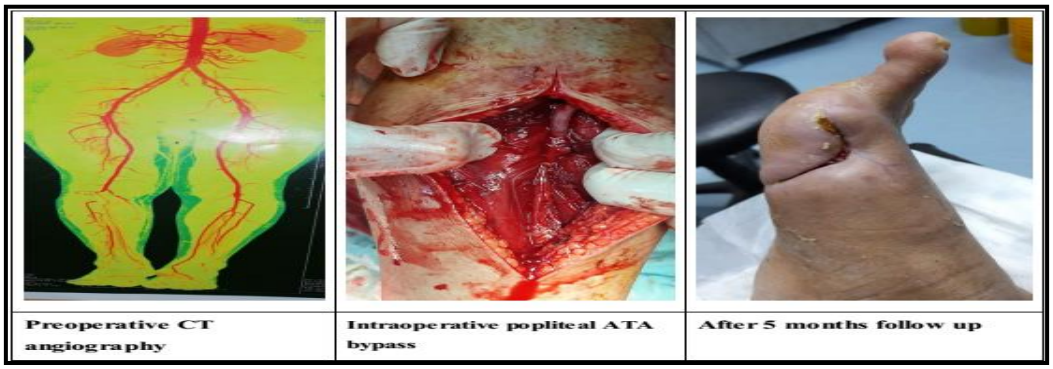

Figure (2): A caseof 69 years old male, known case Hypertensive on mangment, non diabetic, and x smoker, presented with infected ischemic dry gangrene in right foot , no palpable distal pulse at the ankle level but popliteal pulse was palpable, by Doppler u/s monophasic waves on posterior tibial artery only and, ABI was 0.38 at posterior tibial artery. Post operative: patient had good general condition, foot warm by examination with good signals on anterior tibial artery tibial artery, ABI post operative was 0.52.

Follow-up:

Follow up was done by the Rutherford recommended standards for reports dealing with lower extremity ischemia by using the life table and Kaplan-Meier survival curve. For every week till first month, then every 3 months. Early postoperative outcome. Success in relieving the patient compliant. Limb salvage for the two groups was demonstrated in another LT table. Hemodynamic improvement was assessed by ankle brachial pressure index (ABI), performed before and after the procedure and every 3-4 months. Complication associated with procedure. Re-stenosis or occlusion of the dilated arterial segment by duplex u/s. Time of wound healing and symptom relief.

Outcome:

The outcome for all patients was assessed focusing on the following end points as technical and clinical success and follow-up for primary patency at 1, 3, and 6, months.

Statistical analysis

Data were analyzed using IBM SPSS 23.0 for windows (SPSS Inc., Chicago, IL, USA) and NCSS 11for windows (NCSS LCC., Kaysville, UT, USA). Quantitative data were expressed as mean ± standard deviation (SD). Qualitative data were expressed as frequency and percentage. The following tests were done: Independent sample t- test, Mann-whitny test, Chi-square (X2) test and Fisher Exact test were used. Probability (P-value): P-value <0.05 was considered significant, P-value <0.001 was considered as highly significant and P-value >0.05 was considered insignificant.

RESULTS:

The study conducted in 24 patients with critical lower limb ischemia (CLI) due to Infragenicular lesions with mean age of 69.01±7.11 years (ranged, 55-75 years) and regard sex majority were male 16 and 8 females they allocated in two groups **(Figure 3 & 4)**.

Regarding the predisposing factors and medical history, the majority 75% of group 1, and 58.3 % of group 2 had had DM. The majority 41.7% of group 1 and 66.7% of group 2 were hypertensive patients. Also, there were 7 (58.3%) patients in group 1 and 4 (33.3%) patients in group 2 who were cardiac. In addition, there were 6 patients (50%) in group 1, and 9 patients' (75%) in group 2 with dyslipidemia respectively. Also, 92.6% of patients ing group I and all patients in group 2 were smoking. Statistically, there was no significant difference between studied groups in comorbidities as diabetes, hypertension, cardiovascular diseases, dyslipidemia and smoking ($p > 0.05$) **(Table 1)**.

About 25% of patients were complaining of (ischemic rest pain) in the first group versus 33.3% in the second one and 50% of them with minor tissue loss versus 41.7% in both groups respectively on other hand about 25% of cases in both groups suffered from major tissue loss. Statistically, there was no significant difference between groups regards main complain as rest pain and major or minor tissue loss. The majority of both groups had minor tissue loss **(Table 2)**.

There was no significantly difference associated with lesions length between the studied groups. The majority of lesions length was 5-10 cm in 10 (41.7%) patients, 5 (21%) patients had lesions length < 5 cm and 9 (37%) patients had lesions length ≥10 cm ($p > 0.05$) **(Table 3)**.

The arteries that underwent dilatation were 7 anterior tibial arteries, 5 posterior tibial artery, 7 distal popliteal artery and 8 peroneal arteries. Total number was more than our cases as more than one dilatation was done to the case **(Table 4)**.

The percentage of technical success was 58.3% in EVT group and 50% in bypass group. Regarding the percentage of hemodynamic success in EVT group was 83.3 % compared to 58.3% in bypass group. Statistically, there was a significant difference of hemodynamic success among the studied groups ($p = 0.04$). Additionally, there was no significant association of technical success between the studied groups ($p > 0.05$) **(Table 5)**.

There were two (16.7%) cases in EVT group versus 5 (41.7%) cases in bypass group undergoing to the major amputation. Statistically, there were significant differences in limb salvage between the studied groups ($p = 0.04$) **(Table 6)**.

The probability of artery patency in endovascular therapy group is higher than in bypass treatment in the 1st month, 2nd month and 4th month **(Table 7)**.

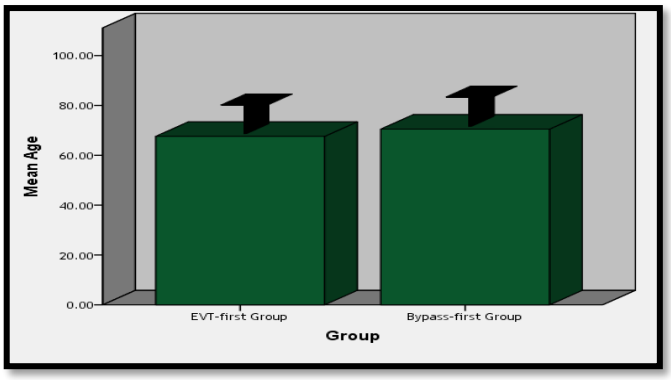

Figure (3): Mean age of the studied groups.

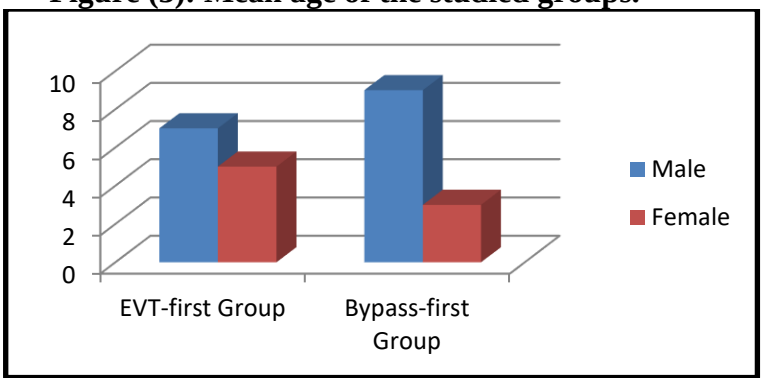

Figure (4): Sex distribution between studied groups.

Table (1): Co-morbidities and risk factors distribution between studied groups:

Variable	EVT Group (n=12)	Bypass Group (n=12)	χ^2	P value
DM Diabetic Non-diabetic	 9 (75%) 3 (25%)	 7 (58.3%) 5 (41.7%)	0.75	0.38 NS
HTN Yes No	 5 (41.7%) 7 (58.3)	 8 (66.7%) 4 (33.3%)	1.51	0.22 NS
CVD Yes No	 7 (58.3%) 5 (41.7%)	 4 (33.3%) 8 (66.7%)	1.51	0.22 NS
Dyslipidemia Yes No	 6 (50%) 6 (50%)	 9 (75%) 3 (25%)	1.6	0.21 NS
Smoking Yes No	 11 (92.6%) 1 (7.4%)	 12 (75%) 0 (0.0%)	0.68	0.41 NS

DM: Diabetes Mellitus, HTN: Hypertension, CVD: Cardiovascular Disease, χ^2:Chi square test, NS: Non significant (P>0.05)

Table (2): Main complain distribution between studied groups

Variable	EVT Group (n=12)	Bypass Group (n=12)	χ^2	P value
Rest pain				
Yes	3 (25%)	4 (33.3%)	0.202	0.65 NS
No	9 (75%)	8 (66.7%)		
Minor tissue loss				
Yes	6 (50%)	5 (41.7%)	0.16	0.68 NS
No	6 (50%)	7 (58.3%)		
Major tissue loss				
Yes	3 (25%)	3 (25%)	0.0	1.0 NS
No	9 (75%)	9 (75%)		

χ^2:Chi square test, NS: Non significant (P>0.05)

Table (3): Comparison between lesions length among the patients groups:

Lesions length	EVT Group (n=12)	Bypass Group (n=12)	χ^2	P value
< 5 cm	5 (41.7%)	0 (0%)	5.4	0.07 NS
5 – 10 cm	4 (33.3%)	6 (50%)		
≥ 10 cm	3 (25%)	6 (50%)		

χ^2:Chi square test, NS: Non significant (P>0.05)

Table (4): Arteries underwent PTA.

Variable	Anterior tibial artery	Posterior tibial artery	Distal popliteal Artery	Peroneal artery	Total No. of Sites
Number of dilatation (No. & %)	7(25.9%)	5(18.5%)	7(25.9%)	8 (29.6%)	27 (100%)

Table (5): Comparison between technical and hemodynamic success among the studied groups

Variable	EVT Group (n=12)	Bypass Group (n=12)	χ^2	P value
Technical Success				
Failed	5 (41.7%)	6 (50 %)	0.17	0.68 NS
Success	7 (58.3%)	6 (50 %)		
Hemodynamic Success				
Failed	2 (16.7%)	5 (41.7%)	4.44	0.04* S
Success	10 (83.3%)	7 (58.3%)		

χ^2:Chi square test, NS: Non significant (P>0.05), *:Significant (P<0.05)

Table (6): Limb salvage between studied groups.

Variable	EVT Group (n=12)	Bypass Group (n=12)	χ^2	P value
Amputation				
Yes	2 (16.7%)	5 (41.7%)	4.44	0.04* S
No	10 (83.3%)	7 (58.3%)		

χ^2:Chi square test, *: Significant (P<0.05)

Table (7): Comparison between infrapopliteal angioplasty and bypass with respect to artery patency and thrombosis.

Treatment	Follow-up time (months)						
	0	1	2	3	4	5	6
EVT							
Total	12	12	12	10	10	10	10
Thrombosis	0	0	2	0	0	0	0
Survival	12	12	10	10	10	10	10
Bypass							
Total	12	12	10	8	8	6	6
Thrombosis	0	2	2	0	2	0	0
Survival	12	10	8	8	6	6	6

DISCUSSION:

Critical limb ischemia (CLI) is one of the most widespread peripheral arterial diseases that lead to significant morbidity and mortality. The outcomes of developing CLI are often severe, from both economic and health-related quality-of-life stand-points; even after revascularization. At one year, about one third of patients have undergone amputation, only 25% of patients have resolution of their symptoms, 20% continue to have symptoms, and 25% are dead **(6).**

A mortality rate of 20% within 6 months after the diagnosis and 50% at 5 years has been reported **(7).** This excessive mortality may be related to the systemic cardiovascular diseases, including coronary artery disease and cerebrovascular arterial disease **(8)**.

For patients with CLI, surgical bypass grafting (preferably with autologous vein) remains the gold standard of revascularization, with 5-year limb salvage rates exceeding 80% in patients presenting with a non-healing ulcer or rest pain (**9**).

To date, there is still an open debate on the first-line strategy between open surgery and endovascular revascularization. Some studies discussed that angioplasty has shown good results in term of short-term survival, limb salvage, feasibility and complications which favorably made angioplasty as a tempting first-choice treatment in CLI patients especially for infrainguinal lesions **(10)**.

Regarding the risk factors and medical history, the current study showed the majority 75% of group 1, and 58.3 % of group 2 had had DM. The majority 41.7% of group 1 and 66.7% of group 2 were hypertensive patients. Also, there were 7 (58.3%) patients in group 1 and 4 (33.3%) patients in group 2 who were cardiac. In addition, there were 6 patients (50%) in group 1, and 9 patients' (75%) in group 2 with dyslipidemia respectively. Also, 92.6% of patients ing group I and all patients in group 2 were smoking. Statistically, there was no significant difference between studied groups in comorbidities as diabetes, hypertension, cardiovascular diseases,

dyslipidemia and smoking ($p > 0.05$). These findings were in accordance with the study of **Tsuchiya et al** (**11**).

The possibility of developing CLI is increased by well-recognized risk factors. **Fu et al. (12)** reported the literature published in the period between 2000 and 2014, using terms "angioplasty", "bypass", with CLI patients; which resulted in 7 trials met the inclusion criteria in the review. Therefore, the current study compared our patients' demographic characteristics, risk factors and comorbidities to those of patients in their meta-analysis.

Recently, **Metwally et al.** (**13**) demonstrated that, all of the studied patients were diabetics, half of them were hypertensive. Two thirds of their patients were smokers, and the largest percentage of them had positive history of coronary heart disease and hyperlipidemia.

According to the main complain distribution between studied groups, the current study revealed that 25% of patients were complaining of (ischemic rest pain) in the first group versus 33.3% in the second one and 50% of them with minor tissue loss versus 41.7% in both groups respectively. On other hand about 25% of cases in both groups suffered from major tissue loss. Statistically, there was no significant difference between groups regards main complain as rest pain and major or minor tissue loss. The majority of both groups had minor tissue loss. This finding was agreed with the study of **Tsuchiya et al** (**11**).

In surgical group in the current study, our results versus **Martini and Andreozzi (14)** who conducted a study on 90 patients with CLI underwent surgical management, show that patients were presented with rest pain (18, 4% vs. 31%) while patients major tissue loss (50% vs. 68%).

Regarding the lesions length, the current study shows no significantly difference associated with lesions length between the studied groups. The majority of lesions length was 5-10 cm in 10 (41.7%) patients, 5 (21%) patients had lesions length < 5 cm and 9 (37%) patients had lesions length ≥10 cm. In contrast, the study of **Kok et al**.(**15**) conducted to evaluate limb salvage, defined as freedom from major amputation, and to identify predictors of major amputation in patients with infrapopliteal PAD, the majority of patients were of long length lesions > 10 cm (77%), then patients with 5-10 cm lesion (21%) and lastly short segment lesion < 5 cm lesion (2%).

Our study was agree with **Mustapha et al.** (**16**) who reported the major predictive of clinical success were Rutherford category of patients, failure was more associated with tissue loss (P= 0.02), length of lesion, the longer the lesion the more failure (>10 cm) (P =0.041), type of the lesion, failure was associated with multiple and occlusive lesions (P =0.001) rather than stenotic and focal lesions.

According to site underwent PTA, the current study revealed that the arteries that underwent dilatation were 7 (25.9%) anterior tibial arteries; 5 (18.5%) posterior tibial artery; 7 (25.9%) distal popliteal artery and 8 (29.6%) peroneal arteries. Therefore, our result shows a total number arteries underwent PTA was more than our cases as more than one dilatation was done to the case. These findings are comparable to **Schmidt et al**. (**17**) conducted a study to investigate the efficacy of drug-eluting balloons (DEBs) in the treatment of long infrapopliteal lesions with regard to the short-term restenosis rate and midterm clinical result, and found that anterior tibial artery represents (57%), posterior tibial artery (19%), peroneal artery (21%) and distal popliteal artery (13%).

In comparison between technical and hemodynamic success among the studied groups, the current study revealed that, the percentage of technical success was 58.3%

in EVT-first group and 50% in bypass-first group. Regarding the percentage of hemodynamic success in EVT-first group was 83.3 % compared to 58.3% in bypass-first group. Statistically, there was a significant difference of hemodynamic success among the studied groups (p = 0.04)). In accordance to this cohort results; **Antoniou et al. (18)** reported technical and hemodynamic success rates of 100 and 95%, respectively, from 60 patients who underwent 61 single-step hybrid procedures.

Additionally, **Zou et al. (19)** and **Jung et al. (20)** reported technical success rates of 98 and 100%, respectively, following the same management protocol.

Regarding the follow-up for all patients; the current study illustrated that the probability of artery patency in endovascular therapy group is higher than in bypass treatment in the 1st month, 2nd month and 4th month. Most studies did not describe the standard use of best medical treatment or outcome for relief of ischemic pain, wound healing, or functional improvement.

Infrapopliteal angioplasty and bypass surgery both provide an acceptable limb salvage rate, but patency appears to be better after bypass surgery. Both modalities are likely to be complementary. Additional randomized trials are indicated to provide a treatment algorithm for patients with CLI and infrapopliteal arterial occlusive disease. Our findings were going with the studies of **Schamp et al. (21); Fekry et al. (22)**.

CONCLUSION:

Below-knee endovascular interventions have better management compared to open bypass for patients with critical limb ischemia. Also, fir patients with CLI, endovascular treatment has resulted in excellent technical success as well as limb salvage rates according to several case series.

Endovascular techniques are a viable treatment approach for limb salvage in patients with infrageniculate critical limb ischemia, and can be considered as a first-line approach in patients presenting with diabetes and/or tissue loss.

No Conflict of interest.

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