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1 **What is the secondary patency of thrombosed bypasses of the lower limbs cleared by**
2 **fibrinolysis in situ?**

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8 **ABSTRACT**^[SEP]**Objectives:** In case of acute thrombosis, lower limbs bypasses can, in certain
9 cases, be cleared by local intra-arterial fibrinolysis (LIF). The aim of this study was to evaluate
10 the secondary patency of thrombosed bypasses after fibrinolysis.^[SEP]**Methods:** This retrospective
11 study includes all patients hospitalized for thrombosed bypasses of the lower limbs that were
12 treated with in situ fibrinolysis using urokinase, between 2004 and 2013, in two French university
13 hospital centers. Fibrinolysis was indicated in case of recent thrombosis (< 3 weeks) provoking
14 acute limb ischemia without sensory-motor deficit and in the absence of general
15 contraindications. The secondary patency of the grafts was defined as the time after fibrinolysis
16 without a new thrombotic event.^[SEP]**Results:** There were 207 patients, hospitalized for recent
17 thrombosis of 244 bypasses. The LIF was efficient in 74% of the cases (n=180). Secondary
18 patency of these bypasses, was 54.2% and 32.4% overall, 68.3% and 50.3% for the supra-
19 inguinal bypasses and 48.3% and 21.5% for the infra-inguinal bypasses, at 1 year and 5 years
20 respectively. There is a significant difference (p = 0.002) regarding the permeability of the supra-
21 inguinal and infra-inguinal bypasses. The survival rate was 75% (\pm 6.4%) at 5 years and the limb
22 salvage rate was 89% (\pm 3.3%), 78.2% (\pm 5.1%) and 75% (\pm 5.8%) at 1 year, 3 years et 5 years
23 respectively. The only independent factor
24 influencing the secondary patency of infra-inguinal bypasses that was significant in a multivariate
25 analysis was the infragenicular localization of the distal anastomosis (p=0.023). **Conclusions:**
26 LIF is an effective approach that often allows the identification of the underlying cause,
27 permitting elective adjunctive treatment of the underlying cause. Although LIF is at least as
28 effective as its therapeutic alternatives described in the literature, the secondary patency of the
29 bypasses remains modest and encourages close monitoring, particularly in patients with an

30 infragenicular bypass.

31 **INTRODUCTION**

32 Acute limb ischemia might occur during the evolution of lower extremity arterial occlusive
33 disease, caused by a thrombosis in native arteries or bypasses, but also by emboli. The most
34 appropriate strategy for the management of thrombosis of bypasses in case of acute limb
35 ischemia is still debated by vascular surgeons. Local intra-arterial fibrinolysis (LIF), a technique
36 described since the 1980s, has a particular place in this strategy, for patients with thrombosis of
37 bypasses provoking acute limb ischemia without sensory-motor deficit⁽¹⁾. In that respect the goal
38 of LIF is to reestablish the arterial patency and to unmask the underlying cause of the thrombosis.
39 It allows the consecutive treatment of the underlying cause in order to prevent recurrence of the
40 thrombosis. The use of this technique has since been the subject of numerous publications that
41 report a percentage of success of clearance of bypasses of over 70%⁽²⁻⁹⁾. In our centers a
42 specific protocol for LIF, established and unchanged since more than 25 years, has similarly
43 demonstrated its effectiveness^(10,11). Primary patency of different bypasses of the lower limbs
44 has already exhaustively been reported in the literature. The primary patency rate of aorto-bi-iliac
45 and aorto-bifemoral bypasses are 91% and 87% at 5 and 10 years respectively for patients with
46 claudication and 87% and 82% at 5 and 10 years respectively for patients with acute ischemia
47^(12,13). The primary patency rate of infra-inguinal bypasses at 5 years varied from 55 to 64% for
48 venous bypasses and from 37-57% for prosthetic bypasses^(14,15). However few data are
49 available in the literature describing secondary patency at long term follow up of thrombosed
50 bypasses that have been cleared with LIF.

51 The primary end point of this retrospective study was to determine the long-term secondary
52 patency of thrombosed bypasses of the lower limbs, which underwent successful fibrinolysis. The
53 secondary end points of this study were to investigate the morbidity associated with LIF and to
54 research the possible factors influencing the permeability of the bypasses after LIF.

55 **MATERIALS AND METHODS**

56 **Population:**

57 This retrospective study includes all patients presenting at two university hospital centers (Angers
58 and Lyon) between January 2004 and December 2013, with acute lower limb ischemia without
59 sensory-motor deficit, provoked by acute thrombosis of a bypass, that have benefited from a
60 successful clearing by LIF.

61 Acute ischemia without deficits or subacute ischemia of the lower limbs is defined by the sudden
62 onset of lower limb pain or degradation of the patient's maximum walking distance. In order to
63 be eligible for fibrinolytic treatment, the duration of the symptoms of ischemia has to be less than
64 21 days and the ischemia should be classified as Rutherford Category IIa.

65 The protocol for fibrinolysis in situ was similar in both centers. The fibrinolytic agent used in our
66 study is urokinase (Actosolv®, Eumedica sa, Belgium), which is delivered intra-arterial in situ.
67 After an optional bolus of urokinase, a continuous infusion of 2500 IU/kg/h urokinase was
68 administered via a thrombolysis catheter, placed within the recent thrombus in combination with
69 100 IU/kg/12h heparin via a peripheral venous line.

70 Daily radiological monitoring was performed to verify the progression of the thrombolysis and
71 the achieving patency of arterial tree, and to allow the eventual repositioning of the catheter. The
72 criteria for stopping fibrinolysis were: success (complete clearance of the bypasses), the
73 occurrence of clinical complications (death, bleeding or hematoma requiring discontinuation of
74 LIF, acute renal failure (elevations of creatinemia greater than 25µmol / L with or without clinical
75 signs)) or biological complications (fibrinogen < 1g/L or a drop of more than 1g/L in 6hours,
76 platelets < 100.000/mm³, hemoglobin decreases and < 8g/dL) or technical failure (absence of
77 lysis of the thrombus after 72 hours of LIF).

78 The demographic data included: age, gender and cardiovascular risks factors. The following
79 information has been collected for the bypasses : localization (supra-/infra-inguinal, supra- /infra-
80 genicular), material (venous or prosthetic) and age.

81 Concerning the LIF procedure the following data have been collected: the duration of the
82 ischemia before the start of the LIF, the duration of the LIF, its success or failure, the eventual
83 complications, the etiology of the thrombosis if it was identified and the consecutive treatment of
84 the underlying cause if performed.

85 **Follow up:**

86 A follow-up was set up with a clinical examination and a Doppler ultrasound at 3 months, 6
87 months and once a year. The follow up of each patient was stopped at the date of the latest
88 doppler ultrasonography made to verify the permeability of the bypasses. For this purpose, a
89 direct follow-up with the doctors or the angiologists in charge of the patients was performed in
90 case of missing data. Eventual cases of recurrence of thrombosis or re-interventions on the same
91 limb and eventual amputation or mortality of the patients were searched and retrieved when
92 possible. The secondary patency of the grafts was defined as the time after fibrinolysis without a
93 new thrombotic event. In case of iterative thrombosis of bypasses cleared several times with LIF,
94 only the first LIF and the time until the following thrombosis were taken into account. For
95 patients lost to follow up or deceased, the follow up was stopped on the date of the last ultrasound
96 showing the patency of the bypasses.

97 **Statistical Analysis:**

98 The analyses were performed using the software Excel and SPSS (SPSSTM Inc, Chicago,
99 Illinois) version 15.0. The continuous variables are described in terms of means and standard
100 deviation or medians and extremes. The statistical link between two nominal qualitative variables
101 were performed using the chi-square test. Data on the patency of the bypasses were analyzed
102 using the Kaplan-Meyer method. Univariate and multivariate analysis of the factors influencing
103 the patency were made using regression logistic model.

104 **RESULTS**

105 From the two centers participating in the study, between January 2004 and December 2013, 371
106 LIF procedures of the lower limbs were performed. 127 of these LIF procedures were carried out
107 on native arteries or other specific circumstances and were therefore excluded from this study.
108 The other 244 LIF procedures on bypasses in 207 patients were included in this study. The
109 demographic characteristics are summarized in table I. The average age of the study population
110 was 66 ± 13 years. The distribution of the types of bypasses was as follows: 73 supra-inguinal
111 bypasses (30%) and 189 infra-inguinal bypasses (77,5%) (whereof 18 supra-inguinal with crural
112 extension), 71 infra-genicular (29%), 79 venous bypasses (32%) and 192 prosthetic bypasses

113 (78%) (whereof 27 composite bypasses). The median primary patency of the bypasses before the
114 first LIF was 4.5 years (2 months-24 years). The success rate of LIF was 74% (n=180). LIF was
115 successful with complete clearance in 87.3% of the supra-inguinal bypasses and 70% of the infra-
116 inguinal bypasses ($p = 0.002$). In the patients with successful fibrinolysis, an objective underlying
117 cause for the thrombosis was found in 85% of the cases (n=153). More specifically in 31% distal
118 anastomotic stenoses (n=56) and in 24% degradations of the arterial tree (n=43) were observed.
119 Etiological treatment, consecutive to the clearance was executed in 58% of the cases (n=104);
120 endovascular treatment in 39% of the cases (n=70), with implantation of stents in 17% of the
121 cases (n=30). Conventional direct surgical reparation was performed in 25% of the patients
122 (n=45), including 9.4% (n=17) for distal anastomosis repair.

123 For 3.9% (n=8) patients lost to follow up, the follow up was stopped on the date of the last
124 ultrasound showing the patency of the bypasses.

125 Secondary patency of the bypasses was 59% and 32% overall, 68% and 50% for the supra-
126 inguinal bypasses and 48% and 21.5% for the infra-inguinal bypasses, at 1 year and 5 years
127 respectively, with a significant difference between the latter two subgroups ($p = 0.002$). We have
128 respectively, 54% and 42% one year patency for prosthetic bypasses and venous bypasses
129 without statistically significant differences. Univariate analysis identified the infragenicular
130 localization of the distal anastomosis ($p = 0.006$) and the time of ischemia before the start of the
131 LIF < 48 hours ($p = 0.049$) as the only factors significantly influencing the secondary patency of
132 the bypasses (Table II). The infragenicular localization of the distal anastomosis appeared as the
133 only independent factor ($p = 0.023$) (OR = 2) influencing the secondary patency of the bypasses
134 in a multivariate analysis (Table II).

135 At the end of the follow-up, the survival rate of patients successfully treated with fibrinolysis was
136 82% ($\pm 5.2\%$) at 3 years and 75% at 5 years ($\pm 6.4\%$). The limb salvage rate of patients
137 successfully treated with fibrinolysis was 89% ($\pm 3.3\%$), 78.2% ($\pm 5.1\%$) and 75% ($\pm 5.8\%$) at 1
138 year, 3 years et 5 years respectively.

139 The complication rate of LIF was 18.4% (n=45), whereof 12% (n=30) were bleedings or
140 hematomas that necessitated discontinuation of LIF and 6% (n=15) were acute renal failures.
141 Surgery was indicated for the management of the complication in 2% of the cases (n=5). Two

142 deaths (0.8%) occurred during the LIF treatment. One patient of 83 years with atrial fibrillation
143 died of an ischemic stroke 3 hours after the start of LIF. Another patient of 60 years without
144 history of ulcers or a digestive tumor, had hematemesis on day 1 of the LIF; the bypass was
145 already cleared and the LIF was stopped. The patient died of hemorrhagic shock despite
146 resuscitation. The average hospital duration of LIF and consecutive treatments was 10 ± 7 days.
147 The mean follow-up of the patients after the procedure was 70 ± 39 months.

148 **DISCUSSION**

149 The management of patients with acute ischemia of the lower limbs without sensory-motor
150 deficit caused by bypasses thrombosis remains a complex situation for vascular surgeons. The
151 therapeutic strategy depends on the clinical status of the patient, the duration of the ischemia and
152 the suspected etiology of the thrombosis⁽¹⁶⁾. The treatment with LIF, which is usual
153 practice in the university hospitals of Angers and Lyon, relies on a well-established longstanding
154 protocol. The present study reports a 74% success rate of LIF, which is in line with what is found
155 in the literature^(2-4,5-9,17,18). This success rate decreases as the localization of the distal
156 anastomosis in the lower limb descends. At the infra-inguinal level there is no significant
157 difference between the prosthetic and venous bypasses regarding the success rate.

158 Although other fibrinolytic agents might be used, urokinase has several advantages, it represents
159 a lower risk of general fibrinolysis, a shorter infusion time and less antigenicity than for example
160 streptokinase^(5,6,8,19-21).

161 Importantly, a constant protocol, with close clinical and biological surveillance of the patient,
162 makes it possible to obtain an acceptable complication rate in comparison with other studies
163 (hemorrhagic risk of about 10%)⁽¹⁷⁻¹⁹⁾, with similar mortality rate found in the literature (0% to
164 5.2%)^(7,8,19,22).

165 Angioplasty with or without stenting of distal anastomotic stenoses was the most frequently used

166 adjunctive treatment. These results confirm those found in the data series of Van Holten⁽²³⁾. The
167 endovascular treatment further limits the complications related to iterative surgical access.
168 Nevertheless conventional surgical reinterventions remained indicated in 25% of the patients,
169 mainly to establish extensions of the bypasses in case of important damage to distal arterial
170 runoff or poor long-term results of an endovascular intervention.

171 The observed secondary patency of thrombosed bypasses treated with LIF is better than the
172 secondary patency found after fibrinolysis in the study of Nehler et al (59% vs 32% at 1 year and
173 32% vs 19% at 5 years)⁽¹⁷⁾. For infra-inguinal bypasses, the present study reports secondary
174 patency of 48% at 1 year and 31% at 2 years; these figures are still superior to the data reported
175 after LIF by Nackman et al (32% at 1 year and 25% at 2 years)⁽³⁾. In addition the results of this
176 study are included in the data ranges of 25%-60% secondary patency at 1

177 year found in other LIF studies^(2,9). For venous bypasses we found a secondary patency of only
178 42% at one year and of 12.5% at 5 years, which may seem disappointing in comparison to the
179 numbers of 65% at 5 years found after LIF by Conrad et al⁽¹⁸⁾. However, this difference might
180 be explained by the fact that in the current group of patients 72% of the venous grafts are
181 infragenicular. As in the current group of patients the infragenicular position of the distal
182 anastomosis is the main factor negatively influencing the secondary patency of the bypasses in
183 multivariate analysis (OR= 2(IC95% 1.1-3.59)), the secondary patency of the venous grafts is
184 thus majorly influenced by the localization of their local anastomosis (the higher the distal
185 anastomosis is localized, the better the secondary patency is).

186 Factors that have been described in the literature to influence secondary patency after LIF are:
187 primary patency longer than 1 year, the duration of the ischemia before the LIF, the localization
188 of the distal anastomosis and the treatment of the underlying lesion^(2-4,6,18). In the present
189 study, distal bypasses showed a significantly worse secondary patency in univariate (p=0,006)
190 and multivariate (p=0,023) analysis. This is in line with the data of Conrad⁽¹⁸⁾ which found
191 similar results in univariate analysis (p=0.02) but in their study the differences were not
192 significant in multivariate analysis (p=0.73). These results encourage close surveillance of

193 patients with infragenicular bypasses, which have the worst prognosis.

194 The limb salvage rate in our data series are comparable to the one of Kühn and Conrad after
195 fibrinolysis ^(19,18) and is better than the one presented in the LIF data series of Ouriel ^(5,7),
196 however it is important to note that in our series we only took into account the patients that were
197 successfully treated with fibrinolysis. The long-term mortality of the study population in our data
198 series is also comparable to the one at 5 years of Conrad ⁽¹⁸⁾.

199 The design of this study does not allow the direct comparison of LIF with other therapeutic
200 interventions for subacute limb ischemia. Nevertheless, the therapeutic alternatives for LIF for
201 the treatment of subacute limb ischemia caused by thrombosis of bypasses of the lower limbs
202 are: thrombectomy with a Fogarty catheter and revascularization with another bypass. Only few
203 prospective randomized studies have compared the patency after LIF with immediate surgery
204 (associated or not with thrombectomy) for the treatment of subacute limb ischemia caused by
205 thrombosis of bypasses of the lower limbs, no clear differences could be found in these
206 comparisons. In non-comparative studies the overall patency that has been described after
207 thrombectomy with a Fogarty catheter was 20-30% at 5 years for venous bypasses and 30% at 2
208 years for prosthetic bypasses, the authors also found that early treatment of bypass is preferable
209 (ideally within 24h to obtain the best secondary patency) ^(24,25). The patency that has been
210 described after repetitive revascularization with bypasses was around 50% at 5 years for venous
211 bypasses and 25% at 5 years for prosthetic bypasses, with 25% of complications related to the
212 access points ^(7,8,9,26). The retrospective data series of Baril found a patency of 82% at 1 year
213 for bypasses in the context of acute limb ischemia, but only 33% of the cases of acute limb
214 ischemia were due to bypasses thrombosis ⁽²⁷⁾.

215 Prospective, randomized studies that compare morbidity and mortality outcomes between LIF
216 and alternative therapeutic strategies are limited to 1 year follow-up. The STILE trial⁽⁸⁾
217 concluded after 1 year of follow-up that in the overall population, there was no significant
218 difference between LIF and surgery. However, in subgroup analysis, this prospective,
219 randomized study advocated the choice of LIF, for limb ischemia of less than 14 days and

220 surgery for limb ischemia of more than 14 days. For patients with limb ischemia of less than 14
221 days, the limb salvage rate was 87.7% for LIF and 62.5% for surgery and the survival rate was
222 94.4% for LIF and 90% for surgery at 6 months.

223 In non-comparative studies Baril⁽²⁷⁾ found 78% limb salvage and 79% survival rate at 1 year in
224 the data series of acute limb ischemia (whereof only 32.8% were on bypasses) revascularized
225 with bypasses in comparison to 89% limb salvage rate and 92% survival rate at 1 year, in

226 current data series. In a long-term follow-up, Barlett⁽²⁶⁾ found a 59% limb salvage rate at 5
227 years for repetitive revascularization surgery, in comparison with 75% in current data series and a
228 mortality similar to current data series at 5 years.^[1] Although LIF appears better than surgery in
229 terms of limb salvage, it is not pertinent to compare LIF with surgery, LIF must be an integral
230 part of the therapeutic arsenal of surgeons. In this way, it can delay or limit the need for urgent
231 conventional surgery. As a matter of fact, conventional surgery itself presents with its own
232 important complications, such as cutaneous complications or infections related to repetitive
233 access in sclerotic areas, major in hospital adverse events⁽²⁷⁾ and problems of material for the
234 establishment of repetitive bypasses in fragile patients.

235 Despite our large population, our data series has some limitations essentially because it is a
236 retrospective study that does not compare LIF with other therapies; nevertheless our data further
237 confirms the place of LIF for the clearing of thrombosed bypasses of the lower limbs.

238 **CONCLUSION**

239 Bypasses thrombosis remains a serious event in the evolution of arterial occlusive disease of the
240 lower limbs. In situ fibrinolysis of bypasses of the lower limbs is a safe and effective
241 pharmacological thrombus-removing approach that, if successful, often allows the identification
242 of the underlying cause, allowing elective adjunctive treatment of the cause of thrombosis. As
243 such it should be a part of the arsenal of vascular surgeons. Although LIF is at least as effective
244 as its therapeutic alternatives described in the literature, the secondary patency of the bypasses
245 remains modest and encourages close monitoring, particularly in patients with infragenicular
246 bypasses.

247 **Declarations of interest: none**

248 **Author contributions**

249 Conception and design: TK, JP, SH, PF, MA Analysis and interpretation: TK, JP Acquisition of
250 data: TK, NDS^[1]_{SEP} Writing the article: TK, JP, MA

251 Critical revision of the article: TK, JP Final approval of the article: TK, JP Overall responsibility:
252 TK, JP

253 **Opinion of the ethics committee:**

254 This study was submitted to the ethics committees of Angers and Lyon university hospitals and
255 obtained a favorable opinion. It was conducted in accordance with the rules of ethics and the
256 protection of medical confidentiality.

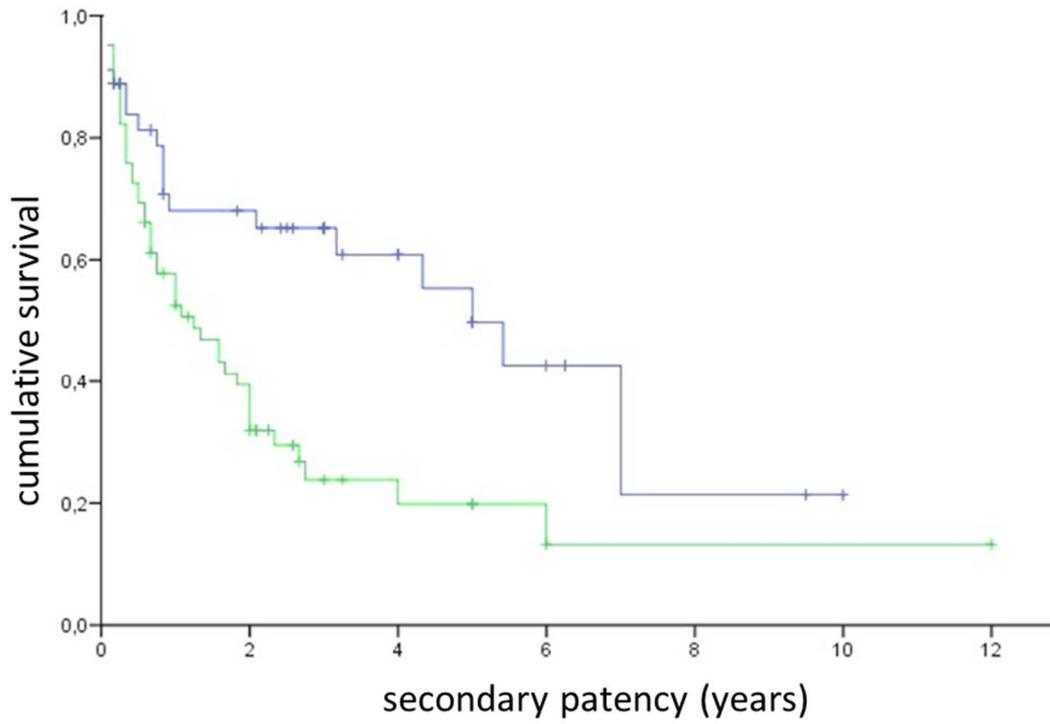
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- 332



	73	44	40	30	15	12	11	supra-inguinal grafts
Patients at risk	189	80	55	27	13	14	5	infra-inguinal grafts

Fig 1: Curve of secondary patency of supra-inguinal grafts (blue line) and of infra-inguinal grafts (green line) ($p=0,002$).

Table I: Demography

<i>Demography</i>	<i>n(%)</i>
Men	165(80)
Diabetes	50(24)
Arterial hypertension	186(90)
Active tobacco use	76(37)
Dyslipidemia	165(80)
Coronary artery disease	64(31)
Anticoagulant therapy	35(17)
Anti aggregate therapy	196(95)

Tableau II: Univariate and Multivariate analysis of factors and their influence on the patency of the bypasses

<i>Factors</i>	Univariate analysis	Multivariate analysis		
	<i>p</i>	<i>n</i> (%)	<i>p</i>	<i>OR</i> (<i>IC95%</i>)
Infragenicular bypasses	0.006	57(81%)	0.023	2(1.01-3.56)
Ischemia ≤ 48h	0.049	81(80%)	0.141	1,46(0.88-2.42)
Age of the bypasses > 1 an	0.512	107(66%)	0.835	1.06(0.6-1.89)
Identification of the underlying lesion	0.711	133(65%)	0.443	0,77(0.39-1.5)
Treatment of the underlying lesion	0.734			
Surgical treatment	0.141			
Chronic renal failure	0.45			
Tobacco	0.199			
Arterial hypertension	0.795			
Diabetes	0.637			
Coronary artery disease	0.439			
Cancer	0.834			