Comparison of the Effect of Skeletonized and Pedicled Left Internal Thoracic Artery Harvesting Techniques in Coronary Artery Bypass Surgery

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ABSTRACT

BACKGROUND

We wanted to study the effect of 2 LIMA (Left Internal Mammary Artery) harvesting techniques (skeletonization and pedicled) on ITA's (Internal Thoracic Arteries) flow, length, postoperative sternal wound infection and postoperative pain.

METHODS

This is a randomized controlled trial of the two different methods of internal mammary artery harvesting. The study was conducted in the Department of Cardiothoracic Surgery, Nizam's Institute of Medical Sciences (NIMS) and included people undergoing coronary artery bypass grafting (CABG) over a period of 18 months from January 2016 to July 2017.

RESULTS

In study subjects, male participants were 28 (70 %). The mean flowrate of skeletonized group was 99.7 ± 5.03 and that of the pedicled group was 60.5 ± 3.97; the mean difference (39.2) between the two groups was statistically significant. The mean length of skeletonized group was 21.55 ± 2.26 and that of the pedicled group was 15.6 ± 2.39; the mean difference (5.95) between the two groups was statistically significant. In the skeletonized group, 1 (5 %) had no pain, 8 (40 %) had mild pain, 6 (30 %) had moderate pain, 4 (20 %) had severe pain, and 1 (5 %) had very severe pain. In the pedicled group, 6 (30 %) had mild pain, 6 (30 %) had moderate pain, 5 (25 %) had severe pain and 3 (15 %) had very severe pain. The difference in the proportion of postoperative sternal infections within the study group was statistically not significant.

CONCLUSIONS

Skeletonization technique has higher mean free flow (of the LIMA) and mean length (of the left internal thoracic artery graft) than that of pedicled technique.

KEYWORDS

Internal Thoracic Artery, Myocardial Revascularization, Skeletonization Technique

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BACKGROUND

Cardiovascular diseases are reported to be the highest contributor to morbidity and mortality globally. Even when the individual diseases are concerned, ischaemic heart disease was reported to be leading cause of mortality across the globe. According to recent estimates, an estimated 422.7 million CVD (Cardiovascular Disease) cases and 17.92 million CVD deaths were registered worldwide in 2015.[1] In India, cardiovascular diseases (CVDs) have now become India's leading cause of mortality. CVD is responsible for a fifth of all mortality. The main causes are ischaemic heart disease and stroke, which are responsible for > 80 % of CVD deaths. An approximate age standardized CVD death rate of 272 per 100 000 people in India is higher than the global average of 235 per 100 000 population in the global burden of disease report. Premature mortality rose by 59 percent from 23.2 million (1990) to 37 million (2010) in terms of years of life lost due to CVD in India.[2] Coronary artery disease encompasses a wide spectrum of disease, ranging from mild chronic stable angina to severe acute myocardial infarction leading to sudden death. The management also depends on the nature and severity of the disease at presentation. The gold standard for multivessel and left main coronary disease treatment remains coronary artery bypass surgery. After CABG.[3], the use of the Internal Thoracic Arteries (ITAs) as bypass conduits was correlated with enhanced long-term outcome.

Many internal thoracic artery grafts are usually harvested as a pedicle, which requires the dissection on either side of a rim of tissue covering the artery. But several drawbacks are associated with this technique. In the early postoperative period, vasospasm and hypoperfusion are an important concern, particularly in the presence of vasoactive medications. Sternal perfusion impairment and increased deep sternal wound infections may be associated with it, especially in diabetic patients receiving bilateral ITAs. Another critical problem is increased and constant postoperative pain.[4] This process, labelled as skeletonized harvesting, includes only the ITA's harvest without any surrounding tissue. As the arterial conduit that has been dissected from all surrounding tissues, the accompanying veins, fascia, lymphatics, adipose tissue, and chest wall, the Skeletonized Internal Thoracic Artery (SKT-ITA) can be described. The technique leaves the adventitia as the outermost layer of the conduit harvested.[5]

As a solution to many of the issues associated with ITA harvesting, skeletonized harvesting has been published. While this approach carries the potential risk of increased arterial injury, none of the studies published to date have documented any differences in microscopic injury with ITA harvesting skeletonization. Skeletonization's proposed advantages include increased flow and duration, decreased rates of sternal infection, and decreased pain. However, the majority of these initial studies were observational in nature and there was a considerable amount of uncertainty regarding the superiority of the skeletonized harvesting over pedicled harvesting.[6] Even though many recent randomized controlled trials have been conducted on the subject, the clear guideline has not evolved due to a limited number of trials on the subject. The availability of the studies on Indian population is further limited. Hence, there is a need to conduct clinical trials comparing the two techniques on the Indian population. The current study has been conducted with an objective of enhancing the available evidence on the subject.

METHODS

The study was a randomized controlled trial of two different methods of internal mammary artery harvesting. The study was conducted in the Department of Cardiothoracic Surgery, Nizam Institute of Medical Sciences, among people undergoing coronary artery bypass grafting over a period of 18 months from January 2016 to July 2017. Ethics approval was obtained from institute Human Ethics Committee. Informed written consent was sought from all the patients.
Group A: Skeletonized harvesting.
Group B: Pedicled harvesting.

Inclusion Criteria

Patient with coronary artery disease, who are planned for elective coronary artery bypass grafting surgery with informed consent.

Exclusion Criteria

Emergency surgery, history of cardiac surgery, history of antiplatelet drug use with the exception of ASA (Acetyl-Salicylic Acid) 80 mg / day during the 5 days, preoperative coagulation disorder, left ventricular ejection fraction less than 20 %, preoperative renal dysfunction (serum creatinine > 1.2 mg / dL), preoperative hepatic dysfunction (serum aspartate / alanine transferase > 60 U / L), preoperative electrolyte imbalance, and chronic diuretic therapy, inability to return for follow up visits and use of intra-aortic balloon pump.

Considering the smaller sample size, to avoid unequal group sizes, block randomization method was used to allocate the study participants to treatment groups. The block size used was 4, with 2 subjects randomized to each of the two treatment groups within each block. The sequencing of interventions, within each block, was done by simple random sampling using the random number tables in a predetermined direction.

Sequentially Numbered, Opaque Sealed Envelopes (SNOSE) method was used for allocation concealment in the study. The patients were admitted to cardiac surgery ward from the outpatient department or from cardiology department. History, examination and baseline investigations were carried out. Patients were properly counseled about the surgical procedure and the proposed intervention. An informed consent was taken. Patients were randomly allocated to one of the two groups with the help of random number table, were performed by two senior consultant cardiac surgeons who were proficient in harvesting both pedicled and skeletonized LIMA and were randomly assigned to the cases selected for the study.

The left pleura was dissected laterally in group A so that along its course the LITA (Left Internal Thoracic Artery) and its concomitant veins could be seen. In the first intercostal space, where it is less sticky to the chest wall, the internal thoracic fascia was incised only medial to the LITA. From this point on, the LITA skeletonization was done distally, leaving all concomitant veins in the chest wall. Most of the dissection was blunt, apart from removing the fascia. The tributaries were connected tangentially and distally to the vessel wall and were broken with scissors to prevent heat injury. The concomitant vein was split in the first intercostal space after the LITA was harvested to its bifurcation level, and skeletonization was performed proximally up to the subclavian artery. Care has been taken to prevent damage to the phrenic nerve.

LITA was harvested as a pedicle in group B. The internal thoracic fascia was incised approximately 0.5 cm away from concomitant veins along both sides of the LITA with electrocautery. Next, with electrocautery, the flap of fascia, muscle, and fat tissue containing the LITA and concomitant veins was dissected, working from its distal to proximal ends, and ligating the major branches of LITA with Ligaclips (Ethicon, Somerville, NJ).

Intraoperative Assessment of ITA Flow

All the CABG procedures were done via median sternotomy on standard cardiopulmonary bypass, systemic hypothermia (32 C), tepid ante grade cardioplegia and aortic root venting. Free flow of the LIMA was measured manually as flow per unit time, i.e. as mean per-operative blood flow in mL per minute during cardiopulmonary bypass just before the LIMA to LAD anastomosis by allowing it to bleed into a 100 mL container over 20 seconds and at zero resistance. Mean arterial pressure was maintained at 70 (+ 5) mmHg during the assessment of LIMA flow. A minimum flow of 30 mL per minute or 10 mL per 20 seconds was acceptable.

Intraoperative Assessment of ITA Length

By means of a bulldog clamp, the distal end is occluded, and the length of the LITA graft is determined using a sterile ruler (cm) from the subclavian artery to the bifurcation point.

Postoperative Assessment of Pain

The chest wall pain assessment was conducted by a blind observer prior to discharge (4 to 6 days postoperatively) and 4 weeks postoperatively. With a 100 mm Visual Analogue Scale (VAS; 0 - no pain, 100 - worst pain), a questionnaire designed to measure the degree of pain was quantified.

The requirements for identifying a surgical site infection is in compliance with the recommendations of the Centres for Disease Control. If only the skin and subcutaneous tissue were involved, a sternal wound infection was considered superficial, deep when the infection penetrated the sternum but did not include it, and organ/ space when sternal osteomyelitis or mediastinitis occurred. Postoperative symptoms of the sternal wound have been measured and compared during postoperative visits.

Statistical Methods

Study group (Skeletonized, Pedicled) were considered as a primary explanatory variable. Flow rate, length, postoperative pain, post-op sternal infection were considered as primary outcome variables. Age, gender, previous co-morbidities etc were considered as other potential confounding variables. By mean and standard deviation for quantitative variables, frequency, and proportion for categorical variables, descriptive analysis was performed. Appropriate diagrams such as bar diagrams, pie diagrams, and box plots were also used to display data.

With respect to quantitative variables, both the study groups were compared using unpaired t-tests. Using the chi square test or Fisher's exact test, categorical variables were compared between the two classes. P value < 0.05 was deemed statistically important. For statistical analysis, IBM SPSS version 22 was used.

RESULTS

A total of 40 subjects were included in the analysis. Among the study population, 20 (50 %) were skeletonized group and another 20 (50 %) were pedicled group. The mean age was 60.75 ± 7.76 in the study population. The range between 48 years to 79 years in the study population (95 % CI 58.27 to 63.23). Male participants were 28 (70 %) remaining 12 (30 %) were female participants.

Symptoms	Frequency	Percentage
Diabetics		
Yes	21	52.50 %
No	19	47.50 %
Dyslipidaemia		
Yes	16	40.00 %
No	24	60.00 %
Hypercholesterolemia		
Yes	9	22.50 %
No	31	77.50 %
Hypertension		
Yes	8	20.00 %
No	32	80.00 %
CCS Angina Class		
Yes	5	12.50 %
No	35	87.50 %

Table 1. Descriptive Analysis of Symptoms in the Study Population

Age	Group		Chi Square	P Value
	Skeletonized (N = 20)	Pedicled (N = 20)		
Skeletonized	59.55 ± 4.84	2.150	-2.34	6.64
Pedicled	61.70 ± 8.67			
Gender				
Male	15 (75 %)	13 (65 %)	0.476	0.490
Female	5 (25 %)	7 (35 %)		

Table 2. Comparison of Group with Gender of Study Population (N = 40)

Among the study population, 21 (52.50 %) had diabetics, 16 (40 %) had dyslipidaemia, 9 (22.50 %) had hypercholesterolaemia, 8 (20 %) had hypertension, and 5 (12.50 %) had CCS (Canadian Cardiovascular Society) angina class.

The mean age of skeletonized group was 59.55 ± 4.84 and the pedicled was 61.70 ± 8.67, with skeletonized group, 15 (75 %) participants were male and 5 (25 %) participants were female. Among the pedicled group, 13 (65 %) participants were male and 7 (35 %) participants were female. The difference in the proportion of age and gender between study group was statistically not significant (p value < 0.05).

Diabetics	Group Skeletonized (N = 20)	Pedicled (N =20)	Chi Square	P Value
Yes	10 (50 %)	11 (55 %)	0.100	0.752
No	10 (50 %)	9 (45 %)		
Hypertension				
Yes	5 (25 %)	3 (15 %)	0.625	0.429
No	15 (75 %)	17 (85 %)		
Hypercholesterolemia				
Yes	5 (25 %)	4 (20 %)	0.143	0.705
No	15 (75 %)	16 (80 %)		
CCS Angina Class				
Yes	3 (15 %)	2 (10 %)	0.229	0.633
No	17 (85 %)	18 (90 %)		
Dyslipidaemia				
Yes	7 (35 %)	9 (45%)	0.417	0.519
No	13 (65 %)	11 (55 %)		

Table 3. Comparison of Group with Comorbidities of the Study Population (N = 40)

The difference in the proportion of diabetics, hypertension, hypercholesterolaemia, CCS angina class and dyslipidaemia status between study group was statistically not significant. The mean flowrate of skeletonized group was 99.7 ± 5.03 and the pedicled was 60.5 ± 3.97, and the mean difference (39.2) between two groups was statistically significant (p value < 0.001). The mean length of skeletonized group was 21.55 ± 2.26 and the pedicled was 15.6 ± 2.39, and the mean difference (5.95) between two groups was statistically significant. (P value < 0.001). Among the skeletonized group, 1 patient (5 %) had no pain, 8 (40 %) had mild pain, 6 (30 %) had moderate pain, 4 (20 %) had severe pain and 1 (5 %) had very severe pain. Among the pedicled group, 6 (30 %) had mild pain, 6 (30 %) had moderate pain, 5 (25 %) had severe pain and 3 (15 %) had very severe pain.

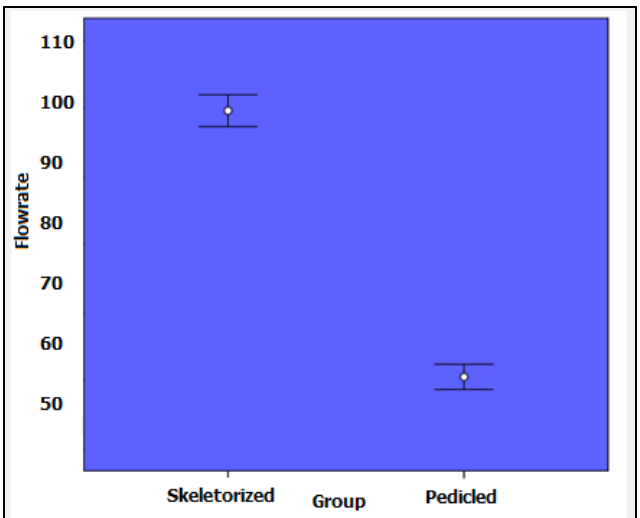

Figure 1. Comparison of Mean Flow Rate between the Study Groups (N = 40)

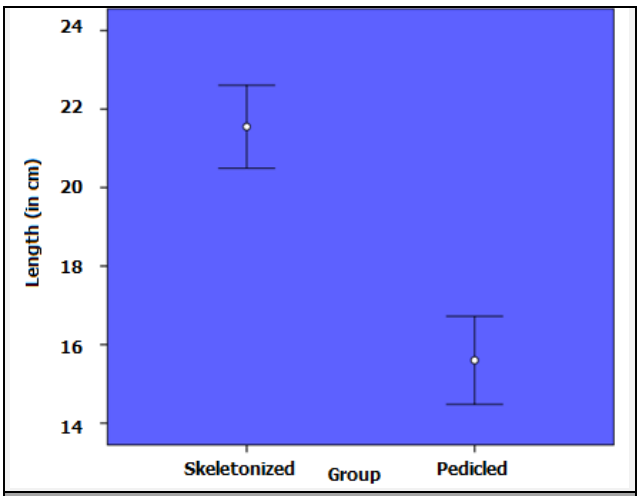

Figure 2. Comparison of Mean Length (in cm) between the Study Groups (N = 40)

Post-Operative Pain	Group Skeletonized	Pedicled
No Pain	1 (5 %)	0 (0 %)
Mild	8 (40 %)	6 (30 %)
Moderate	6 (30 %)	6 (30 %)
Severe	4 (20 %)	5 (25 %)
Very Severe	1 (5 %)	3 (15 %)

Table 4. Comparison of Group with Post-Operative Pain in the Study Population (N = 40)

*No statistical test was applied- due to 0 subjects in the cells

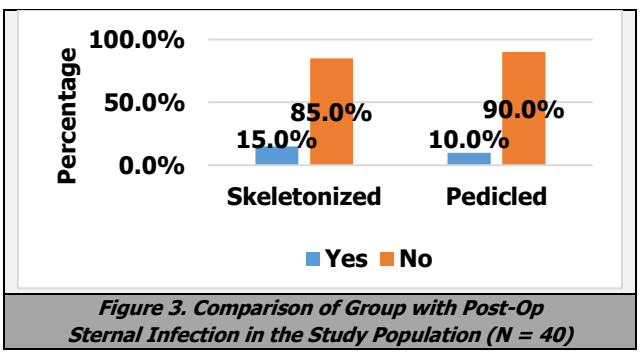

Figure 3. Comparison of Group with Post-Op Sternal Infection in the Study Population (N = 40)

Among the skeletonized group, 3 (15 %) had postoperative sternal infection. Among the pedicled group, 2 (10 %) had postoperative sternal infection. The difference in the proportion of postoperative sternal infection between study group was statistically not significant. (P value 0.633).

DISCUSSION

Though CVD tops the list of contributors to mortality and morbidity in adults, there occurred a dramatic reduction in deaths attributable to coronary heart disease in recent decades in all high-income and some middle-income countries. The justification of it comes from the evidence of reduction of related risk factors like smoking, hypertension, dyslipidaemia, etc coupled with expanding medical therapy with the use of antihypertensives, oral and injectable hypoglycaemics as well as statins. In addition, the role of surgical and interventional revascularization techniques should not be antiquated as they play a significant role in prolonging the survival of the affected people. Hence, our study was done to evaluate the fruitfulness of

skeletonization technique over the pedicled technique of revascularization.

The aging has an important role to play in risk for chronic diseases and hence they have a significant impact on quality of life. The mean age of this study population was 60.75 ± 7.76 years and it ranged from 48 years to 79 years. In concordance with this, Codecasa, R., et al. have recruited males aged 59 ± 4 years and females aged 59 ± 4 years in their study.[7] This was not dissimilar to the study from Hirose, H., et al. who have included patients with an average age of 66.2 years.[8] In contrary, Gideon, S., et al. have recruited patients with mean age above 70 years.[9] With the left-sided shift of age group for the incidence of CVDs, enormous of options are open for the surgeons to explore a newer technique than preferring conventional methods.

Among the study population, male participants were 28 (70 %) and remaining 12 (30 %) were female participants. Supporting to this, one study has included 93 % males and 86 % males enrolled their study participants to BIMA (Bilateral Internal Mammary Artery) and SIMA (Single Internal Mammary Artery) group respectively.[7] In contrast to these studies Kurlansky, P. A., et al. have recruited patients that included only women in it.[10] Although men had a higher prevalence of more than three diseased coronary arteries and left ventricular dysfunction, studies showed that women tend to be older, diabetic and also they have stage 3 to 5 chronic kidney disease, and sometimes chronic lung disease. According to one study, this group contributed to the majority of cases included in non-elective CABG and are less likely to receive an internal mammary artery graft.[11] All these factors succumb females to have an increased risk of operative mortality than post-CABG. Even though one study has shown declining annual rate of CABG surgeries by 53.7 % in men and 57.8 % in women over the past decade in addition to diminishing rate of in-hospital mortality among women.

Among the study population, 20 (50 %) were a skeletonized group and another 20 (50 %) were a pedicled group. Among the study population, 21 (52.50 %) had diabetics, 16 (40 %) had dyslipidaemia, 9 (22.50 %) had hypercholesterolemia, 8 (20 %) had hypertension, and 5 (12.50 %) had CCS angina class. Age, gender, diabetes, hypertension, hypercholesterolemia, dyslipidemia, CCS Angina not significantly different between the group.

The mean flow rate was 80.1 ± 20.35 in the study population. The range between 53 to 115 in the study population. The mean flow rate of the skeletonized group was 99.7 ± 5.03 and the pedicled was 60.5 ± 3.97, and the mean difference (39.2) between two groups was statistically significant. Supporting this, one study has given a satisfying evidence that describes the higher patency of ITA grafts in the skeletonized group (2.26 ± 0.40 mm) than that in the pedicled group (1.95 ± 0.17 mm) that was statistically significant.[12] One study has shown results that are not dissimilar as the flow rates of the skeletonized group (197.2 ± 66.6 mL / min) are higher than that in the pedicled group (147.1 ± 70.5 mL / min) with statistically significant results. Deja, M. A., et al.[13] study also supported our findings as the free LITA blood flow was 100.3 ± 14.84 mL / min in skeletonized compared against a mere 66.3 ± 7.42 mL / min in the nonskeletonized group (p = 0.048). Not dissimilar were the findings from a recent study done by Kandemir, O., et al. that showed higher flow rate in skeletonized than in the pedicled group (62.4 ± 4.8 mL / min versus 88.6 ± 6.9 mL/min) with statistically significant results.[13] In contrary, one study declared lower ITA flow rate in skeletonized arteries (7.4 ± 0.9 versus 10.1 ± 1.0 mL / min; P = 0.01) than non-skeletonized arteries.

The mean length was 18.58 ± 3.79 in the study population. The range between 11 cm to 25 cm in the study population. The mean length of the skeletonized group was 21.55 ± 2.26 and the pedicled was 15.6 ± 2.39, and the mean difference (5.95) between two groups was statistically significant (p value < 0.001). In concordance with this, Deja, M. A., et al. described the lengthier LITA graft used in the skeletonized than the nonskeletonized group.[13] In contrary, Boodhwani, M., et al.[15] required more ITA length in the skeletonized group (18.2 ± 0.3) than non-skeletonized group (17.7 ± 0.3 cm) though it was not significant (P > .05).

In this study, among the skeletonized group, 1 (5 %) had no pain, 8 (40 %) had mild pain, 6 (30 %) had moderate pain, 4 (20 %) had severe pain and 1 (5 %) had very severe pain, while in the pedicled group, 6 (30 %) had mild pain, 6 (30 %) had moderate pain, 5 (25 %) had severe pain and 3 (15 %) had very severe pain. One study by Bar-El, Y., et al. reviewed and commented that prevalence of postoperative chest pain remained comparable between the Skeletonized-LIMA group (45 %) and Pedicled-LIMA (50 %) through the V group have reported a significantly lesser pain (18 %, P < .05).[16] Yet, the findings from Boodhwani, M., et al. strengthened our findings as they have concluded decreased pain at the 3-month follow-up and a reduction n in major sensory deficits at the 4-week and 3-month (17 % versus 50 %; P = 0.002) follow-ups in the skeletonization group when compared against the non-skeletonized.[15] Although, the results of Markman, P. L., et al proved contrary that showed comparable incidence of neuropathic pain between the groups (5 % in skeletonized group versus 10 % in pedicled group P > .05) at 7 weeks and 0 % in skeletonized group versus 10 % in pedicled group P > .05 at 21 weeks.[17]

Among the skeletonized group, 3 (15 %) had a post-operative sternal infection. Among the pedicled group, 2 (10 %) had postoperative sternal infection. The difference in the proportion of postoperative sternal infection between study groups was statistically not significant. This finding was supported by a review from Ali, E., et al. which stated higher patency rates that exceeded more than 95 % in ten non-comparative studies and postulated that the skeletonization technique produced lesser degree of devascularization of the sternum thereby reducing the sternal wound infection.[18]

CONCLUSIONS

It is well known that the resistance to atherosclerosis makes the internal thoracic artery (ITA) graft, the best conduit for re-vascularization with added long-term patency rates of all

conduits that are being used for myocardial revascularization. There is also evidence that supports their superiority over SV grafts in the delayed progression from moderate to severe stenosis or maintaining longer patency rates. With overwhelming evidence of various grafting techniques in practice, our study adds evidence to the same by describing the efficacy of skeletonization technique over pedicled technique when performed on elderly subjects. Revascularization of the left coronary system using a skeletonized LIMA resulted in excellent clinical results and grafting in the hospital and mid-term due to morphological variations, such as the derivation of its blood supply from the vasa vasorum, its well-developed internal elastic membrane, its innervation, and a comparatively low number of smooth muscle cells. The research concluded that the technique of skeletonization had a higher mean free flow (of the LIMA) and mean length (of the LITA graft) than the pedicled technique.

Limitations

Data used in this study are from a tertiary care center and generalization is difficult. Regression analysis for prediction of association between dependent and independent variables was hardly evaluated.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.
Financial or other competing interests: None.
Disclosure forms provided by the authors are available with the full text of this article at jebmh.com.

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