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Research

Intracranial Atherosclerotic Disease: Do New-Generation Stents Have Better Effect Than Medical Therapy?

İntrakranial Aterosklerotik Hastalık: Yeni Nesil Stentler Tıbbi Tedaviden Daha mı Etkili?

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ABSTRACT

Objective: To compare the results of stenting and medical therapy in patients with intracranial atherosclerotic disease (ICAD).
Methods: Twenty patients treated between August 2021 and April 2024 were retrospectively analyzed.
Results: Age, occlusion site, dual antiplatelet therapy and score-ICAD were statistically significant in patients who underwent intracranial stenting.
Conclusion: Due to the innovations in interventional medicine, stenting may be a better option than medical treatment for patients with ICAD.
Keywords: Intracranial atherosclerotic disease, stenting, medical therapy

ÖZ

Amaç: İntrakranial aterosklerotik hastalığı (İKAH) olan hastalarda stentleme ve tıbbi tedavi sonuçlarını karşılaştırmak.
Gereç ve Yöntem: Ağustos 2021 ile Nisan 2024 arasında tedavi edilen yirmi hasta retrospektif olarak analiz edildi.
Bulgular: İntrakranial stentleme uygulanan hastalarda yaş, oklüzyon yeri, ikili antiplatelet tedavi ve score-İKAH istatistiksel olarak anlamlıydı.
Sonuç: Girişimsel tıptaki yenilikler nedeniyle, İKAH'lı hastalar için stentleme tıbbi tedaviden daha iyi bir seçenek olabilir.
Anahtar Kelimeler: İntrakranial aterosklerotik hastalık, stentleme, medikal tedavi

INTRODUCTION

Intracranial atherosclerotic disease (ICAD) is a considerable risk factor for ischemic stroke. The incidence varies among different populations. ICAD is estimated to represent 8%-46% of cases worldwide (1-3).

Treatment modalities show a difference between acute management and secondary prevention (4). Higher risk of failure of recanalization and poor prognosis were observed in patients with ICAD-related large vessel occlusion (LVO) compared to LVO of other causes (5). Rescue therapy is often required after failure of recanalization and may include intra-arterial antiplatelets such as glycoprotein IIb/IIIa inhibitors or intravenous prasugrel, antithrombotic agents, angioplasty, stenting, or a combination of the above (4,6).

Secondary prevention consists of medical therapy, including the most recommended dual anti-platelet therapy (DAPT), risk factor control, i.e., appropriate management of hypertension (HT), diabetes, hyperlipidemia (HL), obesity, smoking, and physical activity, MF, (angioplasty and stenting), and surgical treatments such as encephaloduroarteriosynangiosis (1,4,7).

In the current study, the aim was to compare the results of stenting and medical therapy in patients with ICAD.

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METHODS

Participants

We retrospectively reviewed the medical records of all patients with symptomatic ICAD between August 2021 and April 2024. Inclusion criteria were: (1) age >18 years, (2) anterior or posterior circulation intracranial artery stenosis of at least 70%, (3) ischemic stroke or transient ischemic attack (TIA) in the previous 3 months, (4) undergoing stenting or receiving best medical therapy. Patients with non-atherosclerotic stenosis such as vasculitis or dissection, and patients with LVO due to ICAD who underwent acute EVT were excluded. This study University of Health Sciences Türkiye, Ümraniye Training and Research Hospital Scientific Research Ethics Committee (number: B.10.1.TKH.4.34.H.GP.0.01/41, date: 08.02.2024).

Data Collection and Follow-Up Outcomes

For each subject, baseline characteristics (age, sex, co-morbid diseases), onset time, antithrombotic drugs prior to onset, modified Rankin Scale (mRS) score prior to onset, National Institutes of Health Stroke Scale (NIHSS) score at admission, major arterial stenosis site, type of stenting devices, intraprocedural administration of loading antiplatelets, procedural complications, degree of reperfusion, continuation of medications, and CHA_2DS_2-VASc were evaluated. Blood glucose, blood pressure, and lipid profiles at admission were recorded.

Definitions

European Cooperative Acute Stroke Study II criteria were used for defining intracranial hemorrhage. Symptomatic intracerebral hemorrhage was defined as any hemorrhage associated with a worsening of the NIHSS score ³4 within 24 hours. Extracranial complications were defined as pneumonia, urinary tract infections, acute renal failure, hematuria and gastrointestinal bleeding. CHA_2DS_2-VASc is a score, that can help to determine the one-year risk of thromboembolism events in non-anticoagulant patients with non-valvular atrial fibrillation (AF). The other parameters were age, sex, history of congestive heart failure, HT, cerebral and peripheral arterial disease, and diabetes. Follow-up was conducted through telephone interviews or outpatient clinic visits. mRS of ≤2 was considered a good clinical outcomes. At the follow-up day 90, 1 year and 2 years, patients were divided into three groups: good prognosis (mRS ≤2), poor prognosis (2< mRS ≤5) and mortality (mRS=6). Score-ICAD (8) is a 20-point scale: absence of AF (5); vascular risk factor burden (1) for each of HT, diabetes, smoking, and HL, multifocal single artery stenoses on CT angiography (3); absence of territorial cortical infarct (3); presence of borderzone infarct (3), and ipsilateral carotid siphon calcification (2).

Stenting Procedure

The stenting procedure was performed using a standard transfemoral approach, under general anesthesia. A bolus of 70-100 IU/kg of heparin was given intravenously immediately after insertion of the long femoral sheath. A long guiding sheath was placed within the cervical internal carotid artery (ICA) or vertebral artery. A 6-French distal access catheter [Fargo (Balt Extrusion, Montmorency, France), Neuron (Stryker, Fremont, California, USA), or Navien (Covidien, Irvine, California, USA)] was then placed coaxially within the guiding sheath. The stenotic segment was bypassed with a balloon catheter (NeuroSpeed; Acandis GmbH, Pforzheim, Germany). The balloon was inflated slowly at the level of stenosis, and the Credo stent (Acandis GmbH, Pforzheim, Germany) was deployed through the balloon catheter. A critical stenosis in the middle segment of the basilar artery and a stenosis in the M1 segment of the middle cerebral artery (MCA) before and after the stenting procedure are shown in figures 1 and 2.

Prior to the intervention, all the patients were mostly on DAPT with aspirin and ticagrelor. DAPT was continued for at least 6 months, after which it was switched to monotherapy, usually as 100 mg aspirin. Management of other risk factors such as blood pressure, HL, and diabetes was done.

Statistical Analysis

Number (n) and percentage (%) values were used to show the distribution of individuals within demographic categories.

The suitability of the continuous variables in the study for normality was evaluated graphically and with the Shapiro-Wilk test. Mean ± standard deviation and Median (minimum-maximum) values were used to display the descriptive statistics of the variables.

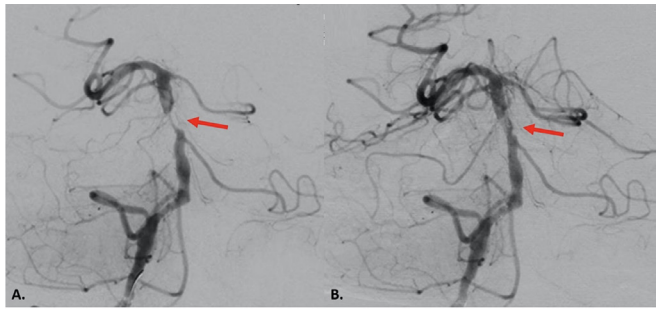

Figure 1. Right vertebral artery injection (A) shows a critical stenosis (arrow) in the middle segment of the basilar artery, in a 79-year-old man with a medical history of recurrent posterior system strokes. After deployment of the Credo (Acandis) and Elvis Evo (MicroVention, Aliso Viejo, CA, USA) stents, the right vertebral artery injection (B) shows restored flow in the stenotic segment (arrow)

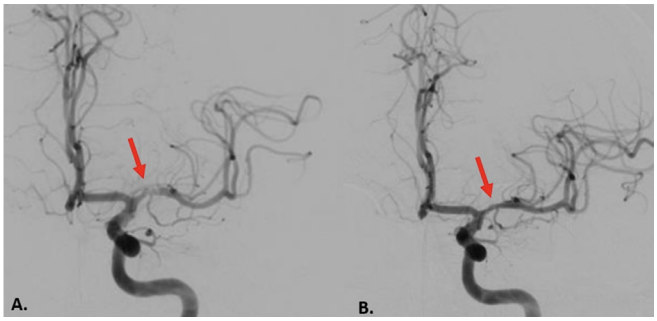

Figure 2. Left internal carotid artery injection (A) shows a stenosis (arrow) in the M1 segment middle segment of the middle cerebral artery, in a 64-year-old woman with a medical history of recurrent left hemispheric strokes. After deployment of the Credo stent (Acandis), the left internal carotid artery injection (B) shows restored flow in the stenotic segment (arrow)

Independent sample t-test, CHA_2DS_2-VASc score, arrival glucose, systolic blood pressure, NIHSS, mRS, 24th hour NIHSS, Mann-Whitney U test was used to compare 90th day mRS, exit treatment time, and triglyceride values.

Cross tables were created to compare categorical variables according to intracranial stent placement status, and number (n), percentage (%), and chi-square (c^2) test statistics were given.

IBM SPSS Statistics 21.0 (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) and MS-Excel 2007 programs were used for statistical analyses and calculations. The statistical significance level was accepted as a $p<0.05$.

RESULTS

A total of 20 patients met the inclusion criteria. The average age of the patients participating in the study was 70.45±8.27 years. Forty percent (n=8) of the patients were female and 60.0% (n=12) were male. HT was present in 19 patients (95.0%), diabetes mellitus in nine (45.0%), HL in eight (40.0%), coronary artery disease in six (30.0%), cerebrovascular disease in six (30.0%), TIA in nine (45.0%). Four patients (20.0%) were found to have AF. At admission, 35.0% (n=7) of the patients had no antiplatelet therapy, 50.0% (n=10) had monotherapy, 10.0% (n=2) had DAPT, and 5.0% (n=1) had anticoagulant and antiplatelet therapy. The average CHA_2DS_2-VASc score of patients was 5.20±1.24. There were three patients with direct oral anticoagulant (15.0%) and four with anti-lipid treatment (40.0%). The mean serum glucose level at admission was 139.95±66.47 mg/dL, the systolic blood pressure average was 161.20±26.15, the diastolic blood pressure average was 86.85±12.17, the mRS average was 0.20±0.52, and the NIHSS average was 1.90±2.57. Thirty-five percent (n=7) of the stenosis site sites were basilar, 55.0% (n=11) were MCA, 5.0% (n=1) were ICA, and 5.0% (n=1) were vertebral. The average post-stroke elective stenting period was 22.93±20.27 days. Additionally, it was found that 10 patients (71.5%) had Credo 4x20, two (14.3%) had Credo 3x20, and one (7.1%) had Credo 4x15 and Credo 5x20. The 24th hour NIHSS was 2.05±2.66. There were two patients (10.0%) with hemorrhagic transformation in the stenting group. The 90th day mRS was 0.80±1.06. While 70.0% (n=14) of the patients had an intracranial stent, 30.0% (n=6) were treated with medical therapy. The discharge treatment of patients was as follows: 45.0% (n=9) received aspirin+ticagrelor, 30.0% (n=6) received aspirin+clopidogrel, 10.0% (n=2) received monotherapy with ticagrelor, 10.0% (n=2) received apixaban+clopidogrel, and 5.0% (n=1) received aspirin+ticagrelor+rivaroxaban. The average treatment time was 8.72±7.13 months. The total cholesterol was 190.20±60.52 mg/dL, the low-density lipoprotein cholesterol, was 120.35±53.22 mg/dL, the high-density lipoprotein cholesterol was 41.95±10.75 mg/dL, the triglycerides were 147.65±77.89 mg/dL, and the ICAD score was 15.00±2.92 (Table 1).

The average age of patients who were treated with medical therapy was 76.50±7.56 years, and the average age of patients who underwent intracranial stenting was 67.86±7.34 years. A statistically significant difference was detected between the ages of patients based on stenting status ($t=2.394$, $p=0.028$). The stenosis site was MCA in all (n=6) patients with medical therapy; basilar was the stenotic site in 50.0% (n=7) of patients who underwent stenting; MCA in 35.8% (n=5); and others (ICA and vertebral) in 14.2% (n=2). A statistically significant difference was detected in terms of site of stenosis in the stenting group ($\chi^2=7.013$, $p=0.038$). The discharge treatment was aspirin+clopidogrel in the medical therapy group (n=6). Aspirin+ticagrelor was given in 64.3% (n=9) of the patients who underwent stenting, and apixaban+clopidogrel was the discharge treatment in 14.3% (n=2). Two patients had mono ticagrelor, and one had aspirin+ticagrelor+rivoraxaban. A statistically significant difference was detected in terms of discharge treatment in the stenting group ($\chi^2=17.642$, $p<0.001$). The average ICAD score was 13.33±2.58 for patients with medical therapy, and 16.67±2.34 for patients with stenting. A statistically significant difference was seen between the ICAD scores of patients ($t=2.334$, $p=0.041$). No statistically significant difference was detected in other parameters ($p>0.05$). No stent restenosis was seen in the study group (Table 2).

Table 1. Demographic characteristics of study group

	All patients (n=20)
Age (year) Avr±SD	70.45±8.27
Gender, n (%)	
Female	8 (40.0)
Male	12 (60.0)
Co-morbidities, n (%)	
HT	19 (95.0)
DM	9 (45.0)
HL	8 (40.0)
PAD	0 (0.0)
CAD	6 (30.0)
CVD	12 (60.0)
TIA	9 (45.0)
CHF	0 (0.0)
AF	4 (20.0)
Admission antiplatelet, n (%)	
Non	7 (35.0)
Mono	10 (50.0)
Dual	2 (10.0)
With Anticoagulant	1 (5.0)
Cha_2ds_2vasc Avr±SD	5.20±1.24
Doac, n (%)	
No	17 (85.0)
Yes	3 (15.0)
Anti-Lipid, n (%)	
No	12 (60.0)
Yes	8 (40.0)
Admission glucose Avr±SD	139.95±66.47
Admission systolic pressure Avr±SD	161.20±26.15
Admission diastolic pressure Avr±SD	86.85±12.17
mRS Avr±SD	0.20±0.52
NIHSS Avr±SD	1.90±2.57
Stenosis site, n (%)	
Basilar	7 (35.0)
MCA	11 (55.0)
ICA	1 (5.0)
Vertebral	1 (5.0)
***Time to stenting** (day) Avr±SD	22.93±20.27
24 hour NIHSS Avr±SD	2.05±2.66
90 Day mRS Avr±SD	0.80±1.06
Intracranial stent, n (%)	
No	6 (30.0)
Yes	14 (70.0)
Discharge treatment, n (%)	
Asa + ticagrelor	9 (45.0)
Asa + ticagrelor + rivoraxaban	1 (5.0)
Apixaban + clopidogrel	2 (10.0)
Mono ticagrelor	2 (1.00)
Asa + clopidogrel	6 (30.0)
Discharge treatment period (month) Avr ± SD	8.72±7.13
Stent re-stenosis, n (%)	
No	20 (100.0)
Total Cholesterol Avr±SD	190.20±60.52
LDL-C Avr±SD	120.35±53.22
HDL-C Avr±SD	41.95±10.75
Triglyceride Avr±SD	147.65±77.89
ICAD score Avr±SD	15.00±2.92

*Only stenting patients
SD: Standard deviation, HT: Hypertension DM: Diabetes mellitus, HL: Hyperlipidemia, PAD: Peripheral artery disease,
CAD: Coronary artery disease, CVD: Cerebrovascular disease,
TIA: Transient ischemic attack, CHF: Congestive heart failure,
AF: Atrial fibrillation, mRS: Modified Rankin Scale, NIHSS: National Institutes of Health Stroke Scale, MCA: Middle cerebral artery, ICA: Internal carotid artery, Asa:
LDL-C: Low-density lipoprotein cholesterol, HDL-C: High-density lipoprotein cholesterol, ICAD: Intracranial atherosclerotic disease

DISCUSSION

Age, stenosis site, DAPT, and score-ICAD were statistically significant in patients who underwent intracranial stenting in this study.

EVT of ICAD is in evolution (1). Stenting vs Aggressive Medical Therapy for Intracranial Artery Stenosis and the Vitesse Intracranial Stent Study for Ischemic Stroke Therapy trials showed worse prognosis in the stenting group than in patients with medical therapy (9,10). As a result, EVT with intracranial angioplasty and/or stenting is not recommended as a first-choice treatment (1,4,5,7). EVT of LVO strokes due to ICAD is also challenging (11,12). In our study, we compared the patients who had symptomatic ICAD and underwent stenting for secondary prevention with patients who had symptomatic ICAD and were treated with medical therapy.

Age is a non-modifiable risk factor for atherosclerosis, and the incidence of ICAD increases with age (13). In our study, there was a statistically significant difference in age between groups. In the stenting group, the population was younger. Serious adverse events were more commonly associated with increased age in patients who underwent intracranial stenting due to ICAD (14). Younger age was associated with new or recurrent infarcts in post hoc analysis of mechanisms of early recurrence in ICAD (15). Adverse events and the risk of recurrent stroke in the young patient population would influence operator choice when deciding on stenting.

Table 2. Comparison of stenting versus medical therapy

	Intracranial stent			
	No (n=6)	**Yes (n=14)**	**Test statistics**	
	Avr±SD Median (Min.-Max.)	**Avr±SD Median (Min.-Max.)**	**t; c^2; z**	**p-value**
Age (year)	76.50±7.56	67.86±7.34	t=2.394	0.028
	76.0 (66-89)	67.0 (56-81)		
Gender, n (%)				
Female	4 (66.7)	4 (28.6)	-	0.137*
Male	2 (33.3)	10 (71.4)		
Comorbidities, n (%)				
HT	5 (83.3)	14 (100.0)	-	0.300*
DM	1 (16.7)	8 (57.1)	-	0.119*
HL	2 (33.3)	6 (42.9)	-	0.545*
CAD	1 (16.7)	5 (35.7)	-	0.387*
CVD	3 (50.0)	9 (64.3)	-	0.455*
TIA	3 (50.0)	6 (42.9)	-	0.574*
AF	1 (16.7)	3 (21.4)	-	0.657*
Admission antiplatelet, n (%)				
No	2 (33.3)	5 (35.7)	=1.569	0.870
Mono	4 (66.7)	6 (42.9)		
Dual	0 (0.0)	2 (14.3)		
With anticoagulant	0 (0.0)	1 (7.1)		
Cha_2ds_2vasc	5.50±0.84	5.07±1.38	z=0.646	0.547
	6.0 (4-6)	5.0 (3-7)		
Doac, n (%)				
No	6 (100.0)	11 (78.6)	-	0.319*
Yes	0 (0.0)	3 (21.4)		
Anti-Lipid				
No	3 (50.0)	6 (64.3)	-	0.455*
Yes	3 (50.0)	5 (35.7)		
Admission glucose	129.00±68.02	144.64±67.81	z=1.279	0.207
	106.0 (85-265)	118.0 (96-343)		
Admission systolic pressure	168.33±24.63	158.14±27.06	z=0.829	0.444
	175.0 (130-200)	150.0 (120-225)		
Admission diastolic pressure	89.33±15.51	85.79±10.95	t=0.587	0.565
	85.0 (70-110)	83.0 (70-110)		
mRS	0.00±0.00	0.29±0.61	z=1.195	0.494
	0.0 (0-0)	0.0 (0-2)		
NIHSS	2.50±3.89	1.64±1.91	z=0.177	0.904
	0.0 (0-8)	1.5 (0-6)		
Stenosis site, n (%)				
Basilar	0 (0.0)	7 (50.0)	=7.013	0.038
MCA	6 (100.0)	5 (35.8)		
Other	0 (0.0)	2 (14.2)		
24 Hour NIHSS	2.17±3.37	2.00±2.45	z=0.353	0.779
	0.0 (0-7)	1.5 (0-8)		

Table 2. Continued

	Intracranial stent			
	No (n=6)	**Yes (n=14)**	**Test statistics**	
	Avr±SD Median (Min.-Max.)	**Avr±SD Median (Min.-Max.)**	**t; c^2; z**	**p-value**
Hemorrhagic transformation, n (%)				
No	6 (100.0)	12 (85.7)	-	0.479*
Yes	0 (0.0)	2 (14.3)		
90 Day mRS	0.17±0.41	1.07±1.14	z=1.945	0.076
	0.0 (0-1)	1.0 (0-3)		
Discharge treatment, n (%)				
Asa+ticagrelor	0 (0.0)	9 (64.3)	=17.642	<0.001
Asa+ticagrelor+rivaroxaban	0 (0.0)	1 (7.1)		
Apixaban+clopidogrel	0 (0.0)	2 (14.3)		
Mono ticagrelor	0 (0.0)	2 (14.3)		
Asa+clopidogrel	6 (100.0)	0 (0.0)		
Treatment time (month)	14.17±10.93	6.00±0.0	z=1.549	0.291
	15.0 (1-24)	6.0 (6-6)		
Total cholesterol	203.83±59.55	184.36±62.18	t=0.649	0.524
	211.5 (104-286)	185.0 (105-337)		
LDL-C	126.50±54.40	117.71±54.56	t=0.330	0.745
	131.0 (38-208)	111.5 (29-231)		
HDL-C	46.67±8.31	39.93±11.29	t=1.309	0.207
	47.0 (34-59)	40.0 (11-56)		
Triglyceride	151.67±60.64	145.93±86.28	z=0.660	0.547
	157.0 (78-247)	126.0 (63-366)		
ICAD score	13.33±2.58	16.67±2.34	t=2.334	0.041
	13.5 (9-17)	17.0 (14-19)		

SD: Standard deviation, Min.: Minimum, Max.: Maximum, HT: Hypertension DM: Diabetes mellitus, HL: Hyperlipidemia, CAD: Coronary artery disease, CVD: Cerebrovascular disease, TIA: Transient ischemic attack, AF: Atrial fibrillation, mRS: Modified Rankin Scale, NIHSS: National Institutes of Health Stroke Scale, LDL-C: Low-density lipoprotein cholesterol, HDL-C: High-density lipoprotein cholesterol, ICAD: Intracranial atherosclerotic disease

In this study, there were seven patients with basilar ICAD, and all underwent stenting. There are studies showing that recurrent stroke/ TIA rates were higher in patients with symptomatic posterior-circulation ICAD (5). Furthermore, basilar artery strokes are one of the most devastating neurological conditions (16). This would explain the tendency for stenting basilar ICAD.

DAPT is recommended for patients with symptomatic ICAD (17). The data is unclear regarding the choice of aspirin and clopidogrel or aspirin and ticagrelor as DAPT following stenting. In our center, due to the risk of clopidogrel resistance, there is a tendency to choose aspirin and ticagrelor treatment, and continue maintenance for six months in patients undergoing intracranial stenting. There was a statistically significant difference in post-stenting therapy. Aspirin and ticagrelor as DAPT were a significant therapy.

A Tarek et al. (8) developed and validated a scoring system for pre-thrombectomy diagnosis of ICAD (8). They showed that scores ≥12 were associated with 90% specificity and 63% sensitivity. In our study, the average ICAD score was 15. The score was higher in the stenting group, and the difference was statistically significant. The Score-ICAD may be useful not only for pre-thrombectomy but also for elective stenting. This Score-ICAD also underlines the vascular risk factors, so patients with excess might be candidates for stenting in our study.

Recent data suggest that delayed stenting, a mean of 21 days or longer, post event may be potentially superior to medical therapy (1). In our study, the average time from symptom onset to stenting was 22 days. No in-stent restenosis was seen in our series.

Study Limitations

There are some limitations in the present study. This was a retrospective study, and the sample size was small. Clopidogrel resistance was not evaluated in all patients. Only the Credo stent was used for the stenting of the lesions.

CONCLUSION

In conclusion, with new-generation stents, stenting may have a greater role in the secondary prevention of ICAD than the best medical treatment. Further studies are needed.

ETHICS

Ethics Committee Approval: This study University of Health Sciences Türkiye, Ümraniye Training and Research Hospital Scientific Research Ethics Committee (decision no: 234344965, date: 08.02.2024).

Informed Consent: Retrospective study.

FOOTNOTES

Authorship Contributions

Surgical and Medical Practices: L.R., I.K.A., M.V., Consept: L.R., Design: LR., Data Collection or Processing: L.R., I.K.A., M.F.P., Analysis or Interpretation: L.R., O.M.T., Literature Search: L.R., M.F.P., Writing: L.R., O.M.T.

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