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Original Research Article

## Comparative study to evaluate the effect of colloid coload versus crystalloid coload for prevention of spinal anaesthesia induced hypotension and effect on fetal Apgar score in patients undergoing elective lower segment caesarean section: a prospective observational study

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### ABSTRACT

**Background:** Spinal anesthesia for LSCS has a high incidence of maternal hypotension which can be severe and disastrous for the fetus and the mother. Coload in these patients is a physiologically more appropriate method for preventing spinal anesthesia induced hypotension.

**Methods:** 100 ASA I patients for elective LSCS were randomly divided into two equal groups to either receive 1000ml colloid (6% Hetastarch) or 1000ml crystalloids (Ringer lactate) as coload. NIBP, heart rate SPO2 and incidence of nausea and vomiting and use of ephedrine to treat any hypotension was recorded. Fetal outcome was measured using APGAR score at 0, 1 and 5 minutes.

**Results:** The incidence of hypotension was lesser with colloid coload group (41.7%) as compared to the crystalloid coload group (58.3%) but the difference between the two groups was statistically insignificant. Similarly, no statistically significant difference was noted in the incidence of nausea and vomiting and Fetal APGAR score between the two groups.

**Conclusions:** Both Colloid and Crystalloid coload is effective in decreasing the incidence of spinal anesthesia induced hypotension during LSCS with lesser incidence of hypotension and nausea vomiting with colloid coload.

**Keywords:** Apgar, Crystalloid, Colloid, Coload, Ephedrine, Hypotension, LSCS, Preload, Spinal anesthesia

### INTRODUCTION

Both general and regional anesthesia are acceptable anesthetic methods for use during caesarean section, however regional anesthesia is preferred as it allows

mother to be awake and react immediately with her baby.<sup>1</sup> General Anesthesia is complicated by high rates of difficult and failed intubation with risk of pulmonary aspiration and depressant effects on neonates.<sup>1</sup> The spinal anesthesia has been used safely and minimizes the blood

loss, providing post-operative analgesia and lowering the incidence of postoperative thromboembolism.<sup>2-4</sup>

However it has a high incidence of maternal hypotension.<sup>5</sup> This is related to decrease in peripheral vascular resistance, increased sensitivity to local anesthetics, epidural venous engorgement and gravid uterus causing aortocaval compression in pregnancy.<sup>6,7</sup> Higher the segmental sympathetic blockade, the greater risk of hypotension and associated emetic symptoms.<sup>8</sup> Untreated hypotension results in nausea and vomiting and in more severe causes there may be risk of decreased consciousness, Cardiovascular collapse, respiratory depression and cardiac arrest.<sup>9</sup> Hypotension may cause decrease in utero-placental blood flow, impaired fetal oxygenation and fetal acidosis.<sup>10</sup> Different methods have been investigated alone and in combination for both its prevention and treatment.<sup>11</sup> Prophylactic use of vasopressors, preloading with crystalloids or colloids and left uterine displacement have all been advocated to prevent hypotension following spinal anaesthesia.<sup>12-15</sup> Prevention of hypotension following spinal anaesthesia for LSCS may result in better outcome than treating it once it has occurred.<sup>16</sup>

The use of preloading for prevention of post spinal hypotension is well established practice.<sup>17</sup> This practice is currently challenged due to its less reliability in preventing it.<sup>18-20</sup> Also preload crystalloid may be disadvantageous in patients with renal impairment or borderline cardiopulmonary status.<sup>21</sup>

An alternative approach to administer fluid bolus starting at the time of intrathecal injection of local anaesthetic, also known as Coload has been recently described for the prevention of post spinal anesthesia hypotension in LSCS.<sup>22</sup> Coload may be physiologically more appropriate because the maximum effect can be achieved during the time when the spinal block occurs and thus limit fluid redistribution and excretion.<sup>23</sup> However, experience with this approach is limited and both crystalloids and colloid have been used for the same.<sup>24</sup>

In this context, the present study was under taken and the primary outcome studied was impact on incidence of post spinal hypotension through colloid coload and crystalloid coload. The secondary outcomes measured were ephedrine requirement for maintaining maternal BP, maternal nausea/vomiting and neonatal outcome in terms of fetal APGAR scores.<sup>25</sup>

## METHODS

This prospective randomized, double blind study was carried out over a period of 18 months. After approval from the institutional ethics committee 100 patients of ASA class I with a singleton full term pregnancy in the age group of 20-35 years scheduled for elective cesarean section under spinal anesthesia were enrolled for study.

Patients were prospectively recruited into the study and randomly allocated to either of the two study groups using computer generated table of random numbers at the time of pre-anesthetic evaluation. Written informed consent was obtained for all the patients for participation in the study.

The two groups were designated as below:

### Group X

Received coload of 1000ml of 6% Hetastarch solution (Colloid) infused by a pressurized IV infusion set pressurized to 300mmHg

### Group Y

Received coload of 1000ml of ringer's lactate solution (Crystalloid) infused by a pressurized IV infusion set pressurized to 300mmHg.

Patients presenting with fetal distress or emergency LSCS, multiple pregnancies, obesity, preeclampsia/eclampsia, or any other co-existing diseases were excluded from the study. Similarly, patients with any contraindications to spinal anesthesia or having known fetal abnormalities were also excluded from the study. Patients were admitted 24 hours before surgery at this time pre-anesthetic evaluation was done. Baseline demographic and obstetric data including the gestational age, parity, and weight of patient was noted. On arrival in the operating room I.V line was secured and standard monitoring including NIBP, ECG and pulse oximetry was started.

The infusion bags containing the fluids for coload were prepared and sealed by the pharmacist who was blinded to the study. The bag containing the Colloid, 1000 ml of 6% Hetastarch, was sealed and labeled as fluid X were as the infusion bag containing the Crystalloid, 1000 ml of Ringer lactate, was labeled as fluid Y.

Standardized anesthesia technique was used to perform spinal anesthesia in all patients under the guidance of a senior consultant. Spinal anesthesia was administered under aseptic precautions in both groups using 3ml of 0.5 % of hyperbaric bupivacaine, injected slowly over 20 seconds at the L3-L4 level with a 25 gauge Quincke needle in the sitting position.

At the time of identification of CSF, the patients of Group X received 1000ml of 6% hetastarch and Group Y received 1000ml of Ringers lactate solution. Each infusion was completed in 10 minutes. After completion of injection of local anaesthetic, patients were positioned supine with 15 degree left lateral tilt.

Two anesthesiologists were involved in the study for each subject and they were blinded to the nature of the fluid

used and the study group of the patient assigned. The first anaesthesiologist placed the sealed and pre-labeled study fluid in pressurized infusion system, pressurized to 300 mmHg and was solely responsible for its subsequent administration according to the study protocol.

The second anesthesiologist conducted spinal anaesthesia and prepared vasoactive drug, recorded the hemodynamic variables and was also responsible for administration of the vasoactive drugs.

NIBP measurements and Heart rate were recorded at baseline and three-minute intervals from the start of the regional block for the first 20 minutes, and then at five-minute intervals until the completion of surgery. The height of the sensory block was assessed using pin prick sensory method. Surgery was allowed to proceed after a block to T6 was established and the block level at the end of surgery was documented. Hypotension was defined as 20% decrease in blood pressure from baseline or a systolic blood pressure of less than 90 mmhg or Mean arterial pressure less than 65mmhg. Any episode of hypotension was treated with 5 mg ephedrine intravenously repeated every two minutes until mean arterial pressure recovered to within 80% of the starting value. At delivery all patients received 20 IU of injection Oxytocin intravenously and no further oxytocin was given intra operatively. At least three further readings were taken three minutes apart after completion of surgery.

Neonatal outcome was assessed by recording the Apgar score of the baby at birth, 1 minute and 5 minutes.

Nausea and vomiting was assessed at three-minute intervals after the spinal anaesthesia until the end of the surgery using a 3-point scale as below:

- 1= no nausea and no vomiting
- 2 = nausea only
- 3 = both nausea and vomiting

After the completion of the surgery all the patients were shifted to post anesthesia recovery unit for monitoring.

### Statistical analysis

Mean with SD was calculated for continuous and frequency proportions and was used for the presentation of both the continuous and categorical variables.

Data were entered and coded in MS Excel (2013) and the statistical software SPSS (Version 22, SPSS Inc., Chicago, IL, USA) was used for the entire statistical analysis. Bar diagram and line diagram was used for graphical presentation of the data.

Student's t or Mann-Whitney 'U' test was used for finding the quantitative variables with two independent groups while Chi-square/Fisher's test was used for

finding the statistical significance between qualitative variables. The 'p' value of less than 0.05 ( $p < 0.05$ ) was considered as statistically significant.

## RESULTS

The total number of patients recruited in the study was 100 with 50 in each group X and group Y.

However, two patients in group X were dropped out as they were converted to general anaesthesia due to the patchy block. One of the patients required intraoperative blood transfusion in group Y and was also dropped out of the study.

The various demographic characteristics and duration of surgery in the two patient groups X and Y are shown in Table 1.

Comparison of age and weight distribution between the group Y and group X as showed in Table 1 revealed no statistically significant difference between the two groups.

In group X 45.8% patients were primigravida and 54.2% patients were multipara while as in group Y 42.8% of the patients were primigravida and 57.2% patients were multipara.

There was no statistically significant difference observed between the two groups. The mean duration of surgery in group X was 55.6 minutes and in group Y, it was 57.2 minutes the difference was however statistically insignificant, Table 1.

**Table 1: Demographic characteristics of the two groups.**

Group	No.	Mean	SD	P value	Remarks
<b>Distribution of age (years)</b>					
X	48	25.8	1.733	0.422	NS
Y	49	25.5	1.982		
<b>Distribution of Weight (Kgs)</b>					
X	48	61.7	3.069	0.599	NS
Y	49	61.4	3.004		
<b>Duration of Surgery (Minutes)</b>					
X	48	55.6	5.066	0.089	NS
Y	49	57.2	4.326		
<b>Distribution of Parity</b>					
Parity	Group X			Group Y	
	No.	%age		No.	%age
Primi	22	45.8		21	42.8
Multi	26	54.2		28	57.2
p value = 0.687 (NS)					

X = Colloid; Y = Crystalloid

On comparing the neural block levels achieved no statistically significant difference was noted between the two groups.

In group X, 4.1% patients achieved sensory level of T3, 22.9% achieved T4 level, 20.8% achieved T5 level and 52.1% achieved T6 level, while as in crystalloid group (group Y) 10.2% patients achieved sensory level of T3, 22.2% achieved T4 level, 20.4% achieved T5 and 46.9% achieved T6 level, Table 2.

**Table 2: Comparison of Block Height between the two groups.**

Block Height	Group X		Group Y	
	No.	%age	No.	%age
T3	2	4.1	5	10.2
T4	11	22.9	11	22.4
T5	10	20.8	10	20.4
T6	25	52.1	23	46.9

p value = 0.702 (NS)

X = Colloid; Y= Crystalloid

About 53% parturients developed hypotension in crystalloid group while as in colloid group only 41.7% parturients developed hypotension. More episodes of hypotension were found in the crystalloid group; however, the difference was statistically insignificant, Table 3.

**Table 3: Incidence of Hypotension between the two groups.**

Hypotension	Group X		Group Y	
	No.	%age	No.	%age
Yes	20	41.7	26	53.0
No	28	58.3	23	46.9

p value = 0.161 (NS)

X = Colloid; Y= Crystalloid

**Table 4: Comparison of heart rate (beats per min) between the two groups.**

Time interval	Group X		Group Y		P value	Remarks
	Mean	SD	Mean	SD		
0 Min	87.88	3.57	88.20	4.16	0.681	NS
3 Min	89.86	3.96	88.62	4.13	0.129	NS
6 Min	88.12	4.13	87.98	4.19	0.867	NS
9 Min	90.92	5.30	91.30	3.92	0.685	NS
12 Min	89.20	3.87	89.02	3.84	0.816	NS
15 Min	87.40	4.02	88.34	3.98	0.243	NS
18 Min	88.20	3.60	87.52	3.53	0.342	NS
21 Min	89.70	4.29	90.80	4.30	0.203	NS
26 Min	89.72	4.64	88.56	4.66	0.215	NS
31 Min	87.54	3.80	86.56	3.92	0.207	NS
36 Min	88.30	4.12	89.10	4.97	0.383	NS
41 Min	89.46	4.14	88.38	3.76	0.175	NS
46 Min	86.50	4.57	85.44	5.53	0.299	NS
51 Min	84.76	4.30	83.83	5.71	0.414	NS
56 Min	85.04	2.76	85.71	3.71	0.432	NS
61 Min	84.27	2.09	83.89	4.31	0.759	NS

X = Colloid; Y= Crystalloid

Heart rate was recorded at the baseline, at 3 minutes interval after spinal anesthesia up to 21 minutes and

thereafter at 5 minutes interval till end of surgery in both group X and group Y, there was no statistically significant difference noted between the two groups, Table 4.

Systolic blood pressure was recorded at baseline, at 3 minutes intervals after spinal anesthesia up to 21 minutes and thereafter every 5 minutes interval till the end of the surgery in both group X and group Y.

However no statistically significant difference was noted between the two groups, Table 5.

**Table 5: Comparison of systolic blood pressure (mmHg) between the two groups.**

Time	Group X		Group Y		P value	Remarks
	Mean	SD	Mean	SD		
0 Min	121.3	2.37	120.9	3.03	0.464	NS
3 Min	120.5	2.87	120.3	3.07	0.789	NS
6 Min	118.6	4.25	118.0	8.58	0.669	NS
9 Min	117.4	8.45	116.6	9.40	0.664	NS
12 Min	116.8	8.70	115.3	8.80	0.394	NS
15 Min	113.5	8.17	111.4	8.60	0.214	NS
18 Min	114.0	8.74	111.9	10.28	0.274	NS
21 Min	110.1	8.88	108.5	10.68	0.417	NS
26 Min	109.2	8.39	110.6	11.35	0.485	NS
31 Min	112.3	9.49	108.7	10.73	0.079	NS
36 Min	113.4	8.86	112.8	10.56	0.759	NS
41 Min	116.6	10.84	117.5	11.23	0.704	NS
46 Min	117.8	10.17	117.4	9.38	0.838	NS
51 Min	118.0	9.94	117.0	9.78	0.642	NS
56 Min	117.2	10.40	116.0	8.58	0.625	NS
61 Min	117.3	2.35	115.7	10.87	0.578	NS

X = Colloid; Y= Crystalloid

On comparing the diastolic blood pressure between the group X and group Y, no statistically significant difference was noted, Table 6.

**Table 6: Comparison of diastolic blood pressure (mmHg) between the two groups.**

Time	Group X		Group Y		P value	Remarks
	Mean	SD	Mean	SD		
0 Min	77.2	4.37	77.1	4.378	0.96	NS
3 Min	74.2	3.19	74.0	3.217	0.69	NS
6 Min	76.0	4.36	75.9	6.822	0.90	NS
9 Min	71.7	5.75	71.6	5.281	0.93	NS
12 Min	70.9	6.45	70.5	5.719	0.74	NS
15 Min	68.2	4.76	67.6	4.437	0.52	NS
18 Min	69.7	5.75	68.4	5.857	0.27	NS
21 Min	66.4	4.92	64.7	7.327	0.18	NS
26 Min	65.8	5.70	64.4	6.849	0.27	NS
31 Min	67.3	5.37	66.8	5.733	0.65	NS
36 Min	68.5	4.78	67.1	6.227	0.23	NS
41 Min	69.4	6.19	69.0	6.171	0.76	NS
46 Min	71.1	4.76	71.3	5.037	0.81	NS
51 Min	72.9	4.58	72.8	5.895	0.95	NS
56 Min	73.6	4.43	73.9	5.890	0.82	NS
61 Min	76.1	2.33	75.6	6.455	0.75	NS

X = Colloid; Y= Crystalloid

Mean arterial pressure was recorded between the two groups at baseline, at 3 minutes intervals after spinal anesthesia up to 21 minutes and there after every 5 minutes interval till the end of the surgery in both group X and group Y.

The results were statistically insignificant when compared with each other, Table 7.

**Table 7: Comparison of mean arterial pressure (mmHg) between group X and Y.**

MAP At	Group X		Group Y		p value	Remarks
	Mean	SD	Mean	SD		
0 Min	91.9	2.96	91.7	3.32	0.792	NS
3 Min	89.6	2.30	89.4	2.48	0.668	NS
6 Min	90.2	3.90	89.9	6.63	0.796	NS
9 Min	86.9	6.19	86.6	6.03	0.796	NS
12 Min	86.2	5.85	85.4	5.82	0.496	NS
15 Min	83.3	5.02	82.2	5.12	0.281	NS
18 Min	84.5	5.92	82.9	6.63	0.206	NS
21 Min	81.0	5.30	79.3	7.54	0.195	NS
26 Min	80.3	5.76	79.8	7.32	0.705	NS
31 Min	82.3	5.83	80.8	6.39	0.233	NS
36 Min	83.5	4.85	82.3	6.90	0.317	NS
41 Min	85.1	6.71	85.2	6.99	0.983	NS
46 Min	86.7	5.63	86.7	5.93	0.979	NS
51 Min	87.9	5.87	87.6	6.31	0.776	NS
56 Min	88.2	5.80	88.0	6.26	0.899	NS
61 Min	89.9	1.86	88.9	7.16	0.627	NS

X = Colloid; Y= Crystalloid

Difference between the Vasopressors needed among the two groups was statistically insignificant with the p value of 0.161.

In group X only 39.5% patients required vasopressors, while as in group Y 48.9% patients required vasopressor, Table 8.

**Table 8: Comparison of vasopressor doses needed between group X and Y.**

Vasopressor needed	Group X		Group Y	
	No.	%Age	No.	%Age
Yes	19	39.5	24	48.9
No	29	60.4	25	51.0

p value = 0.161 (NS)

X = Colloid; Y= Crystalloid

Cumulative doses of vasopressors administered among the two groups were statistically insignificant with the p value of 0.429.

In group X 18.7% patients required single dose of vasopressor, 16.6% needed double dose and 4.2% required 3 doses during surgery while as in group Y 18.4% of the patients required single dose of vasopressor, 22.4% needed double dose, 6.1% required 3 doses and in 2% 4 doses were required during surgery, Table 9.

**Table 9: Cumulative Vasopressor Doses in groups CO and CR.**

Doses	Group X		Group Y	
	No.	%age	No.	%age
Nil	29	60.4	25	51.0
1	9	18.7	9	18.4
2	8	16.6	11	22.4
3	2	4.2	3	6.1
4	0	0	1	2.0

p value = 0.429 (NS)

X = Colloid; Y= Crystalloid

In group X, average Apgar score at birth is 7.78, at 1 min is 9.02, at 5 min is 9.54 while as in group Y, average Apgar score at birth, 1 min and 5 min is 7.72, 8.90 and 9.60 respectively. There was no statistically significant difference in the Apgar score at birth, 1 min and 5 min between the groups X and Y, Table 10.

**Table 10: Comparison of Apgar Score between two groups at birth, 1min and 5 min.**

Apgar Score At	Group X		Group Y		p value	Remarks
	Mean	SD	Mean	SD		
Birth	7.78	0.61	7.72	0.671	0.642	NS
1 Min	9.02	0.74	8.90	0.678	0.401	NS
5 Min	9.54	0.50	9.60	0.495	0.549	NS

**Table 11: Nausea/vomiting in two groups**

Nausea/Vomiting	Group X		Group Y	
	No.	%Age	No.	%Age
Yes	2	4.1	4	8.1
No	46	95.8	45	91.8

p value = 0.678 (NS)

X = Colloid; Y= Crystalloid

Only 4.1% parturients develop nausea and vomiting in group X, and in group Y, 8.1% parturients develop nausea and vomiting. There was no statistically significant difference observed between the two groups, Table 11.

## DISCUSSION

Spinal anaesthesia often results in maternal hypotension which can result in fetal and maternal complications.<sup>2,26</sup> Several measures have been described to prevent and treat this complication.<sup>12,13</sup> Recently the concept of coloadng has been introduced to reduce the incidence of hypotension following spinal anaesthesia for cesarean section.<sup>23,27</sup> Even with use of these preventive measures the incidence is about 53% to 80% and without any of these preventive measures the incidence can be as high as 82%.<sup>28,29</sup>

The primary outcome of present study was the incidence of hypotension in the two groups. The secondary

outcomes studied were need for ephedrine requirement for maintaining maternal blood pressure, incidence of nausea and vomiting and neonatal outcome in terms of fetal Apgar score. Ephedrine was used for hypotension as it is readily available and is more effective for increasing arterial blood pressure with preservation of utero placental blood flow.<sup>29</sup> Hyperbaric bupivacaine 0.5% was used for its effective block and easy availability.<sup>30</sup>

Crystalloid preloading may lead to dilutional anemia, decreased colloidal oncotic pressure and subsequent pulmonary edema and may not be effective even after infusing larger volumes.<sup>25,33</sup> Colloid preloading is more effective but with a concern for anaphylaxis and increased cost.<sup>31,32</sup>

In terms of demographic variables like age, height and weight the two groups were comparable, and the difference was statistically insignificant. The height of the block achieved was comparable with the two groups with no statistically significant difference.

Present study revealed that the incidence of hypotension was lesser with colloid coload group (41.7%) as compared to the crystalloid coload group (53.0%) but the difference between the two groups was statistically insignificant. Our result was comparable to the results of Naskar et al, Mamdouh et al and Mcdonald et al. who found that colloid coload was better than crystalloid coload in terms of decreasing incidence of hypotension, decreasing nausea and vomiting but no statistical significant difference was seen between the two groups.<sup>34,35,36</sup>

Carvalho B et al, also suggested that fluid coload at the time of administration of the intrathecal local anesthetic may be more rational physiological approach for the prevention of post spinal hypotension.<sup>37</sup>

In contrast to these findings, Teoh and Sia et al found that 15ml/kg colloid preload but not coload significantly increased maternal cardiac output within the first 5minutes after spinal injection, with no difference in the incidence of hypotension.<sup>38</sup> Similarly Bouchnak et al, reported higher incidence of hypotension in the coload group (96.6%) than in the preload group (86.6%) while comparing 20ml/kg of crystalloid as coload or preload in obstetric population.<sup>39</sup>

The wide variation in the incidence of hypotension in these studies may be explained by differences in the definition of hypotension and different volumes and protocols of fluid administration used in the studies.<sup>32</sup>

In our study, the mean arterial pressure between the two groups was comparable and the difference was statistically insignificant at all measured intervals. Moreover, the systolic and diastolic blood pressure of the two groups followed a trend comparable to the mean arterial pressure with a statistically insignificant

difference between the two groups. The results were comparable with the findings of Mc Donald et al, Naskar Chhandasi et al.<sup>34,36</sup>

In present study, heart rate showed increasing trend from the baseline value in both the groups throughout the perioperative period. However, the difference was statistically insignificant between the two groups. Same results were found by Mc Donald et al, Naskar Chhandasi et al in their respective studies.<sup>34,36</sup>

In this study, colloid coload was found to decrease the total amount of ephedrine used as compared to crystalloid coload group however, the difference was again statistically insignificant. Mamdouh et al in their study also found decrease requirement of ephedrine in the colloid group.<sup>37</sup> However these results are in contradiction to study done by Dyer et al where it was reported that crystalloid coload resulted in decrease in ephedrine requirement to maintain the maternal blood pressure.<sup>22</sup>

Regarding neonatal outcome, there was no significant difference between the two groups as evidenced by fetal APGAR score at birth, 1 and 5minutes after birth. These findings are supported by a systematic review conducted by Anna Lee, Warwick, Ngan Kee.<sup>10,31</sup> Recent literatures also shows that despite the high prevalence of maternal hypotension, term infants can tolerate this placental blood perfusion challenge without any major negative consequences.<sup>40</sup>

Regarding the incidence of nausea and vomiting, our results were in agreement with Smiley RM who reported that, the incidence of nausea and vomiting was significantly lower with colloid than crystalloid, suggesting that patients given colloid may obtain more clinical benefit.<sup>41</sup>

Present study shows that both crystalloid and colloid coload are equally effective in decreasing the incidence of spinal anaesthesia induced hypotension for LSCS patients, with colloid having a more favourable profile. However further studies are needed at a larger scale to evaluate the role coload in terms of choice of fluid, dosage prescribed, and duration and exact timing of infusion desired for improved physiological outcome.

Present study had several limitations. The lack of a control group or placebo group precluded determination of an absolute reduction in the incidence of hypotension. Moreover, Apgar score was taken for rapid evaluation of fetal outcome in place of umbilical blood pH and blood gas status which could have given more accurate physiological effects of spinal anesthesia induced hypotension on fetus.

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