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Research Article

Comparison of Quality of Labor Analgesia by NPRS Score Upon Single Dose Intrathecal Labor Analgesia Between Bupivacaine With Adjuvants (Fentanyl And Dexmedetomidine) And Bupivacaine With Adjuvants (Fentanyl And Morphine): A Randomized Comparative Double Blind Study

Dr. Gian Chauhan[1], Dr. Kartik Syal[2], Dr. Rajeev Sood[3],Dr. Geetika Gupta Syal[4], Dr. Sanjay Rathod[5], Dr. Rajeev Bansal[6]*, Dr. Manoj Maitan[7], Dr. AnshitAbhi Pathania[8], Dr. Anu Shree Bansal[9] ,Dr. Madhav Verma[10] , Dr. Sijo[11] & Dr. Amit Sachdeva[12]

[1]Professor, [2]Associate Professor, [6,10]Junior Resident,[7] Senior Resident Department of Anaesthesiology, [3]Professor, [4]Assistant Professor, [5]Junior Resident Department of obstetrics & gynaecology, [8]Assistant Professor, Department of Anaesthesiology SLBSMC Mandi (Himachal Pradesh), [9]Research Scholar, Kurukshetra (Haryana),[11]Consultant Anesthesiologist, Elite Mission Hospital, Thrissur, Kerala, [12]Senior Resident, Department of Community Medicine Indira Gandhi Medical College, Shimla, India

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Abstract: **Background:** Intrathecal analgesics using (ITA) local anesthetics and adjuvants like narcotics are safe and effective alternative to epidural anesthesia. The objective of the study is toassess and compare quality of labor analgesia through NPRS Score upon single dose ITA between bupivacaine with adjuvants (fentanyl and dexmedetomidine) and bupivacaine with adjuvants (fentanyl and morphine).Material & Methods: The present study was a prospective, randomized and double blinded controlled study.120 parturients allocated into two equal groups ($G\text{-}_D$& $G\text{-}_M$) of 60 patients using block Randomization Technique. Group $G\text{-}_D$ received Bupivaciane, Fentanyl &Dexmedetomedine while $G\text{-}_M$received Bupivaciane, Fentanyl & Morphine. Quality of analgesia was assessed through NPRS Scale and and analyzed using Epi Info V7.**Results:** Difference in ***mean NPRS score*** between both *Group*($\boldsymbol{G_D}$) and *Group*($\boldsymbol{G_M}$)was found to be non- significant at baseline as well as at various time interval till 5 hours. At 0 minutesi.e.the mean NPRS was comparable (p>.05) in both the groups, (8.65±0.48 in*Group*($\boldsymbol{G_M}$)and 8.58±0.49 in*Group*($\boldsymbol{G_D}$)respectively).After 3 minutes Itdecreased to 3.03±0.18 in *Group*($\boldsymbol{G_M}$)and 3.10 ± 0.35 minutes in*Group*($\boldsymbol{G_D}$)respectively,however itremained less than 5 (3.05±0.229 in*Group*($\boldsymbol{G_M}$)and 3.12±0.331 in*Group*($\boldsymbol{G_D}$) respectively till 4 hoursof intrathecal injection. Further itincreased to 4.75±0.50 in*Group*($\boldsymbol{G_M}$)and 5.00 ± 0.00 in*Group*($\boldsymbol{G_D}$)respectivelybut the mean NPRS was comparable (p>.05) in both the groups. **Conclusion**: we found that intrathecallabour analgesia is an effective and safe mode of analgesia. The mean NPRS score remained less than 5 in both the groups till 4.5 hours and was comparable throughout.

Keywords:NPRS Scale, Intrathecal labor analgesia Bupivaciane, Fentanyl, Dexmedetomedine, Morphine.

INTRODUCTION

Perception of pain by a laboring female is a dynamic process that involves both peripheral and central mechanisms. There are many factors that have an influence on the degree of pain experienced by a woman during labor, including emotional support to the parturient during labor-psychological preparation, past experiences of labor pains, the patient's expectation of labor and induction and augmentation of labor (Alleemudder, D. I. *et al* .,2015; & Lynch, L. 2014).

The ideal technique for labor analgesia should provide rapid, effective, economical and safe pain relief for all stages of labor without compromising fetal vital physiology and wellbeing. An ideal technique would leave the mother awake, alert, comfortable with preserved ability to ambulate and bear down throughout the labor (Minty, R. G. *et al.*, 2007).

Intrathecal analgesics using local anaesthetics and adjuvants like narcotics are safe and effective

alternative to epidural anaesthesia especially in rural and peripheral areas where epidural catheterization may not be possible (Minty, R. G. *et al* ., 2007).

The NPRS is a segmented numeric version of the visual analog scale (VAS) in which a respondent selects a whole number (0–10 integers) that best reflects the intensity of his/her pain. The common format is a horizontal bar or line. Similar to the VAS, the NPRS is anchored by terms describing pain severity extremes. It is a uni-dimensional measure of pain intensity NPRS Scales have shown high correlations with other pain-assessment tools in several studies (Haefeli, M., &Elfering, A. 2006; &Numeric_Pain_Rating_Scalehttps://www.physio-pedia.com).

A very few studies have been done on ITA and its correlation with NPRS scale in laboring patients especially in this hilly state where epidural analgesia is not feasible in most of the institutes (AbdElBarr, T. *et al* ., 2014; Yeh, H. M. *et al* ., 2001; Hess, P. E. *et al* ., 2003; &Younes, M. 2017).Our study evaluates the quality of analgesia by NPRS scale when dexmedetomidine was given intrathecally with hyperbaric 0.5% bupivacaine and fentanyl. In view of previous studies, our study also compared the intrathecal morphine with dexmedetomidine as an adjuvant.

MATERIALS AND METHODS

The present study was a prospective, randomized and double blinded controlled study , done with the objective To assess and compare quality of labor analgesia through NPRS Score upon giving single dose intrathecallabour analgesia between bupivacaine with adjuvants (fentanyl and dexmedetomidine) and bupivacaine with adjuvants (fentanyl and morphine)in a period of one year from 1st July, 2018 to 30th June, 2019. The study was conducted after obtaining the ethical committee clearance and informed consent from the parturient by department of Anesthesia &Department of Obstetrics and Gynecology at Kamla Nehru State Hospital for Mother and Child, IGMC, Shimla.

Anticipating minimum of 20% decrease in NPRS Score at the time of delivery considering significance of 95% {α 0.05} and 80% Power of study {β 0.2}, we had undertaken this study in 120 patients. Double blind randomization was done to allocate 120 parturient. Fulfilling the inclusion criteria, they were allocated into two equal groups of 60 patients using computerized block Randomization Technique.

Technique of Anesthesia in both groups was

Group(G_D)**:**received Single dose of Intrathecal analgesia:-	*Group*(G_M)**:**received Single dose of Intrathecal analgesia:-
0.5ml of 0.5% bupivacaine heavy(2.5mg) with	0.5ml of 0.5% bupivacaine 0.5%heavy (2.5mg) with
0.5ml Fentanyl (25mcg) and	0.5ml fentanyl (25mcg) and
1ml of Dexmedetomedine (5mcg) [50mcg/ml Dexmedetomedinediluted in NS to make a concentration of 5 mcg/ml]	1ml Morphine (250mcg) [15 mg/ml diluted to make 250 mcg/ml];
The total injectate : 2ml	The total injectate : 2ml

On admission to labour room detailed history and examination was undertaken. Parturient with cervical dilatation of 4-6 cm was randomly allocated into two groups using sealed envelopes. An anesthetist not involved in the study opened the already coded and sealed envelope for the parturient to pick from. All aseptic precautions were undertaken and the procedure was done in operation theatre.L3-L4 inter-space was identified and 26-27 G spinal needle was introduced median/Para median approach. Correct placement of spinal needle in subarachnoid space was confirmed by free flow of cerebrospinal fluid and coded drug was injected. Patient was kept in supine position for 10 min, and then allowed to ambulate with assistant.

Quality of analgesia was assessed by 11-point numeric NPRS score. In a Numerical pain Rating Scale (NPRS), patients were asked to give the number between 0 and 10, that fits best to their pain intensity. Zero usually represents 'no pain at all' whereas the upper limit represents 'the worst pain ever possible (Haefeli, M., & Elfering, A. 2006; & Numeric_Pain_Rating_Scale https://www.physio-pedia.com).'

Data was entered in MS Excel and analyzed using Epi Info Software Version 7. For qualitative variables frequency/percentage was calculated while for quantitative variables mean/ standard deviation was calculated. Appropriate statistical tests like paired t –test / Chi Square was applied for the measure of association. P value <0.05 was taken as statistically significant.

RESULTS

The two groups were comparable in terms of patients Socio-demographic characteristics (age, parity, period of gestation, etc.)

Table- 1: Distribution of study participants according to Age and POG

	***Group*(G_{-D}) (N=60)**	**Percentage**	***Group*(G_{-M}) (N=60)**	**Percentage**	**P value**
Age					
≤ 20	3	5%	4	6.7%	
21-25	30	50%	26	43.3%	0.853
26-30	22	36.7%	23	38.3%	
31-35	5	8.3%	7	11.7%	
Mean age (Years)	25.48± 3.601		25.82± 3.703		0.618
POG (weeks)					
$37\text{-}38^{+6}$	17	28.3%	19	31.7%	
$39\text{-}40^{+6}$	42	70%	39	65%	0.757
41-42	1	1.7%	2	3.3%	
Mean POG (wks)	39.08±1.046		39.08±1.154		1.000

Table 1 showed that the maximum number of parturient in *Group* (G_{-D})(50%) and in *Group*(G_{-M})(43.3%) were in age group between 21-25 years. The mean age in *Group* (G_{-D})(25.48±3.601yr) and in *Group* (G_{-M})(25.82±3.703yr). Majority of subjects were between 37-40 weeks i.e. 98.3% in *Group* (G_{-D}) and 96.7% in *Group* (G_{-M}). The *mean POG of the parturient* which was 39.08± 1.046 weeks in *Group* (G_{-D}) and 39.08±1.154 weeks in *Group*(G_{-M}).

Table 2:NPRS (numerical pain rating scale) intergroup comparison

	Group	**N**	**Mean Score**	**Std. Deviation**	**P value**
$NPRS_{BL}$	G_{-D}	60	8.58	.497	.457
	G_{-M}	60	8.65	.481	
NPRST1	G_{-D}	60	8.53	.503	.465
	G_{-M}	60	8.60	.494	
NPRST3	G_{-D}	60	3.10	.354	0.198
	G_{-M}	60	3.03	.181	
NPRS4	G_{-D}	60	3.08	.381	.346
	G_{-M}	60	3.02	.390	
NPRS5	G_{-D}	60	3.07	.252	.475
	G_{-M}	60	3.03	.258	
NPRS10	G_{-D}	60	3.05	.341	1.000
	G_{-M}	60	3.05	.287	
NPRST20	G_{-D}	60	3.05	.287	1.000
	G_{-M}	60	3.05	.341	
NPRST25	G_{-D}	60	3.07	.312	.563
	G_{-M}	60	3.03	.317	
NPRS30	G_{-D}	60	3.10	.303	.162
	G_{-M}	60	3.02	.344	
$NPRS_{60}$	G_{-D}	60	3.07	.252	.736
	G_{-M}	60	3.05	.287	
NPRS1.5H	G_{-D}	60	3.02	.129	.414
	G_{-M}	60	3.05	.287	
NPRS2H	G_{-D}	60	3.07	.252	.525
	G_{-M}	60	3.03	.317	
NPRS2.5H	G_{-D}	60	3.07	.252	.761
	G_{-M}	60	3.05	.341	
NPRS3H	G_{-D}	60	3.05	.341	.136
	G_{-M}	60	2.95	.387	
NPRS3.5H	G_{-D}	53	3.02	.137	.206
	G_{-M}	60	3.07	.252	
NPRS4H	G_{-D}	33	3.12	.331	.334
	G_{-M}	37	3.05	.229	
NPRS4.5H	G_{-D}	3	5.00	.000	.
	G_{-M}	4	4.75	.500	.391

Table 2 depicted that Difference in ***mean NPRS score*** between both *Group*(***G-D***) and *Group*(***G-M***)was found to be non- significant at baseline as well as at various time interval till 5 hours. At 0 minutesi.e.the mean NPRS was comparable (p>.05) in both the groups, (8.65±0.48 in*Group*(***G-M***)and 8.58±0.49 in*Group*(***G-D***)respectively).After 3 minutes Itdecreased to 3.03±0.18 in *Group*(***G-M***)and 3.10 ± 0.35 minutes in*Group*(***G-D***)respectively,howeveritremained less than 5 (3.05±0.229 in*Group*(***G-M***)and 3.12±0.331 in*Group*(***G-D***) respectively till 4 hoursof intrathecal injection. Further itincreased to 4.75±0.50 in*Group*(***G-M***)and 5.00 ± 0.00 in*Group*(***G-D***)respectivelybut the mean NPRS was comparable (p>.05) in both the groups.

None of the patients of either group delivered in the first 3 hours(n=60). 7 patients delivered after 3½hours in *Group*(***G-D***) and no patient delivered in *Group*(***G-M***)after similar time.After 4 hours, 27 patients delivered in *Group*(***G-D***) and 23 patients delivered in *Group*(***G-M***). At the end of 4 ½hours 3 patients in *Group*(***G-D***) and 4 patients in *Group*(***G-M***) remained undelivered, that is 57 out of 60(95%) patients delivered in *Group*(***G-D***) and 56 out of 60 (93%) delivered in *Group*(***G-M***).

DISCUSSION

In the present study all the parturient females were evaluated for postoperative analgesia on the basis of *NPRS* (Numerical Pain Rating Scale) on a scale of 0 to 10, 0 being no pain and 10 was worst pain possible. The *mean NPRS score* between both *Group*(G_{-D}) and *Group*(G_{-M})was found to be non- significant at baseline as well as at various time interval till 5 hours.

The result of our study coincides with the study by AbdElBarr T *et al.*,[6]onlabour analgesia wherethey observed that the visual analogue scores after 5,15,30, 60, 90, 120, 150 minutesremainedlower in Spinal group that received 3.75 mg hyperbaric bupivacaine + 25 µgfentanylwith0.75 ml saline is a good alternativeto epidural analgesia using 4 ml bupivacaine with 4 ml saline and 1 ml fentanyl in relieving labour pains.

In another study by Yeh, H. M.*et al* .,(2001) in 100 patients, they found that use of intrathecal bupivacaine 2.5 mg and 12.5 ug fentanyl decreased VAS to 1/10 which remained so till end of delivery. This was similar to our findings where we found VAS to be below 4, number which is considered to be comfortable for the patient, during our entire study period.

HESS *et al.*,(2003)conducted a study on labour analgesia using a small dose of spinal bupivacaine/fentanyl alone or in combination with a small dose of morphine. Sixty parturients were enrolled in this placebo-controlled, double-blinded, randomized trial. All women received a spinal injection of 12.5 µg fentanyl with 2 mg of bupivacaine. The *morphine group (MBF)* also received 125 µg of morphine; *the placebo group (BF)* received saline. Pain scores were less than 3 of 10 within 10 minutes of injection, lasting for the entire delivery period.

In a study done by Younes*et al* .,(2017) on IT hyperbaric bupivacaine 0.5% at a dose of 1 ml plus 25 ug fentanyl 0.5 mlfor labour pain a comparative study with continuous epidural analgesia with bupivacaine showedthatVAS remained < 3 throughout the observed period i.e. till 150 minutes.

In another studydone by Tshibuyi*et al* .,(2013)in 98 patients for labour analgesia, they compared two groups; group I had bupivacaine 2.5mg, fentanyl 25 ug and in second group they added morphine 150 ug to this combination. Similar to our findings they also found out that these combination gave effective analgesia in labouring patients lasting for 3 hours, having VAS < 3 during the entire study period. They also found out that addition of morphine provided more effective VAS in the period after 90 minutes of intrathecal injection.

Mathur*et al.*,(2017) conducted the prospective study to evaluate the progress of labour and hemodynamic changes in the mother and fetus with intrathecal analgesia using bupivacaine and fentanyl during normal vaginal delivery.*GroupSA*(n = 30) received an intrathecal injection of 0.5% hyperbaric bupivacaine 2.5 mg and fentanyl 25 µg and compared with *Group C* (n = 30) who refused to give consent for neuraxial analgesia. T.In their study the mean VAS score never increased to more than 4 till the end of observed period in any group.

Similar to study done by Shah V *et al* .,(2018) for labour analgesia, *Group A*(n=50) patients were administered intrathecaldexmedetomedine in 1 ml normal saline , *Group B*(n=50) patients were administeredIntrathecal 20 ugfentanyl in 1 ml of normal saline and in *Group C*(n=50) patients were administered5 ugdexmed and 10 ug fentanyl in 1ml normal saline.Theyfoundthat all patients achieved VASless than 3 after 5 min.

Similar to our studydone by Madishetti, E. R., &Aasim, S. A. (2018) for labour analgesia(n =40) in each group, *GroupD* (5 microgram) *GroupF* (20 microgram), *Group DF* (dexmed 5 microgram and fentanyl 10microgram) inthedf group. All the patients in three groups had baseline VAS ranged from 7 -10. At 5 minutes ,VASscore became less than 3in all three groups .In their study,VAS was recorded every 1min for 10 minutesand then every 10 minutes till VAS reached more than 3.

CONCLUSION

Thus to conclude, through our randomised controlled prospective Blind study, we found that intrathecallabour analgesia is an effective and safe mode of analgesia. The mean NPRS score remained less than 5 in both the groups till 4.5 hours and was comparable throughout.

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