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A Randomised Controlled Study Comparing Intrathecal Hyperbaric BupivacaineFentanyl Mixture and IsobaricBupivacaineFentanyl mixture In Common Urological Procedures

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Abstract;

Background: *Sub arachnoid block with additives is a popoluar option among anesthesiologists in infraumbilicalsurgeries.It provides amlple benefits like quicker onset, better quality of anaestheisa and prolonged duration.Various additives like opioids ,α-2 agonists,neostigmine and magnesium are added to improve the quality of anaesthesia.*

Methods:*Eighty ASA 1 and 2 patients scheduled for common elective urological procedures such as transuretheral resection of prostate, ureteroscopy and transuretheral resection of bladder tumours under subarachnoid block were prospectively enrolled. GroupA patientsreceived3mlofpreservativefree0.5%isobaric bupivacaine with 25 mcg of fentanyl and GroupB patients received 3ml of preservative free 0.5% hyperbaric bupivacaine with 25 mcg of fentanyl. Characteristics of sensory and motor blockade such as the time of onset, duration of block , maximum height of sensory block ,haemodynamic changes such as variations in heart rate and blood pressure,the need for supplementation with intravenous sedation or general anaesthesia and adverse effects such as giddiness, nausea, vomiting, shivering, pruritis and respiratorydepression were noted.*

Results: *In our study, the mean time of onset of sensory block was rapid in Group B (1.13 min) than inGroup A (4.25min) and the difference was significant and the mean duration of sensory block was longer in group B when compared to Group A and the difference was statistically significant. In our study,the incidence of adverse effects such as nausea, hypoytension and shivering were higher in hyperbaric bupivacaine with fentanyl group when compared to isobaric bupivacaine with fentanyl group.*

Conclusion*;The present study concludes that the quality of sensory and motor blockade achieved is better with hyperbaric bupivacaine and fentanylgroup.Thehaemodynamic parameters are stable in isobaric bupivacaine and fentanyl group.The need for supplementation with intravenous sedation is lower in the hyperbaric bupivacaine and fentanylgroup.The incidence of adverse effects is lower in the isobaric bupivacaine and fentanylgroup.*

Keywords:*Hyperbaric,Isobaric,bupivacaine,Fentanyl.*

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I. Introduction

Subarachnoid block provides effective sensory and motor blockade with faster onset.Thebaricity and the dose of drug administered are the most important determinants of blockachieved.[1]Many drugs are used as adjuncts to local anaesthetic solutions like opioids,alpha 2 agonists,vasoconstrictors, neostigmine,magnesium and others.This addition of adjuvants has further expanded the advantage of regional anaesthesia like rapid onset of action, reduction of the local anaesthetic requirements, reduction of the risk of local anaesthetictoxicity,prolongation of the sensory block, improvement of the analgesic quality, improvement of the hemodynamic stability and prolongation of duration of postoperative analgesia[2]. Fentanyl which is highly lipid soluble, has a rapid onset and shorter duration of action when compared to hydrophilic opioids such as morphine[3]. Additionof fentanyl to bupivacaine will reduce its dose requirement and prolong its duration ofanalgesia[4].This study is designed to observe the effect of baricity of local anaesthetic solution on the characteristics of subarachnoidblockade. The aim of the study is to compare the efficacy and haemodynamic effects of intrathecal isobaric bupivacaine with fentany mixture and hyperbaric bupivacaine with fentanyl mixture in common urological procedures.

The following factors were compared :

1. Characteristics of sensory and motor blockade such as the time of onset, duration of block and maximum height of sensory block achieved.
2. Haemodynamic changes such as variations in heart rate and blood pressure.
3. The need for supplementation with intravenous sedation or general anaesthesia.

4. Adverse effects such as giddiness, nausea, vomiting, shivering, pruritisandrespiratorydepression.

II. Materials And Methods

After obtaining approval from the institutional ethical committee and informed written consent, 80 ASA 1 and 2 patients scheduled for common elective urological procedures performed under subarachnoid block were prospectively enrolled. GROUPA:Patientsreceived3mlofpreservativefree0.5%isobaricbupivacaine with 25 mcg of fentanyl.GROUP B: Patients received 3ml of preservative free 0.5% hyperbaric bupivacaine with 25 mcg of fentanyl. The inclusion criteria for the study were 18-60 years of age of both gender ASA1and2 patients..Refusal by patient,hypovolemia ,spinaldeformity and patients withpre-existing neurologicaldeficit are excluded from the study. Patients were premedicatedwith tablet alprazolam 5mg the night before surgery. In the operating room, appropriate equipment for airway management and emergency drugs were keptready. Patients were shifted to the operating room andpositioned.Following arrival in operation theatre ,intravenous access was established with 18 G cannula.The patients were preloaded with crystalloids at 10ml/kg.Pulseoxymeter, electrocardiogram and noninvasive blood pressure monitors were connected.The patients were placed in sitting position and lumbar puncture was performed under strict aseptic precautions at L3 –L4 space using 27 G Quincke's spinalneedle.Theanaesthesiologist performing the procedure was blinded to the drug injected. According to the allocated group, the patients received either hyperbaric bupivacaine or isobaric bupivacaine 3ml with 25 mcg of fentanyl . After the injection, patients were thenplaced in supine position. After 10 minutes the patients were put in lithotomyposition.Ananaesthesiologist blinded to patient allocation and study group performed the intraoperative and postoperative assessment. Systolic and diastolic blood pressure,heart rate and respiratory rate were recorded at 1^{st}min,5^{th} minute and thereafter every 5 minutes upto 30 minutes and then every 10 minutes till 60minutes.

Hypotension was said to have occurred if the systolic blood pressure and diastolic blood pressure had fallen below 20% from the base line and was treated with supplemental oxygen , increasing the infusion rate of intravenous fluids and injection Ephedrine in incremental doses of 6mg.On completion of surgery, patients were transfered to postoperative ward after complete resolution of motor blockade and stabilization of bloodpressure.Motor block was assessed by using Modified BromageScale.The time of onset of motor block was defined as the time interval between the local anaesthetic solution injected and the establishment of grade 4 on Bromagescale.The time of onset of sensory block was assessed as the time interval between local anaesthetic injection to the onset of complete loss of pinprick sensation in anterior axillary line bilaterally at T10 level.The level of sensory block achieved after 20 mins of local anesthetic injection was taken as the maximum level of sensory block achieved .Two segment regression time from the maximum level of sensory block achieved was taken as the duration of sensory block. Adverse effects such as giddiness, nausea, vomiting, shivering, pruritis and respiratory depression werenoted. The patients were supplemented with intravenous sedation with injection midazolam 0.05mg/kg or general anaesthesia when the subarachnoid block was inadequate or when the duration of block did not last longer than the duration ofsurgery.

III. Results

The mean age (in years) of patients in group A was 50.53 and the mean age of the patients in group B was 48.95. The age distribution in both groups were comparable and the difference was not statistically significant (p value 0.52)(Table1).

Table1:Patient characteristics.

Parameter	Group A(n=40)	GroupB(n=40)	P-value
Age in years	50.53	48.95	0.52
Sex(male/female)	(31/9)	(33/7)	0.57

31 patients were male and 9 patients were female in group A whereas in group B , 33 were male patients and 7 were female patients. The gender of the patients in both groups were comparable and was not statistically significant (p value0.576). In our study, the mean time of onset of sensory block was rapid in Group B (1.13 min) than in Group A (4.25min) and the difference was significant with p value (0.000)(Table2).

Table 2: Comparison of time of onset of sensory blockade between the two groups.

Group	**Range(min)**	**Mean(min)**	**S.D**	**p value**
A	3 – 6	4.25	±.59	0.000 Significant
B	1 - 2	1.13	±.34	

In our study the mean time of onset of motor block was rapid in Group B (1.25min) than in Group A (5.25min) and the difference was significant with p value (0.000)(Table3).

Table 3: Comparison of time of onset of motor blockade between the two groups.

Group	Range(min)	Mean(min)	S.D	p value
A	5– 6	5.25	±.44	0.000
B	1 – 2	1.25	±.44	Significant

In our study, the mean duration of sensory block was longer in group B when compared to Group A and the difference was statistically significant.The mean duration of sensory block in group A was 130.75±5.723 minutes whereas for group B it was 189.50±9.59 minutes.The difference was significant with p value0.000(Table4).

Table 4: Comparison of duration of sensory block between the two groups.

Group	Range(min)	Mean(min)	S.D	p value
A	120 - 150	130.75	± 5.72	0.000
B	180 - 220	189.50	± 9.59	Significant

In our study,the mean duration of motor block in group A was 183.00±7.232 minutes whereas for Group B it was 230.25 ± 8.62 minutes. The difference between the two groups was statistically significant (p value 0.000)(Table5).

Table5: Comparison of duration of motor block between the twogroups.

Group	Range(min)	Mean(min)	S.D	p value
A	170 – 200	183.00	±7.23	0.000
B	220 – 250	230.25	±8.62	Significant

In our study,the maximal block height achieved after 20 minutes was higher in Group B when compared to Group A and the difference was highly significant (p value 0.000)(Table6).

Table6: Comparisonofmaximumblockheight achieved between the twogroups

Maximum sensory block height after 20 minutes	Group A		Group B	
	Number	%	Number	%
T 4	-	-	6	15
T 6	1	2.5	34	85
T 8	7	17.5	-	-
T 10	32	80	-	-
Total	40	100	40	100
p value	0.000 Significant			

Table 7: Comparison of systolic blood pressure between the two groups.

Time interval(min)	Systolic blood pressure(mmHg)		p value	Significance
	Group A	Group B		
	Mean±S.D	Mean±S.D		
0	132.00±7.23	134.75±5.98	0.068	Not Significant
1	127.05±2.93	116.95±3.36	0.000	Significant
5	118.70±8.93	109.80±6.86	0.000	Significant
10	119.85±11.54	105.95±10.75	0.000	Significant
15	120.20±8.56	107.65±8.69	0.000	Significant
20	123.95±7.39	112.50±7.76	0.000	Significant
25	125.50±6.82	125.40±3.70	0.935	Not Significant
30	123.45±3.79	122.90±2.35	0.438	Not Significant
40	126.60±5.53	127.25±3.28	0.525	Not Significant
50	127.25±4.89	128.05±3.58	0.407	Not Significant
60	128.05±4.73	129.60±4.53	0.139	Not Significant

32(80%) patients had a block height of T10 , 7 (17.5%) patients had a block height of T8 and one (2.5%) patient had a block height of T6 in Group A.34 (85%) patients had a block height of T6 and 6 (15%) patients had a block height of T4 in groupB.In our study, the change in systolic (Table7)and diastolic blood pressure(Table8) (from 1 minute to 20 minutes) was greater in hyperbaric Bupivacaine -Fentanyl group when compared to isobaric Bupivacaine –Fentanyl group and the difference was statistically significant (pvalue0.000).

Table 8: Comparison of diastolic blood pressure between the two groups.

Time interval(min)	Diastolic blood pressure (mmHg)		p value	Significance
	Group A	Group B		
	Mean±S.D	Mean±S.D		
0	77.90±7.18	80.20±4.81	0.097	Not Significant
1	70.30±4.91	65.50±7.31	0.001	Significant
5	70.95±7.07	58.85±7.72	0.000	Significant
10	70.15±9.79	56.00±8.49	0.000	Significant
15	71.15±7.85	61.30±8.05	0.000	Significant
20	72.45±5.11	63.60±7.09	0.000	Significant
25	74.65±5.42	73.15±5.31	0.215	Not Significant
30	74.55±5.12	74.00±4.22	0.602	Not Significant
40	76.05±3.80	77.05±4.32	0.275	Not Significant
50	77.70±3.75	78.30±3.93	0.487	Not Significant
60	78.70±2.77	79.45±3.89	0.324	Not Significant

Table 9: Comparison of incidence of adverse effects between the two groups.

Adverse effects	**Group A**		**Group B**	
	Number	**%**	**Number**	**%**
Hypotension	5	12.5	18	45
Bradycardia	-	-	1	2.5
Nausea	2	5	13	32.5
Vomiting	-	-	-	-
Shivering	-	-	2	5
Giddiness	-	-	-	-
Pruritis	-	-	-	-
Respiratory Depression (rate < 10)	-	-	-	-
Total	40	100	40	100
p value	0.000 Significant			

In our study the incidence of adverse effects such as nausea , hypoytension and shivering were higher in hyperbaric Bupivacaine – Fentanyl group when compared to isobaric Bupivacaine – Fentanyl group.13(32.5%) patients had complained of nausea and 2(5%) patients had complained of shivering in hyperbaric Bupivacaine – Fentanyl group.Only 2(5%) patients complained of nausea in isobaric Bupivacaine –Fentanyl group whereas shivering was reported by none. The difference in incidence of adverse effects when comparing both the groups were statistically significant (p value (0.000)(Table9).

IV. Discussion

Subarachnoid block is one of the most extensively used technique for urological surgeries because of its simplicity, speed, reliability and minimal exposure to depressant drugs. However subarachnoid block has the disadvantage of sympathetic and motor blockade resulting in hypotension ,bradycardia and immobility .Studies show that the baricity of local anaesthetic solution relative to patient position determine the characteristics of the sensory and motor blockachieved[5].

Isobaric solution does not move under the influence of gravity in the cerebrospinal fluid. Hyperbaric solution, being heavier than cerebrospinal fluid tends to settle down in the most dependent aspect of subarachnoid space which is determined by the position of the patient. The effect of gravity determines the distribution of hypobaric and hyperbaric solution in sitting, trendelenberg and jacknifeposition.[6]

Many adjuvants are administered either intrathecally or intravenously to prolong the duration of analgesia achieved by the local anaesthetic solution and to reduce the complications. There are numerous benefits of adding opioids like fentanyl with local anaesthetics for subarachnoid block when compared to systemicopioids.

In a study conducted by Duggal, et al, the time of onset of sensory block at desired level was shorter in Ropivacaine - Fentanyl group when compared to patients receiving only intrathecalropivacaine and the duration of sensory block was longer in the ropivacaine -fentanylgroup.[7]This was similar to the study conducted by Imbelloni et al where the mean time of onset of motor block in isobaric bupivacaine-fentanyl group was 5 minutes whereas the mean time of onset of motor block was 1 minute for hyperbaric bupivacaine-fentanylgroup.[8] In the study conducted by Gupka et al, the mean duration of analgesia was 402.50±37.21 minutes for hyperbaric bupivacaine - fentanyl group whereas for isobaric bupivacaine- fentanyl group it was 288.90±25.22 minutes.[9]In the study conducted by Hallworth et al, mean duration of sensory block was 80.03 ± 8.12 minutes for isobaric bupivacaine whereas for hyperbaric bupivacaine it was 103.47±10.18minutes.[10] In a study conducted by Hussain et al, maximum block height achieved in hyperbaric bupivacaine group was T5 when compared to isobaric bupivacaine group where the maximum block height achieved was T10, the difference being statistically significant($p<0.01$).[11] In our study, the change in systolic and diastolic blood pressure (from 1 minute to 20 minutes) was greater in hyperbaric bupivacaine -fentanyl group when compared to isobaric bupivacaine –fentanyl group and the difference was statistically significant (pvalue0.000).

In a study conducted by Hussain et al, the change in systolic and diastolic blood pressure was greater in hyperbaric bupivacaine group when compared to isobaric bupivacaine group and the difference was statistically significant ($p<0.01$).[12]Yurtlu et al concluded that the incidence of hypotension was statisticaly high

in hyperbaric bupivacaine group when compared to isobaric bupivacaine group, the difference was statistically significant ($p<0.05$).[13] In a study conducted by Toptas M et al, the incidence of hypotension from (5 to 15 minutes) was significantly higher in hyperbaric bupivacaine –fentanyl group when compared to isobaric bupivacaine - fentanyl group, the difference was statistically significant($p<0.05$).[13]Hussain et al found that the incidence of hypotension was significantly higher in hyperbaric bupivacaine –fentanyl group when compared to isobaric bupivacaine -fentanyl group and the difference was statisticaly significant ($p<0.001$).[14]In our study , the incidence of adverse effects such as nausea , hypoytension and shivering were higher in hyperbaric bupivacaine – fentanyl group when compared to isobaric bupivacaine – fentanyl group.13(32.5%) patients had complained of nausea and 2(5%) patients had complained of shivering in hyperbaric bupivacaine –fentanyl group.Only 2(5%) patients complained of nausea in isobaric bupivacaine –fentanyl group whereas shivering was reported by none. The difference in incidence of adverse effects when comparing both the groups were statistically significant (p value 0.000).The results were similar to the study conducted by Upadya et al in which patients in isobaric Bupivacaine group had fewer incidence of nausea when compared to patients in hyperbaric bupivacaine group, the difference being statistically significant ($p<0.05$).[15] In a study conducted by Solakovic et al, there was an increased incidence of adverse effects in hyperbaric bupivacaine – fentanyl group when compared to isobaric bupivacaine –fentanyl group.[16]

V. Conclusion

The present study concludes that the quality of sensory and motor blockade achieved is better with hyperbaric bupivacaine and fentanylgroup.Thehaemodynamic parameters are stable in isobaric bupivacaine and fentanyl group.The need for supplementation with intravenous sedation is lower in the hyperbaric bupivacaine and fentanylgroup.The incidence of adverse effects is lower in the isobaric bupivacaine and fentanylgroup.

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