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A prospective randomized comparative analysis between opioid based anaesthesia vs opioid free anaesthesia on depth of anaesthesia and intraoperative hemodynamics in patients undergoing elective laparoscopic surgeries lasting less than 3 hours

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ABSTRACT

Background: To avoid the adverse effects of opioid usage, an opioid-free multimodal approach for analgesia can be applied. This study was conducted with an aim to compare the effect of opioid-free anesthesia (dexmedetomidine, lignocaine, dexamethasone and ketamine) and opioid-based anesthesia (fentanyl) on maintaining depth of anaesthesia and intraoperative hemodynamic stability in patients scheduled for Laparoscopic surgeries.

Materials and Methods: We conducted a prospective randomized comparative study on ASA Grade 1 – 2 patients admitted for laparoscopic abdominal surgeries sampling by block Randomization technique with sample size of 60 (30 in each group). In opioid based group, anaesthesia was induced with Inj. Fentanyl 2 mcg/kg before induction while in opioid-free group loading dose of Inj. Dexmedetomidine 1 mcg/kg over 10 min, infusion 0.5 mcg/kg/hr, Inj. Lignocaine 1.5 mg/kg, infusion of 1.5 mg/kg/hr after loading dose, Inj. Dexamethasone 8 mg, Inj. Ketamine 0.5 mg/kg was given. Intraoperatively, the hemodynamic stability and depth of anaesthesia was assessed by measuring the heart rate, blood pressure and BIS values.

Results: In the opioid-free group we had few significant decreases in HR and increases in MAP. The depth of anaesthesia was adequate and comparable to the opioid-based group. Hemodynamically, overall heart rates did not vary much between the two groups and the MAP values were higher in the opioid-free group closer to intubation and extubation**.**

Conclusion: Opioid-free, multimodal approach can safely replace the single opioid-based approach of anaesthesia management in the conduct of general anaesthesia.

1. Introduction

Laparoscopic abdominal surgeries have become the main modality of surgery nowadays due to its minimally invasive nature and decreased duration of hospital stay. Patients come in for a day care surgery or get discharged the following day with expectation of a pain-free post-operative period as most of them expect to return to their day-to-day activities sooner than following open surgery. Although pain is less intense following laparoscopic surgery than after open surgery, some patients nevertheless experience significant discomfort in the first 24 hours after surgery.[1,2]

This calls for an adequate pain management that keeps the patient comfortable and pain-free. Laparoscopic surgeries are conducted under general anaesthesia with either inhalational and intravenous drugs or a combination of both for induction and maintenance. Anaesthesiologists have used either intraoperative or post-operative opioid

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infusions or bolus doses for pain management. The problem arises when patients develop side effects such as nausea, vomiting, respiratory depression, dependence on administration of opioids for pain relief.

To avoid the adverse effects of opioid usage that further prolongs the hospital stay, an opioid-free multimodal approach for analgesia can be applied. Because smaller doses of synergistically interacting drugs can be administered, some adverse effects might be reduced.[3] This decreases the opioid dosage used while simultaneously providing adequate pain relief. As the pain from laparoscopic surgery is multifactorial, several methods of analgesia combined will help reduce the postoperative pain. The concept of multimodal analgesia is to administer multiple drugs that act at different levels of the pain pathway thereby producing better analgesia than a single drug.

Intraoperatively, pain cannot be directly assessed when the patient is under general anaesthesia. However, the hemodynamic stability and depth of anaesthesia can be assessed by measuring the heart rate, blood pressure and BIS values thereby indirectly giving an idea of adequacy of analgesia and response to various stresses and stimuli during the surgery.

The most common opioid used for analgesia during anaesthesia is fentanyl. Replacing this opioid with multiple drugs like dexmedetomidine, lignocaine, dexamethasone, magnesium sulphate and ketamine seems to give adequate analgesia with minimal adverse effects. Additionally, the amount of analgesic needed in the post operative period has also been shown to be reduced.[4,5]

There are increasing number of studies on opioid free anaesthesia and multi modal analgesia and the results are showing similar or better results than opioid based anaesthesia with regards to postoperative pain, analgesic requirement, duration of PACU stay and adverse effects.[4,6]

Therefore, in our study we aim to compare the intraoperative hemodynamic stability and depth of anaesthesia in patients undergoing laparoscopic abdominal surgeries under opioid based vs opioid free anaesthesia using the following drugs: Dexmedetomidine, Lignocaine, Ketamine and Dexamethasone.

2. Aim and Objectives

2.1. Aim

To compare the effect of opioid-free anesthesia (using dexmedetomidine, lignocaine, dexamethasone and ketamine) and opioid-based anesthesia (using fentanyl) on maintaining depth of anaesthesia and intraoperative hemodynamic stability in patients scheduled for Laparoscopic surgeries.

2.2. Objectives

To compare depth of anaesthesia, intraoperative heart rate and mean arterial pressures between opioid based group and opioid free group.

3. Materials and Methods

After ethical committee approval and written informedconsent we conducted a prospective randomized comparative study with study population of patients admitted for laparoscopic abdominal surgeries lasting less than three hours sampling by block Randomization technique with sample size of 60 (30 in each group).

We included ASA Grade 1 – 2 patients, age within 18 – 70 years, posted for elective laparoscopic surgeries less than 3 hours such as laparoscopic cholecystectomy, laparoscopic appendicectomy. The exclusions were: Patient refusal, patients with known allergy to study drugs, patients with opioid addiction, patients with dysrhythmias, congestive heart failure, morbid obesity (BMI> 35), patients on opioids or non-steroidal anti-inflammatory drugs within 1 week, or for chronic pain treatment.

3.1. Methodology

All the patients were examined prior to study. Patients' pre anaesthetic check-up including detailed history, general physical and systemic examination and all necessary investigations needed for the conduct of anaesthesia was done. Patients were kept nil oral from midnight before the day of surgery. In the operating theatre, pulse oximeter, non-invasive blood pressure and ECG monitors were attached and baseline values were recorded. IV access was secured with an IV cannula. BIS monitor was attached appropriately and baseline value noted. Preoxygenation was done for 3 minutes before induction of anaesthesia.

3.2. Opioid based group (Group A)

In the opioid-based group, anaesthesia was induced with Inj. Fentanyl 2 μg/kg and Inj. Propofol 2 mg/kg. Followed by Inj. Atracurium 0.5 mg/kg for tracheal intubation. A repeat dose of Inj. Fentanyl 1 μg/kg was given at 2 hours intraoperatively.

3.3. Opioid free group (Group B)

In the opioid-free group, following a loading dose of Inj. Dexmedetomidine 1 μg/kg over 10 min, anaesthesia was induced with Inj. Propofol 2 mg/kg. Followed by Inj. Atracurium 0.5 mg/kg and Inj. Dexmedetomidine infusion 0.5 μg/kg/hr. Inj. Lignocaine 1.5 mg/kg was administered at induction and an infusion of 1.5 mg/kg/hr was started immediately after the loading dose. Inj. Dexamethasone 8 mg was given intravenously at induction. Inj. Ketamine 0.5 mg/kg was given before incision in this group.

3.4. Both Groups

After intubation, patient's lungs were mechanically ventilated with an oxygen-air mixture to maintain end-tidal CO_2 between 35- and 40-mm Hg. The patients were maintained with 1.0 MAC (Minimum Alveolar Concentration) Sevoflurane. Depth of anesthesia was evaluated by monitoring intraoperative hemodynamic values (heart rate, blood pressure) and BIS value every 15 minutes. 4 mg of Inj. Ondansetron iv and Inj. Pantaprazole 40 mg iv was administered intraoperatively in both groups for prevention of postoperative nausea and vomiting. Paracetamol iv 1 gm was given in both groups before the end of surgery. At the end of surgery, neuromuscular blockade was reversed using intravenous Inj. Neostigmine (0.05 mg/kg) and Inj. Glycopyrrolate (0.01mg/kg). The trachea was extubated when adequate spontaneous ventilation (tidal volume> 4 ml/kg) was established. Both lignocaine and dexmedetomidine infusions were stopped before extubation.

3.5. Statistical analysis

Normality of the continuous variables was assessed by Shapiro-Wilk's test. Normally distributed continuous variable was expressed as Mean ± SD, otherwise median (Interquartile range-IQR). Categorical variables was expressed as percentage. Comparison of continuous variables which are normally distributed, was done by sample t test, otherwise Mann-Whitney U test. Comparison of categorical variables was done by Chi^2test/ Fisher's Exact test. Data entry was done using Microsoft excel spreadsheet. Data analysis was carried out by SPSS version 25.0. All p values <0.05 was considered as statistically significant.

4. Observation and Results

60 patients admitted for laparoscopic abdominal surgeries were randomized into 2 groups: Group A (n=30) with fentanyl and Group B(n=30) with dexmedetomidine, lignocaine, ketamine and dexamethasone. Clinical parameters were studied in both the groups.

Confounding variables such as age, sex and duration of surgery were all comparable in both the groups.

4.1. Age and weight distribution

Our objective was to compare depth of anaesthesia, intraoperative heart rate and mean arterial pressures between the opioid-based group and opioid free groups. The parameters assessed were heart rate, mean arterial pressure and bispectral index.

The heart rate at extubation was significantly lower in group B than group A (p<0.05). The heart rates at all other times showed no significant difference.

4.2. Systolic blood pressure (SBP)

The SBP showed significant difference(p<0.05) at 5 mins after intubation, 45 mins, 1 hour, 1 hour 15 mins, at extubation, 5 mins after extubation and at recovery room.

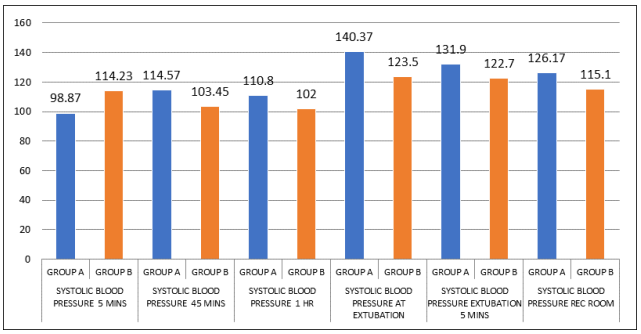

Fig. 1: Barchart showing comparison between systolic blood rates in Group A and Group B

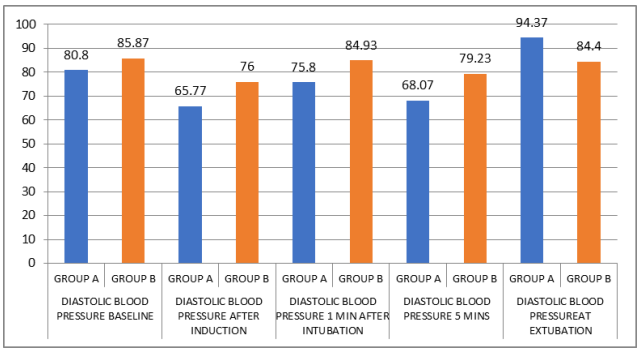

Fig. 2: Bar chart showing comparison diastolic blood pressure in Group A and Group B

5. Discussion

In recent years, opioids have been widely used perioperatively for analgesic purposes. The intraoperative use of either large bolus doses or continuous infusions of opioids is linked with postoperative hyperalgesia[7] and increased analgesic consumption. In day-care surgeries, opioid related side effects, such as postoperative nausea and vomiting (PONV), prolonged sedation, ileus and urinary retention may delay recovery and discharge or cause unanticipated hospital readmission. The postoperative pain after laparoscopic surgery is complex in nature and therefore its treatment should be multimodal and opioid sparing to accelerate recovery.[8]

Although a single anaesthetic drug, such as an inhaled agent or propofol, can produce unconsciousness and immobilisation, achieving autonomic nervous system (ANS) control during surgery with just one drug is far more difficult and requires much greater concentrations. Without

Table 1: Comparison of mean age and mean weight between groups

	Group	N	Mean	Std. Deviation	P value
Age	Group A	30	40.90	13.785	0.888
	Group B	30	40.43	11.702	
Weight	Group A	30	64.97	12.249	0.485
	Group B	30	67.03	10.480	

Table 2: Mean difference in heart rate between group A and group B (Independent t test)

	Group	N	Mean	p value
Heart rate baseline	Group A	30	78.20	0.956
	Group B	30	78.37	
Heart rate after induction	Group A	30	73.37	0.578
	Group B	30	71.80	
Heart rate 1 min after int	Group A	30	79.57	0.825
	Group B	30	80.43	
Heart rate 5 mins	Group a	30	73.80	0.401
	Group B	30	76.23	
Heart rate 15 mins	Group A	30	75.70	0.319
	Group B	30	77.83	
Heart rate 30 mins	Group A	30	71.83	0.908
	Group B	30	72.20	
Heart rate 45 mins	Group A	30	71.97	0.768
	Group B	29	71.10	
Heart rate 1 hr	Group A	25	70.16	0.993
	Group B	27	70.19	
Heart rate at extubation	Group A	30	94.03	0.003*
	Group B	30	81.33	
Heart rate extubation 5 min	Group A	30	82.13	0.153
	Group B	30	76.87	
Heart rate rec room	Group A	30	72.80	0.576
	Group B	30	71.07	

frequent, severe pre-stimulus haemodynamic depression and prolonged recovery, hypnotic medications administered alone cannot prevent heart rate and blood pressure increases in response to surgical stimulation. To suppress ANS responses to nociception, anaesthetic practitioners have used two medications in recent decades: an inhaled agent or propofol in conjunction with a second drug. Opioids have been the most regularly employed second medication since the introduction of the balanced anaesthesia approach. Opioids have a long history of use in modulating ANS responses to nociception and have also played an important role in postoperative pain management.[3]

In the past few years, the idea of multimodal approach in general anaesthesia has grown to encompass more medicines that target diverse neuroanatomical circuits and multiple neurophysiologic mechanisms, replicating the multimodal analgesia model in the acute pain management area. Short acting opioids (e.g., remifentanil), alpha-2 agonists (e.g., dexmedetomidine), local anaesthetics (e.g., lignocaine), and N-methyl-D-aspartate receptor antagonists (e.g., magnesium, ketamine) are all included in the suggested pharmacopoeia for multimodal general anaesthesia. The pharmacologic foundation of multimodal general anaesthesia approach is based on the well-established finding that when anaesthetic medicines with diverse mechanisms are combined, they often interact synergistically, similar to balanced anaesthesia. This synergy affords certain advantages, including faster recovery because the slope of the concentration-effect relationship steepens with synergy, meaning that small reductions in drug concentration lead to larger decreases in drug effect, fastening the passive process of anaesthetic emergence. Because smaller doses of synergistically interacting drugs can be administered, some dose-related adverse effects can be prevented.[3]

Nowadays propofol is used as an induction agent and the second drug used commonly is an opioid. The most common opioid adjunct that is being used is fentanyl which is a synthetic opioid. Opioid has side effects like itching, nausea, vomiting, constipation, respiratory depression, drowsiness, reduced concentration and attention.[3]

In our study, we chose to study multimodal anaesthesia using the following drugs: Dexmedetomidine which is an $\alpha 2$ agonist, lignocaine which is a sodium channel blocker with analgesic property, ketamine which is an NMDA antagonist and dexamethasone, a corticosteroid

Table 3: Mean difference in mean arterial pressure between group A and group B (Independent t test)

	Group	N	Mean	Std. Dev	p value
MAP baseline	Group A	30	96.07	10.478	.175
	Group B	30	99.67	9.824	
MAP after induction	Group A	30	76.43	14.495	.018*
	Group B	30	85.80	15.205	
MAP 1 min after intubation	Group A	30	87.13	15.671	.023*
	Group B	30	96.90	16.707	
MAP 5 min	Group A	30	77.80	11.382	.001*
	Group B	30	89.90	14.492	
MAP 15 min	Group A	30	89.63	16.378	.860
	Group B	30	88.93	14.161	
MAP 30 Min	Group A	30	88.23	14.562	.986
	Group B	30	88.30	14.714	
MAP 45 min	Group A	30	87.30	15.623	.986
	Group B	29	82.86	12.665	
MAP 1 hr	Group A	25	82.56	13.131	.237
	Group B	27	83.11	11.168	
MAP 1 hr 15 min	Group A	11	85.18	11.303	.871
	Group B	17	79.94	9.100	
MAP at extubation	Group A	30	106.77	12.929	.003*
	Group B	30	96.27	13.305	
MAP extubation 5 min	Group A	30	98.20	13.601	.115
	Group B	30	92.53	13.848	
MAP rec room	Group A	30	88.53	12.077	.160
	Group B	30	84.40	10.351	

Table 4: Mean difference in BIS between group A and group B (Independent t test)

	Group	N	Mean	Std. Dev	p value
BIS baseline	Group A	30	95.47	2.583	.834
	Group B	30	95.30	3.476	
BIS after induction	Group A	30	42.60	10.308	.046*
	Group B	30	36.43	12.942	
BIS 1 min after intubation	Group A	30	44.57	10.536	.053
	Group B	30	38.93	11.492	
BIS 5 mins	Group A	30	49.07	8.986	.000*
	Group B	30	39.80	8.319	
BIS 15 mins	Group A	30	43.23	10.957	.137
	Group B	30	39.37	8.775	
BIS 30 mins	Group A	30	41.80	8.015	.600
	Group B	30	42.93	8.610	
BIS 45 mins	Group A	30	43.47	9.566	.332
	Group B	29	45.97	10.037	
BIS 1 hr	Group A	25	47.36	11.172	.564
	Group B	27	45.74	8.852	
BIS 1 hr 15 mins	Group A	11	48.45	13.567	.691
	Group B	17	46.53	9.988	
BIS 1 hr 30 mins	Group A	4	48.75	9.500	.883
	Group B	10	48.00	8.014	
BIS at ext	Group A	30	77.07	7.196	0.074
	Group B	30	80.13	5.764	
BIS at ext 5 min	Group A	30	89.80	6.641	0.454
	Group B	30	91.17	7.372	

with added analgesic potency, in comparison with the traditional method of employing a single opioid drug i.e., Fentanyl for analgesia.

Our prospective randomized double blinded study included 60 patients belonging to ASA physical status I and II posted for laparoscopic surgeries of duration less than 3 hours. The surgeries included are laparoscopic cholecystectomy and laparoscopic appendicectomy.

All the 60 patients were randomized into 2 groups with 30 in each group. Group A received 2 mcg/kg of fentanyl along with 2 mg/kg of Propofol and 0.5 mg/kg atracurium for muscle relaxation and group B received 1 mcg/kg of dexmedetomidine in 10 minutes as loading dose and lignocaine 1.5 mg/kg bolus dose along with 2 mg/kg of Propofol and 0.5 mg atracurium.

The doses of dexmedetomidine, lignocaine, fentanyl and atracurium used in our study was based on the study by Bakan M et al[8] where they used 0.6 mcg/kg dexmedetomidine as bolus, 2 mcg/kg fentanyl, 1.5 mg/kg lignocaine and 0.5 mg/kg atracurium.

From the study by Bhardwaj et al[9] and Gurbet A et al,[4]we based our infusion doses for dexmedetomidine and lignocaine.

5.1. Hemodynamic stability

In the studies done by Bhardwaj et al[9] and Bushra Abdul Hadi et al,[5] there were no significant changes in the perioperative hemodynamic profile. Bakan M et al[8] in their study determined that heart rate and mean arterial pressure values after induction, at intubation and 1st, 4th, 7th and 10th min of pneumoperitoneum were significantly higher in the group using dexmedetomidine and lignocaine. N. Turgut et al[10] in their study determined that though heart rates did not vary among the two groups MAP values in dexmedetomidine group were significantly higher than in Fentanyl group only after intubation while before and after extubation MAP values were higher in the fentanyl group. The previous studies comparing opioid free anaesthesia with opioid based anaesthesia have primarily focussed on the post-operative analgesia, total analgesic use, patient comfort and recovery.

In our study intraoperative hemodynamics is the primary objective. We recorded the heart rate, mean arterial blood pressures right from baseline, through extubation till the patient reaches recovery room. We found that in the heart rate, there was not much difference except during extubation where the heart rate was significantly lower in group B. At extubation the mean heart rate in Group A was 94.03 while in Group B it was 81.33.

Among the mean arterial pressures, in our study, there was significant difference after induction, 1 and 5 minutes after intubation, and at extubation. Similar to previous studies by Bakan M et al[8] and N. Turgut et al,[10] at the above-mentioned times, MAP was higher in group B i.e., in the opioid free group.

In the study by Bakan M et al,[8] during anaesthesia, remifentanil group experienced more hypotensive episodes, while dexmedetomidine and lignocaine group experienced more hypertensive events, both of which were statistically significant. There were no such hypotensive or hypertensive occurrences in our study.

In view of the heart rate (HR) and mean arterial pressure (MAP) values in Group B, our results reflect that of previous observations. Though we found no significant reduction in HR in group B, there was significant increase in MAP when compared to group A. Our observations may be due to the biphasic response of the drug Dexmedetomidine - an initial increase in blood pressure and a decrease in heart rate as a reflex due to a2b receptor stimulation.[11]

5.2. Depth of anaesthesia

Bakan M et al[8] and Bhardwaj et al[9] had both monitored BIS in their patients but kept it constant and did not compare the depth of anaesthesia between the test and control groups. BIS values were not documented in other studies. In our study, we had kept MAC constant by varying Sevoflurane and BIS values were recorded. We aimed to study the intraoperative depth between the two groups. Coming to the BIS values recorded in our study, there was significant difference at induction and 5 minutes after intubation. BIS values were higher in group A than group B. After induction, in Group the mean BIS was 42.60 whereas in Group B it was 36.43. Similarly, 5 minutes after intubation, mean BIS was 49.07 in Group A and 39.80 in Group B. In both groups the depth of anaesthesia was adequate but group B had lower BIS values than group A.

BIS values were maintained between 35 and 60 throughout the intraoperative period in both the groups. There was no increase in BIS values above 65 during the surgery in both groups denoting that there was no lightening of plane of anaesthesia. At the time of extubation, we found no significant difference in BIS values as we stop the infusions before extubation. This helps to overcome the delayed recovery of patients as was shown in other studies.[12]

Summing up the observations of our study, in the opioid-free group we had decrease in HR and increase in MAP. In addition, the depth of anaesthesia was adequate and comparable to the opioid-based group.

Hemodynamically, heart rates did not vary much between the two groups and the MAP values were higher in the opioid-free group closer to intubation and extubation. This rise in blood pressure due to intubation and extubation response could be eliminated by increasing the dose of Dexmedetomidine and continuing the infusion even after extubation and also in the recovery room. This will provide stable hemodynamics and reduced pain in the post-operative period.

6. Limitations

There are certain limitations in our study. The sample size in our study was 60. Larger sample size might yield more reliable results. We have included only ASA grade 1 and 2 and only laparoscopic surgeries lasting less than 3 hours, the results cannot be applied to high-risk patients and long duration surgeries

7. Conclusion

Heart rate at extubation is significantly lower in Group B than in Group A. At all other times, there is no significant difference in heart rates among the two groups. There were no extreme increases or decreases in heart rate in Group B.

Mean arterial pressure (MAP) is significantly higher in Group B than in Group A after induction, 1 minute and 5 minutes after intubation and at extubation. At all other times, there is no significant difference in Mean arterial pressure among the two groups. Inspite of higher MAP values, there were no profound increases in MAP values among patients of Group B.

Bispectral index (BIS) is significantly lower in Group B than in Group A at induction and at 5 minutes after intubation. At all other times the BIS showed no significant difference among the two groups.

This opioid-free, multimodal regimen consisting of Dexmedetomidine, Lignocaine, Ketamine and Dexamethasone provides reduction of post-operative pain scores, total analgesic consumption and elimination of the distressing side-effects of opioids. Additionally, it gives similar intra-operative hemodynamic stability and depth of anaesthesia comparable to the opioid-based approach.

Thus, it can be safely used in ASA-1 and 2 patients who do not have any contraindications for these drugs and also for patients at risk of opioid dependence.

Therefore, this opioid-free, multimodal approach can replace the single opioid-based approach of anaesthesia management and eventually become the routine approach for management of analgesia in the conduct of general anaesthesia.

8. Recommendations

This opioid-free, multimodal regimen consisting of Dexmedetomidine, Lignocaine, Ketamine and Dexamethasone can be safely used in ASA-1 and 2 patients undergoing laparoscopic surgeries lasting less than 3 hours. Similar studies can be done in paediatric populations, in high risk, elderly age groups and on longer duration laparoscopic surgeries.

9. Source of Funding

None.

10. Conflict of Interest

None.

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