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Projection of visual material on postoperative delirium in patients undergoing cardiac surgery

A double blind randomized clinical trial

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Abstract

Background: Postoperative delirium is a neurobehavioral disorder that can appear after surgery. It is characterized by an altered level of consciousness and impaired cognitive function. The aim of this study was to evaluate the impact of visual projection of images of relatives or loved ones in patients undergoing cardiac surgery in the immediate postoperative period, and its influence on the incidence and development of postoperative delirium.

Methods: A randomized, double-blind clinical trial was designed in the immediate postoperative period of adult patients undergoing cardiac surgery. Consolidated Statement of Reporting Trials guidelines were followed. A control group (CG) and an intervention group (IG) were established. In the IG, the patients underwent a visual projection, while the usual unit treatment was carried out with the CG. Sociodemographic, anthropometric, anesthetic, and surgical variables were also recorded. The postoperative delirium assessment scale used was the confusion assessment method for diagnosing delirium in intensive care unit patients.

Results: Information was collected from 104 patients undergoing cardiac surgery. Most of the patients included in the study were men (66.35%) and the most performed surgical intervention was aortic valve replacement (34.62%). In the CG, positive patients in postoperative delirium increased from 19.23% to 25%, while in the IG they decreased from 5.77% to 1.92%. The logistic regression analysis presents a prediction model where the variables that influence the model are gender and group membership, meaning that being female and belonging to the IG significantly reduce the presence of delirium.

Conclusion: The projection of visual material reduced the incidence of postoperative delirium in patients undergoing cardiac surgery, although it cannot be established that it is effective as a treatment once the pathology is already established.

Abbreviations: CAM-ICU = confusion assessment method for diagnosing delirium in intensive care units patients, CG = control group, ICU = intensive care units, IG = intervention group, MMSE = mini-mental state examination.

Keywords: cardiac surgery, delirium, intensive care, mental health, perioperative care, pictures of relatives

1. Introduction

Postoperative delirium is a neurobehavioral disorder that can appear after surgery. It is characterized by an altered level of consciousness and impaired cognitive function, manifested by impaired memory, disorientation, agitation, and/or slurred speech. Its onset is sudden, fluctuating and reversible, it cannot be explained by a previous or evolving neurocognitive disorder and it manifests itself in a short period of time (hours or days).[1,2]

Delirium is clinically classified as hyperactive, hypoactive, and mixed. Hyperactive is a subtype in which the patient shows signs of increased activity of the sympathetic system while hypoactive consists of a decreased response to stimuli,

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

The protocol of this study was approved in March 2021 by the Drug Research Ethics Committee of León University Hospital Complex with reference (CEIm 2155).

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drowsiness, bradypsychia, and lethargy. Mixed delusion combines characteristics of the hyperactive and hypoactive[3,4] elements. Currently, the exact pathophysiology of postoperative delirium is unknown, which could be due to the heterogeneity of the syndrome.[5]

The predisposing factors for postoperative delirium are those inherent to the patient and which condition him to develop the pathology. Among them, age is the main risk factor for its onset.[6,7] The precipitating factors of postoperative delirium are those external to the patient and which contribute to the development of the disease.[8] Regarding the type of surgery, cardiac,[8] traumatological,[8] and urgent[6] in this order, can cause the development of postoperative delirium.

Staying in intensive care units (ICU) or resuscitation units, especially without ambient light and without objects that help the patient orient himself, for example, clocks and calendars, seems to trigger the presence of delirium. The use of physical restraints in these units could further aggravate the patient's condition.[8]

The incidence reported in the literature consulted ranges from 10% to 90%.[9] This wide margin is due to the fact that the percentage of patients who develop the pathology varies significantly depending on the patient's age, whether the surgery is scheduled or urgent, the type and the duration of the intervention, or the detection methods and diagnostic criteria used.[9–11] The most widely used scale for the diagnosis of delirium in critical care units is the CAM-ICU scale (confusion assessment method for diagnosing delirium in intensive care units patients).[12]

Delirium can be managed both pharmacologically and without drugs. Haloperidol[13] and dexmedetomidine[14] stand out among the most widely used drugs. The non-pharmacological interventions most mentioned by the authors in the management of postoperative delirium include the reorientation of patients using objects such as clocks and calendars in their room,[15] maintaining good nutrition and hydration,[13] performing adequate pain management,[13] maintaining good lighting, avoiding excessive noise,[16] allowing early use of hearing aids,[14,16] and glasses[14,16] or promoting early mobilization.[7]

The general objective of this study was to evaluate the impact of visual projection of images of relatives or loved ones in patients undergoing cardiac surgery in the immediate postoperative period, and its possible influence on the incidence and development of postoperative delirium.

2. Materials and methods

2.1. Ethical statement

The study followed the Consolidated Statement of Reporting Trials guidelines. The protocol complied with the Declaration of Helsinki and has been approved by an Ethics Committee. Confidentiality of personal data was ensured at all times. Written informed consent was obtained from all patients. The registry in was performed in ClinicalTrials.gov.

2.2. Design

A single-blind randomized clinical trial was designed with an intervention group (IG) and a control group (CG). The study was carried out among patients undergoing cardiac surgery and was carried out between June and August 2023.

The CG received the usual treatment from the unit for postoperative delirium, based mainly on the use of haloperidol and/or dexmedetomidine, as well as mechanical restraints when the patient required it, while the IG received a visual projection of images of relatives or loved ones as a method of prevention and treatment of postoperative delirium.

2.3. Population

The study population consisted of patients undergoing heart surgery (aortic valve replacement, mitral valve replacement, and/or coronary bypass) in the immediate postoperative period during their stay in the cardiac resuscitation unit. All patients included in the study were over 18 years of age. The patients decided to participate voluntarily, after having been informed of the purpose of the study, as well as what their participation consisted of, by signing an informed consent.

2.4. Sample

The estimated sample size for a difference between 2 proportions, with a statistical power of 80% for an alpha significance level of 0.05 with a prevalence of postoperative delirium of 30% and a rate of loss to follow-up of 10%, was 52 patients per group.

2.5. Randomization and blinding of the sample

A CG was established, on which the usual practice of the unit regarding postoperative delirium was carried out, as well as an IG on which pictures of relatives was projected in the resuscitation box. Randomization of participants into one or the other group was ensured using OxMaR computer software.[17]

The masking of the sample was single-blind. Although the observer who administered the measurement scale nor the investigator who analyzed the data knew whether the subjects had received the study intervention or not, the participants were inevitably aware of their group assignment.

2.6. Inclusion and exclusion criteria

The inclusion criteria involved: undergoing elective cardiac surgery, the requirement of admission to the cardiac resuscitation unit, being over 18 years of age, agreeing to participate in the study, not being sedated for at least 24 hours, presenting an adequate level of consciousness and being able to communicate in Spanish. All patients who did not meet any of the inclusion criteria were excluded.

2.7. Variables

These consisted of sociodemographic variables such as age and gender, anthropometric weight, height, BMI. Social variables consisted whether the patient lived alone or accompanied etc as well as surgical, anesthetic and postoperative care characteristics such as the type of intervention, use of drugs, time mechanical ventilation or extracorporeal circulation, etc.

Variables related to postoperative delirium were also collected, such as the positive or negative result of the CAM-ICU scale, as well as those related to the projection of pictures of relatives, pharmacological measures or mechanical restraints used.

Finally, the objective score obtained in the mini-mental state examination (MMSE) was recorded in order to assess the patient's prior cognitive status.

2.8. Instrument

An "ad hoc" registration sheet was prepared in order to facilitate data collection. The record sheet contained sociodemographic data, surgical and anesthetic characteristics, as well as postoperative and postoperative delirium care. In addition, the CAM-ICU scale[12] as well as the MMSE[18] was applied to the patients included in the study.

Table 1

Global distribution of the clinical history of the patients stratified by control group and intervention group.

Variable		Frequency	Percentage		Frequency	Percentage
	Control			Intervention		
(AHT)	Yes	35	67.31%	Yes	31	59.62%
	No	17	32.69%	No	21	40.38%
Dyslipidemia	Yes	18	34.62%	Yes	21	40.38%
	No	34	65.38%	No	31	59.62%
Smoking habit	Yes	11	21.15%	Yes	14	26.92%
	No	41	78.85%	No	38	73.08%
Diabetes	Yes	14	26.92%	Yes	10	19.23%
	No	38	73.08%	No	42	80.77%
Obesity	Yes	7	13.46%	Yes	8	15.38%
	No	45	86.54%	No	44	84.62%
Alcohol	Yes	1	1.92%	Yes	3	5.77%
	No	51	98.08%	No	49	94.23%
Ex alcohol	Yes	6	11.54%	Yes	3	5.77%
	No	46	88.46%	No	49	94.23%
Drugs	Yes	5	9.62%	Yes	6	11.54%
	No	47	90.38%	No	46	88.46%
Prosthesis	None	43	82.69%	None	42	80.77%
	Visual	8	15.38%	Visual	8	15.38%
	Auditory	1	1.92%	Auditory	2	3.85%

AHT = arterial hypertension.

2.9. Development of the intervention

Patients were randomized into 2 groups (CG and IG) after explaining the study and offering voluntary participation.

Initially, regardless of the group to which they belonged, all patients were administered the MMSE scale to assess their initial cognitive state and their sociodemographic and anthropometric data were collected.

In the IG, patients and/or companions were asked to provide pictures of relatives, which could consist of photographs of loved ones and/or places known to the patient. Thirty minutes after the extubation of the patients, the CAM-ICU scale was administered, recording its value as R0. At night, the projection of images provided by the patient were replaced by a nocturnal visual projection (night sky with stars and moon), ensuring that the patient was able to identify that it was nighttime. Finally, at 9:00 AM, a nurse who had not worked at night and therefore did not know which patients had received the intervention, administered the CAM-ICU scale again, recording its value as R1.

In the CG, after the surgical intervention and 30 minutes after the patient's extubation the CAM-ICU scale was administered, recording its value as R0. The following day, at 9:00 AM, another nurse administered the CAM-ICU scale, noting its value as R1. If postoperative delirium was detected during the day and night, the unit's usual treatment was followed: administration of haloperidol and/or dexmedetomidine.

In both cases, according to the unit's protocol, patients are extubated 2 hours after receiving the patient in the unit. Except for very justified reasons, this time is not altered.

2.10. Statistical analysis

The information was recorded in a database created with the Excel computer program. Statistical analysis was performed with Epi Info™ 7.2 software and R Studio version 1.3.1093.

For the descriptive analysis of the variables, the mean, standard deviation, minimum, and maximum values were calculated for the quantitative variables, and the relative frequencies and percentages were calculated for the qualitative variables.

For the study of the association between categorical variables, the chi-square statistic or Fisher exact test was used when the data were independent, while for the related data the McNemar test was used for 2 groups, transforming the variables into dichotomous ones for its analysis. Stratified analysis was performed using the Mantel–Haenzsel test.

For the multivariate analysis, the logistic regression model was used, including the variables included in the analysis. The stepAIC function from the R MASS package was used.

To validate the results, in terms of significance, a confidence level of 95% was used and any value of $P < .05$ was considered significant.

3. Results

3.1. Global characteristics of the participants

Table 1 shows the global distribution of the personal clinical history of the participating patients included in the study. Information was collected from 104 patients undergoing cardiac surgery. Most of the patients included in the study were men (66.35%), retirees (76.92%), and they lived with someone else (98.08%).

Table 2 shows the overall distribution of the type of surgical intervention, type of vasoactive drug administered, and anesthetics used in induction and maintenance. The most frequent surgical interventions were aortic valve replacement (34.62%) and coronary bypass (34.62%). The most used vasoactive drug in the operating room and/or in the resuscitation unit was nitroglycerin (26.92%) and the most administered drug in the induction or maintenance of anesthesia was propofol (38.46%), followed by the combination of propofol and sevoflurane (34.62%).

The patients who participated in the study presented an average age of 67.28 years (SD = 10.55), with an average weight and height of 76 kg (SD = 14.77) and 165.38 cm (SD = 18.44), respectively. The mean score obtained on the MMSE scale was 28.96 points (SD = 1.68). The relationship between the score obtained on the MMSE by the participants, organized by CG and IG, was not statistically significant ($P = .35$).The average time of mechanical ventilation in the operating room was 283.83 minutes (SD = 80.67) and for extracorporeal circulation it was 95.36 minutes (SD = 28.30).

3.2. Characteristics of the participants according to the CG/IG

The patients were randomly assigned to the CG and IG, so that 52 patients were distributed in each group. No statistical

Table 2

Global distribution of surgical interventions performed, vasoactive drugs administered, and anesthetics, stratified by control group and intervention group.

		Control		Intervention	
Variable		**Frequency**	**Percentage**	**Frequency**	**Percentage**
Surgical intervention	Aortic valve replacement	19	38.46%	17	32.69%
	Bypass	18	34.62%	17	32.69%
	Mitral valve replacement	8	15.38%	7	13.46%
	Aortic valve replacement and bypass	3	5.77%	6	11.54%
	Aortic valve replacement and mitral valve replacement	2	3.84%	3	5.77%
	Myxoma	1	1.92%	1	1.92%
	Mitral valve replacement and bypass	1	1.92%	1	1.92%
Vasoactive drugs	None	22	42.31%	16	30.77%
	Nitroglycerine	11	21.15%	17	32.69%
	Norepinephrine	7	13.46%	7	13.46%
	Atropine	3	5.77%	5	9.62%
	Ephedrine	4	7.69%	3	5.77%
	Dobutamine	3	5.77%	2	3.85%
	Phenylephrine	1	1.92%	2	3.85%
Induction/maintenance anesthesia	Propofol	16	30.77%	22	42.31%
	Propofol and sevoflurane	19	36.54%	17	32.69%
	Sevoflurane	15	28.85%	10	19.23%
	Etomidate and sevoflurane	2	3.85%	5	5.77%

Table 3

Distribution of the initial and final CAM-ICU for the control and intervention group.

	Initial CAM-ICU			Final CAM-ICU		
	Negative	**Positive**	***P*-value**	**Negative**	**Positive**	***P*-value**
Control group	42 (80.77%)	10 (19.23%)	.072	39 (75%)	13 (25%)	<.001
Intervention group	49 (94.23%)	3 (5.77%)		51 (98.08%)	1 (1.92%)	

CAM-ICU = confusion assessment method for the intensive care unit.

differences were found between the CG and IG except in gender, where there were more women than men in the IG compared to the CG (76.92% vs 55.77%; $P = .037$). There were also no statistically significant differences between drinkers and ex-drinkers and the appearance of postoperative delirium ($P > .05$).

3.3. Overall effects of the intervention on postoperative delirium

The initial values of the CAM-ICU, measured 30 minutes post extubation, did not show statistically significant differences by group, with 13 (13/104; 12.5%) positive patients being identified, of which 10 belonged to the CG (10/52; 19.52%), and 3 belonged to the IG (3/52; 5.77%) ($P = .072$).

The effect of the intervention/screening significantly reduced the number of positives statistically, as 14 positive patients were identified (14/102; 13.5%). Thirteen were from the CG (13/52; 25%) and 1 was from the IG (1/52; 1.92%), which was statistically significant ($P < .001$).

Table 3 compares the distribution of the initial and final CAM-ICU organized by CG and IG. In the CG, the number of negatives was reduced from 42 to 39, while the group of positives increased from 10 to 13 patients. On the other hand, in the IG, the number of negatives increased from 49 to 51 and the number of positives decreased from 3 to 1 patient.

3.4. Effects of the intervention on patient follow-up

There were no statistically significant differences in the CAM-ICU values of the CG and IG patients at baseline and at follow-up. The changes in the CAM-ICU values for the total sample are shown in Table 4. Most of the patients (86) who were negative at the beginning, continued negative during follow-up (82.69%). Nine patients (8.65%) remained positive. Five patients (4.81%) developed delirium (were positive) during follow-up, while 4 patients (3.85%) became negative during the investigation process. The difference in change from baseline to follow-up was not statistically significant (McNemar Chi-square = 0.011, $P = .739$).

In the CG, most of the patients identified as negative (37) according to the CAM-ICU and remained negative during follow-up (71.15%). Two initially positive patients were identified as negative at follow-up and 5 negatives (9.62%) developed delirium at follow-up. The difference in the change from baseline to follow-up was not statistically significant (McNemar Chi-square = 1.286, $P = .257$) (Table 5). In the IG, most of the patients who were identified as negative (49) according to the CAM-ICU remained negative during follow-up (94.23%). Two initially positive patients (3.85%) became negative during follow-up and no patient developed delirium during the investigation process. The difference in the change from baseline to follow-up was not statistically significant (McNemar Chi-square = 2, $P = .157$) (Table 5).

3.5. Multinomial logistic regression

Firstly, a complete model was generated by introducing the predictor variables: age, weight, height, MMSE, mechanic ventilation, gender, smoking habit, arterial hypertension, obesity, dyslipidemia, addictions and group, with the CAM-ICU (positive/negative) being the dependent variable (Table 6).

Table 4

Distribution of the CAM-ICU values at baseline and during follow-up.

		Post-intervention					
		Negative		Positive		Total	
Global CAM-ICU		n	%	n	%	n	%
Pre-intervention	Negative	86	82.69	5	4.81	91	87.5
	Positive	4	3.85	9	8.65	13	12.5
	Total	90	86.54	14	13.5	104	100

CAM-ICU = confusion assessment method for the intensive care unit.

Table 5

Distribution of the CAM-ICU values at baseline and during follow-up in the control and intervention group.

		Post-intervention					
		Negative		Positive		Total	
CAM-ICU control group		n	%	n	%	n	%
Pre-intervention	Negative	37	71.15	5	9.62	42	80.8
	Positive	2	3.85	8	15.4	10	19.2
	Total	39	75	13	25	52	100
		Negative		Positive		Total	
CAM-ICU intervention group		n	%	n	%	n	%
Pre-intervention	Negative	49	94.23	0	0	49	94.2
	Positive	2	3.85	1	1.92	3	5.77
	Total	51	98.08	1	1.92	52	100

CAM-ICU = confusion assessment method for the intensive care unit.

Table 6

Summary of the results of the final logistic regression model.

	Estimate	Std. error	*z* value	Pr(>|z|)
(Intercept)	-0.307	0.5086	-0.604	0.5461
Group (intervention)	-2.372	1.1026	-2.151	0.0315
Gender (women)	-1.6314	0.7811	-2.089	0.0367

According to the model, the *logarithm of odds* that a patient presents postanesthetic delirium according to the CAM-ICU scale is negatively related to belonging to the IG (partial coefficient = -2.37), with this relationship being significant (*P* value = .0315). There is also a significant negative relationship between the logarithm of odds of being positive in postanesthetic delirium and the patient's gender (*P* value = .0367), being lower for the same group if the patient is female.

The model as a whole is significant ($P < .001$) and the contribution of both predictors is also significant. Once we have verified that the model is significant, we interpret the model coefficients and in order to do this, we eliminate the logarithms with the exponential of the model coefficients, thus obtaining the following: IG = 0.0933, female gender = 0.1956.

This indicates that if the rest of the variables remain constant, belonging to the IG means that the probability of having delirium is reduced by 2.37 units or 9.33% in the probability of occurrence versus nonoccurrence (positive vs negative). Similarly, being a woman decreases the probability of occurrence versus nonoccurrence (positive vs negative) by 1.63 units or 19.56%.

Next, we made a prediction using the test data set and the probabilities for each observation, thus transforming it by means of a discrimination threshold. Once we had the class of each observation, we compared the predictions against the actual values of the test. A matrix was obtained, in which the model has correctly classified 21 negative observations that are really negative, 2 positive observations, which are really positive 1, and has classified 6 positive observations when they are negative and 2 negative observations that are positive.

The model has obtained a success rate of 74.19% and an error rate of 25.81%. The resulting model shows a sensitivity of 50%, a specificity of 77.78%, a positive predictive value of 25%, and a negative predictive value of 91.30%.

4. Discussion

The results obtained made it possible to determine the effectiveness of an intervention based on imaging in the previously described patients, as treatment or prevention of postoperative delirium.

Several studies indicate that age is the main risk factor for the development of postoperative delirium.[16,19] The progressive aging of the population in Europe, with an increasingly long living population that requires surgical care, and which will be increasingly susceptible to postoperative delirium.[20]

The surgeries performed most frequently were aortic valve replacement and coronary bypass, which accounted for 34.62% in both cases of the total number of surgeries performed. These data are similar to those obtained in another study carried out in which >40% were coronary by-passes and >20% were valve replacements.[21] In our study, no statistically significant differences were found between the type of surgery and the development of postoperative delirium.

Similarly, the mean extracorporeal circulation time was 95.36 minutes, a value similar to that obtained in another study,[21] in which extracorporeal circulation had mean values of 90 to 100 minutes. There were no statistical differences between the extracorporeal circulation time and the onset of postoperative delirium.

Our results suggest a percentage of positive patients slightly higher than the data obtained in another study carried out,[22] where they estimated that the incidence of the disease was 10% after analyzing 661 patients who underwent transcatheter aortic valve replacement.

In a meta-analysis, a total of 21 cohort studies were examined, with a total of 6288 patients analyzed, of whom 28% were positive in the pathology.[23] Another study evaluated 1616 patients undergoing cardiac surgery and found an incidence of delirium of 20%, also higher than the data obtained in our study.[24]

After analyzing the impact of visual projection on postoperative delirium, the data obtained suggest that the intervention is effective as a prevention of the pathology, since the number of positives after performing the projection decreases in the IG compared to the CG, with statistically significant differences.

The logistic regression analysis presents a prediction model where the variables that influence the model are gender and group membership, showing that being female and belonging to the IG significantly reduces the presence of delirium. The generated model presents greater specificity than sensitivity.

Some authors suggest that the onset of the pathology is linked to male gender. In our research, the participants were predominantly men and a statistical association was found between male gender and the final determination of the CAM-ICU with a positive result, as in other studies.[25]

The data suggest that the application of non-pharmacological measures carried out by nursing staff may be a useful strategy in the prevention and treatment of postoperative delirium.

The study which was carried out has certain limitations. First of all, due to the randomization of the sample, the probability meant that 10 positive patients belonged to the CG and only 3 belonged to the IG in the initial determination of postoperative delirium.

Such a low number of positive patients in the IG before performing the visual projection could have made it difficult to follow up the patients when it came to knowing the effectiveness of the intervention carried out as a treatment.

A larger sample could have increased the number of positive patients at the start of the intervention and make it possible to know more accurately the progression of the subjects towards a positive or negative value on the diagnostic scale. The sample size was conditioned by the dimensions and characteristics of the cardiac resuscitation unit.

Another limitation that should be acknowledged is the fact that the 2 measurements taken 30 minutes after extubation and the day after the surgical intervention do not allow to clearly discern whether it is postoperative delirium or emergency delirium. Also, due to the single-blind study design, an information bias must be acknowledged, as participants were aware of their group assignment. Therefore, we cannot establish with strong evidence that the use of pictures of relatives is a preventive tool in the appearance of postoperative delirium due to the use of only 2 scores in a very limited period of time.

The extrapolation of the conclusions of this study to the daily care practice in resuscitation units could be focused on the prevention of postoperative delirium. The results obtained suggest that the visual projection of images is an effective and economical tool to address an increasingly incidental problem due to the aging of the population.

Future lines of research derived from the study are aimed at performing visual intervention in patients undergoing other types of surgeries, such as hip or vascular surgeries, since after cardiac surgery these are the surgeries with the highest incidence of postoperative delirium. Moreover, it is necessary to increase measurements and data collection time to obtain stronger evidence and demonstrate with certainty whether or not the application of pictures of relatives is effective as a prevention of postoperative delirium. Also, subsequent studies would be aimed to record the anesthetic depth (electroencephalography) during the surgical intervention to verify its relationship with the appearance of the pathology.

5. Conclusions

The application of pictures of relatives could reduce the incidence of postoperative delirium in patients undergoing cardiac surgery, although it is necessary to carry out studies with a larger sample of patients and over longer periods of time. Despite of the intervention made it possible for some subjects diagnosed with the pathology to get over their cognitive impairment, it cannot be established that it is useful as a treatment for postoperative delirium, but perhaps as a preventive tool.

A relationship was found between gender and the development of postoperative delirium, and that women presented a lower risk of developing the pathology.

Postoperative delirium was not related to the administration of the drugs most frequently used in this type of unit or to the score obtained on the MMSE scale.

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