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RESEARCH ARTICLE

"A CLINICAL COMPARATIVE STUDY OF 8 mg AND 10 mg OF 0.5% HYPERBARIC BUPIVACAINE AND COMBINATION OF EACH WITH 12.5 µg OF FENTANYL FOR SPINAL ANAESTHESIA IN CAESAREAN SECTION"

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Key words:-
Bupivacaine, Fentanyl, Spinal Anaesthesia, Caesarean Section

Abstract

Introduction: Spinal anaesthesia is commonly employed for caesarean delivery. Bupivacaine is the commonly used local anaesthetic for caesarean delivery. Intrathecal Bupivacaine alone may be insufficient to provide complete analgesia despite the high sensory block. The use of neuraxial opioids has gained popularity over the last few years; they may augment the analgesia produced by local anaesthetic through direct binding with the specific spinal receptors. Hence the present study was done to compare the synergistic effect of intrathecally administered Fentanyl 12.5 micrograms with 8 mg and 10 mg of 0.5% hyperbaric Bupivacaine on sensory and motor block characteristics, recovery profile and also quality of intraoperative and postoperativeanalgesia.

Methods: One hundred twenty patients belonging to ASA class I and II with singleton pregnancy with term gestation posted for caesarean section, who have no contraindication for spinal anaesthesia were selected. They were randomly divided into four groups of 30 patients each.

Results: Onset of sensory and motor block were similar in low dose of 0.5% hyperbaric Bupivacaine (8 mg) alone and 0.5% hyperbaric Bupivacaine(8 mg) and Fentanyl(12.5µg) combination groups. However it increased with increasing doses of 0.5% hyperbaric Bupivacaine (10 mg) alone and in 0.5% hyperbaric Bupivacaine (10 mg) and Fentanyl (12.5µg) combination groups.Total duration of analgesia (time from injection of drug to first requisite for analgesics) lasted longer in group IV (257.03±8.46) and group III (206.00±11.80) when compared to group II (166.66±7.00) and group I (143.96±7.25). Quality of anaesthesia was excellent in all the groups. The intraoperative haemodynamic changes were similar in all the groups. Incidences of other side effects were not significant among the groups. The addition of Fentanyl to Bupivacaine significantly delayed the postoperative pain and sensory recovery but motor recovery time did not change with addition of Fentanyl.

Conclusion: Addition of fentanyl to bupivacaine improved the quality of intraoperative anaesthesia and prolonged the postoperative analgesia and also decreased the dose of Bupivacaine. However Bupivacaine 8 mg and 10 mg can also be safely used for spinal anaesthesia in

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caesarean delivery with lesser duration of postoperative analgesia

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Introduction:-

Regional anaesthesia has become more popular in caesarean deliveries becausemostoftheparturientspreferbeingawakeduringchildbirth.Inadditionitis a safer method than generalanaesthesia.[1]Subarachnoid block (SAB) is the anaesthesia technique of choice and is the gold standard for caesarean section because of the ease, effectiveness as well as the rapidityinestablishingadequatelevelsofanalgesia.Inaddition,the small amounts oflocalanaesthetics(LA)administeredmakeplacentaltransferandfoetaluptakeofdrug negligible compared to other regionaltechniques.[2]

Bupivacaine, an amide type of LA was introduced by Ekenstam in 1957 and first used clinically by Telivuo in 1963.[3] It is the most commonly employed LA intrathecally for caesarean section. It is well known that the dose of the drug influences the duration of sensory as well as motor blockade and has a significant effect on the degree of hypotension..

Methods Of Collection Of Data:-

The data was collected in a pretested proforma meeting the objectives of the study. After obtaining approval from the Institutional Ethical Committee and informed written consent from the patients, 120 ASA class I and II pregnant women were selected. They were randomly divided into four groups of 30 patients each. Preoperative assessment was done for each patient. Baseline readings of pulse rate, blood pressure and arterial oxygen saturation were recorded.

Results:-

He following observations were made during the course of the study

Sensory Characteristics:

Table 1:- Time of onset of sensory analgesia to T_{10}.

Group I	2.71±0.33
Group II	2.45±0.29
Group III	2.59±0.43
Group IV	2.23±0.32

Theminimumtimetakenforonsetofsensoryanalgesiato T10ingroupIwas 2min5sec,ingroupIIwas1min50sec,ingroupIIIwas1min40secandingroupIV was 1min 40sec. The maximum time taken for onset of sensory analgesia to T10 in groupIwas3min40sec,ingroupIIwas3min,ingroupIIIwas3minandingroupIV was 2min40sec. 26(86.7%),24(80%),26(86.7%)and19(63.3%)patientsingroupI,II,IIIand IV achieved sensory analgesia to T10 level between 2-3min respectively. 6(20%), 1(3.3%), 11(36.7%) patients group II, III and IV achieved sensory analgesia to T10 levelbetween1-2minrespectively.Andalso4(13.3%)and3(10%)patientsingroupIand III achieved T10 level in 3-4min respectively. Whereas no patients in group I achieved T10 level in 1-2 min and also no patients in group III and IV achieved T10 level in 3-4min.

The mean time of onset of sensory analgesia to T10 in group I was 2.71±0.33 min, in group II was 2.45±0.29min, in group III was 2.59±0.43min and in group IV was 2.23±0.32min which was statistically significant among the groups ($p<0.000$

Table 2:-Time taken to achieve highest level of sensory analgesia.

Time taken to achieve the highest level of sensory analgesia (minutes)	Group I		Group II		Group III		Group IV	
	No. of patients	%	No. of patients	%	No. of patients	%	No. of patients	%
3-4	00	0%	05	16.7%	01	3.3%	09	30%
4-5	05	16.7%	17	56.7%	09	30%	16	53.3%
5-6	21	70%	08	26.7%	18	60%	05	16.7%
6-7	04	13.3%	00	0	02	6.7%	00	0%
Total	30	100%	30	100%	30	100%	30	100%

Mean time (minutes)

Group I	5.71±0.45
Group II	4.89±0.61
Group III	5.12±0.52
Group IV	4.60±0.59

The minimum time taken to achieve highest level of sensory analgesia in group I was 4min 55sec, in group II was 3min 20sec, group III was 4min and in group IV was 3min 30sec. The maximum time taken to achieve highest level of sensory analgesia in group I was 6min 40sec and in group II was 5min 50sec in group III was 6min and in group IV was 5min 40sec.

21(70%), 8(26.7%), 18(60%) and 5(16.7%) patients in group I, II, III and IV achieved highest level of sensory analgesia in 5-6min respectively. 5(16.7%), 17(56.7%),9(30%)and16(53.3%)patientsingroupI,II,IIIandIVachievedhighestlevel of sensory analgesia in 4-5min respectively. 5(16.7%), 1(3.3%) and 9(30%) patients in group II, III and IV achieved highest level of sensory analgesia in 3-4min respectively. 4(13.3%) and 2(6.7%) patients in group I and III achieved highestlevel of sensory analgesia in 6-7min respectively. No patients in group I achieved highest level in 3-4 min and also no patients in group II and IV achieved highest level in 6-7min.

The mean time taken to achieve highest level of sensory analgesia in group I was5.71±0.45min,ingroupIIwas4.89±0.61min,ingroupIIIwas5.12±0.52minand in group IV was 4.60±0.59min which was statistically significant among the groups ($p<0.000$).

Table 3:-Time for two segment sensory regression

Mean time (minutes)

Group I	41.03±2.51
Group II	68.60±5.30
Group III	76.66±5.13
Group IV	89.90±5.97

The minimum time taken for two segment sensory regression in group I was 36min, in group II was 55min, in group III was 65min and in group IV was 80min. The maximum time taken for two segment sensory regression in group I was 46min, ingroupIIwas78min,ingroupIIIwas85minandingroupIVwas105min.Thetime taken for two segment sensory regression in 30(100%) patients in group I was 36-50min. 22(73.3%) and 23(76.7%) patients in group II and III achieved two segment regression in 66-80min respectively. Time taken for two segment sensory regression in 22(73.3%) patients in group IV was81-95min. The mean time for two segment sensory regression in group I was 41.03±2.51min,ingroupIIwas68.60±5.30min,ingroupIIIwas76.66±5.13minand ingroupIVwas89.90±5.97minwhichwasstatisticallysignificantamongthegroups ($p<0.000$).

Table 4:- Time for sensory regression to L_1.

Time for sensory regression to L_1 (minutes)	Group I		Group II		Group III		Group IV	
	No. of	%	No. of	%	No. of	%	No. of	%

	patients		patients		patients		patients	
81-110	26	86.7%	00	0%	00	0%	00	0%
111-140	04	13.3%	28	93.3%	10	33.3%	00	0%
141-170	00	0%	02	6.7%	20	66.7%	05	16.7%
171-200	00	0%	00	0%	00	0%	25	83.3%
Total	30	100%	30	100%	30	100%	30	100%

Mean time (minutes)

Group I	100.0±8.0
Group II	132.46±6.93
Group III	145.60±8.52
Group IV	183.43±9.33

The minimum time taken for sensory regression to L1 in group I was 88min, in group II was 120min, in group III was 128min and in group IV was 165min. The maximumtimetakenforsensoryregressiontoL1ingroupIwas116min,ingroupII was147min,ingroupIIIwas162minandingroupIVwas205min.

The time taken for sensory regression to L1 in 26(86.7%) patients, in groupI was81-110min.ThetimetakenforsensoryregressiontoL1in28(93.3%)patients,in group II was 111-140min. The time taken for sensory regression to L1 in20(66.7%) patients in group III was 141-170min. Time taken for sensory regression to L1 in 25(83.3%) patients, in group IV was 171-200min.

The mean time for sensory regression to L1 in group I was 100.0±8.0min, in groupIIwas132.46±6.93min,ingroupIIIwas145.60±8.52minandingroupIVwas183.43±9.33minwhichwasstatistic allysignificantamongthegroups(p<0.000).

Table 5:- Total duration of analgesia.

Total Duration of Analgesia (minutes)	Group I		Group II		Group III		Group IV	
	No. of patients	%	No. of patients	%	No. of patients	%	No. of patients	%
130-159	29	96.7%	04	13.3%	00	0%	00	0%
160-189	01	3.3%	26	86.7%	03	10%	00	0%
190-219	00	0%	00	0%	24	80%	00	0%
220-249	00	0%	00	0%	03	10%	06	20%
250-279	00	0%	00	0%	00	0%	24	80%
Total	30	100%	30	100%	30	100%	30	100%

The minimum total duration of analgesia in group I was 130min, in group II was 150min, in group III was 188min and in group IV was 238min. The maximum total duration of analgesia in group I was 160min, in group II was 180min, in group III was 224min and in group IV was270min.29(96.7%) patients in group I, 26(86.7%) patients in group II, 24(80%) patientsingroupIIIand24(80%)patientsingroupIVhadtotaldurationofanalgesia between130-159mins,160-189mins,190-219minsand250-279minsrespectively.

The mean time of total duration of analgesia in group I was 143.96±7.25min, in group II was 166.66±7.00min, in group III was 206.00±11.80min and in group IV was257.03±8.46minwhichwasstatisticallysignificantamongthegroups(p<0.000).

Motor Characteristics:

Table 6:- Time of onset of Grade III motor block.

Time of onset of grade III motor block (minutes)	Group I		Group II		Group III		Group IV	
	No. of patients	%	No. of patients	%	No. of patients	%	No. of patients	%

3-4	00	0%	00	0%	01	3.3%	07	23.3%
4-5	02	6.6%	15	50%	01	3.3%	19	63.4%
5-6	13	43.4%	15	50%	15	50%	04	13.3%
6-7	15	50%	00	0%	13	43.4%	00	0%
Total	30	100%	30	100%	30	100%	30	100%

Mean time (minutes):
The minimum time taken for onset of grade III block in group I was 5min, in groupIIwas4min30secingroupIIIwas4minandingroupIVwas3min10sec.Themaximumtimetakenforonsetofgrade IIIblockingroupIwas7min,ingroupIIwas 6min,ingroupIIIwas6min30secandingroupIVwas5min30sec.15(50%) and 13(43.3%) patients in group I and III had onset of grade III motorblockadebetween6-7minwhereasnopatientsingroupIIandIVhadonsetof

grade III motor blockade between 6-7 min. 13(43.3%), 15(50%), 15(50%) and 4(13.3%) patients in group I, II, III and IV had onset of grade III motor blockade between 5-6 min respectively. 15(50%) and 19(63.3%) patients in group II and IV had onset of grade III motor blockade between 4-5min. 1(3.3%) and 7(23.3%) patients in group III and IV had onset of grade III motor blockade between 3-4 min, where as no patient in group I and II had onset of grade III motor blockade in the same time interval.

ThemeantimeofonsetofgradeIIIblockadeingroupIwas6.09±0.54min,in group II was 4.78±0.57min, in group III was 5.86±0.63min and in group IV was 4.62±0.57minwhichwasstatisticallysignificantamongthegroups(p<0.000).

Table 7:- Time between Intrathecal Injection to delivery interval.

Mean time (minutes)	
Group I	7.33±0.84
Group II	7.43±0.81
Group III	7.40±0.89
Group IV	7.56±0.89

The mean time between intrathecal injection to delivery interval in group I was7.33±0.84min,ingroupIIwas7.43±0.81min,ingroupIIIwas7.40±0.89minand in group IV was7.56±0.89min.There was no statistically significant difference among the groups.

Table 8:- APGARat1and5minutesinterval.

APGAR score	Group I	Group II	Group III	Group IV
1 minutes	8	7-8	7-8	7-8
5 minutes	10	10	10	10

No significant differences observed among the four groups at 1 and 5 min interval.
There were no significant haemodynamic alterations in in all the four groups during the study period

Table 9:- Side effects.

Side effects	Group I		Group II		Group III		Group IV	
	No. of patients	%	No. of patients	%	No. of patients	%	No. of patients	%
Hypotension	2	6.6%	5	16.7%	3	10%	6	20%
Bradycardia	1	3.3%	2	6.7%	2	6.7%	2	6.7%
Nausea	1	3.3%	0	0%	0	0%	0	0%
Vomiting	1	3.3%	2	6.7%	2	6.7%	2	6.7%
Pruritis	0	0%	0	0%	1	3.3%	1	3.3%

6.7% in group I, 16.7% in group II, 10% in group III and 20% in group IV developed hypotension and was treated and is not significant between the groups. Bradycardia was noticed in 3.3% of patients in group I, 6.7% in group II, 6.7% in group III and 6.7% in group IV which was not significant. Vomiting was noticed in 3.3%ofpatientsingroupI,6.7%ingroupII,6.7%ingroupIIIand6.7%ingroupIV which was not significant. Nausea was seen in 3.3% of patients in group I. Pruritis was seen in 3.3% of patients in group III and group IV, which was not significant. Noneofthepatientsinallthefourgroupsrequiredintraoperativeanalgesics.

Discussion:-

Sensory Characteristics:

Time of onset of sensory block to T10; In the present study the mean time of onset of sensory analgesia to T10 in group I was 2.71±0.33 min, in group II was 2.45±0.29min, in group III was 2.59±0.43min and in group IV was 2.23±0.32min which was statistically significant among the groups (p<0.000).

Our result concurs with the result observed in Bogra J et al.,[44] in their study they observed that the onset of sensory block to T6 occurred faster with increasing Bupivacaine doses in Bupivacaine only groups and Bupivacaine–Fentanyl combination groups. However they did not measure time of onset analgesia to T10. Choi DH et al.[39] in their study also did not comment on time of onset analgesia toT10.

The time of onset of sensory analgesia to T10 between group I and group II was statistically significant similarly it was significant between group III and groupIV.ThisfindingisconsistentwithBograJetal.[44]studywheretheyconcluded that increase in Bupivacaine dose decreases the time of onset of sensory block. ChoiDHetal.[39]intheirstudydidnotcommentononsetofsensoryanalgesia.

The time of onset of sensory analgesia to T10 between group I and group III was not statistically significant similarly it was not significant between group II and group IV. This finding is consistent with Harsoor SS et al.[45] study and Biswas BN et al.[41] study where they observed that addition of Fentanyl did not alter the onset of sensory block. Similar observations were made by Shende D et al.[11] and Hunt CO etal.[13]

Total duration of analgesia:

In the present study mean time of total duration of analgesia in group I was 143.96±7.25min,ingroupIIwas166.66±7.00min,ingroupIIIwas206.00±11.80minand in group IV was 257.03±8.46min which was statistically significant among the groups(p<0.000).

BiswasBNetal.[41]intheirstudyobservedthemeantotaldurationofanalgesia with 10mg Bupivacaine was 129±9.5 min and in Bupivacaine 10mg – Fentanyl 12.5µg combination group was 183±9min.

HarsoorSSetal.[45]intheirstudyobservedthemeantotaldurationofanalgesia with 8mg Bupivacaine was 103 min and in Bupivacaine 8mg – Fentanyl 12.5µg combination group was 184min.

Motor Characteristics:

Time for onset of grade III motor block:

In the present study the mean time of onset of grade III blockade in group I was6.09±0.54min,ingroupIIwas4.78±0.57min,ingroupIIIwas5.86±0.63minand in group IV was 4.62±0.57min which was statistically significant among the groups (p<0.000).

HarsoorSSetal.[45]intheirstudyobservedthemeantimeofonsetofgradeIII blockade with 8mg Bupivacaine was 4.8 min and in Bupivacaine 8mg – Fentanyl 12.5µgcombinationgroupwas4.3minBiswasBNetal.[41]intheirstudyobservedthe meantimeofonsetofgradeIIIblockadewith10mgBupivacainewas5±1minandiBupivacaine10mg– Fentanyl12.5µgcombinationgroupwas5.4±1.1min

Total duration of motor block

In the present study the mean time of total duration of motor block in group I was 103.83±13.24min, in group II was 128.20±11.57min, in group III was 106.90±10.92min and in group IV was 132.93±12.06min which was statistically significant among the groups(p<0.000).

According to Choi DH et al.[39] the mean time of total duration of motor block with 8mg Bupivacaine alone was 119±16min, with 10mg Bupivacaine alone was 131±31min, with Bupivacaine 8mg-Fentanyl10µg was 108±22min and with Bupivacaine10mg-Fentanyl10µgwas130±31min.Thisfindingisconsistentwithour presentstudyhoweverthedoseofFentanylusedinourstudywas12.5µg fentanyl.

Conclusion:-

Hence, 0.5% hyperbaric Bupivacaine 8 mg with Fentanyl 12.5µg is safe, effective and superior for spinal anaesthesia in caesarean section. 0.5% hyperbaric Bupivacaine 10 mg with Fentanyl 12.5µg combination is also beneficial for spinal anaesthesia which produced longer duration of analgesia when compared to Bupivacaine 8 mg with Fentanyl 12.5µg combination group which is advantageous both intra and postoperatively. But the same combination also produced longer duration of motor block which interferes with early ambulation. 0.5% hyperbaric Bupivacaine 8 mg and 10 mg alone is also sufficient for spinal anaesthesia in caesarean section lasting for shorter duration.

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