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COMPARATIVE STUDY OF PATIENT CONTROLLED EPIDURAL ANALGESIA (PCEA) FOR LABOUR PAIN USING BUPIVACAINE, BUPIVACAINE WITH FENTANYL OR CLONIDINE- PROSPECTIVE, DOUBLE-BLINDED, RANDOMIZED SEQUENTIAL-ALLOCATION STUDY.

SHAHEEN BANO*, SHASHI PRAKASH** AND YASHPAL SINGH***

Declaration

The Declaration of the authors for publication of Research Paper in The Indian Journal of Research Anvikshiki ISSN 0973-9777 Bi-monthly International Journal of all Research: We, ***Shaheen Bano, Shashi Prakash and Yashpal Singh*** the authors of the research paper entitled COMPARATIVE STUDY OF PATIENT CONTROLLED EPIDURAL ANALGESIA (PCEA) FOR LABOUR PAIN USING BUPIVACAINE, BUPIVACAINE WITH FENTANYL OR CLONIDINE- PROSPECTIVE, DOUBLE-BLINDED, RANDOMIZED SEQUENTIAL-ALLOCATION STUDY. declare that , We take the responsibility of the content and material of our paper as We ourself have written it and also have read the manuscript of our paper carefully. Also, We hereby give our consent to publish our paper in Anvikshiki journal , This research paper is our original work and no part of it or it's similar version is published or has been sent for publication anywhere else.We authorise the Editorial Board of the Journal to modify and edit the manuscript. We also give our consent to the Editor of Anvikshiki Journal to own the copyright of our research paper.

Abstract

Background: Patient-controlled epidural analgesia (PCEA) is new modality for labor analgesia that is useful, safe and effective technique. It does not only have the advantage of giving local anesthetic medication via continuous infusion but also covers differences in analgesic requirements**.** In this study synthetic opioids fentanyl and á-2 agonist clonidine used with local anesthetic bupivacaine for comparison of pain relief using PCEA.

Methods: The participants were allocated randomly into one of the following groups according to the drugs used: Group B (n = 20): PCEA solution of 0.0625% bupivacaine alone. Group BF (n = 20): PCEA solution of 0.0625% bupivacaine with 2 mcg/ml fentanyl. Group BC (n = 20): PCEA solution of 0.0625% bupivacaine with 1.5 mcg/ml clonidine. Pain relief and hemodynamic parameter were observed.

Results: It was observed that pain relief was 100% (excellent analgesia) in 8, 14 and 12 patients in group B, BF and BC respectively; 75% (good) in 8, 4 and 6 patients in group B, BF and BC respectively; 50% (satisfactory) in 4, 2 and 2 patients in group B, BF and BC respectively. None of the patients in any of the groups complained that there was no relief in pain after drug administration.

Conclusions: From this study, we conclude that the combination of fentanyl with bupivacaine definitely has an edge over bupivacaine-clonidine and bupivacaine alone in view of pain relief, satisfaction and adverse effects.

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Keywords: Patient controlled Epidural Analgesia (PCEA), Opioids Fentanyl and Tramadol, Local anaesthetic Bupivacaine.

Introduction

In the modern era every woman wants to deliver the child with joy and smile, not with pain and tears. The joy of giving birth is always colored with the fear of pain during labor. Epidural analgesia provides effective pain relief and attenuates the adverse physiological responses to pain. Recent trend is towards the use of dilute concentrations of both local anesthetics and opioids in epidural space so that adequate pain relief can be obtained without accompanying motor blockade. *Patient-controlled epidural analgesia (PCEA)* is new modality for labor analgesia that is useful, safe and effective technique. It does not only have the advantage of giving local anesthetic medication via continuous infusion but also covers differences in analgesic requirements**.** However, infusion pumps required may be costly and the women require instructions on utilization of PCEA. In this study synthetic opioids fentanyl and á-2 agonist clonidine were used with local anesthetic bupivacaine and bupivacaine alone as control group, for comparison using PCEA to objectively establish the superiority of the combination for the relief of labor pain and their effect on conduct of labor and delivery, maternal complications and outcome of the neonate.

Material and Method

After institutional ethical approval and written, informed consent, 60 American Society of Anaesthesiologist (ASA) physical status É or II parturient at term, with spontaneous onset of labor and requesting epidural analgesia, were enrolled into this prospective, double-blinded, randomized sequential-allocation study between July 2009 to June 2010. Patient with history of cephalopelvic disproportion or contracted pelvis, other than vertex presentation, patient not in active phase of labor (<3 cm dilatation), fetal distress prior to the procedure, with bleeding disorders or spinal deformities, pre-eclampsia or eclampsia were excluded from study. The participants were allocated randomly into one of the following groups according to the drugs used: Group B (n = 20): PCEA solution of 0.0625% bupivacaine alone. Group BF (n = 20): PCEA solution of 0.0625% bupivacaine with 2 mcg/ml fentanyl. Group BC (n = 20): PCEA solution of 0.0625% bupivacaine with 1.5 mcg/ml clonidine. The epidural catheters were placed before the active phase of labor as the patients were comfortable and were easily positioned or in active labor when cervical dilatation ≥3cm. But drugs were given only after the labor was well established. All the patients were fasting and bladder and bowel was evacuated before they were shifted to operation theatre. All were preloaded with 500 ml of glucose free lactated ringer's solution over 10-15 minutes through an 18 G IV cannula. The procedure was explained to the parturient and an informed consent was obtained from the patients. A multiport epidural catheter was placed in L3-4 space under strict aseptic and antiseptic precaution, Epidural catheter advanced 4 cm cephaled into the epidural space and secured by gauge piece and adhesive tape and its length taped over the back with its end kept over right shoulder and capped with the bacterial filter provided. Then a 3 ml test dose of 2% lignocaine with adrenaline (1:200,000) was given through the catheter and if after 5 minutes signs of intravascular or intrathecal injection were absent, patients were shifted back to the labor room. When labor was well established- in 1st stage of labor (at cervical dilatation >3cm) 10ml bolus of 0.125% bupivacaine alone given in incremental fashion to all groups and then connected to their respective PCEA solution of 0.0625% bupivacaine alone or with 2mcg/ml fentanyl or 1.5 mcg/ml clonidine according to the group allocated,

at PCEA settings of continuous basal infusion @ 5ml/hr, PCEA demand bolus = 4ml and lockout interval = 15 min. In 2nd stage (at full cervical dilatation) 0.1% bupivacaine, 10ml bolus given in sitting position and again PCEA continued up to the delivery as above setting. Uterine displacement was maintained continuously and each patient was encouraged to turn from side to side or even move around if required. An anesthesiologist who was unaware of the dose or drug given performed all assessments. All the patients were monitored for the following parameters at 0, 10, 20, 30 min…… after giving 1st epidural bolus dose and then at 30 min interval for ongoing labor. Parameter Observed are- Onset of analgesia (minutes), Duration of analgesia, Sensory block (segments), Motor block – Bromage scale, Assessment of pain (VAPS),Maternal sedation-Ramsay Sedation Score. In addition of the above recordings, baseline maternal heart rate and noninvasive blood pressure uterine contraction and fetal heart rate from 30 minutes before the epidural block until the completion of the study were recorded. The occurrence of maternal side effects, such as sedation, pruritus, shivering, nausea, and vomiting were observed and recorded. Upper level of Sensory block achieved is tested by pinprick sensation. Motor strength was assessed for both legs with a four-point Bromage scale. In this scale the intensity of motor block is assessed by the patient's ability to move their lower extremities as given below :

Grade	Criteria	Degree of Block
I	Free movement of legs and feet	Nil (0%)
II	Just able to flex knees with free movement of feet	Partial (33%)
III	Unable to flex knees, but with free movement of feet	Almost Complete (66%)
IV	Unable to move legs or feet	Complete (100%)

Assessment of pain

Objective: It was done using a visual analogue scale (VAS) of 0 to100mm (0 – no pain, 100– severe pain) of the type recommended by Scott and Huskinssion at 30 min. intervals. VAPS was assessed at the peak of contraction by using a slide rule with the patient's side unmarked and the observer' s side marked from 0 to 100 mm.

Subjective: was done on Rupee scale. Chakraborty et al. (2007)

Paisa in A Rupee	Meaning
0	No pain
25	Mild pain
50	Moderate pain
75	Severe pain
100	As bad as could be

Statistical analysis : Statistical analysis was performed by using SPSS 16.0 statistic software. Parameters including total duration of labor, total study drug requirement, pulse rate, oxygen saturation and blood pressure measurements were compared by one way analysis of variance test with Post hoc intergroup comparisons using Bonferonni's correction. Nonparametric data including Apgar score at 1 & 5 min was compared by Mann-whitney U test. Nominal data including mode of delivery, need of demand boluses and side-effects were compared by Fisher's exact test/ chi-sqare test whichever appropriate.

Observation: There was no significant difference among all the groups with respect to mean age, weight, height, pulse rate, mean arterial pressure, and cervical dilatation before epidural analgesia (Table 1). There was significant reduction in pulse rate in group BF and BC as compared to group B after 1 hr of epidural analgesia and up to the delivery. There was significant reduction in pulse rate in group BF as compared to group BC (84.76±2.34 Vs 86.87±2.12 and 80.14±1.98 Vs 81.67±2.12 & 70.76±1.2

Vs 72.12±2.87 per min.) at 1 hr, 2 hr & 4.5 hr. However, significant reduction in pulse rate was also seen in group BC as compared to BF at 2.5 hr interval time. There was no bradycardia seen in any of the group. There was significant fall in MAP in group BC as compared to group B at 1, 2, 3 & 3.5 hr interval and to group BF at 1, 3 & 6 hr interval. Significant fall in MAP was also observed in group BF as compared to group BC at 30 min interval and to group B at 3.5 & 5.5 hr interval. By observation group BC has shown more incidence of significant fall in MAP as compared to group B & group BF. There was no significant difference ($p>0.05$) when total no. of episodes of hypotension compared in all the three groups. The amount of bupivacaine required in the group B, BF and BC was 36.10±5.25, 27.7±4.11 and 29.20±6.75 ml respectively (Table2). However, it was more in group B as compared to the other two groups that was statistically significant. However, no significant difference was between group BF and BC. Table 2 shows the numbers of demand boluses required in the three study groups. The number of demand boluses required in group B was comparatively more (mean 5.45±1.05) as compared to the mean number of demand boluses in other two groups. The difference in the three groups is statistically significant with lowest demand boluses required in group BF as compared to group B and BC. It was observed that pain relief was 100% (excellent analgesia) in 8, 14 and 12 patients in group B, BF and BC respectively; 75% (good) in 8, 4 and 6 patients in group B, BF and BC respectively; 50% (satisfactory) in 4, 2 and 2 patients in group B, BF and BC respectively(Table3) . None of the patients in any of the groups complained that there was no relief in pain after drug administration. The motor-blocking potency was slightly higher in group B as compared to other two groups. However, comparison among different groups did not reveal significant difference in the three groups. After 2 hrs interval group B had 4 patients who had Bromage score of 3 as compared to 2 patients in group BF and 2 patients in group BC. There was no significant difference in the three groups regarding the upper level of sensory block achieved (pinprick sensation). It was 7.35 ± 1.18 (T_5 toT_9), 7.40 ± 1.23 (T_5 toT_9) and 7.10 ± 1.37 (T_5 toT_9) in group B, BF and BC respectively (Table 2). Since the cases in this study were taken for epidural analgesia when cervical dilatation was 3 to 5cm, only the duration of active phase of first stage of labor was considered here. It was noted that patients who received bupivacaine alone (group B) had a slightly longer active phase of first stage of labor, though statistically not significant as compared with other groups (Table2). The duration of second stage of labor followed the similar pattern as the first stage. The three groups were comparable with respect to the duration of second stage of labor. The delivery pattern of the 60 cases in this series is compared .Total 55 parturient (91.6%) had spontaneous vaginal delivery in which 2 parturient (3.3%) had instrumental delivery (forceps or ventouse assistance). In the five patients (8.3%) who ultimately needed a caesarean section. However, there was no significant difference in mode of delivery either SVD or caesarean in all the groups. There was no case of fetal distress during first stage or second stage of labor in all the three groups. There was not a single case of newborn where Apgar score was less than 7 at 5 minutes. There were 5 babies who had Apgar score of 7 at one minute. They improved after suctioning and giving oxygen through a mask. The subsequent Apgar scores at 5 minutes were 9/10 in all the newborns. Subsequently after delivery none of the babies had any problem in the ward and till discharge. The pH of cord blood in the three groups (mean 7.29 ± .09) was normal. The results revealed that in all epidural groups there was significantly less acidosis and there was no significant difference. There was incidence of nausea and vomiting and PDPH in all groups but statistically insignificant ($p>0.05$). There was significant shivering in group BC as compared to group B and BF. There was significant pruritus seen in group BF in comparison to group B and BC. Dryness of mouth was seen more in group BC and significant between group B and BC but there was no significance between group BF and BC. Sedation was

significantly seen in group BF ($p<0.05$) and BC ($p<0.01$) as compared to group B. Sedation was not significant between group BF and BC, however it was more seen with group BC. All parturient who showed sedation were arousable on verbal command. Table 5 shows the response of the parturient to PCEA that would they like to receive PCEA for labor pain in future pregnancy and recommend PCEA for other laboring women? At the end of the study 80, 100 and 95 % patients in group B, BF and BC respectively said that they were satisfied throughout the period of their labor and delivery in view of technique, pain relief and adverse effects. Only 4 (20%) parturient in group B and 1 (5%) parturient in group BC experienced unsatisfaction. All the three groups were comparable with respect to quality of pain relief and patient satisfaction. However, overall most of the parturient (91.66%) were satisfied with PCEA.

Discussion

Pain relief as assessed objectively was better in fentanyl and clonidine group ($p<0.001$) as compared to control group, but it was similar in fentanyl and clonidine group. Celleno D et al Topcu I et al had similar observation that combination of fentanyl or clonidine with bupivacaine produces similar and prolonged analgesia as compared to bupivacaine alone. [1,2]. In clinical practice, a VAPS ≤10 mm is a lower level of analgesia than is required for clinical comfort, because it has been reported that parturient request further intervention during epidural analgesia only when the VAPS exceeds 30 mm. The VAPS is probably the most frequently used scale in research studies, including those in anesthesia. It is relatively easy to use, minimally intrusive, conceptually simple, and its rational scale properties allow meaningful interpretation of percentage difference in VAPS measurements. Although there are some data on maternal satisfaction with analgesia, they are related only to pain relief and not specifically to other characteristics of the block. The area of overall maternal satisfaction deserves further attention.

Significant reduction ($p<0.001$) in pulse rate observed in both fentanyl and clonidine group was also reported by Lyons G et al and Cigarim L Kaba et al that combination of fentanyl or clonidine with bupivacaine causes reduction in pulse rate when compared with bupivacaine alone.[3,4] A significant incidence of fall in MAP ($p<0.001$) observed in clonidine group as compared to fentanyl and control group, but there was no significant hypotension (>20% reduction in MAP from baseline value) observed in all the groups when total no. of episodes of hypotension compared (total no. of episodes of hypotension: 1, 2 & 5 in group B, BF & BC respectively). Kizilarslan S et al have observed no difference ($p>0.05$) in vitals (PR, BP, respiration) between fentanyl and clonidine groups which supports our observation. [5] The absence of hypotension in most of the laboring women was probably due to preloading with ringer lactate solution prior to administration of drugs in epidural space and the use of local anesthetic in lower concentration (0.0625%) and low doses of study drugs (2mcg/ml fentanyl or 1.5mcg/ml clonidine).

Sedation was observed both in fentanyl and clonidine group, but clonidine group showed more sedation than fentanyl. However, all the parturient were arousable on verbal command. No sedation was observed in control group. O Meara ME, Gin T also supported that sedation is more with clonidine group.[6]

No statistically significant difference ($p>0.05$) was observed in the duration of active phase of first stage of labor though control group noted slight prolongation as compared to fentanyl and clonidine group. This slight increase in the duration in control group may be attributed to the increased amount of drug used. The addition of fentanyl or clonidine to bupivacaine has been shown to reduce amount of bupivacaine when compared with bupivacaine alone, supported by Paech MJ et al.[7] Duration of second

stage of labor was almost similar in all the groups and similar observations noted by Philips and Crawford et al, Hault *et al*, Jouppila *et al* and Pearson and Davies reported increased number of instrumental deliveries and prolongation of second stage of labor by epidural analgesia in contradiction to our observation. [8,9,10,11]

Overall 55 parturient had a spontaneous vaginal delivery out of which 2 parturient had instrumental delivery (forceps or ventouse assistance), where the incidence of forceps delivery was 1.6% (only 1 parturient). In the five patients (8.33%) who ultimately needed a caesarean section, the reasons were not related to the technique used. Two were due to fetal distress the cause for which turned out to be tight loops of cord round the neck (per operative finding), two were due to scar (due to previous caesarean section) tenderness, and the remaining one was for cephalopelvic disproportion (due to big size baby). However, there was no significant difference in mode of delivery either SVD or caesarean in all the groups. The results are in support of studies by Evan et al who reported a caesarean section rate of 10% with epidural infusion of bupivacaine.[13] No malrotation was observed in any of the groups. Similar observation seen by Porter *et al* and Philips who reported that there was no increase in the incidence of forceps delivery and malrotation after epidural block.[14,15] The results of this study are in contrast to some early workers who reported decreased incidence of spontaneous vaginal deliveries and a twenty fold increase in the incidence of forceps deliveries. The study of *Hault et al* further confirmed these findings and quoted an instrumental delivery rate of about 70% and 40% in epidural and non epidural groups respectively.[16] This high incidence seems odd considering that we had 3.3% incidence among all our patients who received PCEA. Our results showed that the low incidence of difficult deliveries needing any forceps assistance could be attributed to insistence on early induction (all patients had been induced at cervical dilatation < 5 cm) of epidural analgesia.

There was incidence of nausea and vomiting and PDPH but statistically insignificant in all the groups. There was significant shivering in clonidine group as compared to bupivacaine alone and fentanyl group, also supported by O Meara ME et al. There was significant incidence of pruritus seen in fentanyl group in comparison to clonidine and control group.

Lastly all parturient were asked for satisfaction and response regarding technique used (PCEA), pain relief and side-effects. Fentanyl and clonidine group showed more satisfactory response than control group. Overall, most of the parturient showed satisfactory response to PCEA and wanted to receive the same in future pregnancy and also recommended to other laboring women. Ferrante FM et al and Srivastava Uma et al also supported our observation that PCEA is better than continuous infusion for labor pain. [17,18]

Conclusion

Thus we conclude that quality of pain relief was similar in fentanyl and clonidine group. Hemodynamic parameters were more stable in fentanyl group in comparison to other groups. Adverse effects were lesser in fentanyl group and patient satisfaction was good. Overall bupivacaine with fentanyl group was superior in comparison to other groups.

T A B L E 1 *Demographic data*

	Group B	Group BF	Group BC	p value
Mean age ± SD (years)	23.70±2.20	23.45±3.19	22.96±3.72	>0.05
Mean wt. ± SD (kg)	51.80±2.85	52.40±2.85	52.11±3.36	>0.05
Mean cervical dilation in cm ± SD	4.1500 ± 0.73 (3-5.50)	4.075 ± 0.84 (3-5.50)	3.95 ± 0.81 (3-5.50)	>0.05

p=NS (>0.05)

T A B L E 2 *Comparison of various parameters*

Parameters	Group B	Group BF	Group BC	F-value
Amount of bupivacaine required(ml)	36.10±5.25 (28-46)	27.7±4.11 (14-32)	29.20±6.75 (14-38)	27.080***
Mean No. of demand boluses ± SD	5.45±1.05 (1-5)	2.35±0.58 (1-3)	3.40±0.94 (3-6)	64.219***
No. of episodes of hypotension	1(5%)	2(10%)	5(25%)	
Mean sensory level ± SD	7.35 ± 1.18 (T5-9)	7.40 ± 1.23 (T5-9)	7.10 ± 1.37 (T5-9)	0.323
1st stage of labour in min. (Mean duration ± SD)	324.40 ± 7.72	320.10 ± 10.05	322.90 ± 8.63	1.027
2nd stage of labour in min. (Mean duration ± SD)	30.30 ± 4.18	28.35 ± 4.28	29.45 ± 3.75	1.15
Mode of delivery-spont. Vaginal delivery)	18 (90%)	19 (95%)	18 (90%)	
Mode of delivery-Caesarean	2 (10%)	1 (5%)	2 (10%)	

*** = p<0.001

T A B L E 3 *Quality of pain relief (Analgesia)* :

	Paisa in rupee				
Analgesia →	No analgesia 0	Poor 25	Satisfactory 50	Good 75	Excellent 100
Group B	Nil	Nil	4 (20%)	8 (40%)	8 (40%)
Group BF	Nil	Nil	2 (10)%	4 (20%)	14 (70%)
Group BC	Nil	Nil	2 (10%)	6 (30%)	12 (60%)

χ^2=3.980, p=NS

T A B L E 4A *Visual Analogue Pain Scores at different intervals in different groups :*

Interval	0 Min	10 Min	20 Min	30 Min	1.0 hr	1.5 hr	2.0 hr	2.5 hr	3.0 hr	3.5 hr	4.0 hr	4.5 hr	5.0 hr	5.5 hr	6.0 hr
B	92.75 0±6.29 (75-100)	53.50 ±14.24 (20-80)	21.50 ±6.71 (10-40)	28.50 ±4.06 (5-20)	11.45 ± 4.84 (.00-20.0)	42.75 ± 4.75 (.00-20)	36.76 ± 5.76 (1.00-16)	43.00 ± 6.39 (.00- 30)	34.87 ± 4.68 (5- 30)	45.34 ± 7.5 (3.00-30)	36.56 ± 5.29 (1.5-20)	42.19 ± 6.98 (5-20)	39.20 ± 7.23 (.00-20)	40.89 ± 4.89 (3-25)	42.45 ± 5.78 (1.5-20)
BF	91.0 ±8.20 (80-100)	50.75 ± 10.81 (30-80)	18.75 ±2.55 (15-20)	9.75 ± 2.45 (5-10)	3.00 ± 2.51 (.00-5.0)	3.00 ± 2.51 (.00-5.0)	5.43 ± 3.32 (1.4- 5.0)	10.34 ± 5.98 (.00- 10)	12.20 ± 5.78 (5- 20)	15.02 ± 7.23 (.00- 20)	20.30 ± 3.9 (4- 30)	16.67 ± 5.45 (5-20)	25.56 ± 4.76 (1-10)	15.67 ± 3.89 (1-20)	12.78 ± 5.98 (5-20)
BC	93.75 ± 7.23 (80-100)	52.25 ± 6.17 (60-80)	20.25 ± 9.66 (35-70)	10.30 ±10.14 (20-50)	4.50 ±7.45 (5-30)	3.75 ± 10.81 (.00-30)	6.87 ± 5.96 (1.2-10)	15.65 ± 7.45 (1.5- 20)	18.23 ± 3.69 (.00- 30)	12.89 ± 6.59 (5- 20)	18.12 ±4.89 (10- 30)	20.78 ± 5.76 (1.5-20)	23.56 ± 6.45 (5-18)	8.45 ± 7.34 (.00-15)	12.65 ± 6.34 (3-20)
F-value	0.730	0.312	0.785	54.51 ***	14.309 ***	212.85 ***	235.45 ***	139.51 ***	120.00 ***	130.09 ***	90.777 ***	100. 667 ***	37.299 ***	187. 315 ***	161. 694 ***

*** = p<0.001

T A B L E 4B *Multiple Comparisons:*

Interval	Groups		
	B Vs BF p-value	B Vs BC p-value	BF Vs BC p-value
0 min	NS	NS	NS
10 min	NS	NS	NS
20 min	NS	NS	NS
30 min	<0.001	<0.001	NS

1 hr	<0.001	<0.001	NS
1.5 hr	<0.001	<0.001	NS
2.0 hr	<0.001	<0.001	NS
2.5 hr	<0.001	<0.001	NS
3.0 hr	<0.001	<0.001	NS
3.5 hr	<0.001	<0.001	NS
4.0 hr	<0.001	<0.001	NS
4.5 hr	<0.001	<0.001	NS
5.0 hr	<0.001	<0.001	NS
5.5 hr	<0.001	<0.001	NS
6.0 hr	<0.001	<0.001	NS

T A B L E 5 *Parturient response and acceptability to PCEA*

Groups	Satisfactory	Unsatisfactory
B	16 (80%)	4 (20%)
BF	20 (100%)	Nil
BC	19 (95%)	1 (5%)
Total Parturient	55 (91.66%)	5 (8.33%)

$\chi^2 = 3.980$, p=NS.

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