http://jmscr.igmpublication.org/home/
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossref DOI: https://dx.doi.org/10.18535/jmscr/v7i9.23

IGM Publication
Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

Analgesic efficacy of single low dose intrathecal labour analgesia using fentanyl (25µg), bupivacaine (2.5mg) and morphine (250µg)

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Abstract
Aim of the study: *To evaluate the analgesic efficacy of low dose Intrathecal labour analgesia using fentanyl, bupivacaine and morphine.*
Methodology: *100 parturients with uncomplicated pregnancy in spontaneous or induced labor at cervical dilatation 4-6cm were enrolled for the study. They were randomized into two groups of 50 each, using computer based block randomization. Group 1(N=50) received intrathecal labor analgesia using. fentanyl (25µg), bupivacaine (2.5mg) and morphine (250µg) and Group 2(N=50) received programmed labor. The two groups were well matched in terms of age, weight, height, parity, baseline vitals and mean cervical dilatation at the time of administration of labor analgesia. Duration of analgesia, Visual analog scale score (VAS) and effect on ambulation (EOA) were recorded.*
Result: *All the parturients were assessed on the basis of VAS score on a scale of 0 to 10. One min after administration of labor analgesia, the mean VAS score in group 1(6.74±0.527) was significantly lower when compared with the mean VAS score in group2 (7.74±0.853) (p value = 0.000). The significant difference continued till 300 minutes. The mean duration of labor analgesia in group1 (238.96 ±21.888 min) was significantly more than the mean duration of analgesia in group 2 (98.4±23.505 min). In group 1 significantly more number of parturients had mild EOA till 25 min (P value 0.035). The mild EOA disappeared by 30 min and subsequently no EOA was observed in parturients receiving intrathecal analgesia.*
Conclusion: *Single shot intrathecal labor analgesia is a safe, effective, reliable, cheap and satisfactory method of pain relief during labor and delivery.*
Keywords: *Labor analgesia, Intrathecal labor analgesia, Visual analog scale (VAS) score, Effect on ambulation (EOA), Rescue analgesia, Maternal satisfaction.*

Introduction

The pain of childbirth is the most severe pain any women can endure in their lifetime. The lack of proper psychological preparation combined with fear and anxiety can greatly enhance the patient's sensitivity to pain and further add to discomfort during labor and delivery. Thus pain relief not only provides comfort to patient but also attenuates the release of stress hormones and improves fetal nutrient and oxygen supply[1,2,3].

Maternal pain and stress have adverse effects on fetus. Maternal anxiety is associated with an increase in plasma catecholamines and prolonged increased in sympathomimetic activity, may lead to incoordinate uterine contractions and reduced uteroplacental perfusion[3]. Effective labour analgesia is known to decrease inhibitory effect of endogenous maternal catecholamines on uterine contractility thus improves utero-placental flow, attenuates maternal acidosis and improves maternal well being[1,4]. On the other hand, painless labor is usually short and uneventful, so it seems that pain is not necessary for labor and actually has no beneficial effect on labor. Therefore, effective pain relief with regional analgesia should enhance uterine contractions instead of causing dystocia[5].

Parturients especially those living in developing countries have few or no option for labour pain relief during child birth. 85% of surveyed women in a developing country indicated that they would request labour analgesia if available but only 40% received labor analgesia in practice[6.]

Parentral opioids and sedatives are the most frequently prescribed agents used for analgesia in labour in many poor resource settings. They have little or no effect on labour pain[7]

Currently, epidural anesthesia is the proven obstetric analgesia but expensive whereas programmed labour and Intrathecal labor analgesia are simple easy and effective method for painless and safe delivery. We therefore conducted the study to evaluate the analgesic efficacy of low dose intrathecal labour analgesia.

Aims and Objective

To study the analgesic efficacy of single low dose intrathecal labor analgesia.

Methodology

A study was conducted at Kamla Nehru State Hospital for mother and child, Indira Gandhi Medical College (IGMC) to study the effect of single low dose intrathecal labor analgesia on maternal and fetal outcome for a period of one year with effect from 1st August 2017 to 31st July 2018.

100 laboring parturients without pregnancy complications, scheduled for normal vaginal delivery, fitting into the inclusion criteria and desiring for labor analgesia, were recruited for this prospective randomized study after obtaining informed written consent and clearance from the institute ethics committee.

Inclusion Criteria

- Parturients requesting for labor analgesia
- Age 18-40 yrs
- Booked patients at Gestation 37 weeks – 42 weeks with Singleton uncomplicated pregnancies with cephalic presentation with spontaneous or induced labor.
- Cervical dilatation 4 – 6cm

Exclusion Criteria

- Refusal for labor analgesia
- Contraindication of regional anesthesia
- Pregnancy with medical disorders and pregnancy complications
- Parturient sensitive or allergic to local anesthesia and opiods
- BMI > 30
- Prelabour rupture of membrane (PROM)
- Intra uterine death (IUD) / Intra uterine growth restriction (IUGR) / fetal distress
- Malpresentations
- Previous uterine surgeries including Lower segment cesarean section (LSCS)
- Neuromuscular disorders

The two groups were well matched in terms of age, weight, height, parity, baseline vitals and mean cervical dilatation rate at the time of administration of labor analgesia.

A thorough general physical examination was done. Per abdominal examination, duration, intensity and frequency of uterine contractions were noted. Fetal heart was auscultated and noted. Per vaginum examination was done and cervical dilation, effacement, position and station of presenting part were noted. Pelvic assessment was done to rule out cephalo-pelvic disproportion (CPD) and artificial rupture of membrane (ARM)

was done. Parturients with meconium stained liqor were excluded from the study.

IV line was secured using 18G cannula and 500 ml of ringer lactate was infused. If required, oxytocin augmentation was done to ensure adequate uterine contractions (3-4 contractions in 10 minutes each lasting for 35- 45 seconds). Maternal pulse rate, basal noninvasive blood pressure and oxygen saturation (SpO_2) were recorded.

Group 1: (Intrathecal analgesia). Parturient in group 1 was positioned in left lateral position, L3-L4 interspace was identified and intrathecal injection comprising of total 2ml [0.5 ml of fentanyl (i.e. 25µg), 0.5 ml of 0.5% bupivacaine heavy(2.5mg) and 1ml of morphine (250 µg/ml diluted] was administered under all aseptic precaution using 26G spinal needle by median/paramedian approach. The time of injection was noted and patient kept in supine postion for subsequent 10 min.

Group 2: (Programmed labor). Parturient received programmed labor comprising of 6mg of pentazocine and 2 mg of diazepam after dilution as a bolus through the infusion line. Thereafter inj. Tramadol in the dose of 1mg/kg body weight deep intramuscularly (IM), along with antispasmodic inj. drotaverine 40mg intravenously (IV) was administered. Inj drotaverine was repeated half hourly total three doses.

Rescue analgesia for both groups: Single shot of inj ketamine 0.5mg/kg of body weight in 10 ml normal saline was given intravenously slowly over 10 min at 7-8 cm cervical dilatation as a rescue analgesia in both the groups.

In both the groups the following data was obtained every 5 min for first 20 min, then every 30 min until delivery: maternal vitals and side effects (maternal nausea, vomiting, drowsiness, palpitations and pruritis). Fetal heart rate was recorded. The labour was monitored partographically. The third stage of labor was managed actively to shorten its duration, minimize blood loss and to ensure that the uterus remained retracted alongwith early placental delivery.

Statistical Analysis

Data collected was transformed into MS excel sheet for further processing and analysis. Appropriate statistical software and tools were used for analyzing the data. Parametric and non-parametric test of significance were used accordingly to find the association between different quantitative and qualitative variable of interest P-value < 0.05 was considered as statistically significant.

Observations

100 parturients with uncomplicated pregnancy in spontaneous or induced labor at cervical dilatation 4-6cm were enrolled for the study. They were randomized into two groups of 50 each, using computer based block randomization. Group 1(N=50) received intrathecal labor analgesia and Group 2(N=50) received programmed labor. The two groups were well matched in terms of age, weight, height, parity, baseline vitals and mean cervical dilatation at the time of administration of labor analgesia shown in following tables 1,2 and 3.

Table 4 depicts the VAS score of the subjects in the two groups, at the time of administration and subsequent 390minutes.

Intergroup variation of VAS: All the parturients were assessed on the basis of visual analogue scale (VAS) score on a scale of 0 to 10, 0 being no pain and 10 the worst pain possible. The mean VAS score at 0 min were comparable in the two groups (8.58± 0.499 in group 1 and 8.52± 0.505 in group 2, P value 0.551). One min after administration of labor analgesia (intrathecal or programmed labor) the mean VAS score in group 1(6.74±0.527) was significantly lower when compared with the mean VAS score in group2 (7.74±0.853) (p value = 0.000). The significant difference continued till 300 minutes, subsequently the VAS scores did not differ in the two groups although the VAS score were assessed till 390 minutes.

Intra group variation of VAS: The mean VAS score at 0 min in group 1was 8.58± 0.499. It

decreased to 5 at 1 min after administration of intrathecal injection. It decreased to zero at 4 min after intrathecal analgesia and remained 0 till 120 min of administration of intrathecal analgesia. Subsequently the mean VAS score began to increase but never exceeded 5 till the end of 390min.

In group 2 the mean VAS score at 0 min was 8.52± 0.505. It decreased to7.74±0.853 at 1 min and 4.58±1.090 at 10 min and remained below 5 till 60 minutes of administration of programmed labor. After that it continued to rise till administration of rescue analgesia which was needed at 120 min in the majority (44/50 i.e. 88%) of subject receiving programmed labor. Subsequent to administration of rescue analgesia the mean VAS score again showed a decreasing trend which started at 150 min and continued till the end of 390min.

The mean duration of labor analgesia in group1 was 238.96 ±21.888 min whereas the mean duration of analgesia in group 2 was 98.4±23.505 min. There was significant difference between the mean duration of analgesia in the two groups (P value =.000). Table-5 depicts the mean duration of labor analgesia in the two groups.

Table 6 shows the effect on ambulation (EOA) in the two groups. Severe effect on ambulation was not seen in any parturients in any of the group. All subjects in group2 had no EOA on the contrary only 1/50, 5/50 and 7/50 partureints in group 1 had no EOA at 5, 10 and 15 min respectively and the rest of the subjects in group 1 had mild EOA . Significantly more number of parturients in group 1 had mild EOA at 5min (P value 0.00), 15 min (P value 0.00), 20 min (P value 0.003) and at 25 min (P value 0.035). The mild EOA disappeared by 30 min and subsequently no EOA was observed even in parturients receiving intrathecal analgesia.

In group1, one (2%) parturient required rescue analgesia. In group 2, all 44 parturients required rescue analgesia. Therefore, significantly less number of parturients required rescue analgesia in group 1 as compared to group 2 (P value 0.00). Table-7 depicts the need of rescue analgesia in the two groups.

Table-8 shows maternal satisfaction in the two groups. In group 1, 90% (45/50) parturients were very satisfied after the administration of intrathecal analgesia whereas none of the parturient was very satisfied in group 2. 6% (3/50) parturients in group 1 and 50% (25/50) parturients in group 2 were just satisfied. 12 % (6/50) parturients in group 2 and 2%(1/50) parturients in group1 refused to give any comments.. None of the parturients were unsatisfied in group 1whereas 30% (15/50) parturients remained unsatisfied in group 2. P value 0.000 (Significant).

Table-1

PARAMETERS	Group 1	Group 2	SD
Age (in years)	26.24±3.783	26.62±4.075	0.630
Height (cm)	157.32±3.950	157.46±3.995	0.861
Weight (kg)	74.36±6.133	73.60±6.141	0.537
Period of gestation	38.10±0.863	38.18±1.004	0.670
Mean cervical dilatation at time of labor analgesia administration (cm)	4.86±0.808	4.92±0.804	0.711

Table-2: Gravidity

Gravidity	Group 1 (N=50)	Percentage	Group 2 (N=50)	Percentage
Primigravida	30	60%	31	62%
Multigravida	20	40%	19	38%

Table-3: Onset of Labor

Onset of labor	Group 1 (N=50)	Percentage	Group 2 (N=50)	Percentage
Spontaneous	29	58%	26	52%
Induced	21	42%	24	48%

Table-4: Visual Analogue Scale Score

	Group	N	Mean	SD	P value
VAS at 0 Min	1	50	8.58	±0.499	.551
	2	50	8.52	±0.505	
VAS at 1 Min	1	50	6.74	±0.527	.000*
	2	50	7.74	±0.853	
VAS at 2 Min	1	50	2.44	±0.577	.000*
	2	50	7.08	±1.122	
VAS at 3 Min	1	50	.24	±0.517	.000*
	2	50	6.30	±1.282	
VAS at 4 Min	1	50	.00	±0.000	.000*
	2	50	5.60	±1.457	
VAS at 5 Min	1	50	.00	±0.000	.000*
	2	50	5.02	±1.186	
VAS at 10 Min	1	50	.00	±0.000	.000*
	2	50	4.58	±1.090	
VAS at 15 Min	1	50	.00	±0.000	.000*
	2	50	4.30	±0.707	
VAS at 20 Min	1	50	.00	±0.000	.000*
	2	50	4.08	±0.444	
VAS at 25 Min	1	50	.00	±0.000	.000*
	2	50	4.06	±0.314	
VAS at 30 Min	1	50	.00	±0.000	.000*
	2	50	4.00	±0.350	
VAS at 60 Min	1	50	.00	±0.000	.000*
	2	50	4.20	±0.700	
VAS at 90 Min	1	50	.00	±0.000	.000*
	2	50	4.94	±0.998	
VAS at 120 Min	1	50	.00	±0.000	.000*
	2	50	4.96	±0.947	
VAS at 150 Min	1	50	.06	±0.424	.000*
	2	50	4.78	±0.840	
VAS at 180 Min	1	50	.34	±0.798	.000*
	2	50	4.76	±±.797	
VAS at 210 Min	1	49	.84	±1.048	.000*
	2	49	4.57	±0.979	
VAS at 240 Min	1	49	1.37	±0.782	.000*
	2	48	3.65	±0.911	
VAS at 270 Min	1	49	1.80	±0.841	.000*
	2	47	2.98	±0.608	
VAS at 300 Min	1	49	1.88	±0.807	.000*
	2	46	2.80	±0.619	
VAS at 330 Min	1	49	2.06	±0.801	.100
	2	45	2.29	±0.506	
VAS at 360 Min	1	27	2.26	±0.594	.791
	2	23	2.22	±0.518	
VAS at 390 Min	1	8	2.63	±0.518	.494
	2	3	2.33	±0.577	

*=Significant
VAS: Visual analogue scale
SD: Standard deviation

Table-5: Mean Duration of Labor Analgesia

Group	Mean duration of analgesia (min)	Standard deviation
1	238.96	±21.888
2	98.40	±23.505

P values = .000* (significant)

Table-6: Effect on Ambulation

EOA	GROUP	No. of subjects with no effect	No. of subjects with mild effect	P value	No. of subjects with severe effect
EOAat5min	Group 1	1	49	0.000*	0
	Group 2	50	0		0
EOAat10min	Group 1	5	45	0.00*	0
	Group 2	50	0		0
EOAat15min	Group 1	17	33	0.00*	0
	Group 2	50	0		0
EOAat 20min	Group 1	42	8	0.003*	0
	Group 2	50	0		0
EOAat 25min	Group 1	49	1	0.035*	0
	Group 2	50	0		0
EOAat30min	Group 1	50	0	-	0
	Group 2	50	0		0
EOAat60min	Group 1	50	0	-	0
	Group 2	50	0		0
EOAat90min	Group 1	50	0	-	0
	Group 2	50	0		0
EOAat120min	Group 1	50	0	-	0
	Group 2	50	0		0
EOAat150min	Group 1	50	0	-	0
	Group 2	50	0		0
EOAat180min	Group 1	49	0	-	0
	Group 2	50	0		0
EOAat210min	Group 1	47	0	-	0
	Group 1	49	0		0
EOAat240min	Group 1	27	0	-	0
	Group 2	29	0		0
EOAat270min	Group 1	9	0	-	0
	Group 2	7	0		0

EOA: Effect on ambulation
*= Significant

Table-7: Need for Rescue Analgesia

NEED FOR RECUE ANALGESIA	Group 1 (n=45)	Percentage	Group 2 (n=44)	Percentage
YES	1	2%	44	100%
NO	44	98%	0	0

n: Number of the parturients who deivered vaginally
P value = 0.000* (Significant)

Table-8: Maternal Satisfaction

Maternal satisfaction	Group 1	Percentage	Group 2	Percentage
Very satisfied	45	90%	0	0
Satisfied	3	6%	25	50%
No comments	1	2%	6	12%
Unsatisfied	0	0	15	30%
Very unsatisfied	1	2%	4	8%

Table- 9: Visual Analogue Scale Score (Group 1)

VAS	Tshibuyi PN et al (2013)[10]	Bilge A et al (2017)[11]	Mathur P et al (2018)[7]	Present Study
0 min	7.67±1.872	8.12 ± 1.27	7.60±0.62	8.58±0.499
5min	0±0	1.29 ± 0.71	1.17±1.15	0±0
10 min	0±0	0.11 ± 0.32	0±0	0±0
15 min	0±0	1.03 ± 0.78	0±0	0±0
30 min	NA	0.94 ± 0.63	NA	0±0
90 min	0±0	NA	0.13±0.04	0±0
2 hrs	0.104±0.425	1.40 ± 1.09	1.33±0.67	0±0
2.5 hrs	0.68±1.31	NA	2.36±1.08	.06±0.424
3 hrs	0.87±1.66	1.69 ± 0.83	3.53±0.58	0.34±0.798

Discussion

For this study 100 parturients with uncomplicated pregnancies in spontaneous or induced labor were enrolled at cervical dilatation 4-6cm, irrespective of the parity. The parturients were divided into two groups according to the computer generated randomization block system. Single shot intrathecal labor analgesia attempts to achieve 4 hours window of ambulatory pain control for laboring women. Hence it was administered in the active phase of labor (4-6 cm cervical dilatation) in the present study. The following baseline characteristics were well matched in the two groups: age, gravidity, period of gestation, height, weight, intensity of uterine contractions at time of administration of labor analgesia, cervical dilatation at time of administration of labor analgesia and VAS score at time of administration of labor analgesia.

Analgesic efficacy of intrathecal labor analgesia was assessed. Mean duration of analgesia in the present study (238.96±21.888 minutes) was longer as compared to the studies conducted by Owen MD et al[4]., Nelson KE et al[6], Viitanen H et al[8], and Mathur P et al[9]. Viitanen H et al[8] concluded that the majority of multiparous parturients found intrathecal analgesia (ITL) adequate for pain relief during delivery. The difference can be attributed to the administration of morphine in addition to bupivicaine and fentanyl in the present study whereas the intrathecal labour analgesia comprised of bupivacaine and fentanyl in the rest of the studies. Although pain relief from single shot spinal techniques can be effective, it may often be of insufficient duration to last the length of labor. Some studies have also addressed the duration of spinal analgesia for labor as part of a combined spinal-epidural technique. Yeh et al (2001)[10] found that the addition of 150µg of morphine sulphate to a combination of bupivacaine 2.5mg and fentanyl 25µg prolonged the request for analgesia from 146min to 252 min. However Hess et al (2003)[11] demonstrated that the addition of morphine 150µg to a mixture of intrathecal bupivacaine 2.0mg and fentanyl 25µg failed to prolong spinal analgesia significantly beyond 80 minutes when administered as a part of combined spinal-epidural techniques.

The mean VAS score at 0, 5, 10, 15 and 30 min were also comparable in the studies conducted by Tshibuyi PN et al[12]., Bilge A et a[13]., Mathur P et al[9], and present study. The parturients in all these studies received similar intrathecal analgesia (bupivacaine 2.5mg + fentanyl 25ug) and in addition morphine (dose) was added in the present study and in the study conducted by Tshibuyi PN et al. Addition of the morphine can possibly explain the longer duration of analgesia in these two studies as evident from the table no. 9 which shows lower VAS score at the end of 2 hrs and beyond that. Similarly Yeh et al[10] found a significant increase in the duration of analgesia when 150µg of morphine was added to their spinal drug combination. However Tshibuyi PN et al observed higher incidence of breakthrough pain in parturients who received morphine along with fentanyl and bupivacaine. Hess et al[11] demonstrated that the addition of morphine 150µg to a mixture bupivacaine (2.0mg) and fentanyl (25µg) failed to prolong spinal analgesia significantly beyond 80min when administered as a part of a combined spinal-epidural technique (Table 9 shows the comparison of VAS score among different studies). Therefore well designed randomized controlled trials with the large sample size are needed to evaluate the efficacy of morphine as a part of Intrathecal labor analgesia.

In the present study EOA was observed in 66% as compared to 12.3 % parturients in a study conducted by Anabah T et al[14] (<0.001).Majority of subjects in the study conducted by Anabah T et al[14] had no EOA which can be attributed to lesser dose of morphine (0.20 mg vs. 0.25mg in the present study) . In 34 % parturients we did not observe any EOA whereas EOA was not observed in 87.7% parturients receiving intrathecal labor analgesia in the study by Anabah T et al. None of the subjects had severe EOA in both the studies. EOA did not persist at or beyond 30 min in the present study.

Studies have shown that single shot spinal analgesia can provide satisfying pain relief and might be adopted for use in areas with limited resources. Kuczkowski M et al[15] investigated the maternal satisfaction of Indonesian parturients who received single dose spinal analgesia with bupivacaine-morphine-clonidine during labor. They found that 81% were very satisfied 11% were satisfied with the analgesia. Similarly in the present study 90% women receiving single shot intrathecal labor analgesia were very satisfied, 6% were satisfied, 2% refused to comment and 2% were very unsatisfied due to failed intrathecal labor analgesia and they receive ketamine injection thereafter. Viitanen H et al[8] (2005) also concluded that the spinal analgesia using low dose bupivacaine and fentanyl during active phase of labor is a reliable method of pain relief in laboring women.

Therefore intrathecal labor analgesia using a combination of bupivacaine (2.5mg), fentanyl (25µg) and morphine(250µg) provides effective labor pain control and maternal satisfaction.

Conclusion

Study results show that the intrathecal labor analgesia using fentanyl (25µg), bupivacaine (2.5mg) and morphine (250µg) is safe and provides adequate analgesia during labor and delivery. Intrathecal labor analgesia is easy to perform, faster in onset and provide effective labor analgesia. Single shot intrathecal labor analgesia succeeded in providing a 4hr window of analgesia. Effect on ambulation in single shot intrathecal labor analgesia was only mild and it disappeared at 30 min of administration of labo analgesia.. It can be used as a good alternative to epidural analgesia which is costly and time consuming procedure. The reliability of spinal block, in terms of achieving satisfactory analgesia within a reasonable time limit and providing adequate analgesia till the end of delivery.

Acknowledgement

I am indeed humbled to be given this opportunity to express my gratitude towards all those who have lend their unconditional support in the making of this work.

First and foremost, I thank my supervisor, Dr. Rama Thakur, Associate Professor, KNH, IGMC Shimla, for her constant support and encouragement. Her valuable knowledge and meticulous supervision has not only guided me throughout the course of this study but also helped me immensely in the clear understanding of this subject. She has been an inspiration.

My sincere gratitude to my co-supervisor Dr.Rohini Rao, Assistant Professor, KNH IGMC, Shimla, for her keen interest, critical guidance and support. I shall forever be indebted to her.

My heartfelt thanks to my seniors, Dr. Hemender, Dr Monika Thakur, Dr Uday, Dr. Sandeep Rathore, Dr. Priyanka, Dr Sandeep Sharma, Dr Munisha Dr Pranav, Dr Sonam Negi, Dr Usha, Dr Monica Chauhan for their constant help and encouragement.

A big thanks to my colleagues, Dr Anu, Dr Shriya, Dr Sapna, Dr Anshul, Dr Ajay, Dr Dr Pooja, Dr Shaina Dr Nancy and Dr Sharad Kaushik my juniors. I wish you all best and may you all be crowned with laurels in your life.

A doctor is nothing without his patients and hence, I shall be failing in my duty if I do not thank my patients who very kindly submitted to this study.

My parents Mr Krishan Dass and Raj Rani Samyal, who have forever been my pillars of support. And with much fondness, I thank my friends Dhruv, Shivani, Pushkal, Bharti, Deepa and Sona and who have stood by my side and for adding just the right amount of humor to my life. I also place on record, my gratitude to one and all, who directly or indirectly, have lent their hand in this venture.

And above all, my sincere gratitude to Lord Shiva for bestowing upon me His countless blessings and for always being my guiding light.

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