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Subsequent cardiac surgery after transcatheter aortic valve implantation: Indications and outcomes

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Abstract

Background: Aim of this study was to report on indications and clinical outcomes of patients who underwent subsequent open-cardiac surgery after transcatheter aortic valve implantation TAVI.

Methods: Between 01/2011 and 12/2020 our centre performed 4043 TAVI procedures. Twenty-seven patients (including patients in whom TAVI was performed in other centres) underwent subsequent open-heart surgery via cardiopulmonary bypass. Demographic, intraprocedural data, indications for, and outcomes after surgery were evaluated.

Results: Indications for cardiac surgery (aged 79 [IQR 76-84]; 59.3% male) were endocarditis (n = 11; 40.7%), annular rupture, severe paravalvular leak and severe stenosis in three (11.1%) patients, respectively as well as in one patient each (3.7%) severe tricuspid valve regurgitation, valve thrombosis, valve malposition, valve migration, ostial right coronary artery obstruction, left ventricular rupture and type A aortic dissection. The interval between the index TAVI procedure to open surgery was 3 months (IQR 0-26 months). Eight patients underwent emergent surgical conversions. Immediate procedural and procedural mortality was 25.9% and 40.7%, respectively and all-cause mortality was 51.9% (11/12 died for cardiovascular reasons). No disabling stroke was observed postoperatively. New permanent pacemaker implantation was required in three patients (11.1%).

Conclusions: Subsequent open-cardiac surgery after TAVI is rare, but may urgently become necessary due to TAVI related complications or progressing other cardiac pathologies. Despite a substantial early attrition rate clinical outcome is acceptable and a relevant number of these high-risk patients can be discharged even after emergency conversions. The option of subsequent surgical conversion remains.

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KEYWORDS

aortic valve, aortic valve intervention, emergency conversions, Open surgery after TAVI, reoperation after TAVI, subsequent cardiac surgery, transcatheter aortic valve implantation

1 | INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has been historically done in high-risk patients or patients who are deemed unfit for open-heart surgery. This paradigm has changed over the last decade. The recently published "2021 ESC/EACTS Guideline for the management of patients with valvular heart disease" recommends surgical aortic valve replacement in younger and low-risk patients whereas transfemoral TAVI is recommended in patients over 75 years of age or in high-risk patients. Despite high procedural success rates subsequent open surgery remains an issue, immediately after TAVI implantation or during follow-up. In addition, there is little data on these emergency surgical conversions. Moreover, less is known about the outcome of subsequent surgical procedures for progression of other cardiac pathologies or acute infective endocarditis in real life clinical practise focussing on patients not enrolled in large trials with carful patient selection.

Aim of this study was to report on indications and clinical outcomes of patients who underwent subsequent open-cardiac surgery as emergency surgical conversion or due to other cardiac pathologies following TAVI.

2 | PATIENTS AND METHODS

The institutional review committee of the University of Freiburg approved this retrospective study on February 27, 2020; #71/20 and the need for informed consent was waived. It was conducted according to the declaration of Helsinki.

2.1 | Patients

Between 01/2011 and 12/2020, 4043 patients were treated with TAVI at our centre. Twenty-seven patients (including patients treated with TAVI in referring centres) required subsequent open-cardiac surgery for both immediate and late TAVI complications as well as for progression of other cardiac pathologies. We collected baseline characteristics, including previous cardiac or aortic procedures and reviewed their echocardiograms and computed tomography angiography data. Indications for surgery, intraprocedural details and clinical outcomes were evaluated. Data were reported according to the VARC-2 criteria. Therefore, in-hospital mortality was subclassified into immediate procedural (death within 72 h) and procedural mortality, defined as death within 30 days or during the index procedure hospitalization.⁵ The emergency conversion rate was subclassified into three periods (2011–2013, 2014–2016, and 2017–2020).

2.2 | Clinical decision-making

Every patient referred to our heart centre for aortic valve replacement is evaluated by our multidisciplinary heart team (consisting of clinical and interventional cardiologists, anaesthesiologists, and cardiac surgeons) in detail, carefully weighing the risks and benefits of surgical versus transcatheter aortic valve replacement or implantation. Transthoracic echocardiography and cardiac computed tomography angiography are routinely performed to assess the anatomic feasibility of TAVI. In case our heart team chooses TAVI as treatment of choice, the procedure is carried out conjointly by an interventional cardiologist and cardiac surgeon, irrespective of the access site (femoral, apical, or via the axillary artery). All implantations are routinely carried out in a hybrid operating room.

2.3 | Surgical strategy

Because of continuous surgical involvement and expertize, any implantation-related complications can be addressed by immediate open surgical conversion with cardiopulmonary bypass at any time. Annular rupture was treated by valve removal, patch repair, and conventional biological aortic valve replacement to reduce the extent of surgical replacement and increase the probability of survival. Treatment of infective endocarditis follows current guidelines⁶ and patients are routinely discussed in our interdisciplinary endocarditis board. In case surgical treatment is required, we aim for complete removal of infected valves and tissue. In case of a paravalvular abscess, we excise the latter, and if the sealing by the valve sutures will likely prove insufficient, a pericardial patch is used. Mitral-valve involvement leads to its replacement in most patients. Mitral-valve repair is performed provided there are no signs of a structural damage within the mitral valve. In rare cases of double valve or extensive aortic root endocarditis involving the intervalvular fibrous body, and in patients with substantial calcification of the latter we perform double-valve replacement including reconstruction of the intervalvular fibrous body using a pericardial patch.

2.4 | Statistical analysis

IBM SPSS 27.0 (SPSS Software, IBM Corp.) was used for statistical analysis. Data are presented as median [first quartile, third quartile] or absolute and relative frequencies. The Kaplan–Meier method was used for survival analysis after surgery.

RESULTS

3.1 Patient characteristics

Patient characteristics are summarized in Table 1. Median age of the 16 male and 11 female patients was 79 [IQR 76-84] years. Seven patients suffered from pre-interventional nondisabling neurological impairment. Four patients had undergone previous cardiac or proximal aortic surgery 12.9 [IQR 4.5-15.4].

Echocardiographic and computed tomography angiography measurements

An aortic stenosis was the most common underlying pathology in 24 (89%) patients (mean gradient 47 [IQR 25-55] mmHg). Concomitant severe mitral or tricuspidal valve regurgitation was present in one patient (4%), respectively. A bicuspid aortic valve was diagnosed in two patients (7%). Median annular diameter was 25.6 mm [IQR 23.4-26.7]. Immediate post-TAVI echocardiography revealed a median gradient of 10 [IQR 6-15] and a severe aortic regurgitation in eight (30%) patients. All measurements are summarized in Table 2.

Indications for surgery

The interval between TAVI and subsequent open surgery via cardiopulmonary bypass was three [IQR 0-26] months. Active infective endocarditis was the most common indication for subsequent open surgical conversion (n = 11, 41%) followed by periprocedural annular rupture, severe paravalvular leak and severe stenosis due to leaflet degeneration in 3 (11%), respectively. Figure 1 shows the postimplantation angiography in a patient with annular rupture who underwent immediate emergency conversion. Eight out of 4043 patients primarily treated at our centre underwent emergency subsequent open conversion during or immediately after TAVI (emergent cardiac surgery rate 0.20%). In these eight patients, indications were periprocedureal annular rupture in three (11%) patients and a severe paravalvular postimplantation leak, malpositioning of the valve, valve migration, acute type A aortic dissection, and left ventricular rupture in one (4%) patient, respectively. Emergency conversion rate in the first period (2011-2013) was 0.16% (1/616 patients), within the second period (2014-2016) 0.15% (2/1315 patients) and 0.24% within the last period (2017-2020; 5/2112 patients). The corresponding logistic EuroScores of the entire cohorts were 15.8%, 14.7%, and 14.7%, respectively.

Isolated aortic valve replacement was performed in 11 (40.7%) patients and annular patch repair was necessary in three (11.1%) additional patients. Reconstruction of the intervalvular fibrous body (commando procedure) was carried out in three (11.1%) patients. Indications for surgery are summarized in Table 3.

TABLE 1 Descriptive characteristics of the cohort		
Demographics	n = 27	
Age (years)	79 [IQR 76-84]	
Male	16 (59.3)	
Log EuroScore	6.6 [IQR 4.8-10.3]	
Chronic health conditions and risk factors		
Porcelain aorta	1 (3.7)	
Frailty	6 (22.2)	
Severe liver disease	0 (0.0)	
Hostile chest	2 (7.4)	
Conduit crossing midline	0 (0.0)	
Severe pulmonary arterial hypertension	5 (18.5)	
Severe right ventricular dysfunction	0 (0.0)	
AV block	7 (25.9)	
Atrial fibrillation	11 (40.7)	
Dyslipidemia	12 (44.4)	
Hypertension	22 (81.5)	
Diabetes mellitus	2 (7.4)	
Previous stroke	3 (11.1)	
Pre-TAVI mRS		
0	20 (74.1)	
1	6 (22.2)	
2	1 (3.7)	
History of renal failure	5 (18.5)	
COPD	7 (25.9)	
Coronary artery disease	14 (51.9)	
Bicuspid aortic valve	2 (7.4)	
Previous cardiac or aortic procedures		
Time of previous surgery (years)	12.9 [IQR 4.5-15.4]	
Coronary artery bypass grafting	0 (0.0)	
Aortic valve replacement	2 (7.4)	
Mitral valve replacement	1 (3.7)	
Ascending + aortic valve replacement	1 (3.7)	
Other	1 (3.7)	

Note: Data are presented as median [first quartile; third quartile] or as number.

Abbreviations: COPD, chronic obstructive pulmonary disease; mRS, modified rankin scale.

Clinical outcomes and follow-up

Four patients expired intraoperatively due to uncontrolled bleeding. Immediate procedural and procedural mortality was 25.9% and 40.7%, respectively and all-cause mortality was 51.9% (11/12 died for

TABLE 2 Echocardiography and computed tomography

measurements	
Pre-TAVI echocardiography	
Ejection fraction	55 [IQR 40-60]
Aortic stenosis	25 (92.6)
Mild	0 (0.0)
Moderate	1 (3.7)
severe	24 (88.9)
Mean gradient	47 [IQR 25-55]
Aortic valve area (cm²)	0.8 [IQR 0.6-1.1]
Aortic regurgitation	16 (59.3)
Mild	8 (29.6)
Moderate	6 (22.2)
Severe	2 (7.4)
Mitral regurgitation	20 (74.1)
Mild	17 (63.0)
Moderate	2 (7.4)
Severe	1 (3.7)
Tricuspidal regurgitation	13 (48.1)
Mild	10 (37.0)
Moderate	2 (7.4)
Severe	1 (3.7)
Pre-TAVI computed tomography measurements	
Annulus diameter	25.6 [IQR 23.4-26.7]
Annulus area	482 [IQR 425-554]
Sinus of valsalva height	22.2 [IQR 19.8-23.2]

Pre-TAVI computed tomography measurements	S
Annulus diameter	25.6 [IQR 23.4-26.7]
Annulus area	482 [IQR 425-554]
Sinus of valsalva height	22.2 [IQR 19.8-23.2]
RCA height	16.5 [IQR 13.3-18.8]
LCA height	13 [IQR 10.3-16]

Post-TAVI	echocardiography
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Aortic stenosis	25 (92.6)
Mild	0 (0.0)
Moderate/severe	1 (3.7)
Mean gradient	10 [IQR 6-15]
Aortic regurgitation	16 (59.3)
Mild	5 (18.5)
Moderate	2 (7.4)
Severe	8 (29.6)

Note: Data are presented as number (percentage). Abbreviation: PAU, penetrating aortic ulcer.

cardiovascular reasons). In patients operated as emergency conversions intraoperative, immediate, procedural and all-cause mortality was 25.0%, 25.0%, 37.5%, and 50%, respectively. Among the 11 patients operated on for active infective endocarditis intraoperative, immediate,

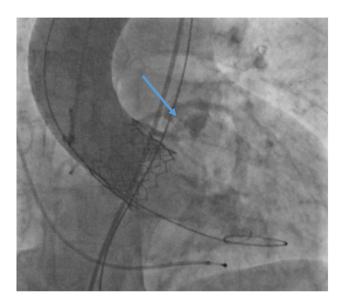


FIGURE 1 Shows a postimplantation angiography in a patient with annular rupture

procedural and all-cause mortality in patients operated was 18.2%, 25.0%, 45.5%, and 63.6%, respectively.

No postoperative disabling stroke was observed while a nondisabling stroke occurred in one patient. New permanent pacemaker implantation was necessary in three patients (11.1%). One patient required an additional, second open operation to remove a large left ventricular thrombus on extra corporal life support. One patient developed recurring endocarditis and was discharged on permanent antibiotic intake. Median follow-up was 2.5 [IOR 1.5: 3.0] years. Clinical outcomes and follow-up data are summarized in Table 4. Figure 2 shows the Kaplan-Meier estimator for survival.

3.5 Patients with infective endocarditis

In total 11 patients suffered from infective endocarditis. The extent of destruction was very heterogenous. Two patients showed multiple large vegetations in combination with valve stenosis. Both received isolated valve replacement. The aortic annulus was destroyed in five patients including four patients with a destructed intervalvular fibrous body. Therefore, the commando procedure was carried out in two patients (including one patient with additional tricuspid valve repair), and three patients underwent extensive patch repair of the aortic annulus and intervalvular fibrous body. Three patients had multiple vegetations but underwent beside aortic valve replacement: mitral valve repair, coronary artery bypass grafting, and tricuspid valve reconstruction including concomitant coronary artery bypass grafting. One patients suffered from an ascending aortic rupture based on destruction of the native tissue due to infective endocarditis. This patients underwent emergency aortic valve and ascending replacement. Seven of those procedures were classified as salvage procedures.

TABLE 3 Procedural characteristics of the cohort

TABLE 3 Procedural characteristics of the cohort		
TAVI implantation data	n = 27	
Predilatation	6 (22.2)	
Postdilatation	6 (22.2)	
Concomitant PCI	0 (25.9)	
Implanted valves		
Medtronic corevalve	4 (14.8)	
JenaValve	3 (11.1)	
Boston Scientific Lotus	2 (7.4)	
Edwards Sapien XT	2 (7.4)	
Edwards Sapien 3	6 (22.2)	
Boston Scientific Symetis	5 (18.5)	
Medtronic Evolut	2 (7.4)	
Medtronic Evolut R	3 (11.1)	
Indication for open surgery		
Endocarditis	11 (40.7)	
Aortic annulus rupture	3 (11.1)	
Severe paravalvular leak	3 (11.1)	
Severe stenosis	3 (11.1)	
Severe tricuspidal valve regurgitation	1 (3.7)	
Valve thrombosis	1 (3.7)	
Malpositioning	1 (3.7)	
Valve migration	1 (3.7)	
RCA obstruction	1 (3.7)	
Left ventricular rupture	1 (3.7)	
Type A aortic dissection	1 (3.7)	
Surgical data		
Interval TAVI—open surgery (months)	3 [IQR 0-26]	
Isolated aortic valve replacement	11 (40.7)	
Isolated tricuspidal valve repair	1 (3.7)	
Isolated CABG	1 (3.7)	
Aortic valve replacement + ascending aorta	3 (11.1)	
Aortic valve replacement + annulus patch repair	2 (7.4)	
Double valve replacement	2 (7.4)	
Commando procedure	3 (11.1)	
Aortic valve replacement + mitral valve repair	1 (3.7)	
Aortic valve replacement + CABG	1 (3.7)	
Aortic valve replacement + CABG + annulus patch repair	1 (3.7)	
Intraoperative data		
OP time (min)	213 [IQR 182-302]	

TABLE 3 (Continued)

TAVI implantation data	n = 27
CBP time (min)	106 [IQR 85-189
Cross clamp time (min)	82 [IQR 57-146]

Note: Data are presented as median [first quartile; third quartile] or as number (percentage).

Abbreviations: CABG, coronary artery bypass grafting; CPB, cardiopulmonary bypass; OP, operation; TAVI, transcatheter aortic valve implantation.

TABLE 4 Clinical outcome and follow-up characteristics of the cohort

conort	
Clinical outcome after surgery	n = 27
Intraoperative death	4 (14.8)
Immediate procedural mortality	7 (25.9)
Procedural mortality	11 (40.7)
All-cause mortality	14 (51.9)
Cardiovascular	11 (40.7)
Noncardiovascular	3 (11.1)
Myocardial infarction	0 (0.0)
Peri-procedural myocardial infarction	0 (0.0)
Spontaneous myocardial infarction	0 (0.0)
Disabling stroke	0 (0.0)
Nondisabling stroke	1 (3.7)
Disabling bleeding	5 (18.5)
Major bleeding	4 (14.8)
Minor bleeding	1 (3.7)
AKIN	
1	1 (3.7)
II	2 (7.4)
III	3 (11.1)
AV-Block III	3 (11.1)
New permanent pacemaker implantation	3 (11.1)
Cardiac tamponade	1 (3.7)
Endocarditis	1 (3.7)
Reoperation with CPB	1 (3.7)
Follow-up data	n = 16
Follow-up (years)	2.5 [1.5-3.0]
Note: Data are presenteddi [firstdi	#h:'#:

Note: Data are presented as median [first quartile; third quartile] or as number (percentage).

Abbreviations: AKIN, Acute Kidney Injury Network; CPB, cardiopulmonary bypass.

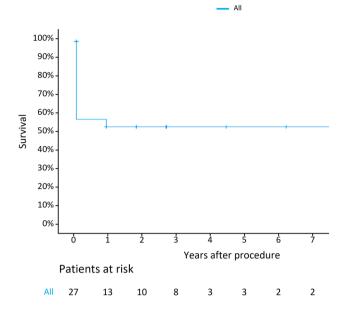


FIGURE 2 Shows the Kaplan–Meier estimates for long term survival after open surgery

4 | DISCUSSION

The most essential findings of this study can be summarized as follows: (I) In TAVI patients emergent surgical conversions or delayed open-cardiac surgery are associated with favorable midterm outcomes. (II) In case of periprocedural life-saving emergent surgical conversion, the majority of patients can be discharged home. (III) The findings of this study underline the value of an interdisciplinary heart team consisting of interventional cardiologists and hybrid cardiac surgeons enabling a shared and enduring periprocedural decision-making

Our study cohort comprises representative TAVI patients in western Europe with regard to comorbidities and underlying aortic valve pathologies. Because the comparably long study period (10 years), the indications for TAVI changed over time and therefore are more comparable to initial TAVI trials then to the most recent ones. ^{1,7} Of note, this study includes patients who had undergone TAVI as performed by many centres in daily practise (including patients with bicuspid aortic valves or severe calcification) in contrast to the patient selection applied in the majority of large trials based on clinical or morphological contraindications. ^{7,8} Considering both age and the respective cardiac and pulmonary comorbidities of the cohort these patients were deemed high-risk for open-surgery or even inoperable.

Preoperative interventional echocardiography revealed concomitant moderate or severe mitral or tricuspid regurgitation in a substantial number of patients. Since, TAVI solely addresses the aortic valve pathology, the natural evolution of mitral and tricuspid valve pathologies remains uncertain. The risks of invasive dual or triple valve treatment needs to be weighed against the potential of valvular improvement following isolated aortic valve treatment. 9,10

In patients developing progressive valvular heart failure, an open surgical approach represents the most durable treatment option even in patients considered initially unsuitable for surgical aortic valve replacement especially if percutaneous edge-to-edge repair is considered unsuitable.

Fortunately, immediate emergent conversions after TAVI are rare and the incidence reported in large recent trails is 0.6%.^{7,8} The main reasons for emergency conversions were annulus rupture, coronary obstruction and left ventricular perforation.^{6,7} Because patients recruited in these trials were highly selected and several exclusion criteria were applied, comparability of these results to daily practice may be complicated.^{6,7} In contrast, the European Registry on Emergent Cardiac Surgery during TAVI (EuRECS-TAVI) investigated real-world data from 79 centres performing 27,760 transfemoral TAVI procedures and identified a slightly higher emergency conversions incidence of 0.76%.4 Single centre studies reported emergency conversion rates between 1.2% and 4.9%. 11,12 Comparing these results to our conversion rate of 0.2% underlines the value of our careful patient selection and may be the result of our well established interdisciplinary team approach. The EuRECS-TAVI data also shows that the increasing experience in each centre as well as the improvement of the valves helped to reduce the conversion rate from 1.07% to 0.70% between 2013 and 2014. However, conversion rates remained stable thereafter and no further decline was observed. In this registry, in-hospital mortality was comparable to our study but the 1-year survival was just 40%.4 Our data suggest that there is an early attrition rate in these life-threatening conditions frequently performed under mechanical chest compression. Nevertheless, if immediate surgical conversion is available and successful, patients can be discharged with very favorable life expectancy (especially when mortality rates after TAVI in general are taken into consideration that are reported to be 63% and 91.6% after 5 and 10 years, respectively even without emergency conversion). 13

There is an ongoing debate regarding the benefit of an interdisciplinary TAVI implantation team consisting of a cardiologist and a cardiac surgeon or whether sole implantation by a cardiologist without cardiac surgical presence can safely be performed because of the limited ability of immediate surgical conversion. A prospective German registry revealed no statistical difference regarding inhospital mortality or major perioperative complications when TAVI was performed with or without a cardiac surgeons on-site. 14 In addition, there are even reports on conservative treatment of for example, annular ruptures, even though there is little data and clinical experience available to consider this approach a standard and sustainable treatment option. ¹⁵ After all, emergency conversions will always become necessary in a varying number of patients and our study shows that several individual patient lives can be saved because of an interdisciplinary heart team presence. Of note, most of these patients can be discharged home with a very favorable longterm life-expectancy.

Overall, there is little evidence about valve related reinterventions after TAVI. 3,16 The frequency of repeat interventions including valve-in-valve procedures after TAVI is reported to be approximately

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2%¹⁶ but there is little data focusing on surgical valve reinterventions (i.e., TAVI explantation and conventional valve replacement). In fact, not all valve related late failures including structural prosthesis deterioration can be treated by a subsequent valve-in-valve procedure, while the majority of patients may require open surgery because of significant paravalvular leaks, size mismatch and active infective endocarditis.³ The incidence of endocarditis after TAVI is reported to be 0.5%-2%^{17,18} and the increasing use of TAVI will inescapably lead to an increasing number of patients with prosthetic valve endocarditis requiring treatment of various extend especially when considering that about 50% of all patients with infective endocarditis require surgical treatment.¹⁹ This fact has to be acknowledged by endocarditis teams within the next decade and several treatment options including extensive surgery have to be faced in future. However, several studies suggested that only a small minority of patients is considered fit for open surgery and the majority is consequently treated palliatively without surgical treatment.²⁰ Our study cohort comprises a substantial number of patients with excessive endocarditis beyond the TAVI prostheses as shown by the extent of performed procedures including the need for reconstruction of the intervalvular fibrous body. Taking these aspects into account, overall short and long term mortality in these patients is acceptable even though the fact has to be acknowledged that these are highly selected patients who received surgical treatment as a bail out strategy in the absence of a promising conservative approach.

5 | LIMITATIONS

This is a retrospective single centre study with all its design related limitations. Moreover, this study cohort comprises only highly selected patients in a high volume center.

6 | CONCLUSIONS

Subsequent open-heart surgery after TAVI is rare, but may urgently become necessary due to TAVI related complications or progressing other cardiac pathologies. Despite a substantial early attrition rate clinical outcome is acceptable and a relevant number of patients can be discharged after surgery for immediate life-threatening TAVI complications. All procedures were high-risk procedures. Therefore, the decision whether to recommend or to withhold surgery must remain a tailored patient-based decision made on a case-to-case basis. The option of subsequent surgical conversion remains an indispensable tool in the setting of a modern heart team-based approach. These results substantiate recommendations regarding both, having a cardiac surgical service on site and performing TAVI as an interdisciplinary team.

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CONFLICTS OF INTEREST

Martin Czerny and Bartosz Rylski are consultants to Terumo Aortic and shareholders of Ascense Medical, Martin Czerny is consultant to Medtronic, Endospan and NEOS, received speaking honoraria from Cryolife-Jotec and Bentley and is shareholder of TEVAR Ltd. Maximilian Kreibich received speaking honoraria from Terumo Aortic.

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