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The Effectiveness of Using Ice Application on Vascular Access Site Complication after Cardiac Catheterization

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I. Introduction

It has been estimated that more than 5 million diagnostic and interventional cardiac catheterizations procedures are performed annually in the United States. Cardiac catheterizations are becoming the gold standard for the diagnosis, evaluation, and treatment of cardiac diseases (American Heart Association**,** 2013). Despite the beneficial effect of cardiac catheterization in reducing morbidity and mortality of the cardiovascular disease, this invasive procedure is not free of complications such as: hematoma, retroperitoneal hemorrhage, pseudo - aneurysm, arteriovenous fistula, arterial occlusion, femoral neuropathy, and infection. (Benson, Wunderly, Perry, Kabboord, et al., 2010). The American College of Cardiology's benchmark for the incidence of all cardiac catheterization complications is no more than 1% for diagnostic and 3% for interventional procedures. However, up to 41% of patients undergo percutaneous coronary procedures develop femoral hematoma (Berry, Kelly, Cobbe and Eteiba, 2010).

Vascular complications expose patients to additional discomfort, extended hospital stay, and higher hospital costs (Jones and Mccutcheon, 2012). Also, patients may require additional treatment, such as blood transfusions and vascular surgery. It is estimated that complications related to the access site result in more than 75,000 surgical procedures annually (Berry, Kelly, Cobber and Eteiba, 2010). Reducing vascular complications, especially hematoma formation, which is the most common access site complications, is a nursing priority after cardiac catheterization (Jones and Mccutcheon, 2012).

Most patients report pain and discomfort at the vascular access site during the sheath removal procedure. Pain and discomfort were one of the four main complains reported by patients during and after cardiac catheterization and post-procedure (Laura, Wentworth, Elizabeth, Bechtum, et al., 2014). Despite the active use of intravenous analgesics to treat and prevent pain associated with femoral sheath removal, many patients continue to have mild pain during the procedure, which indicates that further research is needed to optimize pain management.

The recognition and initial treatment of vascular complications is often a nursing responsibility. Nurses have the ability to reduce patients' pain using non-pharmacological interventions. Researchers have begun to analyze non-pharmacologic nursing interventions targeted procedural pain relief (Kussmaul, Buchbinder, Whitlow, Aker, et al., 2009 and Nordrehaug, Chronos, Priestley, Buller, and Foran, 2010). Cold application for the treatment of acute and chronic pain is considered a nursing non-pharmacologic intervention (Bulechek , Butcher , McCloskey Dohterman , 2008; Herdman, 2009). Currently, ice is used intermittently as a non-pharmacological intervention to reduce procedural pain.

Ice application is a simple and inexpensive therapy which has been accepted for decades as an effective non pharmacologic intervention for pain management. It increases the pain threshold, decreases the inflammatory reaction and spasm (Lehmann, Heath-Lange, and Ferris, 2009). Ice application decreases pain and hematoma size after cardiac catheterization through constricts local blood vessels and decreases tissue temperature. This constriction decreases blood flow and cell metabolism, which can limit hemorrhage into soft tissue. After approximately 20 minutes of ice application, blood vessels in the injured area dilate slowly, increasing the tissue temperature, an effect which is termed "reactive vasodilation." The most useful local therapeutic ice applications include management of edema, swelling and pain or for reducing hemorrhage into soft tissues post catheterization (Laura, Wentworth, Elizabeth, Bechtum, et al., 2014).

Despite the promising benefits of ice therapy for decreasing discomfort and being beneficial in reducing hematoma size, more evidence is needed about the best methods that can be used to prevent post sheath removal complications. This information will enable critical care nurses to better decide the best methods and provide a quality nursing care for their patients. Thus, the purpose of the current study was to examine the Effectiveness of using ice application on vascular access site complication after cardiac catheterization. The vascular access site complications studied in the current study included hematoma size and pain.

II. Theoretical Framework

Several proposed theories suggest that ice as a pain reliever can be effective. Ice has been used in and out of the hospital for pain control related to surgical and traumatic injuries. Its application as a pain reliever is widely accepted, although the mechanism of how ice achieves pain relief is not clear. Some potential explanations for analgesia with ice may include, a decrease in transmission of pain through the nerves; a decrease of inflammation and thereby an increase in the pain threshold; and the cold sensation overriding the pain sensation, also known as the gate control theory (Algafly and George, 2007). In the gate control theory of pain, ice acts on pain receptors to blunt the perception of other mechanical and chemical stimuli, including pain, by closing the "gates" to other sensations at the central nervous system. In accordance with this theory, ice applied directly to a pain stimuli site should decrease pain (Algafly and George, 2007 and Helms and Barone, 2008). Other investigators propose that ice may work in the peripheral nervous system by decreasing the velocity of transmission in the nerve and thereby increasing the pain threshold and pain tolerance along the same nerve (Algafly and George, 2007). Several theories may explain the physiological effects of ice in relation to pain control. It has been stated that ice application, along with pharmacologic interventions, can reduce adverse effects, improve outcomes, decrease hospital stays, decreases the need for dosing with opioids or narcotics, thus decreasing potential medication complications.

III. Hypothesis Of The Study

1- Patients who will receive ice application are more likely to experience less pain at vascular access site than patients who will receive routine hospital care.
2- Patients who will receive ice application are more likely to experience less hematoma size than patients who will receive routine hospital care.

IV. Methods

Design: A quasi experimental design (study/control) used to test the study hypothesis.

Setting: The current study was conducted at cardiac catheteriztion unit of the Teaching Hospital , Menoufia University, Shebin A L Khom, Menoufia Governrate.

Sample: A convenience sample of 100 adult patients who attended the cardiac catheteriztion unit at the Teaching Hospital of Menoufia University. These patients were approached to participate in the study over a two months period from the end of August 2014 to the beginning of November 2014. These patients met the following inclusion criteria: a) adult patient aged 19 - 65years old, b) both sexes, c) ability to give informed consent, and use the Visual Analog Scale (VAS), d) Hemodynamically stable. Patients were excluded if they had a) peripheral vascular disease, b) Low platelet count and low hematocrit on admission, c) uncontrolled hypertension, d) Pregnancy, e) history of platelet dysfunction or known coagulopathy, f) active bleeding from the femoral arterial or venous puncture site which required early removal of the sheath or manual pressure before the planned time of sheath removal. Patients with such conditions were excluded because all these factors increase the risk for the development of vascular access site complications and might influence the study outcomes. One hundred participants who met the study inclusion criteria were divided alternatively and randomly into two equal groups, 50 patients each. The study group received ice application at the vascular access site and the control group received routine hospital car.

V. Tools of Data Collection

A) Interviewing Questionnaire used to collect socio-demographic data such as age, sex, marital status, educational level, and medical history including pain killer medications (Fentamyl, Midazolam and Acetaminophen). Patient weight, chronic diseases such as: Diabetes Mellitus and hypertension and Systolic and diastolic blood pressure were collected by the investigator using semi-structured demographic sheet at the initial data collection point. These data were collected through face to face interview with the patients.

B) Visual Analog Scale for Pain (VAS): the VAS is unidimensional measure of pain intensity, which has been widely used in adult populations. The VAS used to measure patients' pain and satisfaction with vascular access site management. The scale was chosen for its simplicity and efficiency (Dauphin, 2004). The VAS has a possible range of 0 – 10, with 0 being no pain and 10 being the worst pain they ever felt. Regarding to satisfaction, patients were asked, "How would you rate the overall satisfaction with vascular access site pain management?"Where Zero indicates not satisfied and 10 indicate satisfied. The VAS score is determined by measuring in centimetres from the left hand end of the line to the point that the patient marks using a ruler. A higher score indicates greater pain intensity. Based on the distribution of pain, VAS scores described pain intensity as none, mild, moderate, or severe, the following cut of points on the pain VAS have been recommended: no pain (0cm), mild pain (1-4 cm), moderate pain (5–7 cm), and severe pain (8–10 cm) (Laura , Wentworth, Elizabeth , Bechtum, et al., 2014).

Test–retest reliability has been shown to be good, but higher among educated (r = 0.94, P= 0.001) than illiterate patients (r = 0.71, P= 0.001) before and after attending a cardaic or rheumatology out patient clinics **(**Joos ,Peretz and Beguin,2003**).** Validity of VAS has been reported in patients with a variety of cardaic and rheumatic diseases, the pain VAS has been shown to be highly correlated. The correlation between vertical and horizontal orientations of the VAS is 0.99 (Scott and Huskisson, 2001).

C) Hematoma Charcterestic: Site of hematoma development (at the floor ,inside catheter lab or from the catheter lab. to the department), timing according to sheath removal (before and after sheath removal, before and after mobilization) and hematoma size, Small hematoma: hematoma measuring 2 to < 5 cm in diameter; (2) intermediate hematoma: hematoma measuring equal or greater than 5 to 10 cm in diameter, while significant large femoral hematoma was defined as >10 cm in diameter (Laura, Wentworth, Elizabeth, Bechtum, et al., 2014).

Data Collection Procedure

The permission for conducting the study was obtained from the Faculty of Nursing and an official letter was issued to Menoufia University Hospital for seeking permission to carry out the study after explaining the purpose of the study .

Protection of Human Rights:

An oral consent was obtained from the patient who met the study inclusion criteria. During the intial interview, each participant was given a verbal explanation about the purpose, procedure , the benefits of participating in the study and what is expected from him / her. The researcher explained that participation in the study is voluntary and the patient can withdraw from the study at any time without penalty and can refuse to participate in the study. Patients were assured that the information would be confidential. The researcher explained that there is no cost or physical/psychological harm to participate in the study.

Pilot Study:

A pilot study was conducted on 10% of the study sample (ten patients) to test the practicality and applicability of the questionnaire and detect the obstacles and the problems that might be encountered during the data collection. Also help to estimate the time needed to fill in the questionnaire. Patient who participated in the pilot study were excluded from the sample .

Data Collection Procedure

Patients who met the study inclusion criteria were interviewed individually by the researcher in the catheter unite in the critical care unite before starting the session of therapy. Both groups were matched against the study inclusion criteria as much as possible in relation to age, sex, and severity of disease. Patients were randomly assigned into two equal groups, 50 patients each. Patients were assigned to study and control groups through writing the names of the patients on slips of paper, placed in a container and mixe well, then drawnout one name at a time until reaching the required sample. The study group received ice application and the control group received routine hospital care.

The Initial Visit (pre intervention)

The first time the researcher met the participants was considered the baseline measure. Participants were interviewed in the catheter unite to fill in the study questionnaires which included: 1) socio demographic sheet; medical history; systolic and diastolic blood pressure and pain killer medications taking. 2) Visual Analog Scale and 3) Hematoma size.

The Study Group:

Patients assigned to the study group were received ice application to the vascular access sites for 20 minutes before the sheath removal. The ice application was delivered using Novaplus ice bags (Kimberly-Clark Health Care Inc.). Patients received ice application to femoral sites, whether access is on one side exclusively or on both sides. After a sheath was removed and homeostasis was obtained, the study group received another 20 minutes of continuous application of ice to all femoral vascular access sites. Data regarding pain level and the condition of the vascular access site (hematoma) were collected before sheath removal, at homeostasis, one hour after homeostasis, 12 to 16 hours after homeostasis, and after one week. The VAS was used to measure pain at the vascular access sites. Hematoma was measured as a palpable firm area of 5 cm or more in diameter. A review of the medical record allowed data collection of the amount and type of pain medication used from 20 minutes before and continuing for six hours after removal of sheath.

Control group:

After procedure, the standard care requires that most patients were transferred to the interventional cardiovascular unit. The patient must remain in the supine position with the head of bed elevated 30 degrees while sheaths are in place. Patients are not allowed to move any extremity with a sheath and can only move head side to side while sheaths are in place. When the activated clotting time value is equal to or lower than 180, the patient's femoral access lines are removed. Sheaths may be in place for a total of 4 to12 hours (from insertion to removal). Commonly, Patients experience some degree of pain with sheath removal and during bed rest afterward. Standard nursing practice after sheath removal includes assessing patients for pain and administering pain medication as needed such as: Fentanyl, Morphine, Acetaminophen/Oxycodone, or Acetaminophen, or a combination as a physician order.

As a routine care, the sheath removal process involves the application of firm manual pressure over the sheath insertion site while gently removing the sheath from the groin. All venous lines are removed with minimal interval.

Manual pressure is held for three minutes. When venous homeostasis has been achieved, the arterial sheath can be removed. Occlusive pressure is held for another three minutes, with continued, but lessening, pressure applied for another 10 to 20 minutes. After all sheaths have been removed and homeostasis achieved, standard practice entails the application of a non-compression adhesive strip with a gauze pad and the placement of the patient on flat bed rest. After two hours of flat bed rest, the head of the bed can be elevated to 30° maximum and the patient may turn to the arterial site side. After three hours, the patient is allowed to be in any position of comfort. The patient may cautiously begin ambulation with assistance after four hours of homeostasis.

Data Analysis:

Categorical variables were reported as frequency and percent; continuous variables were reported as mean and standard deviation. Comparison of results between the study group and the control group was done for continuous variables using 2-sample t- tests and for categorical variables using Pearson χ^2 or Fisher exact test as appropriate. All analyses used 2-sided tests, and a *P* value less than or equal to .05 was considered statistically significant.

VI. Results

Characteristics of the Study Sample

The mean age of the participants in the control and the study group was 56.16 ±3.71, 55.92 ±5.24 years old respectively. The majority of participants (74%, 84 %) were male in both control and study groups respectively and most of them (80%) were married in both groups. Concerning the educational level of the participants in the study group (60%) have secondary school and (50%) in the control group were university graduates and the majority of participants were working (88 %, 80%) in both control and study groups respectively. See table (1).

Table 1: Characteristics of Study Sample for both Control and Study Groups.

Socio-demographic Characteristics	Study Group (n=50)		Control Group (n=50)		X^2	P
	No	%	No	%		
Age (years) X ± SD	55.92 ±5.24		56.16 ±3.71		0.292	> 0.05
Sex						
• Male	42	84.0	37	74.0	0.147	0.05>
• Female	8	16.0	13	26.0		
Marital Status						
• Married	40	80.0	40	80.0	.112	
• Widow	7	14.0	10	20.0		0.05>
• Divorced	3	6.0	0	0.0		
Level of Education						
• Read and write	7	14.0	8	16.0		
• Secondary School	30	60.0	17	34.0		
• University Graduates	13	26.0	25	50.0	0.115	0.05>
Occupation						
• Working	40	80.0	44	88.0		
• Not working	10	20.0	6	12.0	0.275	0.05>

Table (1) showed that there were no statistical significant differences between study and control group related to socio-demographic characteristics.

Table 2:Frequency and Percentage Distribution Related to Medical History of the Control and Study Groups.

Medical History	Study Group (n=50)		Control Group (n=50)		X^2	P
	No	%	No	%		
Obesity						
• No	37	74.0	41	82.0		
• Yes	13	26.0	9	18.0	0.215	0.05>
History of DM						
• No	35	70.0	33	66.0	0.668	
• Yes	15	30.0	17	34.0		0.05>
History of Hypertension						
• No						
• Yes	45	90.0	42	84.0	0.275	0.05>
	5	10.0	8	16.0		

Table (2) showed that the majority of the participants in the study sample were not obese (82%, 74%), have no medical history of DM (66%, 70%) and have no history of Hypertension (84%, 90%) in both control and study group respectively.

Table 3: Mean and Standard Deviation Regarding Clinical Data of the Control and Study Groups.

Medical History	Study Group (n=50)	Control Group (n=50)
	Mean ± SD	Mean ± SD
Systolic Blood Pressure	126.65 ±5.09	125.62 ±4.63
Diastolic Blood Pressure	76.42 ±3.16	77.81 ±3.46
BMI	27.55 ±2.30	28.44 ±3.53

Table (3) showed that the mean (SD) of systolic blood pressure was 125.62 ±4.63; 126.65 ±5.09 and diastolic blood pressure was 77.81 ±3.46; 76.42 ±3.16 for control and study group and the mean (SD) of body mass index was 28.44 ±3.53; 27.55 ±2.30 in control and study group respectively.

Table 4: Effect of Ice Application Intervention on Vascular Access Site Pain after Cardiac Catheterization in both Control and Study Groups.

Time of Pain	Study Group (n=50)	Control Group (n=50)	P Value
	Mean ± SD	Mean ± SD	
At the time of sheath removal	1.84 ±0.80	2.41 ±0.93	0.031
Hemostasis	3.0 ±0.0	3.11 ±1.13	>0.05
One hour post hemostasis	1.33 ±0.20	1.87 ±0.83	0.05>
12 to 16 hours post hemostasis	1.11 ±0.33	**1.0** ±0.74	0.05>
After Two weeks	1.0±0.0	2.62 ±0.51	0.05>

Table (4) showed that patients in the study group were significantly less likely to report femoral vascular access site pain at the time of sheath removal than patients in the control group (1.84 ±0.80 vs 2.41 ±0.93; *P*=.05). However, there was no statistical significant difference between control and study group related to pain at hemostasis, one hour after hemostasis, at 12–16 hours after hemostasis, and after two weeks.

Table 5: Frequency and Percentage Distribution Related to Medication Use in both Control and Study Groups

Medication	Study Group (n=50)		Control Group (n=50)		P
	No.	%	No.	%	
Fentanyl					
• At sheath removal	37	(74.0)	44	(88.0)	>0.05
• 20 minutes before sheath removal	25	(50.0)	41	(82.0) (30.0)	<0.05
• 6 hours after hemostasis	8	(16.0)	15		>0.05
Midazolam					
• At sheath removal	34	(68.0)	40	(80.0)	>0.05
• 20 minutes before sheath removal	25	(50.0)	41	(82.0)	<0.05
• 6 hours after hemostasis	7	(14.0)	14	(28.0)	>0.05
Acetaminophen	4	(8.0)	15	(30.0)	<0.05

Table (5) showed that less patients in the study group received Midazolam during the sheath removal procedure comparing to the control group (68%, 80%). The majority of patients in the control group (88%) received Fentanyl during the sheath removal procedure comparing to the study group (74%). During the study time period (8%) patients used acetaminophen in the study group compared to (30 %) in the control group.

Table 6:Characteristics of Hematoma for Control and Study Groups

Characteristics of Hematoma	Study Group n = 50		Control Group n = 50		P
	No.	%	No.	%	
Hematoma	20	40.0	19	38.0	>0.05
Place					
• In floor	14	70.0 30.0	12	63.2	>0.05
• In catheter lab.	6		7	36.8	
In floor					
• At sheath removal	5	35.7 42.9	4	33.3	
• Before sheath removal	6		6	50.0	>0.05
• After sheath removal		2.1			
	3		2	16.7	
In catheter lab.					>0.05
• Before mobilization	2	33.3 66.7	2	28.6	
• After mobilization	4		5	71.4	
Size					>0.05
• <5cm	14	70.0 20.0	12	63.2	
• 5-10cm	4	10.0	5	26.3	
• >10cm	2		2	10.5	

Table (6) showed that (42.9%, 50%) of hematoma occurred before sheath removal at floor in both study and control group respectively and the majority of hematoma (66.7%, 71.4) occurred after mobilization in catheter lab in study and control group respectively. Concerning the hematoma size, (70.0 %, 63.2%) of the participants have hematoma size <5cm in both groups respectively.

Table 7: The Effect of Ice Application Intervention on Hematoma Size after Cardiac Catheterization in both Control and Study Groups

Characteristics of Hematoma	Study Group n=50		Control Group n=50		P
	No.	%	No.	%	
Size of Hematoma pre intervention					>0.05
• <5cm					
• 5-10cm	14	70.0 20.0	12	63.2	
• >10cm	4	10.0	5	26.3	
	2		2	10.5	
Size of Hematoma post intervention					
• <5cm	0	0.0	7	36.8	<0.05
• 5-10cm	1	5.0	3	15.8	>0.05
• >10cm	1	5.0	2	10.5	>0.05
• Treated hematoma	18	90.0	7	36.7	0.001

Table (7) showed that there was a statistically significant difference in hematoma size post intervention between control and study group**.**

VII. Discussion

The current study hypothesized that the patients who received ice application are more likely to experience less pain at vascular access site than who received routine hospital care.The present study findings support the study hypotheses and revealed that there was a statistically significant reduction in pain at the time of sheath removal in study group compared to control group. The findings of the current study are similar to was reported by Chlan, Sabo and Savik, (2013) that ice application for 20 minutes decrease pain at the femoral site during sheath removal. Also, findings of the current study are similar to what was reported by Kuzu and Ucar (2012) who found that ice application after cardiac catheterization has a great impact on the reduction of pain at vascular access site. In addition, findings of the current study are consistent with what was reported by Laura , Wentworth, Elizabeth , Bechtum, et al., (2014) who examined the effect of ice application at the vascular access sites for 15 minutes before the sheath removal and found that ice application decrease pain in adults after cardiac catheterization.

The findings of the current study revealed that there was no statistical significant difference between control and study group regarding pain at hemostasis, one hour after hemostasis, 12–16 hours after hemostasis, and after two weeks. Findings are similar to what was reported by Algafly and George (2013) who examined the effect of cryotherapy on pain threshold and pain tolerance after atrial fibrillation radiofrequency catheter ablation and found that, there was no significant statistical decrease of pain at hemostasis, one hour after hemostasis, 12–16 hours after hemostasis, and after two weeks between study group and control group.

Findings of the current study revealed that participants in the study group were less likely to receive acetaminophen, fentanyl and midazolam during the study time period from 20 minutes before sheath removal to 6 hours after hemostasis compared to the control group. Study findings are similar to what was reported by Belli , Rendine and Mazzone (2013) who examined the effect of cold therapy after femoral catheterization on using pain killer and found that, the study group received less fentanyl, midazolam, and acetaminophen compared to the control group. In addition, findings of the current study are similar to what was reported by Peet, McGrath, Brunt and Hilton (2012), that the use of sedatives and opioids for pain relief from 20 minutes before sheath removal to 6 hours after hemostasis can be efficiently reduced by ice application during and after sheath removal and found that ice application intervention reduce the frequency of using pain killer medications. National Institutes of Cardiology (2009) reported that the frequency of pain was reduced by 60 percent and the incidence of sedative use during the study time was reduced by 50 percent with the ice application in adult immediately after cardiac catheterization.

However, the study findings are different from what was reported by McCaffery, (2009) who found that cold therapy is not effective method in pain reduction after cardiac catheterization. Participants in both study and control group reported pain at sheath removal. A possible explanation of the current study findings could be that patients reported pain at time of sheath removal by 70% and this resulting from using ice for short time.

The current study hypothesized that patients who received ice application are more likely to experience reduction in the hematoma size compared to patients who received routine hospital care. The findings of the current study supported the study hypotheses and revealed that there was a statistically significant reduction in the hematoma size in the study group compared to the control group.

Findings of the present study are similar to what was reported by Laura , Wentworth, Elizabeth , Bechtum, et al., (2014) who reported that a decrease in hematoma size was associated with using ice application after cardiac catheterization. Also, The findings of the current study are similar to what was reported by Pracyk, Wall, Longabaugh, Frank, et al., (2014) whom studied the effect of ice application on complications after cardiac catheterization, and found that decrease of hematoma size was associated with application of ice at vascular access site that was approximately 90 percent completely treated than control group.

Findings from the Nurses' Health Study and Health Professionals Weitz, Hirsh and Samama, (2013) suggested that application of ice for 20 minutes or more every hour daily for two weeks reduces the developing of hematoma by 30 percent**.**

Limitation of The Study

The findings of the current study are limited in their generalizability because of the convenience sample, small sample size and using a single setting for data collection.

VIII. Conclusions

Implementation of ice application had led to improving patient comfort and decreasing hematoma size and pain at vascular access site complications after cardiac catheterization. Most patients in study group who used ice application immediately before and after sheath removal experienced less pain and used less pain killer

and have decreased hematoma size. The study findings suggest that the use of ice as an intervention to decrease pain may lessen the need for pharmacologic agents post-procedure.

IX. Recommendations

Ice application is not currently recognized as a standard practice to treat vascular access site complications after cardiac catheterization, yet it is more effective than compression and acceptable to patients. The expansion of the findings of the current study would contribute to the implementation of evidence-based practice. These could be achieved by prepairing training programs for cardiac nurses about the importance of occasionally using ice application for pain management at vascular access sites after cardiac catheterization. Further researches are needed to help validate and identify decreased medication use that has beneficial implications on practice, including a decrease in patient adverse effects, cost, and nursing time used to administer medications to promote comfort. Replication of this study is recommended with several design changes such as, using large sample size; using of randomized selection to achieve appropriate representation of population; and conducting the study in a larger scale to include multicenter.

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