Review Article

Systematic Review of the Frequency and Outcomes of Non-Cardiac Surgery After Drug-Eluting Stent Implantation

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The risk of non-cardiac surgery after coronary stent implantation came to the attention of the medical community in year 2000, when Kaluza et al reported 32% mortality among 25 patients who underwent non-cardiac surgery within 14 days after implantation of a bare metal stent (BMS).[1] Subsequent studies have shown that the risk for perioperative complications significantly decreases after 4-6 weeks from BMS implantation, probably due to endothelial coverage of the stent struts, which minimizes the risk of stent thrombosis in the setting of a hypercoagulable state induced by surgery.[2-5]

Drug-eluting stents (DES) are currently used in the majority of percutaneous coronary interventions in the US and, due to delayed endothelialization, may be at risk for perioperative stent thrombosis for several months or years after stenting. The goal of the present study was to systematically review all published studies on the risk of perioperative complications in patients who require non-cardiac surgery after DES implantation.

Data sources

In January 2010 we conducted a systematic search for studies published in English that examined major adverse cardiac events (MACE), stent thrombosis, and the use of anti-platelet therapy for DES patients undergoing non-cardiac surgery. Online databases (PubMed, Cochrane library, and Google Scholar) and cardiology society web sites (cardiosource.com, tctmd.com, crtonline.org, and escardio.org) were queried using the terms "non-cardiac surgery", "drug-eluting stents", "stent thrombosis", and "major adverse cardiac events". The references in the retrieved articles were also searched for additional citations. Case reports, editorials, and letters were excluded. Studies that reported uncontrolled outcomes after non-cardiac surgery in DES patients were included. We also included the DES subset in studies that included both DES and BMS. All articles were assessed by two reviewers (LA and ESB) before inclusion in the review. In the case of disagreement, the articles were reviewed by a third reviewer (SB).

Extracted data and outcomes examined included year of study; sample size; events during 6, 6 to 12, and >12 months of follow up; and the use of antiplatelet therapy for patients who had events. Supplementary data were also reviewed.

MACE was defined as the composite of death, myocardial infarction, and repeat revascularization during a 30-day fol-

low up after non-cardiac surgery. Major bleeding was defined as hemodynamically significant bleeding in the immediate postoperative period, or bleeding requiring blood transfusion. Dual antiplatelet therapy was defined as the combination of aspirin with a thienopyridine.

Continuous variables were reported as mean ± standard deviation and discrete parameters were reported as percentages and were compared using the chi-square test. Statistical analyses were performed using JMP (SAS, Cary NC, USA) or STATA (StataCorp LP, College Station TX, USA).

Search results

The literature review retrieved 108 publications, of which 95 were excluded (Figure 1). A total of 13 studies reporting on 2884 DES patients undergoing non-cardiac surgery were included in this study (Table 1).[6-18] The mean age of the patients was 66.35 ± 0.74 years and the majority underwent intermediate risk surgery.

Frequency of non-cardiac surgery after DES implantation

Limited published information was found on the frequency of non-cardiac surgery post DES implantation. In the EVENT (Evaluation of Drug Eluting Stents and Ischemic Events) registry major non-cardiac surgery was required in 4.4% of 4637 patients who received a DES between 2004 and 2005.[6] Similarly, in the Scottish Coronary Revascularization Register non-cardiac surgery was needed in 4.4% of 1953 patients undergoing stenting (with either BMS or DES) between 2003 and 2007.[7] In an analysis of 827 patients who received a DES at our institution between 2005 and 2008, the incidence of major or minor non-cardiac surgery was 7% at 1 year, 18% at 2 years, and 22% at 3 years.[19] Foo and colleagues collected data on 9593 Western Australia residents who underwent percutaneous coronary intervention (PCI) with BMS and DES between 2000 and 2004; 6% of patients had non-cardiac surgery (major or minor, excluding gastrointestinal endoscopy) 1 year post PCI.[20] To and colleagues collected data from 11,151 patients who underwent PCI between 1996 and 2001 at Auckland City Hospital, Auckland, New Zealand; 26% of patients had major or minor non-cardiac surgery within 5 years post PCI.[21]

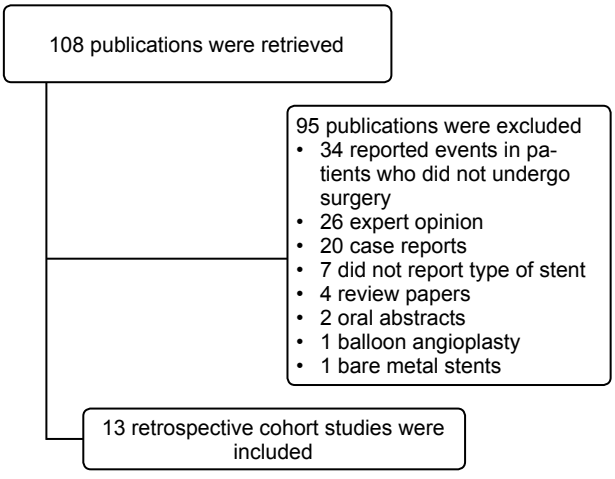

Figure 1. Outline of literature review.

Types of surgery

Nine studies reported the type of surgery performed.[6-10,12,13,17,22] Of 4148 surgeries, 816 (20%) were high risk, 2413 (58%) were intermediate risk, and 919 (22%) were low risk.[6] Four studies did not report the type of surgery.[11,14,15,18]

Perioperative risk

Information on perioperative stent thrombosis was available for 839 patients from 4 studies.[9,10,17,18] Perioperative stent thrombosis occurred in 6 of 258 patients (2.33%, 95% confidence interval [CI]: 0.9-5.0%) who underwent non-cardiac surgery within 6 months from DES implantation, in 4 of 234 patients (1.71%, 95% CI: 0.5-4.3%) who had surgery between 6 and 12 months, and in 3 of 347 patients (0.86%, 95% CI: 0.18-2.51%) who had surgery >12 months post DES implantation (Figure 2, p=0.35). Only one study reported the outcome of 2 patients who developed perioperative stent thrombosis: one patient with left anterior descending artery stent thrombosis underwent coronary bypass graft surgery and another patient with saphenous vein graft stent thrombosis was treated medically.[9]

Six studies reported the incidence of MACE according to the timing of non-cardiac surgery from DES implantation.[8,9,13,15,17,18] MACE occurred in 41 of 404 patients (10.15%, 95% CI: 7.5-13.5%) who underwent non-cardiac surgery <6 months from DES implantation, in 17 of 317 patients (5.36%, 95% CI: 3.3-8.5%) who underwent surgery between 6-12 months, and in 29 out of 435 patients (6.66%, 95% CI: 4.6-9.4)

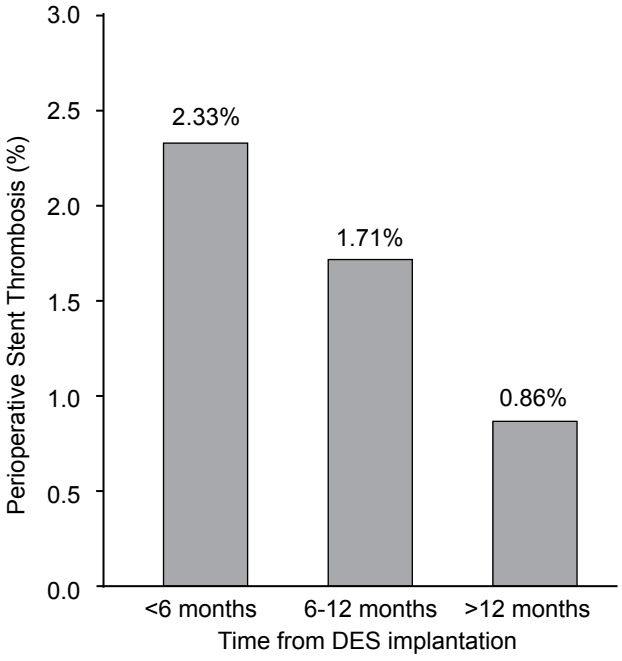

Figure 2. Incidence of perioperative stent thrombosis in patients with drug-eluting stents (DES) as a function of the time elapsed since stent implantation.

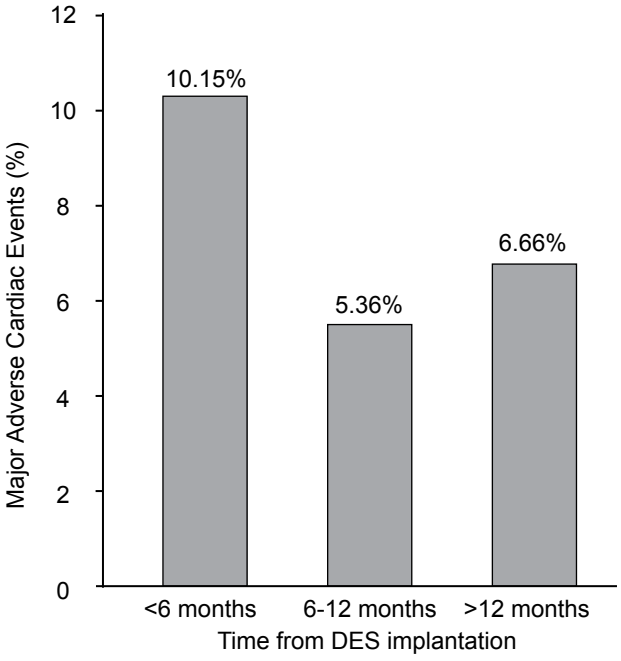

Figure 3. Incidence of major adverse cardiac events among patients with drug-eluting stents (DES) undergoing non-cardiac surgery as a function of the time elapsed between stent implantation and surgery.

who underwent surgery after >12 months (Figure 3, p=0.04).

Antiplatelet therapy and bleeding

Most studies did not report whether antiplatelet therapy was administered during the perioperative period. Antiplatelet therapy was reported for 26 of 36 patients who developed perioperative stent thrombosis: 4 patients (15%) received aspirin only, 5 patients (19%) received dual antiplatelet therapy, and 17 patients (65%) received no antiplatelet therapy during the perioperative period (Figure 4).

Three studies reported the incidence of perioperative bleeding as a function of perioperative antiplatelet therapies.[9,15,17] Bleeding occurred in 7 of 81 (8.4%) patients receiving aspirin only, in 3 of 94 (3.2%) patients who received dual antiplatelet therapy, and in 8 of 175 (4.6%) patients who received no antiplatelet therapy during the perioperative period.

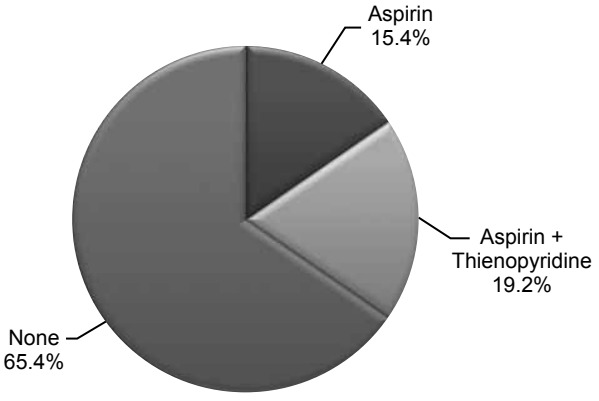

Figure 4. Antiplatelet treatment at the time of stent thrombosis for 26 patients who developed stent thrombosis after non-cardiac surgery.

Discussion

The main findings of our systematic review are that: 1) non-cardiac surgery is often required post DES implantation; 2) the risk for perioperative stent thrombosis is highest during the first 6 months post DES implantation and decreases thereafter; and 3) the majority of patients who developed perioperative stent thrombosis were not receiving any antiplatelet therapy.

Table 1. Summary of published studies describing the outcomes of patients who underwent non-cardiac surgery after drug-eluting stent implantation. All patients on clopidogrel were also receiving aspirin.

Study	n	Event	Event rate with NCS <6 months from stenting	Event rate with NCS 6-12 months from stenting	Event rate with NCS >12 months from stenting	Overall event rate	Event rate in patients that continued ASA	Event rate in patients that continued thieno-pyridine	Event rate in patients that interrupted DAPT
Berger 2010[6]	206	Death	NR	NR	NR	0.5% (1/206)	NR	NR	NR
		MI	NR	NR	NR	1.6% (3/206)	NR	NR	NR
		Stent Thrombosis	NR	NR	NR	–	NR	NR	NR
		Total MACE	NR	NR	NR	1.9% (4/206)	NR	NR	NR
		Major Bleeding	NR	NR	NR	NR	NR	NR	NR
Cruden 2010[7]	570	Death	NR	NR	NR	7% (40/570)	NR	NR	NR
		MI	NR	NR	NR	1.2% (7/570)	NR	NR	NR
		Stent Thrombosis	NR	NR	NR	NR	NR	NR	NR
		Total MACE	< 42 days: 42.4%, >42 days: 12.8%	14.6% (83)	NR	NR	NR	NR	NR
		Major Bleeding	NR	NR	NR	NR	NR	NR	NR
Van Kuijk 2009[8]	376	Death	NR	NR	NR	10.6% (40/376)	NR	NR	NR
		MI	NR	NR	NR	0.5% (2/376)	NR	NR	NR
		Stent Thrombosis	NR	NR	NR	1.6% (6/376)	NR	NR	NR
		Total MACE	24% (23/97)	6% (3/47)	9% (22/232)	13% (48/376)	NR	NR	NR
		Major Bleeding	NR	NR	NR	NR	NR	NR	NR
Assali 2009[9]	78	Death	NR	3% (1/33)	2.2% (1/45)	5.1% (4/78)	NR	NR	NR
		MI	NR	6.1% (2/33)	4.4% (2/45)	5.1% (4/78)	25% (1/4)	50% (2/4)	25% (1/4)
		Stent Thrombosis	NR	3% (1/33)	2.2% (1/45)	2.6% (2/78)	50% (1/2)	50% (1/2)	0%
		Total MACE	NR	9.1% (3/33)	6.7% (3/45)	7.7% (6/78)	33% (2/6)	50% (3/6)	17% (1/6)
		Major Bleeding	NR	NR	NR	16.7% (13/78)	54% (7/13)	23% (3/13)	23% (3/13)
Anwaruddin 2009[10]	481 (606 surge-ries)	Death	NR	NR	NR	5% (32/606)	NR	NR	NR
		MI	NR	NR	NR	4.1% (23/606)	NR	NR	NR
		Stent Thrombosis	3% (6/198)	2% (3/144)	0.8% (2/264)	2% (11/606)	27% (3/11)	36% (4/11)	36% (4/11)
		Total MACE	NR	NR	NR	9% (56/606)	NR	NR	NR
		Major Bleeding	NR	NR	NR	NR	NR	NR	NR

Kim 2008[11]	138	Death	(1/NR)	0%	0%	0.7% (1/138)	0%	0%	100% (1/1)
		MI	0%	(1/NR)	(1/NR)	1.4% (2/138)	0%	0%	100% (2/2)
		Stent Thrombosis	(1/NR)	(1/NR)	(1/NR)	2.2% (3/138)	0%	0%	100% (3/3)
		Total MACE	(1/NR)	(1/NR)	(1/NR)	2.2% (3/138)	0%	0%	100% (3/3)
		Major Bleeding	NR	NR	NR	NR	NR	NR	NR
Godet 2008 (Prospective cohort)[12]	96	Death	NR	NR	NR	2.1% (2/96)	NR	NR	NR
		MI	NR	NR	NR	2.1% (2/96)	NR	NR	NR
		Stent Thrombosis	0%	0%	(1/NR)	1% (1/96)	0%	0%	100% (1/1)
		Total MACE	NR	NR	NR	2.1% (2/96)	NR	NR	NR
		Major Bleeding	0%	0%	0%	0%	NR	NR	NR
Rabbitts 2008[13]	520	Death	NR	NR	NR	2.7% (14/520)	NR	NR	NR
		MI	NR	NR	NR	2.7% (14/520)	NR	NR	NR
		Stent Thrombosis	NR	NR	NR	0.8% (4/520)	NR	NR	NR
		Total MACE	6.1% (14/230)	5.9% (10/170)	3.3% (4/120)	5.4% (28/520)	NR	NR	NR
		Major Bleeding	NR	NR	NR	1% (5/520)	NR	20% (1/5)	NR
Rhee 2008[14]	141	Death	NR	NR	NR	NR	NR	NR	NR
		MI	NR	NR	NR	NR	NR	NR	NR
		Stent Thrombosis	NR	NR	NR	5% (7/141)	0%	0%	100% (7/7)
		Total MACE	NR	NR	NR	NR	NR	NR	NR
		Major Bleeding	NR	NR	NR	NR	NR	NR	NR
Choi 2008[15]	27	Death	NR	NR	NR	NR	NR	NR	NR
		MI	3/17 had CK-MB elevation	0%	NR	11% (3/27)	0%	0%	100% (3/3)
		Stent Thrombosis	NR	NR	NR	NR	NR	NR	NR
		Total MACE	17.6% (3/17)	0% (0/10)	NR	11% (3/27)	0%	0%	100% (3/3)
		Major Bleeding	23% (4/17)	0% (0/10)	NR	14.8% (4/27)	0%	0%	100% (4/4)
Schouten 2007[16]	99	Death	0%	0%	0%	0%	NR	NR	NR
		MI	(2/NR)	(1/NR)	0%	3% (3/99)	0%	0%	100% (3/3)
		Stent Thrombosis	(1/NR)	(1/NR)	0%	2% (2/99)	0%	0%	100% (2/2)
		Total MACE	(2/NR)	(1/NR)	0%	3% (3/99)	0%	0%	100% (3/3)
		Major Bleeding	NR	NR	NR	2% (2/99)	NR	NR	NR
Brotman 2007[17]	114	Death	0%	0%	0%	0%	NR	NR	NR
		MI	2.2% (1/45)	2.3% (1/43)	0% (0/26)	1.7% (2/114)	0%	0%	100% (2/2)
		Stent Thrombosis	0% (0/45)	0% (0/43)	0% (0/26)	0%	NR	NR	NR
		Total MACE	2.2% (1/45)	2.3% (1/43)	0% (0/26)	1.7% (2/114)	0%	0%	100% (2/2)
		Major Bleeding	NR	NR	NR	0.9% (1/114)	0%	0%	100% (1/1)
Compton 2006[18]	38 (41 surgeries)	Death	0% (0/15)	0%(0/14)	0% (0/12)	0%	NR	NR	NR
		MI	0% (0/15)	0% (0/14)	0% (0/12)	0%	NR	NR	NR
		Stent Thrombosis	0% (0/15)	0% (0/14)	0% (0/12)	0%	NR	NR	NR
		Total MACE	0%	0%	0%	0%	NR	NR	NR
		Major Bleeding	NR	NR	NR	4.9% (2/41)	NR	NR	NR

ASA – aspirin; DAPT – dual antiplatelet therapy; MACE – major adverse cardiac events; MI – myocardial infarction; NCS – non-cardiac surgery; NR – not reported.

Frequency of non-cardiac surgery

Based on the limited published and presented data, non-cardiac surgery is needed in 4% to 7% of patients during the first year after DES placement,[6,7,19-21] similar to what has been reported for BMS patients (5% in a series by Vicenzi et al[23]). Although it is not known whether the need for surgery was known prior to stent implantation in the published series (most likely not), it is of paramount importance to inquire about the need for non-cardiac surgery before a stent is implanted.

Perioperative risk

Earlier reports by Brotman et al and Compton et al did not show a difference in the incidence of MACE according to the timing of non-cardiac surgery, but they were underpowered.[17,18] Recent larger studies showed a reduction in the incidence of MACE in the 6-12 and >12 months groups compared to the <6 months group. The overall incidence of MACE among all study patients, regardless of the timing of surgery, was 8.74%. The risk for perioperative stent thrombosis was low (1.73% overall) and decreased over time after DES implantation. However, perioperative stent thrombosis has been reported as late as 68 months post DES implantation.[24]

If the need for non-cardiac surgery is known before PCI, and PCI is still required (for example for patients with acute coronary syndromes), then DES should not be implanted. Balloon angioplasty alone, bare metal stent implantation, or coronary bypass graft surgery should be performed instead, although in the future newer treatment strategies, such as drug-eluting balloons and endothelial progenitor cell capture stents might prove useful.[2, 25-26]

Management of antiplatelet therapy

Dual antiplatelet therapy is currently the cornerstone of stent thrombosis prevention. Premature cessation of dual antiplatelet therapy is the most important predictor of stent thrombosis.[27] However, cessation of both aspirin and thienopyridine is often requested or mandated before non-cardiac surgery to minimize the risk of increased operative bleeding. The cessation of antiplatelet therapy in association with the prothrombotic state induced by surgery may predispose to stent thrombosis.[5] Indeed, in most perioperative stent thrombosis cases in our review, both aspirin and the thienopyridine were discontinued (Figure 4).

Continuation of antiplatelet therapy during the perioperative period may carry an increased risk of bleeding, even with minor procedures such as pacemaker implantation.[28] This risk has to be balanced against the risk of stent thrombosis or other procedure-specific complications. For example, all antiplatelet therapy has to be discontinued in procedures in which bleeding would be catastrophic, such as intracranial or spine surgery, whereas dual antiplatelet therapy may be best continued in low-bleeding risk procedures, such as dental cleaning or tooth extraction.[29] However, there appears to be a reluctance to operate on patients who are under antiplatelet therapy (especially dual antiplatelet therapy), even among interventional cardiologists.[30]

If preoperative dual antiplatelet therapy is unacceptable to the surgical team, then discontinuing the thienopyridine but continuing aspirin is likely to carry a lower risk of stent thrombosis compared to stopping both antiplatelet agents.[31] Accordingly, a science advisory from the American Heart Association, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, American College of Surgeons, and American Dental Association and the American College of Physicians recommended considering the continuation of aspirin during the perioperative period in high-risk DES patients in whom surgery is required within 12 months from DES implantation.[29] Continuation of aspirin alone may still carry an increased risk of bleeding (by a factor of 1.5 in a 2005 meta-analysis), especially for certain procedures, such as transurethral prostatectomy.[32] Aspirin did not increase bleeding risk and had a trend towards providing benefit in a recent randomized, controlled trial.[33] In a survey from 2006, 62% of urologists in the UK asked their patients to stop aspirin before transurethral resection of the prostate and 40% cancelled the surgery if aspirin use was inadvertently continued.[34] More information on procedure-specific bleeding risk with antiplatelet therapy is needed and could facilitate perioperative antiplatelet therapy management in the future. Close communication and collaboration between surgeons, anesthesiologists, cardiologists, internists, primary care providers and all other specialties may improve coordination of the care and decrease the perioperative risk of these patients.[5]

If all antiplatelet agents need to be discontinued before surgery, pre-operative "bridging" with an antiplatelet (usually a glycoprotein IIb/IIIa inhibitor) or

anticoagulant agent could be considered to decrease the risk of stent thrombosis, especially in patients considered to be at high risk. Antiplatelet therapy is preferred, as stent thrombosis is a platelet-mediated event.[35] In a recent study of 30 high-risk patients requiring surgery within 12 months from DES implantation, the administration of tirofiban until 4 hours before surgery provided good results with no cases of death, myocardial infarction, stent thrombosis, or surgical re-exploration due to bleeding during the index admission.[36] A bridging strategy has, however, several limitations, as it requires prolonged hospitalization, may carry increased risk for bleeding, is costly, and does not address the risk during the postoperative period, when the stent thrombosis risk is highest. Regardless of the administration of preoperative bridging therapy, oral antiplatelet therapy should be restarted as soon as possible after surgery (after communication with the surgical team) by administering 325 mg of aspirin and a 300-600 mg loading dose of clopidogrel. Prasugrel should be avoided in the postoperative period due to its higher platelet inhibition potency and resulting increased bleeding risk.[37] In the future, availability of short-acting P2Y12 inhibitors, such as ticagrelor, could enable outpatient "bridging" of DES patients needing early surgery.[38]

Primary PCI is the treatment of choice in the setting of perioperative stent thrombosis, as thrombolytic administration would carry excessive risk in this setting.[30] Prompt recognition and treatment of this life-threatening complication is critical: ideally prior DES patients should undergo surgical procedures in centers with primary PCI capacity to minimize any delays in reperfusion should stent thrombosis occur.

Our study has several important limitations, including unreported or partially reported outcomes and perioperative antiplatelet therapy regimens in the published studies, exclusion of DES patients who developed a complication before surgery, and inclusion of a wide variety of surgical procedures, both minor and major. However, our review nevertheless highlights the frequent need for non-cardiac surgery after DES implantation and confirms that the timing of surgery and the management of perioperative antiplatelet therapy are important for minimizing the perioperative risk of stent thrombosis.

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