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Clinical outcomes and cost comparison of carotid artery angioplasty with stenting versus carotid endarterectomy

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Background: Recently, carotid angioplasty with stenting (CAS) has evolved as an alternative to carotid endarterectomy (CEA) for the treatment of carotid occlusive disease. Some concerns have arisen regarding the high cost of stents and neuroprotection devices, which may inflate the overall procedural costs relative to CEA. We report here a review and analysis contrasting the clinical outcomes and associated hospital costs incurred for patients treated with either CAS or CEA.

Methods: Ninety-four consecutive patients with surgically amenable carotid stenosis were offered CAS or CEA. Forty-six patients elected CAS, and 48 patients underwent CEA. CAS was performed with the Smart Precise or Acculink stents, and all procedures included neuroprotection (Filter Wire or AccUNET). CEA was performed with patients under general anesthesia with routine shunting and with Dacron or bovine pericardium patches. Clinical outcomes such as perioperative mortality, major adverse events (myocardial infarction, stroke, and death), length of stay, and the incidence of hemodynamic instability were analyzed. Total costs, indirect costs, and direct procedural costs associated with hospitalization were also reviewed.

Results: CAS was associated with a shorter length of stay compared with CEA (1.2 vs 2.1 days; $P = .02$). Differences in perioperative mortality (0% vs 2%; $P = \text{NS}$), major adverse events (2% vs 10%; $P = .36$), strokes (2% vs 4%; $P = \text{NS}$), myocardial infarctions (0% vs 4%; $P = .49$), and hypotension necessitating pressor support (21% vs 18%; $P = \text{NS}$) were not statistically significant. By using cost to charge ratio methodology according to the Medicare report, CAS was associated with higher total procedural costs (\$17,402 vs \$12,112; $P = .029$) and direct costs (\$10,522 vs \$7227; $P = .017$). The differences in indirect costs were not significant (\$6879 vs \$4885; $P = .063$).

Conclusions: CAS with neuroprotection was associated with clinical outcomes equivalent to those with CEA but had higher total hospital costs. These higher costs reflect the addition of expensive devices that have improved the technical success and the clinical outcomes associated with CAS. (*J Vasc Surg* 2006;44:270-6.)

Strokes are currently the third leading cause of mortality in the United States.^{1,2} The efficacy of carotid endarterectomy (CEA) in the management of carotid stenosis has been proven, and its durability has been tested through numerous studies, including the North American Symptomatic Carotid Endarterectomy Trial (NASCET),³ Asymptomatic Carotid Artery Stenosis (ACAS),⁴ European Carotid Surgery Trial,⁵ and Asymptomatic Carotid Surgery Trial⁶ studies. The North American Symptomatic Carotid Endarterectomy Trial (NASCET)³ and European Carotid Surgery Trial⁵ studies both demonstrated an absolute risk reduction in subsequent stroke after CEA for patients with symptomatic carotid lesions. Additional studies, such as the Asymptomatic Carotid Artery Stenosis (ACAS) study, demonstrated a similar absolute risk reduction in asymptomatic patients.

The early reported experiences with carotid angioplasty were less promising. Angioplasty alone, when compared with CEA, was associated with unacceptably high rates of stroke and death.⁷ However, several refinements in technique, such as the addition of self-expanding nitinol stents, and distal embolic protection devices have yielded satisfactory results. The data from the SAPHIRE trial⁸ and the recently updated Carotid and Vertebral Artery Transluminal Angioplasty Study trial⁹ have demonstrated clinical outcomes at least not inferior to those reported for CEA. The debate continues as to the clinical equipoise of carotid angioplasty with stenting (CAS) compared with CEA.

Our objective was to report a single-center, non-industry-supported experience with CAS and CEA. The total number of patients reported here is 94. The intent of our investigation was to evaluate and compare the clinical outcomes and the relative costs of CEA and CAS.

MATERIALS AND METHODS

All potential candidates for carotid artery reconstruction were offered either CEA or CAS. The initial process of patient selection included careful education about the risks and benefits associated with each procedure—particularly the results of recent trials evaluating CAS for high-risk patients. The decision to undertake CAS or CEA was made on the basis of patient preference and overall evaluation by

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the vascular surgeon. There were few absolute exclusion criteria for CEA. These included prior neck radiation and high cervical lesions not accessible by CEA. No specific exclusion criteria were noted for CAS. Thus, this was not a randomized trial. This article constitutes our total, consecutive experience with patients from a single institution undergoing CAS ($n = 46$) compared with similar patients undergoing CEA ($n = 48$) from November 2003 to December 2005. Criteria for acceptance of patients for CAS and CEA included an internal carotid artery stenosis of 80% or greater for asymptomatic patients and 50% or greater stenosis for symptomatic patients as measured by duplex ultrasonography. No conflicts of interest were identified before the initiation of this study. This project was approved by the institutional review board at our institution.

Coronary artery disease was assessed before CEA and CAS by reviewing patient history for prior symptoms of angina, prior myocardial infarction (MI), prior coronary angioplasty, and prior coronary artery bypass grafting. Routine preoperative testing for cardiac status included an electrocardiogram. Any irregularities or substantial cardiac history prompted a cardiology consultation, with echocardiograms and nuclear stress testing as indicated. Postoperative cardiac testing was performed only in patients with symptoms (such as chest pain, shortness of breath, hypotension, bradycardia, and mental status changes). Routine evaluation in these cases included an electrocardiogram and cardiac enzymes. Any irregularities prompted cardiology consultation with other diagnostics as necessary.

Briefly, the conduct of CAS followed a standard protocol. All patients were pretreated with clopidogrel (Plavix, Sanofi Aventis, Paris, France) and acetylsalicylic acid (aspirin) for 5 days before the procedure. CAS was performed with patients under conscious sedation in the angio suite. CAS was performed by using the Smart Precise (Cordis Inc, Miami Lakes, FL) or Acculink (Guidant Inc, Indianapolis, IN) stents, and all procedures used either the Filter Wire (Boston Scientific Inc, Natuck, MA) or Accunet (Guidant Inc) cerebral protection device. After placement of the cerebral protection device, patients underwent predilatation of the carotid stenosis with a 4-mm balloon. Postdilatation to between 5 and 5.5 mm was performed on all patients. All patients received 0.5 mg of atropine before balloon angioplasty to minimize bradycardia. Additionally, after stent deployment, all patients received an additional 0.5 mg of atropine before final stent dilatation. After the procedure, patients were maintained on clopidogrel for 6 weeks.

CEA was performed in the operating room with patients under general anesthesia. All patients had routine shunt placement. All CEAs were closed by using either a Dacron (DuPont, Wilmington, Del) patch or a bovine pericardium patch. Patients received intraprocedural heparin 100 U/kg immediately before shunt placement. In addition, all patients initiated therapy with aspirin at least 7 days before surgery and were continued on this medication indefinitely after surgery.

Both CAS and CEA patients were observed overnight in our intensive care unit (ICU) with frequent neurovascular examinations (every hour). Our facility lacks a neurovascular stepdown unit. As such, our patients were housed as boarders in the ICU for neurovascular monitoring. Patients without complications were discharged the next day from the ICU.

Patient data were collected retrospectively, including patient characteristics, patient outcomes, and costs related to the procedures. Clinical outcomes such as technical success (defined as completion of the procedure with a residual stenosis $<30\%$ of the luminal diameter), procedure-related mortality (mortality occurring directly related to or within 30 days of the procedure), major adverse events (the combined rate of mortality, MI, and stroke within 30 days of the procedure), and rates of perioperative MIs were assessed. In addition, the length of the procedure-related stay, the length of the ICU stay, and the incidence of hypotension necessitating pressor agent support were also analyzed.

Cost data for each individual procedure were obtained from our financial services department. All costs were normalized to 2005 dollars based on the consumer price index. To minimize the disparity between hospital charges and subsequent reimbursement from third-party payers, Medicare cost to charge ratio methodology¹⁰ was used to determine adjusted total costs (total costs associated with the procedures and admissions), direct costs (that is, costs directly associated with the procedures and admission, such as materials and room charges), and indirect costs (that is, costs not directly related to the procedures, such as administrative costs, meals, and parking). These costs reflected the actual services received by our patients. Each patient care-related charge was grouped into a major resource department (such as pharmacy, radiology, or surgical supply). The total resources used per department were then adjusted by using a ratio based on Medicare Part A and B payment schedules. The resultant cost data reflect the individual resource utilization per patient per hospital admission. In this way, our cost data are more generalizable to other institutions.

A specific cost breakdown was also performed to determine the source of any cost disparities. The specific categories we studied were room and board-associated costs, surgical vs angiography supply costs, general radiology costs, operating room time costs, laboratory study costs, recovery room-related costs, ICU-related costs, pharmacy costs, and other patient-related costs. Room and board costs were defined as costs associated with utilization of patient beds (ICU and surgical ward beds). Surgical vs angiography suite supply costs reflected supplies used for interventions (such as Dacron patches for CEA and stents and neuroprotection devices for CAS). General radiology costs reflected costs for studies required during routine patient care not directly related to the procedures (such as postoperative carotid duplex scans and chest radiographs). Operating room costs reflected resource utilization of operating room time. Laboratory study costs reflected various

Table I. Patient characteristics

Variable	Carotid endarterectomy group (n = 48)	Carotid angioplasty and stenting group (n = 46)	P value
Mean age (y)	73	69	NS
Peak systolic velocity (cm/s)	321	335	.61
Symptomatic lesions	38%	22%	.05
% Male	56%	50%	.67
Tobacco abuse	63%	48%	.21
Diabetes mellitus	21%	41%	.04
Hypertension	96%	93%	.67
Coronary artery disease	56%	76%	.05
Prior coronary artery bypass graft	33%	30%	.82
Chronic obstructive pulmonary disease	19%	20%	NS

Table II. Comparison to SAPPHIRE patients

Variable	CEA patients (n = 48)	SAPPHIRE CEA (n = 167)	CAS patients (n = 46)	SAPPHIRE CAS (n = 167)
Mean age (y)	73	72.6	69	72.5
% Male	56%	67%	50%	67%
Diabetes mellitus	21%	27.5%	41%	25.3%
Hypertension	96%	85.1%	93%	85.5%
Coronary artery disease	56%	75.5%	76%	85.8%
COPD	19%	13.8%	20%	17%
Prior CABG	33%	30.8%	30%	43.4%
Symptomatic lesions	38%	27.7%	22%	29.9%

CEA, Carotid endarterectomy; CAS, carotid angioplasty with stenting; COPD, chronic obstructive pulmonary disease; CABG, coronary artery bypass grafting.

studies used during these patient admissions (such as serum chemistries or coagulation panels). Recovery room–related costs reflected services rendered after the procedure for monitoring and patient care. ICU-related costs reflected supplies used for ICU care (cardiac monitor, pulmonary artery catheters, and so on). Pharmacy costs entailed resource utilization for all drugs administered during patient admissions. Finally, other patient care–related costs were defined as ancillary services (such as physical therapy or respiratory therapy).

Our CAS and CEA patient data were analyzed and compared by using an unpaired *t* test and the Welch *t* test where appropriate. Parameters with significant *P* values ($\leq .05$) were determined to be associated with a clinically significant effect on outcomes. GraphPad InStat 3 (GraphPad Software, Inc, San Diego, Calif) statistical software was used to analyze the data in this study.

RESULTS

The preprocedure patient characteristics in our CEA arm ($n = 48$) were similar to those in our CAS patients ($n = 46$). The mean age in the CEA group was 73 years, vs 69 years in the CAS group ($P = NS$). The average peak systolic duplex velocity was 321 cm/s in the CEA group vs 335 cm/s in the CAS group ($P = .61$). Our CEA group had more symptomatic lesions (38% vs 22%) than the CAS group ($P = .05$). Both groups also had a nearly even sex distribution (56% male vs 50% male in the CEA and CAS

groups, respectively; $P = .67$). Diabetes was more prevalent in the CAS than in the CEA group (41% vs 21%; $P = .04$). In addition, coronary artery disease was also more prevalent in the CAS vs the CEA group (76% vs 56%; $P = .05$). The remainder of the patient characteristics of our CEA and CAS groups are summarized in Table I. These patient characteristics were also reproduced and compared with the corresponding SAPPHIRE trial patient characteristics in Table II.

Technical success was achieved in all CEA and CAS patients. There was only one procedure-related mortality in the CEA group, and there was none in the CAS group (2% vs 0%; $P = NS$). This mortality was attributed to a fatal MI on the second postoperative day. The rate of major adverse events was 10% in the CEA group and 2% in the CAS group ($P = .36$). There were two strokes in the CEA group, and there was one stroke in the CAS group ($P = NS$). In our CEA group, one stroke occurred immediately after surgery and was nonhemispheric. This patient has symptoms of contralateral arm weakness that continued for several weeks after surgery. No changes were noted on computed tomographic scan or magnetic resonance imaging of the head. The second stroke in our CEA group occurred 7 days after surgery. A computed tomographic scan demonstrated a minor infarct in the territory of the ipsilateral middle cerebral artery (MCA). This patient had symptoms of aphasia and weakness of the contralateral hand. These deficits were noted to be present up to 12 months of follow-up. One

Table III. Clinical outcomes

Variable	Carotid endarterectomy group (n = 48)	Carotid angioplasty and stenting group (n = 46)	P value
Technical success of procedure	100%	100%	NS
Procedure-related mortality	2% (1 death)	0%	NS
Major adverse events	10% (5 events)	2% (1 event)	.36
Strokes	4% (2 strokes)	2% (1 stroke)	NS
Myocardial infarction (MI)	4% (2 MIs)	0%	.49
Length of stay (d)	2.1	1.2	.02
Intensive care unit length of admission (d)	0.8	1.1	.15
Hypotension necessitating pressor support	21%	18%	NS

Table IV. Cost data

Variable	Carotid endarterectomy group (n = 48)	Angioplasty and stenting group (n = 46)	P value
Total costs	\$12,112.28	\$17,402.40	.030
Direct costs	\$ 7227.18	\$10,522.56	.017
Indirect costs	\$ 4884.98	\$ 6879.84	.063

stroke occurred in our CAS group several hours after intervention. The patient presented with somnolence and an expressive aphasia several hours after CAS. A computed tomographic scan was negative, but a magnetic resonance image demonstrated a minor infarct in the ipsilateral MCA territory. These symptoms completely resolved within 7 days of the procedure. There were two MIs in the CEA group, and there was one in the CAS group ($P = .49$). Although the one fatality in the CEA group occurred as a consequence of an MI, the mortality and MI were counted as two major adverse events by the criteria used to define this combined measure of adverse clinical outcomes. The fatal MI was diagnosed by autopsy, and the other adverse events were diagnosed by electrocardiogram changes and elevated cardiac enzymes. These two cardiac events represent subendocardial infarcts. The average length of stay was longer in the surgical vs the CAS group (2.1 vs 1.2 days; $P = .02$). The duration of ICU admission was 0.8 days in the CEA group and 1.1 days in the CAS group ($P = .15$). Hypotension necessitating pressor support occurred in 18% of the CAS group vs 21% in the CEA group, but this was not statistically significant ($P = NS$). These results are listed in Table III.

Our analysis of the costs associated with these two procedures produced the following results. The mean total cost associated with CEA was \$12,112.98, whereas the cost associated with CAS was \$17,402.40. This difference was statistically significant ($P = .03$). The mean direct cost for CEA was \$7227.18, compared with \$10,522.56 for CAS ($P = .02$). A difference was also noted for a mean indirect cost for CEA of \$4884.98 and \$6879.84 for CAS, but this difference did not reach statistical significance ($P = .06$). These data are summarized in Table IV.

A specific cost breakdown was also performed to determine the source of these cost disparities. Specifically, we

Table V. Cost breakdown

Individual cost	CEA group (n = 48)	CAS group (n = 46)	P value
Room and board	\$2351	\$ 1403	.07
Surgical vs angio suite supplies	\$1953	\$15,407	.001
General radiology costs	\$ 263	\$ 107	.09
OR time costs	\$2335	\$ 0	NS
Laboratory costs	\$1815	\$ 195	.001
PACU costs	\$ 403	\$ 110	.001
ICU care costs	\$ 124	\$ 27	.17
Pharmacy costs	\$ 957	\$ 226	.001
Other care-related costs	\$ 850	\$ 222	.02

CEA, Carotid endarterectomy; CAS, carotid angioplasty with stenting; OR, operating room; NS, not significant; PACU, postanesthetic care unit; ICU, intensive care unit.

analyzed room and board, surgical vs angiography supply, general radiology, operating room time, laboratory study, recovery room-related, ICU-related, pharmacy, and other patient-related costs. These results are summarized in Table V. Compared with CAS, CEA was more expensive with respect to laboratory, postanesthetic care unit, pharmacy, and other patient care-related costs. Differences in room and board, general radiology, operating room time, and ICU care costs were not statistically significant. However, a marked difference was noted between the costs of surgical supplies as compared with angiography suite supply costs (\$1953 vs \$15,407; $P = .001$).

DISCUSSION

This study demonstrated that there were no significant differences in the rates of technical success, 30-day combined all-cause mortality and stroke rates, rates of MIs, lengths of ICU admission, or the incidence of clinically significant hypotension. However, a statistically significant reduction in length of stay was noted for CAS vs CEA (1.2 vs 2.1 days); this is consistent with other reports.¹¹⁻¹³ These clinical parameters indicate that CAS is not inferior to CEA.

Recently, the results of several studies have suggested the equivalency of carotid angioplasty and CEA as the technique of carotid angioplasty has been refined.⁹ The outcomes of the SAPHIRE trial reveal a statistical benefit in the major adverse event rate favoring CAS (5.8%) when

compared with CEA (12.6%) at 30 days.⁸ Other authors have described much lower rates of morbidity and mortality when comparing their own experience with CEA in high-risk patients.¹⁴ The results of the Carotid Revascularization Endarterectomy vs Stenting Trial (CREST)¹⁵ and Stent-Supported Percutaneous Angioplasty of the Carotid Artery vs Endarterectomy¹⁶ trials, when they are completed, will provide more data regarding the clinical outcomes associated with these interventions.

Some of the clinical outcomes reported here are not what was initially expected. Postprocedure hypotension necessitating pressor support was high in both our CEA and CAS cohorts. Literature reports of postprocedure hypotension in CAS patients range from 10% to 51%.¹⁷⁻¹⁹ Similar hypotension occurs at a much lesser rate in CEA patients, reported from 3% to 10%.^{18,19} We noted that 21% of our CEA patients and 18% of our CAS patients experienced hypotension necessitating transient pressor support. This complication could certainly increase both adverse events and costs. However, no statistically significant difference was noted between our two treatment groups.

Another potential confounding variable pertains to the length of ICU admission. All our CAS and CEA patients were admitted to the ICU as boarders for neurovascular monitoring. In essence, this practice pattern at our institution might cause an overestimation of care provided and of resource utilization for these admissions.

Length of stay was significantly longer in our CEA group compared with our CAS group (2.1 vs 1.2 days). Our current practice guidelines include a next-day discharge for both CEA and CAS patients. Most surgeons discharge CEA patients the day after surgery, and some have even advocated discharge on the same day for uncomplicated cases. However, our experience included some complicated CEA cases with a longer length of stay.

Analysis of our patient characteristics also demonstrated some statistically significant differences that might represent confounding variables. More patients in our CEA cohort had symptomatic lesions before the procedure, and more CAS patients had comorbid coronary artery disease and diabetes mellitus. The higher incidence of these comorbid states before surgery could skew results in each respective group toward adverse outcomes. However, we do not believe that a selection bias occurred to favor healthier individuals in either cohort.

In contrast to the apparently equivalent clinical outcomes measured, the cost analysis of these data indicated substantially higher total and direct costs associated with CAS compared with CEA. These findings are similar to those reported by Gray et al.²⁰ CAS was far more costly with respect to procedure-related materials. In particular, the angio suite costs of \$15,407 for stents, neuroprotection devices, and other catheters far outweighed the supply costs for CEA (\$1953). Specifically, the carotid stent and neuroprotection devices add approximately \$3800 to \$4000 to the procedure. Because there are currently only two approved stents and three neuroprotection devices for this specific indication, it may be assumed that these high costs

may diminish in the future once competitive devices are approved.

To our knowledge, only a few studies have investigated the cost differential between CEA and CAS.²¹ Some of these studies are in concert with our findings and indicate a higher cost associated with CAS.^{21,22} In contrast, two additional studies did not demonstrate a statistically significant difference in cost, but these studies did not include the routine use of distal embolic protection devices.^{23,24} One study, by Gray et al,²⁰ actually indicated lower costs associated with CAS vs CEA.²⁰ However, this study also did not include the routine use of neuroprotection devices. Currently, to our knowledge, this is the only study to analyze cost data associated with CAS and CEA to reflect the changes brought forth by the Center for Medicare and Medical Services guidelines.²⁵

Some of the results of our cost analysis are also subject to confounding variables. A significant difference in clinical laboratory costs (\$1815 for CEA and \$195 for CAS) was noted in our analysis. The longer length of stay evident in our CEA group could account for greater overall resource utilization. We also noted that no cost was incurred for operating room time in our CAS group. This resource utilization was included in total angio suite supply costs, because angio suite time represents a different level of resource utilization (in terms of equipment, personnel, and operating room scheduling). Differences in laboratory costs did reach statistical significance between our two treatment groups (\$1815 for CEA vs \$195 for CAS; $P = .001$). No routine laboratory tests were indicated for either treatment arm, and the origin of these increased costs remains unclear.

There are several limitations inherent to this study. First and foremost, the limited number of patients may bring the power of this study into question. However, the purpose of this study was to provide an initial single-institutional experience with CEA compared with CAS. Few, if any, articles have been published, to our knowledge, to compare and contrast the clinical outcomes and costs associated with these two modalities. The results of our study are meant to stimulate subsequent trials to address this issue of clinical outcome and cost.

Another limitation of this study is the fact that these data were retrospectively collected. Many inherent biases are prevalent in this type of study, regardless of careful analysis by the investigators. However, CAS with neuroprotection is a relatively new technique, and the results of our analysis may still provide some utility to evaluate this new modality. In addition, this study comprised a consecutive experience with CAS at a single institution. Some groups have indicated that a steep learning curve is inherent to CAS. We did not exclude early cases, because any clinical practice must accept early, and possibly suboptimal, results with CAS.

Any cost analysis is limited by the variable nature of financial data. Although we attempted to normalize our data by adjusting our cost to 2005 dollars and used Medicare cost estimates, it is difficult to fully realize the absolute

resource utilization by patients. We chose to include all patients with complications in this study. Although some might argue that differences in the severity of complications might skew cost data (such as length of stay, ICU costs, and pharmacy costs), these differences in cost reflect the reality of this patient population.

A detailed analysis of the specific costs itemized per patient with respect to the surgical supply and angio suite supply cost departments has confirmed the substantial cost differential we observed. We can justify our data on the basis of two observations. The first observation was that the interventional procedure was not a bundled procedure. Each guidewire, stent (in some cases, multiple stents), neuroprotection device, angioplasty balloon, sheath, angiogram, and catheter used was a separate cost. In comparison, CEA was performed by using bundled costs. Although this unbundled cost coding practice may inflate resource utilization, this practice will likely change in the near future, and this may appropriately reduce some of the cost associated with CAS. A second major difference between CAS and CEA regards the disposable nature of CAS supplies, in comparison to the reusable nature of most vascular surgical sets. Every guidewire, neuroprotection device, angioplasty balloon, and so on was discarded after each case. This represents a significant consumable utilization of resources. To put this into perspective, if every surgical instrument used during CEA were discarded instead of reused, the surgical supply costs would be astronomically higher.

The findings of our internal analysis have demonstrated that CAS is not inferior to CEA in terms of clinical outcomes. In addition, the average length of admission for our CAS group is shorter than for the surgical group. However, a cost savings from shorter admissions is dwarfed by the overwhelmingly high costs associated with catheter-based interventions. Therefore, the routine use of CAS as an alternative to supplant CEA cannot be justified on the basis of clinical outcomes and cost savings. At present, a selective utilization of CAS may be justified in patients unsuitable for CEA. The limiting factor for CAS concerns prohibitive cost differences and not patient outcomes. However, the promise of further technological innovations (such as drug-eluting stents) may further enhance the clinical outcomes associated with this alternative approach.

AUTHOR CONTRIBUTIONS

Conception and design: BP, MD
Analysis and interpretation: BP, JM
Data collection: BP, AM
Writing the article: BP, MD
Critical revision of the article: MD, JM
Final approval of the article: MD, JM
Statistical analysis: AM
Overall responsibility: BP

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