20-year follow-up of rheumatic mitral stenosis patients after percutaneous mitral commissurotomy: invasive transmitral gradient differential as a predictor of events

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Abstract

Percutaneous mitral valve commissurotomy (PMC) is a viable alternative to mitral valve (MV) surgery in the treatment of patients with rheumatic mitral stenosis (RMS).

In this single-center retrospective study of consecutive patients with RMS submitted to PMC from 1991 to 2008, we analyzed clinical, echocardiographic, and hemodynamic data and events during follow-up (FUP) until December 2021. Major adverse cardiovascular events (MACE) were a combined endpoint of all-cause death, cardiovascular hospitalization, and MV re-intervention. A total of 124 patients were enrolled: 108 (87.1%) were female, with a mean age at PMC of 46 [standard deviation (SD) 11] years. PMC was successful in 91.1%, with a mean reduction in invasive transmitral pressure gradient (TMPG) of 8 (SD 7) mmHg at PMC time. During the mean FUP of 20 (SD 6) years, 51 (41.1%) patients had MV re-intervention (86.3% surgery and 13.7% redo-PMC), 37 (29.8%) were hospitalized, and 30 (24.2%) died. Approximately 75% of patients remained MACE-free after 10 years, and this percentage decreased to around 40% after 20 years; at this time mark, about 8 in 10 patients were alive.

A reduction of <5 mmHg in TMPG at PMC time was associated with a 2.7-fold greater rate of MACE compared to a reduction of ≥5 mmHg, independent of MV regurgitation after PMC and moderate disease of other valves (adjusted hazard ratio 2.7; 95% confidence interval 1.395-5.298, p=0.003). In this cohort with favorable long-term results after PMC, a reduction of <5 mmHg in TMPG at PMC time was associated with MACE during FUP. More studies are needed to validate this independent predictor.

Introduction

Rheumatic heart disease (RHD) has decreased worldwide but continues to be a major medical concern in developing countries, remaining the most common cause of cardiovascular morbidity and early mortality in young people worldwide [1].

Mitral valve stenosis (MVS), the most common manifestation of RHD, is a progressive disease of leaflet thickening, commissural fusion, and chordal shortening and fusion, potentially leading to atrial fibrillation (AF), ischemic stroke, pulmonary hypertension, and heart failure. The contemporary treatment strategies for clinically significant rheumatic MVS are percutaneous mitral balloon

commissurotomy (PMC) and mitral valve replacement (MVR) [2].

In symptomatic patients with severe rheumatic MVS and suitable anatomical features, guided by the Wilkins score, the PMC is considered the treatment of choice. On the other hand, patients with contraindication to PMC should undergo MVR. Contraindications to PMC include the presence of left atrium (LA) thrombus, concomitant mitral valve (MV) regurgitation, and excessive MV calcification [3].

Immediate, mid- and long-term results of the procedures are variable depending on many factors, including patient and MV characteristics, as are the local expertise of interventionists and surgeons. A recent meta-analysis of randomized controlled trials concluded that, despite the current insufficient evidence to assert the superiority of either PMC or MVR, considering the higher morbidity associated with cardiac surgery, PMC should be the preferred procedure for young patients with favorable valve morphology [4].

As the era of PMC began in 1984 [5], there is limited data on very long-term outcomes for patients with severe rheumatic MVS who have undergone PMC. Moreover, information about predictors of events remains limited.

The objective of this study is to assess long-term events of rheumatic MVS patients following PMC and to identify potential predictors of such events.

Materials and Methods

Study population

This is an observational, retrospective single-center study performed in the Cardiology Department of Centro Hospitalar Universitário de São João, Porto, Portugal. We included all consecutive patients aged ≥18 years old with clinically significant rheumatic MVS, with mitral valve area (MVA) <1.5 cm^2 and grade ≤2 mitral regurgitation (MR), who underwent PMC between 1st January of 1991 and 31st December of 2008. All patients with asymptomatic MVS, MVA≥1.5 cm^2, grade 3-4 MR, or with intracardiac thrombus were excluded. The patient's information was reviewed from medical records.

Procedure and data collection

After right and left catheterization, PMC was performed with the Inoue commissurotomy technique using an Inoue single balloon (Toray Industries, Inc., NY, USA); atrial septostomy and commissurotomy were X-ray fluoroscopy guided. The balloon diameter and catheter size were chosen based on the patient's height [6].

At procedure time, before and after PMC, simultaneous direct LA and left ventricle (LV) pressures were assessed. Direct LA pressure was obtained after the transseptal technique, while direct LV pressure was acquired by retrogradely introducing a pigtail catheter from the aorta into the LV.

Transmitral pressure gradient (TMPG) was determined by planimetry of the area bounded by the LV and LA pressure tracings in diastole. After PMC, a left ventriculography was done to evaluate MR.

All patients underwent echocardiography at baseline (within 6 months before PMC), within 72 hours after PMC, and 6 months post-procedure. Also, an echocardiogram was performed immediately after PMC to assess the success of the procedure, which was defined as MVA≥1.5 cm^2, along with grade ≤2 MR and no major cardiac complication requiring emergent surgery.

Clinical and other echocardiographic data were collected at baseline and within 6 months post-procedure. Various echocardiographic parameters, namely MVA, TMPG, Wilkins' score, MR grading, and pulmonary systolic artery pressure (PSAP), were recorded.

Long term follow-up was accessed until 31st December of 2021, checking for considered outcomes, through medical records and phone interview. Several possible clinical, echocardiographic and hemodynamic parameters were checked for prognostic value.

Outcomes

The primary outcome consisted of a composite of major adverse cardiovascular events (MACE), including all-cause mortality, MV re-intervention (either re-do PMC or surgery, including valvuloplasty and replacement of MV with biological or mechanical prosthesis), and cardiovascular hospitalization. The latter comprised hospitalizations due to heart failure, stroke or systemic embolism, myocardial infarction, and arrhythmias. Other accessed outcomes were PMC success, peri-procedural complications, valvular infection, and serious bleeding [the Bleeding Academic Research Consortium (BARC) definition type 3 or more] [7].

Statistical analysis

Categorical variables were presented as frequency and percentage and analyzed using a Chi-square test or Fisher's exact test as appropriate. Continuous variables are presented as the mean with standard deviation (SD) or median with interquartile range (IQR) and analyzed using a *t*-test or Mann-Whitney test as appropriate. To test for independent predictors of the composite clinical endpoint, we used Cox survival models. Kaplan-Meier curves for the survival time free from the composite clinical endpoint were constructed with strata; a two-tailed $p<0.05$ was considered statistically significant. All statistical analyses were performed using SPSS Statistics version 27.0 (IBM Corp., Armonk, NY, USA).

Results

Baseline characterization

A total of 124 patients were enrolled; the majority were women (108 (87.1%)), with a mean age of 46 (SD 11) years at PMC time. At baseline, 42 (33.9%) patients were in New York Heart Association (NYHA) class ≥III, and 100 (80.6%) had a Wilkins score ≤8; all patients had preserved biventricular systolic function, and 103 (83.1%) had PSAP greater than 40 mmHg. Table 1 describes the population baseline characterization.

Data related to percutaneous mitral commissurotomy

Using a mean balloon size of 28 (SD 1) mm, PMC was successful in most cases (113 patients, 91.1%), with a mean reduction of invasive TMPG of 8 (SD 7) mmHg, and a median reduction of PSAP of 8 (IQR 10) mmHg. Table 2 displays hemodynamic data pre- and post-PMC.

The procedure was unsuccessful in 11 (8.9%) patients, due to MVA<1.5 cm^2, echocardiographic grade of 3-4 MR or LA rupture with cardiac tamponade in 6 (4.3%), 4 (3.2%), and 1 (0.8%) patients, respectively.

No in-hospital deaths were registered. Major complications related to PMC were observed in 5 (4.0%) patients, with 4 requiring

emergent surgery. Two patients developed grade-4 MR and required MVR. Additionally, one patient experienced a LA rupture with cardiac tamponade, compelling surgical cardiac repair; and another patient had a major bleeding at femoral arterial access, which was managed surgically (both BARC 3b). One patient had a stroke after the procedure and was treated conservatively.

At first echocardiogram within 72 hours post-PMC, a median improvement in MVA of 0.9 (IQR 0.5) cm^2 was documented. Additionally, median reductions in TMPG of 6 (IQR 6) mmHg and in PSAP of 10 (IQR 14) mmHg were observed. Excluding the 2 patients submitted to MV replacement, MR was absent, grade 1, grade 2, and grade 3 in 38 (31.1%), 65(53.3%), 17 (13.9%), and 2 (1.6%) patients, respectively.

Minor complications occurred in 35 (28.2%) patients: 20 (16.1%) had residual inter-auricular communication, 12 (9.7%) had grade 2 or 2+ MR, 1 (0.8%) patient was diagnosed with femoral aneurysm, other with moderate pericardial effusion and another with deep vein thrombosis, all treated conservatively.

Table 1. Baseline patients' clinical and echocardiographic characteristics.

Variable, units	Expressed as	Value
Age, years	Mean (SD)	46 (11)
Female sex	N (%)	108 (87.1%)
Weight, kg	Median (IQR)	60 (13)
Height, cm	Mean (SD)	158 (7)
BMI, kg/m^2	Median (IQR)	24 (4)
NYHA class:	N (%)	
Class I		10 (8.1%)
Class II		72 (58.1%)
Class III		41 (33.1%)
Class IV		1 (0.8%)
Atrial fibrillation	N (%)	72 (41.9%)
Previous mitral valve surgical commissurotomy	N (%)	7 (5.6%)
Wilkins score	Median (IQR)	7 (2)
Wilkins score ≤8	N (%)	100 (80.6%)
Wilkins score 9-11	N (%)	24 (19.7%)
Associated other valve disease, any degree	N (%)	85 (68.5%)
Moderate to severe disease of another valve	N (%)	20 (16.3%)
Tricuspid regurgitation of any grade	N (%)	65 (524%)
Pulmonary systolic artery pressure >40 mmHg	N (%)	103 (83.0%)
Mitral regurgitation severity	N (%)	
Grade 0		69 (55.6%)
Grade 1		53 (42.7%)
Grade 2		2 (1.6%)

IQR, interquartile range; SD, standard deviation; BMI, body mass index; NYHA, New York Heart Association.

Table 2. Hemodynamic evaluation pre- and post-percutaneous mitral valve commissurotomy, by invasive catheterization and by echocardiography. All continuous variables are expressed as medians (interquartile range).

Invasive and echocardiographic parameters	Pre-PMC	Post-PMC	Differential pre- and post-PMC‡
Cath*			
Pulmonary systolic artery pressure, mmHg	44 (20)	37 (15)	8 (10)
Pulmonary diastolic artery pressure, mmHg	20 (9)	15 (6)	5 (8)
Pulmonary mean artery pressure, mmHg	29 (16)	22 (12)	5 (8)
Direct left atrium pressure, mmHg	22 (10)	14 (8)	7 (8)
Transmitral mean pressure gradient, mmHg	12 (5)	4 (4)	8 (7)
Echo**			
Pulmonary systolic artery pressure, mmHg	48 (17)	38 (15)	10 (14)
Transmitral mean pressure gradient, mmHg	10 (8)	4 (4)	6 (6)
Left atrium diameter, mm	47 (7)	46 (10)	1 (7)
Left ventricle end-diastolic diameter, mm	49 (6)	50 (23)	0 (4)
Mitral valve area by planimetry, cm^2	1.0 (1.1)	1.9 (2.4)	-0.9 (0.5)
Mitral valve area by pressure half time, cm^2	1.0 (0.2)	1.9 (0.3)	-0.9 (0.5)

PMC, percutaneous mitral valve commissurotomy. *Cath, during catheterization, invasive hemodynamic parameters were measured before and immediately after PMC. **Echo, echocardiographic parameters were measured at baseline and within 72h after PMC. ‡Differential pre- and post-PMC expressed for each parameter as the difference between the value before PMC and the value after PMC.

Follow-up

At the 6-month appointment, most patients were at NYHA class I (70; 56.5%), followed by class II (50;40.2%), and only 4 patients were at class III. Regarding MR, it was absent, grade 1, grade 2, and grade 3 in 56 (45.9%), 50 (41.0%), 14 (11.5%), and 2 (1.6%) patients, respectively. A total of 16 patients developed *de novo* AF (about one-third of the pool of patients at sinus rhythm at PMC time). No deaths were registered in the first 6 months after the PMC.

During the mean follow-up time of 21 (SD 6) years (minimum of 1 and maximum of 31 years), 30 (24.2%) patients died, 37 (29.8%) were hospitalized due to cardiovascular causes, and 51 (41.1%) patients had at least one MV re-intervention.

The deceased patients were mainly women (27; 90.0%) with a mean age of 71 (SD 11) at the time of death, and the mean time to death after PMC was 18 (SD 6) years. Respectively, 4, 2, and 2 patients died in the context of heart failure, stroke, and septic shock (of intra-abdominal and respiratory origins); the remaining causes of death are unknown due to inaccessible medical records.

Regarding admissions, the majority was due to decompensated heart failure (19; 51.4%), followed by stroke (7; 18.9%), rapid AF with hemodynamic compromise (3; 8.1%), myocardial infarction (3; 8.1%), tachy-brady syndrome requiring pacemaker implantation (3; 8.1%) and digitalis intoxication (2; 5.4%). Patients with at least one admission were mostly women (88.2%), with a mean age of 64 (SD 12) years, and a mean time to first admission since PMC of 15 (SD 6) years.

In parallel, patients at first re-intervention had a mean age of 58 (SD 11) years, and 11 (SD 6) years had passed since PMC. Of the 51 patients who underwent at least one re-intervention, 7 (13.7%) had re-PMC and 44 (86.3%) had surgery. Implantation of a mechanical or biological MV prosthesis occurred in 30 (68.2%) and 12 (27.3%) of the surgical re-intervened patients, respectively; the remaining 2 (4.5%) were submitted to valvuloplasty. During the same procedure, 13 (29.5%) patients underwent concomitant other valve intervention: 10 had tricuspid annuloplasty and 4 aortic valve replacement with biological prosthesis. Later, 6 (4.8%) patients required second re-intervention: 2 patients with two previous PMC and 1 patient with previous PMC and surgical valvuloplasty had substitution of MV with mechanical prosthesis; 1 patient had a third PMC; another patient with biological MV prosthesis underwent PMC. The remained patient had a mechanical MV prosthesis and underwent substitution of the aortic valve with a biological prosthesis in the context of a native aortic valve endocarditis. No other cases of endocarditis were documented.

Concerning time-to-event analysis, 74.9%, 40.4% and 25.0% of patients kept MACE-free after 10, 20 and 30 years, respectively; as for mortality of all causes, the probability of survival for PMC intervened patients was 95.7%, 81.4% and 50.2% at 10, 20 and 30 years, correspondingly (see Figure 1 for Kaplan Meier curves). Regarding re-intervention, 79.8%, 56.3%, and 48.8% of patients remained free from re-intervention after 10, 20, and 30 years, respectively.

Using Cox regression, uni- and multianalysis of eventual predictors of MACE are displayed in Table 3. We found that a reduction <5 mmHg in invasive TMPG at PMC time was associated with a 2.2-fold greater rate of MACE compared to patients with a reduction ≥5 mmHg [crude hazard ratio (HR_{crude}) 2.2; 95% confidence interval (CI) 1.319-3.813, p=0.003]. After adjusting for the presence of MR after PMC (HR_{crude} 1.7; 95% CI 1.020-2.950, p=0.042) and for moderate disease of other valves (HR_{crude} 1.9; 95% CI 1.070-3.267, p=0.028), the observed effect remained significant and was even greater (adjusted HR 2.7; 95% CI 1.395-5.298, p=0.003).

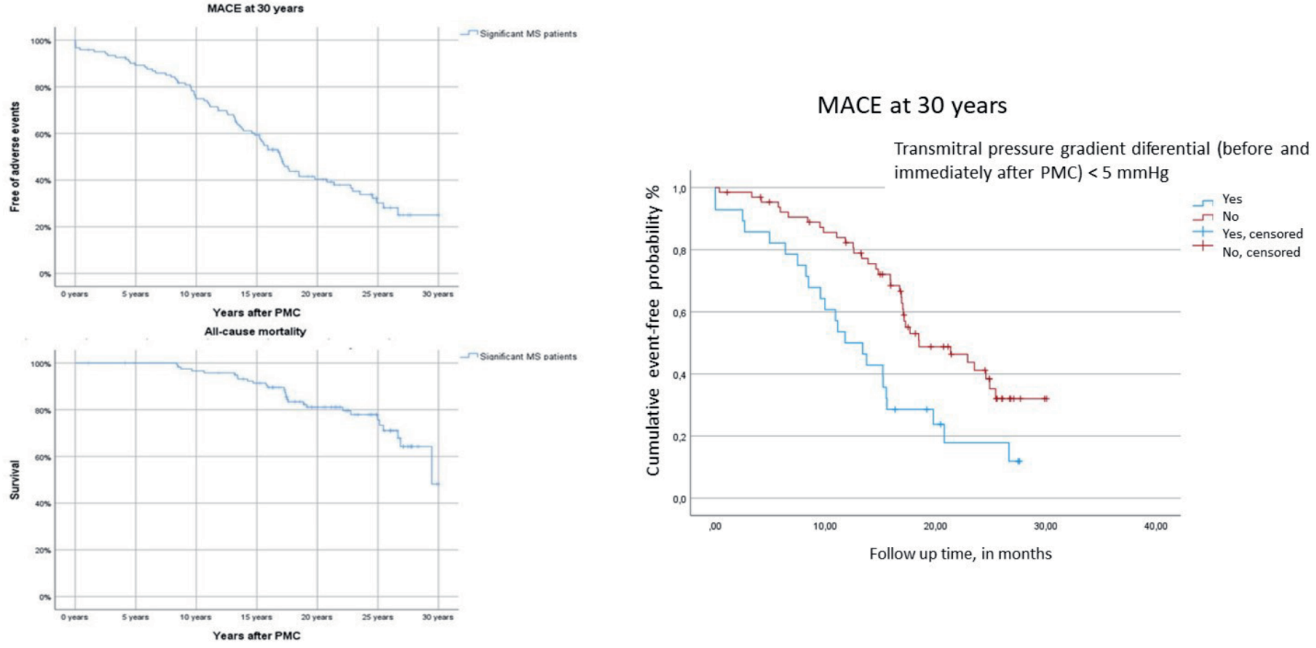

Figure 1. On the left, Kaplan-Meier curves regarding major adverse cardiovascular events (MACE) and mortality during follow-up of patients submitted to percutaneous mitral valve commissurotomy (PMC). On the right, also displayed MACE subdivided accordingly to the presence or absence of reduction <5 mmHg in transmitral pressure gradient at PMC time.

Discussion

Most studies addressing follow-up after PMC do not exceed 10 years [8-10]. This study adds some extra insights regarding very long-term follow-up of patients who performed PMC – even after 30 years, the probability of being alive was about 50%.

When compared to other studies with long-term FUP, the documented overall survival at 20 years of 81.4% is similar to that of Fawzy, Bouleti *et al.*, and Kubota *et al.* cohorts – 70.5%, 73.3%, and 75%, respectively. Also, Braiteh *et al*. reported a 90.5% survival at 15 years [11-14].

In our cohort, the deceased patients were elder (mean age 71 years), about 10 years younger than the mean age of death in general population in Portugal (in 2021, of 82 years old) [15]. Also, an average of 17 years had passed since the PMC, which combined with no in-hospital deaths, and successfully treated periprocedural complications, denotes the safety and good short to long-term results of the procedure.

About one-third of the patients were at least one time hospitalized due to cardiovascular causes; also, about 40% of patients required at least one mitral re-intervention, underscoring the chronicity of the RHD, manifested by a natural history of MV restenosis, LA dilatation, with higher risk of AF and stroke [16]. The majority were submitted to surgery, which could be in part explained by the significant proportion of patients who required concomitant surgery for another valve.

The search for outcome predictors after PMC has captured the attention of numerous authors, aiming to enhance patient selection and procedural techniques. Generally, the identified independent predictors predominantly revolve around baseline clinical factors (such as age, body surface area, NYHA classification, and AF) and anatomical characteristics (including echocardiographic valve area, mean gradient, MV calcification, and LA diameter). Immediate procedural outcomes, such as echocardiographic final mean gradient, final MVA, and final MR, also play a pivotal role in outcome prediction. Moreover, in the work of Bouleti *et al.*, it is demonstrated and validated a 13-point scoring system for "late results", but it lacked hemodynamic variables. Interestingly, there is conflicting data regarding the Wilkins score as a predictor of events. Furthermore, in our cohort, the Wilkins score greater than 8 did not predict events, probably denoting the PMC efficacy even in the grey zone of 9 to 11 [11-14,17-19].

When analyzing such studies, we have to take into account the heterogeneous follow-up times, as well as different composites of MACE considered. For example, Bouletti *et al*. considered "late functional results" as a composite of cardiovascular death, MV re-intervention, and NYHA III-IV; Fawzy *et al*. considered a similar composite but with death from all causes; in Kubota *et al.*, MACE was composed of death and re-intervention, while Braiteh *et al.* just looked for mortality predictors [11-14]. In our cohort, we decided to also add the hospitalizations of cardiovascular cause to the MACE composite, due to its clinical and health care burden relevance. Other studies also have determined predictors of MV restenosis, but because we did not perform a standardized echocardiographic follow-up, this type of analysis could not be done [18].

To our knowledge, this is the first study to document a reduction of <5 mmHg in invasive TMPG at the PMC procedure, as an independent predictor for events. This effect was further magnified after

Table 3. Univariate and multivariate analysis of predictors of primary outcome.

Variable	Univariate analysis			Multivariate analysis		
	Crude hazard ratio	95% CI	p	Adjusted hazard ratio	95% CI	p
Differential of invasive TMPG pre and after PMC		1.033-4.324	0.040		1.395-5.598	0.003
<5 mmHg	2.114			2.719		
≥5 mmHg	1			1		
Fluoroscopic MR immediately after PMC, any degree		1.020-2.950	0.042		1.157-4.383	0.017
Yes	1.735			2.251		
No	1			1		
Associated moderate to severe disease of other valves		1.070-3.267	0.028		1.018-4.707	0.045
Yes	1.870			2.189		
No	1			1		
Age, years	1.036	1.014-1.058	0.001	1.040	0.999-1.082	0.057
SexMaleFemale	0.8921	0.470-1.691	0.726	Not included		
Atrial fibrillation at PMC timeYesNo	0.6931	0.441-1.088	0.111	Not included		
NYHA class ≥III at baselineYesNo	1.2091	0.457-3.197	0.702	Not included		
Wilkins score >8YesNo	1.1411	0.949-1.33	0.161	Not included		
Invasive PSAP at baseline, mmHg	0.996	0.980-1.012	0.616	Not included		
Differential of invasive PSAP pre and after PMC, mmHg	0.971	0.941-1.002	0.069	Not included		
Echocardiographic PSAP at baseline, mmHg	1.007	0.996-1.109	0.240	Not included		
Differential of echocardiographic PSAP pre and after PMC, mmHg	0.990	0.971-1.010	0.324	Not included		
Differential of echocardiographic TMPG pre and after PMC, mmHg	1.052	1.002-1.104	0.531	Not included		

95% CI, 95% confidence interval; TMPG, transmitral mean pressure gradient; PMC, percutaneous mitral commissurotomy; MR, mitral regurgitation; NYHA, New York Heart Association. PSAP: pulmonary systolic arterial pressure. Note: The variable "Differential of invasive TMPG pre and after PMC" was associated with the primary outcome (hazard ratio of 0.901; 95% CI 0.849-0.957 and p<0.001). To perform a more practical analysis of this variable, we discretized it into a binary format using the 25th percentile as the threshold (5 mmHg).

adjusting for MR and moderate disease in other valves, possibly indicating a more accurate reflection of the actual hemodynamic improvement. We believe this could have clinical implications, as a practical and objective "cut-off" to help the interventional cardiologist during the procedure, besides the MVA and MR. Of course, further multicentric studies with a standardized MACE definition will be needed to validate this predictor.

Limitations

This study had several limitations. First, given its retrospective nature, outcomes were prone to review bias and subject to confounding from other factors. There was no data regarding quality of life or rates of mitral re-stenosis. As PMC was performed in a single tertiary referral center study, results may not reflect the practices in other populations worldwide.

Conclusions

PMC was safe and effective in clinically significant rheumatic MS. Most of the patients were free from adverse events after 10 years, and 80% were alive after 20 years; still, about 40% required re-intervention. A reduction of <5 mmHg of invasive TMPG post-PMC during the procedure was associated with more events during follow-up, indicating a possible target to guide interventional cardiologists during the PMC procedure; more studies are needed to validate this independent predictor.

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