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A Comparative Study of EpiduralButorphanol And Epidural Fentanyl AsAdjuvants To Bupivacaine In Lower Abdominal Surgeries.

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I. Introduction:

Theinternational associationfor thestudy of pain defines pain as"an unpleasant actual or potential tissue damage or described in terms ofsuchdamage. Sopainisnotjustasensorymodalitybutitisanexperience. There is an interplay between objective, physiological, sensorycomponentsofpainanditssubjective, emotional,psychologicalcomponents. Other than pshychological trauma, pain is shown to affect thephysiology of almost all the systems including respiratory, cardiovascularandmetabolicprofilethereby increasingmorbidity[1].Thereforepropermanagementofpainremainsoneofthemostimportant domain. Modern dayanaestheticteчniquesarenotonlyconfinedinrelievingpainduringsurgerybutalsoduringpostoperativeperiod. It ispossibletoperformallsurgeriesundergeneralanaesthesia,butadditionof regionaltechniquestotheanaesthesiologist'sarmamentariumaddsflexibilityandskillsthatbenefitsthepatientsintraan dpost-operatively.

Epiduralanaesthesia/analgesiaisoneofthebestacceptedandmost commonlyemployedtechniqueinmodernanaesthesiologyforlowerabdominal, pelvic, perineal, thoracic and lower limb surgeries.It providessurgicalanaesthesiaaswellaspostoperative analgesia.

Postoperativepain treatment should be an integral part of routinesurgical and anaesthetic management both for humanitarian reasons and toreducemorbidity,associatedcomplicationsaswellastoacceleraterehabilitation.

Epidural anaesthesia providesgood operative conditions with goodsensoryandmotorblockade,contractedbowelsretainingadequatespontaneousrespiration,hemodynamicstabilit yandfacilitiesforpostoperative analgesia. Discovery ofopioid receptors in the spinal cordandsubsequentdevelopmentofepidural/intrathecaladministrationof opioid has opened a new horizon in pain management in the perioperativeperiod.

Bupivacaine is widely used in epidural anaesthesia. It is an amidelocalanaestheticwithasymmetriccarbonatom. Thisdrugiswidelyusedforepiduralanaesthesiaandanalgesiabecauseofitslongdurationofactionanddifferentialblocka deinlowerconcentrations.

Fentanylisanphenylpiperidinederivativeandsyntheticopioidagonist with rapid onset and short duration of action. Itis 75 – 125 timesmorepotentthan morphine.

Butorphanoltartarateisasyntheticopioidagonistandanagonistwith analgesic potency 4-8 times thatof morphine.Itis considered safethanpureopioidagonistbecauseofitsceilingeffectonrespiratorydepression,lower addiction potential with sedation comparable to or morethanmorphine,lesserincidenceofnausea,vomiting,pruritiswhichisdesirablein thepostoperativeperiod[3].

The present studywas designed to compare epidural bupivacainewithbutorphanolandepiduralbupivacainewithfentanylinlowerabdominalsurgeries.

AIMSANDOBJECTIVESOFTHESTUDY

This study aims to compare the efficacy of butorphanol and fentanyladdedasadjuvantstobupivacaineinepiduralanaesthesiaforelectivelower abdominal surgeries. The following points would be considered forcomparison:

1. Onset and completion of sensory blockade
2. Level of sensory block

3. Duration of analgesia
4. Quality of analgesia
5. Pain score
6. Side effects

II. MaterialsAndMethods:

This study is a comparative and prospective study conducted at ThanjavurMedicalCollege.Afterobtainingclearancefrominstitutionalethicalcommittee and informed consent, a total of 60 patients of either sex agedbetween 20-60yearsbelonging to ASA physical status I &II scheduled forelectivelowerabdominalsurgerieswererandomlyselected.

INCLUSIONCRITERIA:

- Patientsagedbetween20-60yrs
- Weighingbetween40-70kgs
- Both maleandfemale
- ASAgradeI&II
- Patientsundergoing electivelowerabdominalsurgeries

EXCLUSIONCRITERIA:

- Pregnantwomen
- Patientwithh/ocardiacandrespiratorydisorders
- Patientwithh/ohepaticandrenaldiseases
- Patientwithh/oconvulsions,neurologicaldeficits
- Spinal deformitiesandpsychiatricdiseases
- ASAgradeIII&IV
- Coagulopathiesandpatientswithinfectionatthepuncturesite.

III. Methodology

60patientspostedforelectivelowerabdominalsurgerieswererandomly selectedfor the study.All patients were thoroughly examinedandinvestigatedpreoperativelyonedaybeforesurgeryandexplainedabout the anesthetic technique. Routine preoperative investigations weredone. All the patients were educated about the verbal numerical pain scaleforassessmentofpain.

GradingofpostoperativepainisdoneusingVisualanalogScale(VAS).Thepatientwill beaskedtoquantify theirpainusing VASpain scale, giving a score of 0 to10, with 0- indicating no painand 10indicating theworstpossiblepain.

Writteninformedconsentwasobtained.Allpatientsreceivedpremedication at 10p.m on the night before surgery with Tab. Alprazolam0.25mgandTab.Ranitidine150mgandthereafteradvisednilperoral.

On theday of surgery patients were shifted to the operating room,andmultiparametermonitorswere connected.Thebaselineheartrate,$SpO_2$and blood pressure(systolic, diastolic and MAP) were recorded. An18G iv cannula was inserted and patients were preloaded with10ml/kg ofRingerlactateover15-30minutespriortoepiduralblock.

The anaesthesia machine, airway equipments and emergency drugs werekeptready.

Patientswerepositionedinrightlateraldecubitusposture.ObservingsterileprecautionsL3-L4spacewasidentified.Skinwasinfiltrated with local anesthetic inj. 1% lignocaine 2ml. Epidural space wasidentified with an 18G Tuohys needle, by using loss of resistance to airtechnique and a 19G epidural catheter was insertedabout 5cms into theepidural space and secured in place. Throughout the procedure patient'svitalsweremonitored.

` A test dose of 3ml of 1.5% lignocaine with adrenaline(1:2,00,000)was given to rule out intravascular or intrathecal placement of the catheter.Thepatientwasmadetoliesupine.Fiveminutesaftertestdose,confirming the absence of intrathecal or intravascular placement, 20ml ofstudy drug was injected through epidural catheter depending on the studygroup.

Patients were divided into two groups:

1. Group BB: Bupivacaine with Butorphanol- 0.5 % Inj Bupivacaine (18 ml) + Inj Butorphanol 1mg (1 ml) + Normal saline 1ml = 20 ml
2. Group BF: Bupivacaine with Fentanyl-0.5% Inj Bupivacaine (18 ml)+ Inj Fentanyl 100mcg (2 ml)= 20 ml

Allpatientsweregivenoxygenat5L/minthroughfacemask.

Nointravenousanalgesicsorsedation wereadministeredduring thesurgery.
The time of injection of study drugwas notedat"0" time.The drug wasinjected approximately at the rate of 1ml/second and the height of sensoryblockadewasdeterminedbyelicitingpinprick test. Intheperioperativeperiodthefollowingparameterswerestudied:

1. Vital parameters such as HR,BP, SPO_2,RR were continuously monitoredevery5minsforthefirst15minsandthenonwardsevery15minsthroughouttheintraoperativeperiodandevery ½anhourinthepost operative period for 2hours. Intraooperative hypotension if any was treatedwith iv fluids, O_2 supplementation and titrated doses of ephedrine3-6mgormephenteramine3-6mgiv.Bradycardia ifanywastreatedwithInj.Atropine.

2. Onset ofanalgesia is the time taken from injection of local anaestheticsolution uptolossofpinpricksensationinanydermatome.

3. Completion ofanalgesia is the time taken from the initial onset ofanalgesia upto the time when analgesia attained its maxium dermatomelevel,with nofurtherrisefor5mins.

4. Qualityofanalgesiawasgradedasfollows:

- Good-Nocomplaintofpain ordiscomfortduring theprocedure
- Fair-Pain or discomfort felt only during specific stages of procedure liketractiononviscera/peritoneum.
- Poor-Painduringsurgeryandneededtopupwithepidurallocal anaestheticsolution.

5. Durationofanalgesiaisthetimetakenfromtheonsetofanalgesiauptothetimewhen VAS reached ascoreof5.

6. Sedationscorewasassessedusingsubjectivesedation score:

0 awake,conscious,nosedationtoslightlyrestless
1 calmandcomposed
2 awakensonverbalcommand
3 awakenson gentletactilestimulation
4 awakensonlyonvigorousshaking
5 unarousable

POSTOPERATIVEOBSERVATIONS:

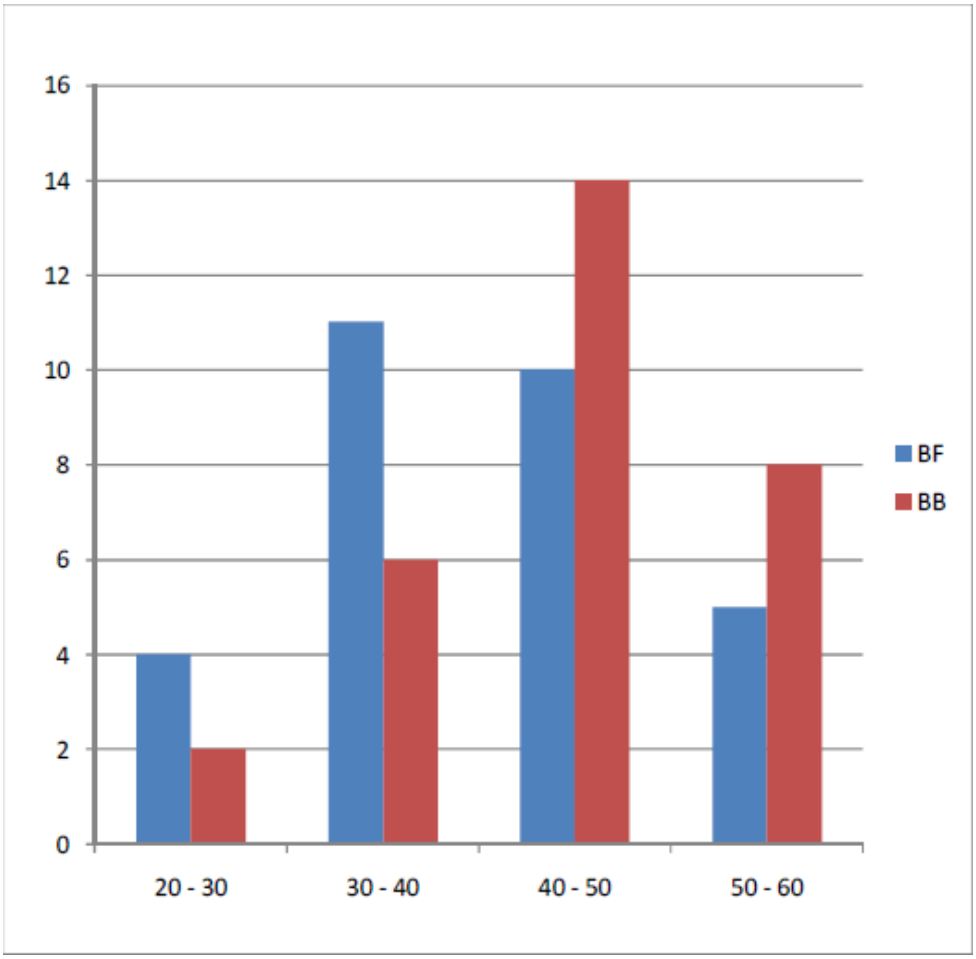
The following parameters were observed in the post operative period:**1.Pain score – VISUAL ANALOGUE SCALE**, every hour till 8hrs.
2.Vitalswererecordedatthesametimeintervalsasthepainscore.
When the VAS score reached 5, rescue analgesia was given through theepidural catheter and thestudy in the patient
ceased.Complicationslikenausea,vomiting,urinaryretention,headache,pruritisandrespiratorydepressionifanywere notedandtreatedaccordingly.

IV. ObservationAndResults

ThedatacollectedwassubjectedtostatisticalanalysisusingStatistical Package for Social Sciences. Chi-square test and the student 't'test was used to test the significance of difference between the two groups.A'p'value<0.05wastakento denoteasignificance.
Table 1: Comparison of age between BB and BF groups
Boththegroupswerecomparablewithrespecttodemographicprofileslikeage,sex,weight.
Patients aged 20 – 60yrs were included in the study. The mean age is 41.37yearsin BB group and 41.63 years in BF group. There is no statisticaldifferenceintheagecomparisonbetweenthetwogroups.

GROUP	MEAN(years)	S.D±	Statistical significance
BB Group(n=30)	41.37	6.071	T= -1.96 Df = 48 0.8457> 0.05
BF Group(n=30)	41.63	4.311	

GRAPH 1: COMPARISON OF AGE



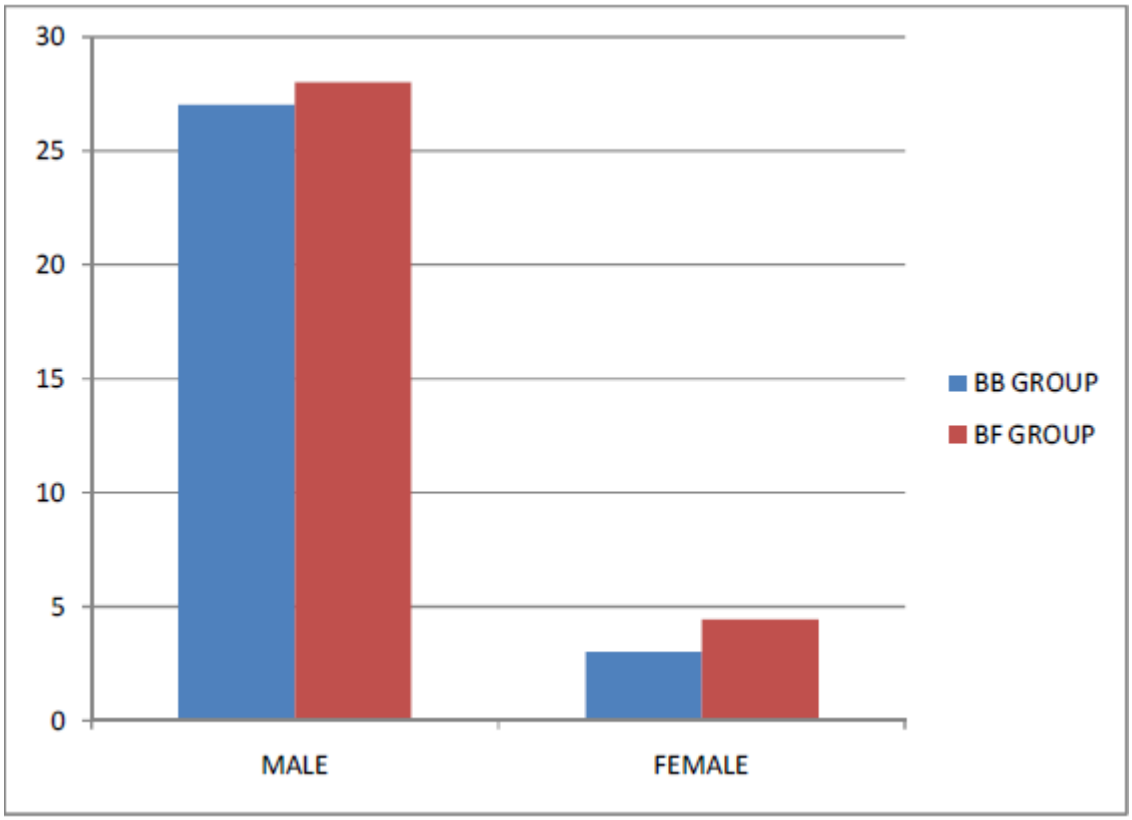
(AGE IN YEARS)

TABLE 2: COMPARISON OF SEX AMONG BB AND BF GROUPS

SEX	*BB GROUP* *N = 30*	*BF GROUP* *N = 30*	Statistical signifiance
MALE	27(90%)	28(92%)	$X^2 = 0.758$ Df = 1 0.384 > 0.05
FEMALE	3(10%)	2(8%)	

90% of patients in BB group aremales, 92% in BF group aremales. 10%in BB group are females and 8% in BF group are females. There is nostatisticaldifferenceinsexcomparisonbetweenthetwogroups.

GRAPH 2: SEX COMPARISON



MAJORITY OF PATIENTS IN BOTH THE GROUPS WERE MALES

TABLE 3: COMPARISON OF MEAN HEART RATE

TIME IN MINUTES	GROUP BB		GROUP BF		STATISTICAL INFERENCE
	MEAN/MINS	S.D	MEAN/MINS	S.D	
0	84.50	±7.408	83.80	±7.392	0.769>0.05 NS
5	87.33	±9.488	87.80	±9.368	0.849>0.05 NS
10	84.87	±9.850	86.17	±8.848	0.593>0.05 NS
15	82.87	±9.726	84.53	±8.693	0.487>0.05 NS
20	80.83	±9.959	83.57	±8.451	0.256>0.05 NS
25	79.97	±9.764	83.13	±8.645	0.189>0.05 NS
30	78.87	±10.06	82.03	±8.282	0.189>0.05 NS
40	77.23	±9.517	81.07	±7.570	0.090>0.05 NS
50	75.60	±9.328	75.68	±9.126	1.000>0.05 NS
60	74.77	±9.175	74.67	±9.089	1.000>0.05 NS
70	74.33	±8.856	74.13	±8.813	1.000>0.05 NS
80	73.97	±9.528	74.17	±9.108	0.935>0.05 NS
90	73.07	±9.303	73.20	±9.103	0.955>0.05 NS
100	72.80	±8.608	73.10	±8.658	1.000>0.05 NS
110	72.43	±8.557	72.32	±8.432	1.000>0.05 NS
120	72.20	±7.490	72.57	±7.398	1.000>0.05 NS

Thereisstastically no significant differenceinmeanheart ratefrom 5minutes to 120 minutes between the groups BB and BF. Mean heart in BBgroupwas75.60/minandBF groupwas74.67/min.

GRAPH 3: COMPARISON OF MEAN HEART RATE

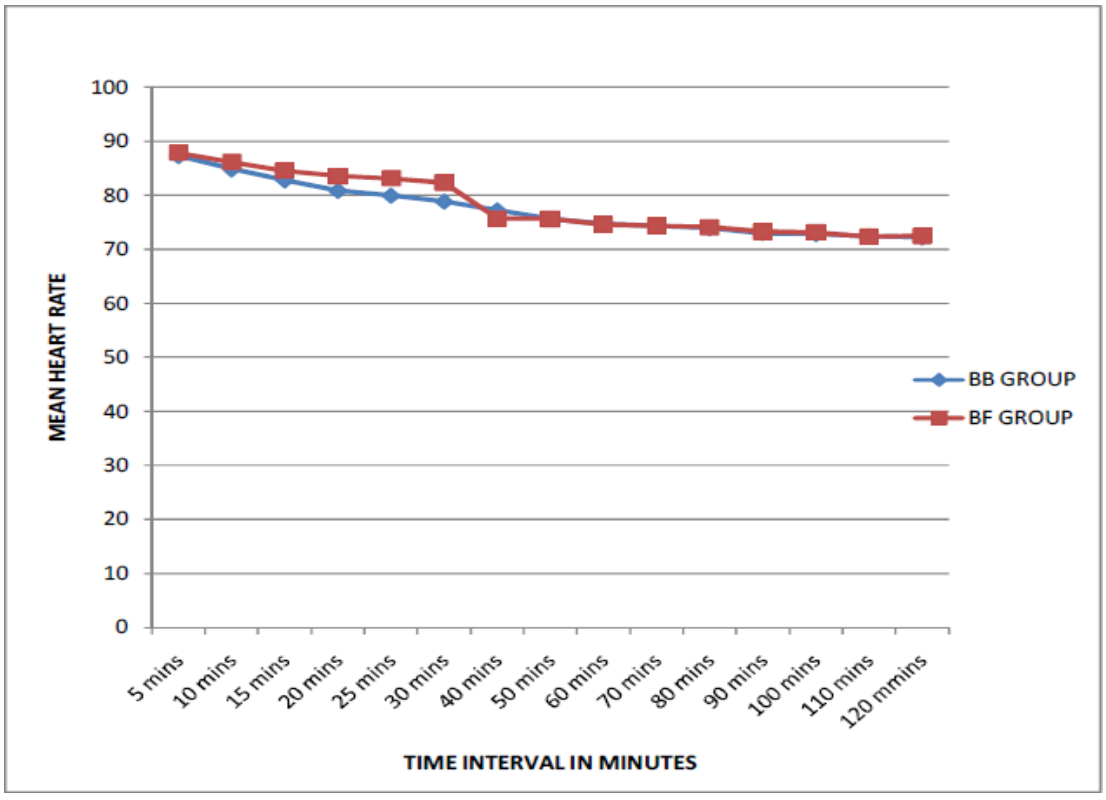


TABLE 4: COMPARISON OF MEAN ARTERIAL BP

TIME IN MINUTES	GROUP BB		GROUP BF		STATISTICAL INFERENCE
	MEAN/mmHg	S.D	MEAN/mmHg	S.D	
0	92.7667	±6.083	89.7000	±7.278	0.969>0.05 NS
5	90.8667	±7.152	90.6667	±8.035	0.919>0.05 NS
10	87.6000	±6.975	87.4000	±7.686	0.918>0.05 NS
15	85.2000	±7.274	85.0667	±7.965	0.996>0.05 NS
20	83.4333	±7.219	83.3667	±7.880	0.973>0.05 NS
25	82.1333	±6.489	81.9333	±7.248	0.911>0.05 NS
30	80.5000	±6.323	80.3333	±7.018	0.923>0.05 NS
40	79.6667	±6.171	79.5667	±6.382	0.951>0.05 NS
50	78.8000	±5.695	76 7.7333	±5.976	0.965>0.05 NS
60	79.0000	±5.219	78.9333	±5.426	0.961>0.05 NS
70	80.3000	±4.403	80.3000	±4.587	1.000>0.05 NS
80	81.1667	±4.534	81.3000	±4.617	0.911>0.05 NS
90	83.2333	±4.336	82.6667	±4.412	0.618>0.05 NS
100	84.0667	±4.109	83.5333	±4.116	0.617>0.05 NS
110	86.1000	±4.369	85.4333	±4.272	0.550>0.05 NS

There is statistically no significant difference in the mean arterial pressurefrom 5minutesto120minutesbetween BBgroupandBF group.Themean arterial blood pressure in BB group is 83.4 mmHg±1.26(S.D.) and inBF groupis81.3mmHg±1.05(S.D.).

GRAPH 4: COMPARISON OF MEAN ARTERIAL BP

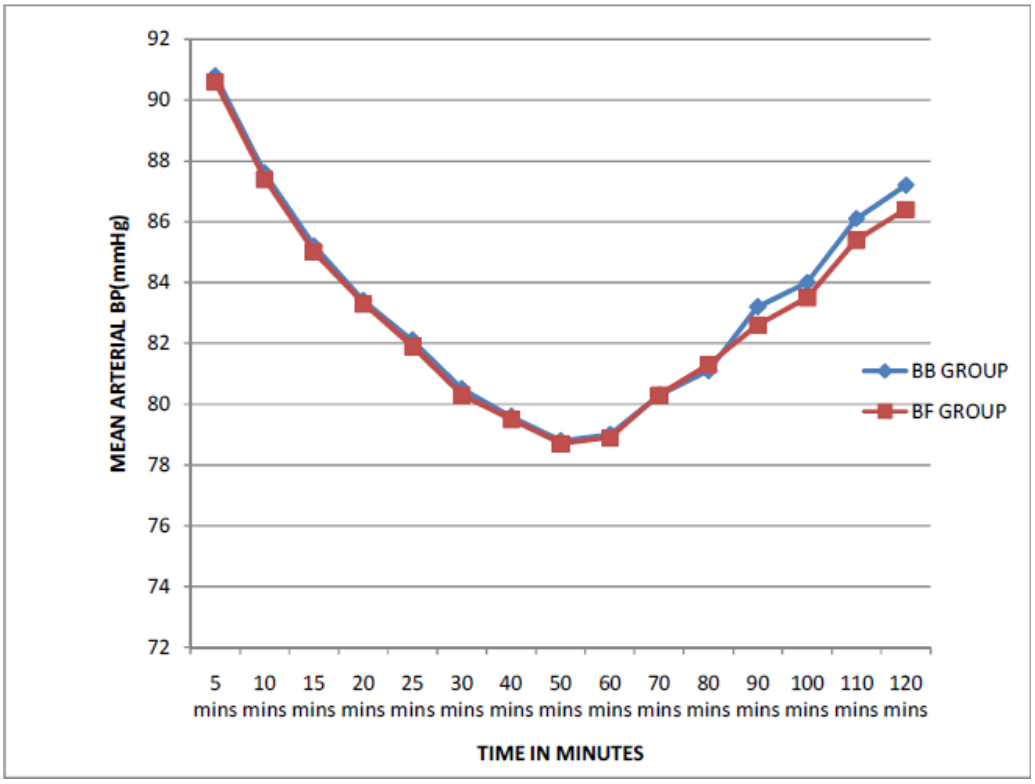


TABLE 5: COMPARISON OF MEAN RESPIRATORY RATE

TIME IN MINUTES	MEAN/MINUTES		S.D. ±		STASTISTICAL INFERENCE
	GROUP BB	GROUP BF	GROUP BB	GROUP BF	
0	13.4	13.7	1.042	0.868	0.286>0.05 NS
5	13.7	13.2	0.069	0.695	1.000>0.05 NS
10	14.9	14.2	1.709	1.092	0.064>0.05 NS
15	14.6	14	1.401	1.050	1.000>0.05 NS
20	13.7	13.8	1.250	0.924	0.967>0.05 NS
25	13	13.4	1.188	1.072	0.176>0.05 NS
30	12.8	12.9	1.156	1.033	0.558>0.05 NS
40	12.2	12.6	1.104	0.932	0.170>0.05 NS
50	12	12.5	1.080	0.937	0.492>0.05 NS
60	12	12.1	1.082	0.791	0.499>0.05 NS
70	11.9	11.83	1.172	0.647	0.684>0.05 NS
80	12.0	12.2	0.932	0.839	1.000>0.05 NS
90	12.1	12	1.074	0.909	0.606>0.05 NS
100	12.3	12.1	0.994	0.937	0.426>0.05 NS
110	12.2	12.4	0.935	0.865	0.392>0.05 NS
120	12.3	12.5	0.927	0.858	0.390>0.05 NS

There is statistically no significant difference in the mean respiratory ratefrom5minsto120minsbetweenBBgroupandBFgroup.ThemeanrespiratoryrateinBB groupis12.6 andinBFgroupis12.9.

GRAPH 5: MEAN RESPIRATORY RATE IN BF AND BB GROUPS

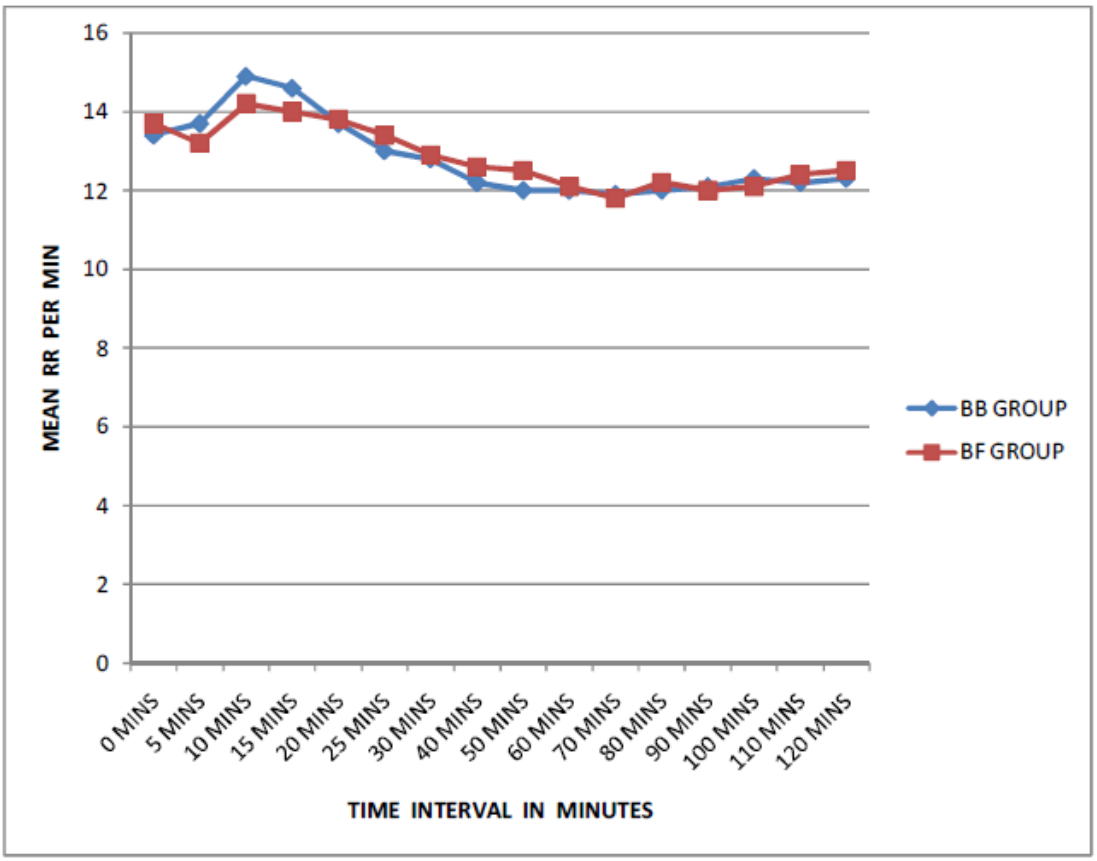


TABLE 6: COMPARISON OF MEAN SPO2 IN BF AND BB GROUPS

TIME IN MINUTES	GROUP BB		GROUP BF		STASTISTICAL INFERENCE
	MEAN %	S.D.	MEAN %	S.D.	
0	98.5	±0.507	98.5	±0.504	0.799>0.05 NS
5	98.4	±0.502	98.5	±0.501	0.769>0.05 NS
10	98.4	±0.500	98.4	±0.502	0.748>0.05 NS
15	98.3	±0.479	98.3	±0.504	0.434>0.05 NS
20	98.2	±0.450	98.2	±0.479	0.581>0.05 NS
25	98	±0.365	98	±0.450	0.302>0.05 NS
30	98	±0.183	98	±0.365	0.656>0.05 NS
40	98	±0.101	97.9	±0.183	0.321>0.05 NS
50	98	±0.263	97.9	±0.183	0.570>0.05 NS
60	97.7	±0.365	97.8	±0.346	0.477>0.05 NS
70	97.6	±0.485	97.6	±0.498	0.125>0.05 NS
80	97.6	±0.508	97.6	±0.490	0.305>0.05 NS
90	97.8	±0.379	97.7	±0.449	0.356>0.05 NS
100	97.8	±0.345	97.8	±0.345	1.000>0.05 NS
110	97.8	±0.365	97.8	±0,182	0.656>0.05 NS
120	97.9	±0.253	98	±0.101	0.155>0.05 NS

ThereisnostatisticalsignificanceinmeanSpo_2from5minutesto120minutesinbetween BBgroup andBF group.

GRAPH 6: MEAN SPO2 IN BF AND BB GROUPS OVER 0 TO 120 MINUTES

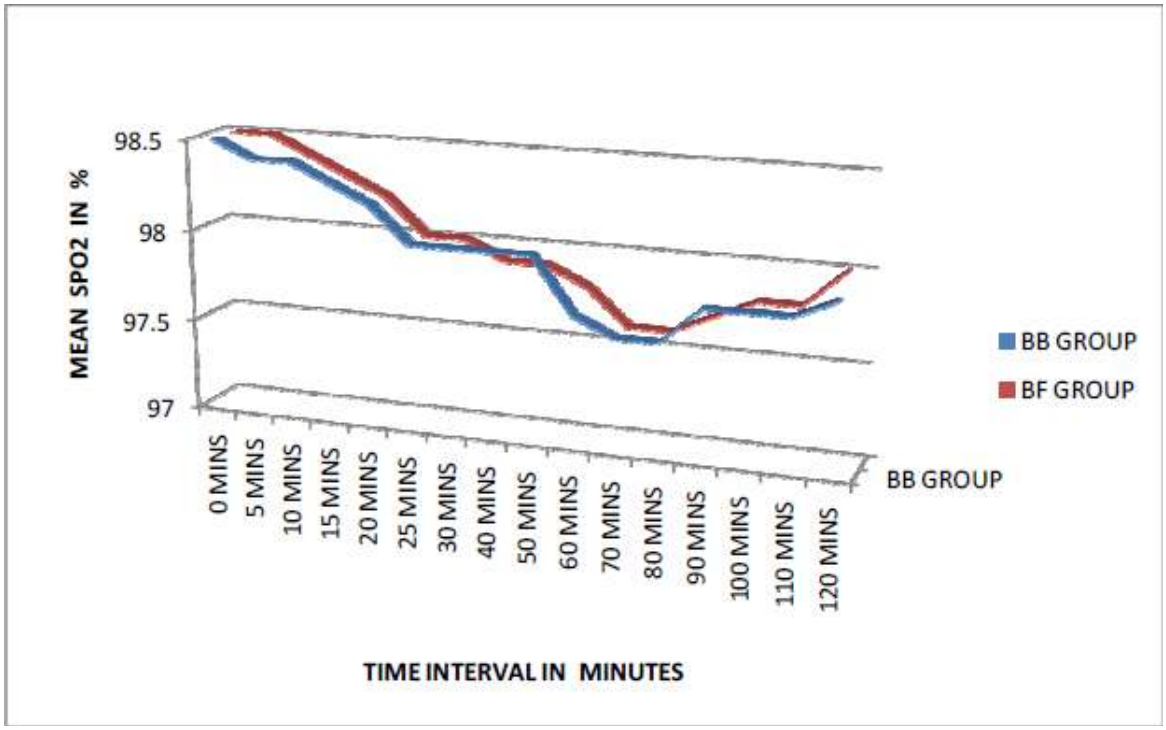


TABLE 7: SEDATION CHARACTERISTICS IN BF AND BB GROUP

TIME IN MINUTES	SUBJECTIVE SEDATION SCORE(% OF CASES												STATISTCAL INFERENCE
	GROUP BB						GROUP BF						
	0	1	2	3	4	5	0	1	2	3	4	5	
30		100					85	15					0.001< 0.05 S
60			100					100					0.001< 0.05 S
90			100					80	20				0.000< 0.05 S
120			75	25			12	32	56				0.003< 0.05 S

IngroupBB, 100%patienthadsedation scoreof1at 30minutes,whereas in group BF 85% patients had a sedation score of 0 at 30 minutes.At60,90and120minutesmajority ofthepatientsingroupBBhadasedation score of 2 and 3, whereasin groupBF thesedation score was1and2.

TABLE 8: ONSET AND DURATION OF SENSORY BLOCK IN BF AND BB GROUP

There is no significant statistical difference in the time of onset ofsensoryandmotorblock,completionofsensoryandmotorblockinbetweengroupBBandgroupBF.Meanonsettimeof sensoryblock,completion of sensory block,onset of motor block and completion of motorblockin group BB is 5.73minutes,10.1 minutes,4.45 minutes and 29.58minutesrespectively.InBFgroup,meantimeofsetofsensory,completion of sensory block,onset of motor block and completion of motorblockare5.96mins,10.53mins,4.88minsand31.45minsrespectively.

PARAMETERS	GROUP BB		GROUP BF		STATISTICAL INFERENCE
	MEAN IN MINUTES	S.D.	MEAN IN MINUTES	S.D.	
ONSET OF SENSORY BLOCK	5.73	1.48	5.96	1.67	0.871>0.05 Not Significant
COMPLETION OF SENSORY BLOCK	10.10	1.26	10.53	0.89	0.132>0.05 Not Significant
ONSET OF MOTOR BLOCK	4.45	0.30	4.88	0.30	0.310>0.05 Not Significant
COMPLETION OF MOTOR BLOCK	29.58	1.04	31.45	0.91	0.128>0.05 Not significant

GRAPH 8: BLOCK CHARECTERISTICS

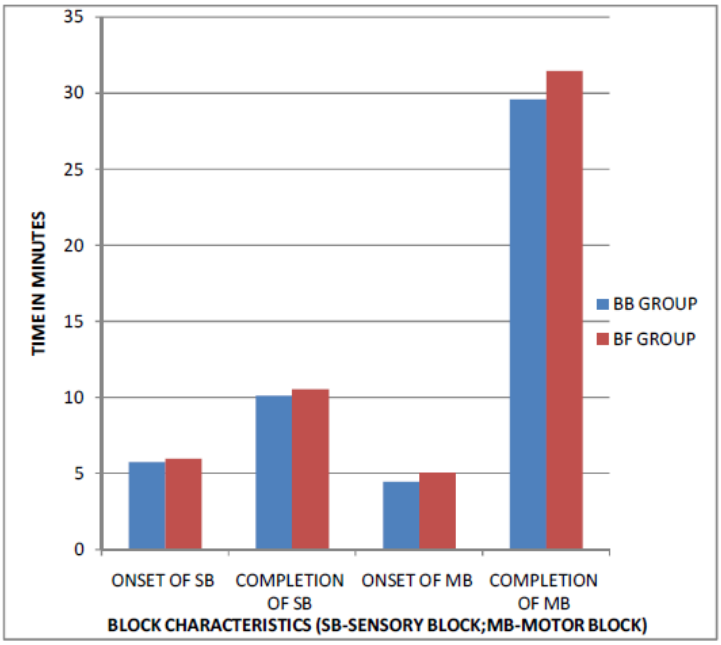


TABLE 9: COMPARISON OF DURATION OF ANALGESIA IN BF AND BB GROUPS

Thereis statistically significant difference in the duration ofanalgesiabetween group BB and group BF. The duration of analgesia was longestwith butorphanol group(5-9 hours; mean-7.1 hours), whereas in group BFwas 3-9hours,mean 5.2hrs.

PARAMETER	GROUP BB		GROUP BF		STATISTICAL INFERENCE
	MEAN HOURS	±S.D.	MEAN HOURS	±S.D	
DURATION OF ANALGESIA	7.1	1.008	5.2	1.080	0.001<0.05 SIGNIFICANT

GRAPH 9: DURATION OF ANALGESIA

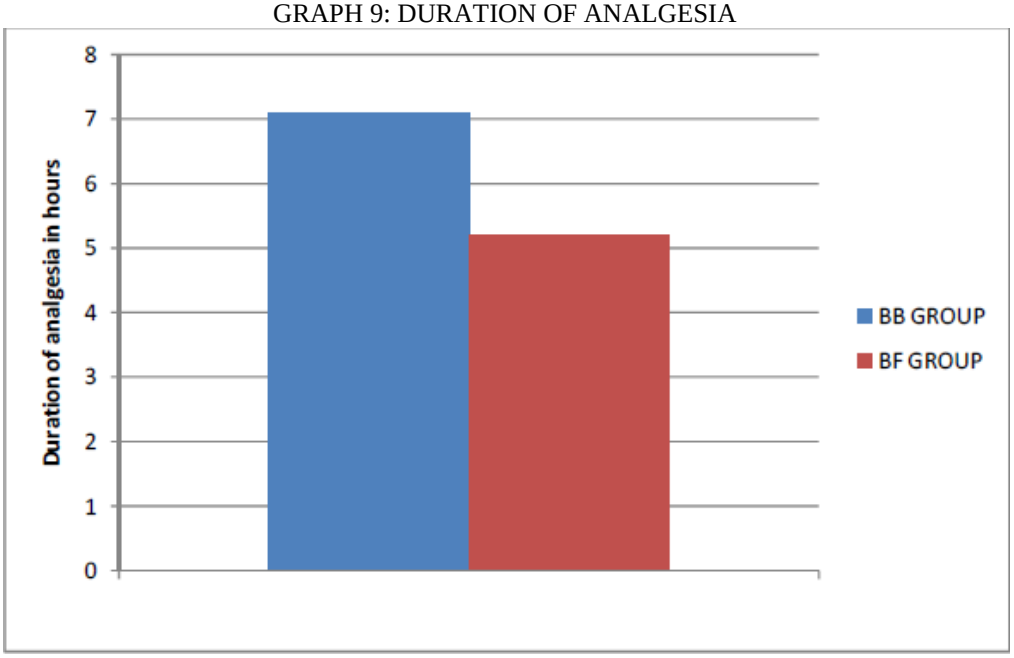
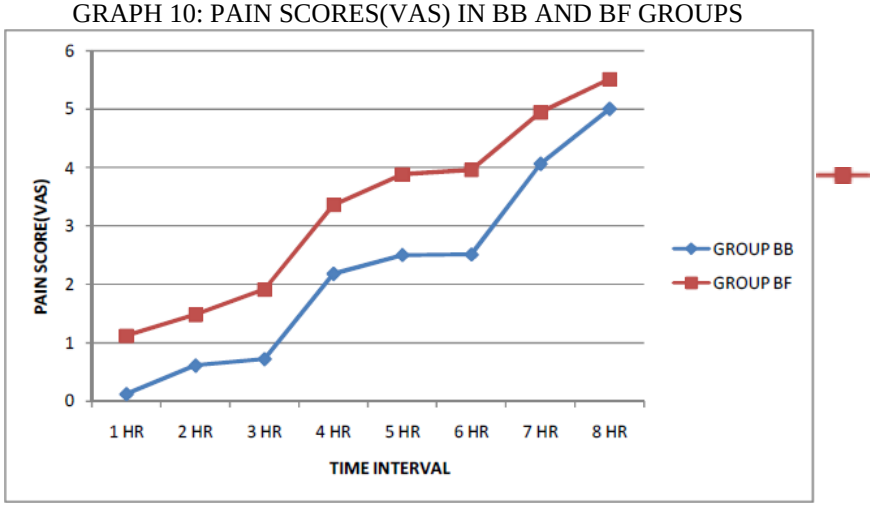


TABLE 10: MEAN POSTOPERATIVE PAIN SCORES(VAS) IN BOTH THE GROUPS AT DIFFERENT TIME INTERVALS

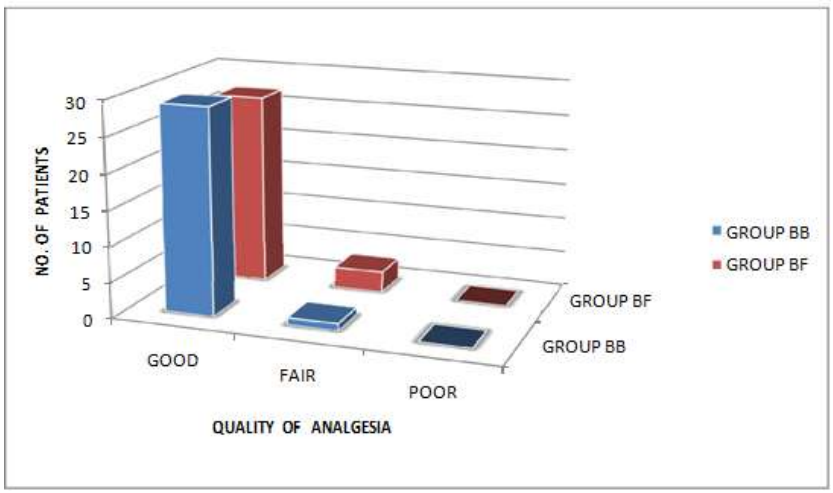
TIME INTERVAL	GROUP BB		GROUP BF		STATISTICAL SIGNIFICANCE
	MEAN	±S.D.	MEAN	±S.D.	
1 HR	0.12	0.71	1.12	0.45	0.000<0.05 S
2 HR	0.61	0.61	1.48	0.91	0.008<0.05 S
3 HR	0.72	0.60	1.91	0.56	0.021<0.05 S
4 HR	2.18	0.87	3.06	1.70	0.001<0.05 S
5 HR	2.50	1.17	3.88	0.96	0.003<0.05 S
6 HR	2.51	1.07	3.96	0.91	0.012<0.05 S
7 HR	4.06	0.61	4.94	0.56	0.001<0.05 S
8 HR	5.00	0.08	5.51	0.54	0.44>0.05 NS

GRAPH 10: PAIN SCORES(VAS) IN BB AND BF GROUPS



As shown in graph 9, the pain scores as assessed on VAS were low andremainedlowfor a significant timein thepost operative periodin groupBB when compared togroup BF.

GRAPH 11: QUALITY OF ANALGESIA

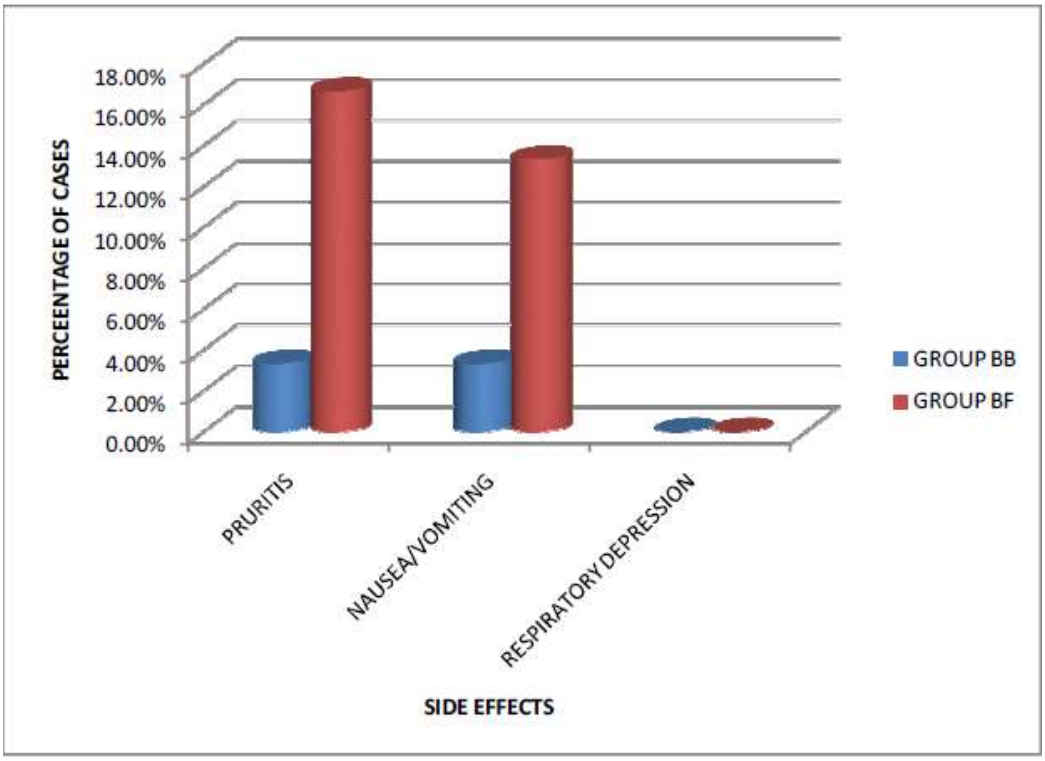


Majority of the patients in both groupBB and Group BF had good qualityofanalgesia.Noneofthepatientsrequiredtopupdosesoflocalanaestheticsintraoperatively.

TABLE 11: COMPARISON OF SIDE EFFECTS IN BB AND BF GROUPS

SIDE EFFECTS	GROUP BB (n=30)	GROUP BF (n=30)	p Value
Pruritis	1	6	0.353>0.05 NS
Nausea/vomiting	1	4	0.671>0.05 NS
Respiratory depression	0	0	0

GRAPH 12: COMPARISON OF SIDE EFFECTS



V. Discussion

Opioids are being extensively used as adjuvants to local anaestheticsto improve the quality oftheblock and to produce dose-sparing effect.Epiduraladministrationofvariousanalgesicshavegainedpopularityfollowing the discovery of opioid receptorsin the spinal cord. The use ofepidural techniques also offer the advantage of post-operative analgesia.There are a number of studies to prove the efficacy of adding opioids tolocalanaesthetics.Opioidreceptorsarefoundtobehighlyspecificreceptorslocatedinspecificregionsofcentralnervoussystemandperipheralnervoussystem.Theopioidreceptorslocatedinthedorsalhornof spinal cord mediate both pre and post synaptic effects modulating thenociceptiveinputwithoutsensoryormotorblockade.Epiduraladministration of opioids have found to be superior than intravenous orintramuscularinjectionofopioids.

Although in recent times various opioids have been used for postoperativeanalgesia,earliermorphineandpethidinewerethestandarddrugs,whichwereassociatedwithincreasedincidenceofdelayedrespiratorydepressionandabusepotential.Stimulationofspinalopiatereceptorsproducesspinalanalgesiawithlessersideeffects.

Butorphanol amixedopioid , with an agonist and antagonist actionat μ receptor and an agonist action at kappa receptor, is found to producepotent analgesia with fewer side effects and very low abuse potential. It ishighlylipidsolubleandhasgreateraffinitytoopioidreceptors,whichcontributestoitsgreaterpotencyand efficacy.

Fentanyl,beingasyntheticopioidreceptoragonist,isfoundtoproduceanalgesiabybindingtosupra-spinalopioidreceptorswhenadministered into the epidural space. It is better retained in the epiduralspace because of its high lipid solubility. Following administration into theepidural space, systemic absorption occurs, but it has a shorter half life,hencethereislesscirculatingplasmadrugconcentration.Epiduraladministrationoffentanylisassociatedwithreducedrespiratorydepression andlesser incidence of side effects like nausea, vomiting andpruritis.

Thepresentstudyisprospective,randomized,comparativestudydonetocomparetheefficacyofbutorphanolandfentanyladdedasadjuvantstobupivacaineinepiduralanaesthesiainlowerabdominalsurgeries with respect to intra operative hemodynamic stability and postoperative analgesia. A total of 60 patients both male andfemale belongingtotheagegroupof20-60yearswerestudied,amongwhichmajorityofthepatients were aged between 40-50 years and majority of the 60 patientsunderwentgeneralsurgery.

Duringthepreoperativeassessment,thepatientswereclearlyexplainedabouttheanaestheticprocedureandalsoeducatedabouttheassessmentofpaininthepostoperativeperiodusingVAS.Writtenconsent was obtained from all the patients. At 10 pm on the night beforesurgery, all patients were premedicated with Tab. Alprazolam 0.25 mg andTab.Ranitidine150mgandadvisednilperoralfromthenonwards.Patients were randomly divided into two groups of 30 per group,Group BB- bupivacaine with butorphanol and Group BF- bupivacaine withfentanyl. All

the surgeries were doneunder lumbar epidural anaesthesiawith a total volume of 20 ml of study drug in each group. Intra operativelyvitalparameterslikepulserate,meanarterialbloodpressure,oxygensaturation, respiratory rate were recorded every 5 minutes from the time ofinjectingthestudydrugupto30minutesandthenonwardsevery10minutesupto120minutes.Similarlythesedationscorethroughouttheintra-operative period, the time of onset and completionof sensory block,the time of onset and completion of motor block,side effects if any wererecorded

Therewasnocaseofepiduralfailureandnopatientrequiredepidural top-up with local anaesthetics in the intra operative period. In thepost- operative periodpainwas assessed using the VAS, every hour upto8hrs.

At the same time the vital parameters and side effects were alsorecorded and treated accordingly. When the VAS > 5, the patients weregiven rescue analgesia with Tramadol 100mg in 10ml ofnormal salinethroughtheepiduralcatheterandstudyinthatpatientceasedandthedurationofanalgesiawasnoted.Thedurationof analgesiawassignificantly seen to beprolonged with bupivacaine-butorphanol group(BB)

INOURSTUDY:

INTRAOPHEMODYNAMICS:

In our study,the majority of patients were hemodynamically stableintra-operatively.Comparison of heart rateandMAPwithin thegroupswasdoneusingpaired‘t’testwhereascomparisonofheartrateandMAPinbetweenthetwogroupswasdoneusingunpaired‘t’test.

The mean arterial BP in Group BB was 83.4 mm Hg± 1.26 (S.D)mmHg and in group BF was 81.3mm Hg± 1.05 (S.D) mm Hg. The meanreductioninMAPwasstatisticallyinsignificantbetweenboththegroups.In both groupsBB and BF, there was a fall from the baseline MAP of 92.7mmHg±6.08(S.D.) and 89.7 mmHg±7.27(S.D.) respectively to 78.8mmHgand76.7mmHg at 40-50minstimeinterval which wasnotstatisticallysignificant.

The mean pulse rate in Group BB was 75.6±1.35(S.D.)/min and inGroup BF was 74.67±0.92(S.D.)/min. The statistical analysis showed thattherewasnosignificantdifferencebetweenthetwogroups.

Themean respiratory rateingroupBB was12.6± 1.32(S.D.)/minand in group BF was 12.9±0.98(S.D.)/min. The statistical study showed nosignificantdifferenceinthemeanrespiratoryratebetweenthe2groups.

Oxygen saturation (SPO_2) maintained between 98-97% in both thegroups.Noneofthepatientsinboththegroupsshoweddesaturation(SPO_2<95%).

Ourstudycanbecomparedtothefollowingstudies:

Goughetal.,in1988usedepiduralfentanyl1.5µg/kgbodyweightin 10ml of sterile solution and concluded that the range of mean(S.D) ofcardio- respiratory variables like heart rate 84(±2) to 95(±18) beats/ min,systolic BP of 121(±19) to 133(±14) mm of Hg, diastolic BP of 70(±10) to76(±10) mmof Hg andRR of 14(±3) to 16(±4) / min variednegligiblyfrom basalrecordings.

Premila Malik, Chhavi Manchanda, Naveen Malhotra et al., in2006 conducted a study to assess and compare the safety and efficacy ofpostoperative analgesia with epidural butorphanol 2mg and fentanyl 50µg.Their study showed that there was no significant changes in pulse rate,systolic and diastolic BP, RR and SpO2 in the 2 groups at different timeintervalsthroughoutthe24hoursstudyperiod(p>0.05).

SEDATIONSCORES:

Catherine O Hunt in her study has reported a higher incidence ofsedation with epidural butorphanol and is a dose dependent side effect. Inour study sedation scores were higher with butorphanol group as comparedwithfentanylgroup.Meanvalueofsubjectivesedationscorewas1.00±0.06ingroupBFand3.0±0.64ingroup BB.Majorityofthepatientshadmildsedation.Thepatientswereawakebutdrowsy.Thiswasstatisticallysignificant(p<0.001).

JS Naulty in his study notedthat sedation wassignificant,but wasof mild type (arousable with verbal response).72% of patients on epiduralbutorphanol 2mg hadclinically significantsedation in a study by **ThereseKetal.**

RutterDVetal.,in1981reportedthatfentanyl100µgforpostoperativepainreliefproducedincreaseinsedation.

ONSETANDCOMPLETIONOFSENSORYBLOCK:

In our studytheonset and completion ofanalgesiawas

hastenedwiththeadditionofbutorphanolandfentanyl.Buttherewasnostatisticallysignificantdifferencedetweenthetwogroups.Additionof1mg butorphanol to 20ml 0.5% bupivacaine reduced the latency of onset ofanalgesiato5-9minsandcompletion ofanalgesiaoccurredearlier(9-14mins, mean10.10mins). InBFgroupalsotheonsetofanalgesiawasrapid(5-10mins; mean 5.95 mins) and completion of analgesia occured in(9-15mins;mean 10.96 mins).

Mok et al., in 1986dida study toevaluate the analgesicefficacyand safety of epidural butorphanol 4mg in comparison to that of epiduralmorphine 5mg in patients with postoperative pain. Onset of pain relief withepiduralbutorphanolappearedat15minutesandpeakedat30minutes.
Maurice Lippmann in 1988 has reported in his study that epiduralbutorphanol4mgusedforpostoperativeanalgesiainnon-obstetricabdominalsurgerieshasproducedanalgesiawithin15minutes.
Abboud et al.in 1986studiedthe efficacy ofepidural butorphanolfor post operative pain relief and reported the onset of analgesia with 1mgbutorphanolwas15mins.
Cousins and Mather et al. in 1984reported the time of onset ofanalgesiawithepiduralfentanyl100µgto be5-10mins.
Rutter DVet al., in 1981 reportedthat 100µg ofepidural fentanylfor postoperative pain relief had a rapid onset of action i.e almost 50%reduction inmeanpainwithin5 minutes.
In a study by **Lomessay A et al.,** in 1984 concluded that epiduralfentanyl 200µg provides rapid analgesia that remains optimum during 2hoursdespitetheintensity andpainstimulation.

Naulty JS et al., in 1985 used different doses of epidural fentanyl inparturientsfollowingcaesareandelivery.Theyconcludedthatfentanyl100µg producedpain scoresof0in3-6minutes.

QUALITYOFANALGESIA:
In our study majority of the patients in both group BB and group BFreported good quality of analgesia. None of the patients in both the groupsrequiredtopup doseoflocalanaestheticsintraoperatively.
Quisqueya T et al., in 1991 compared epidural butorphanol in dosesof 1mg, 2mg and 4mg with morphine 5mg. He concluded that each dose ofbutorphanol producedgreater pain reliefthan morphineat 15, 30, 45and60 minutes($p<0.05$).
Lytle SA et al., in 1991 did a retrospective analysis with fentanyl(50µg) and showed that epidural fentanyl provides good to excellent painrelief.
Sugimoto M et al., in 1997 compared the degree of analgesia usingdifferent doses of epidural fentanyl and found that epidural fentanyl 25µgprovidedsuperioranalgesiathan12.5µg.

Hwang KB, Chung CJ, Lee et al., in 2004 compared analgesicefficacy of epidural butorphanol and epidural fentanyl and concluded thatthere was no significant difference in the quality of analgesia between thetwogroups.

POSTOPERATIVEPAINSCORES:
In our study the pain scores as assessed on the VAS were low andremained low for a significant time in the post operative period in bothgroup BB and group BF. The range of post operative pain scores in groupBB at 1, 2,3,4,5,6,7 hours were between 0-5, where as in BF group for thesame time interval was between 3-6. There was a statistically significantdifferenceinpainscoreinbetweenboththegroups.

DURATIONOFANALGESIA:
In our study the duration of analgesia was significantly prolongedwith the addition of opioids to local anaesthetics. The mean duration ofanalgesia with the group BF was 5.2 hours, where as in Group BB was 7.1hours.Ourstudywasconsistentwiththoseobservedby**CousinsandMarther et al**.,1984 and **Peach et al.,**in 1990, who observed the meanduration of analgesia with epidural fentanyl was 5.7 hours and 5.2 hoursrespectively.**Maliketal.,**in2006studiedthedurationofanalgesiawithepiduralbutorphanolwithvaryingdosesandobservedthatepiduralbutorphanol produceda significantly longer durationofanalgesiawhencomparedto fentanyl.

SIDEEFFECTS:
Narcotics arewell knownfor theirpotentialsideeffects suchaspruritis,nausea,vomiting,urinaryretentionandrespiratorydepression.Delayedrespiratorydepression isoneofthemost troublesomeofthesesideeffects.

Pruritis: In our study 3.33% of patients in butorphanol group had pruritisand whereas 16.66% of patients in fentanyl group had pruritis which wasstatisticallyinsignificant(p>0.05).
In a study by **Ackermann et al.,** in 1989, 7% of patients reportedpruritiswith2mgofepiduralbutorphanolandinastudybyPalaciosetalin1991,1.4%ofpatientsreportedpruritis with2mgofbutorphanol.
In a study by **Lytle SA et al.,** in 1991 using fentanyl 50µg ,4% ofpatientshad pruritis.

Nauseaandvomiting:
Inourstudy3.3%ofpatientsinbutorphanolgrouphadnauseawhereasinfentanylgroup13.33%ofpatientshadnauseawhi chwasinsignificantstatistically (p>0.05).
Nopatientsonepiduralbutorphanolhadnauseaorvomitinginseparatestudies conductedby **JS Naultyetal.,andCatherine OHuntetal**.InastudybyLytleSAetal.,in1991,nauseawasreportedin25.5%ofcases.
PremilaMalik,ChhaviManchanda,NaveenMalhotrain2006comparedtheefficacyofepiduralbutorphanol2mgandfen tanyl50µgfound that the incidence of nausea and vomiting was higher in fentanylgroup.

Respiratorydepression: In our currentstudy, none of the patientsinbutorphanolgrouporfentanylgroupreportedrespiratorydepressionwhich wasconsistentwiththefollowingstudies.

No patients had respiratory depression with butorphanol in studiesconducted by **Maurice Lippmann et al**., in 1988, **Catherine O Hunt et alin 1989,JSNaultyetal.,in 1989.**
Rutter DV et al., in 1981 reported decrease in respiratory rate inpatientswhoreceived100µgoffentanyl.
Negre I et al., in 1987 observed the effect of 200µg of fentanyl onventilatory response tocarbon dioxide and concluded that fentanyl inducesa non systemic ventilatory response that may be due to rostral spread of thedrug.

VI. Summary

This prospective randomized controlled clinical comparative studyentitled"**ACOMPARATIVESTUDYOFEPIDURALBUTORPHANOLANDEPIDURALFENTANYL AS ADJUVANTSTOBUPIVACAINEINLOWERABDOMINALSURGERIES"**was conducted in 60 patients of either sex, aged between 20- 60 years of ASAgradeIandIIadmittedforelectivesurgeriestoThanjavurMedicalCollege,fromJune2012toJuly2014.
Writteninformedconsentwastakenandpre-anaestheticevaluationwasdone.Allcasesweregivenepiduralanaesthesiausing0.5% bupivacaine with butorphanol 1mg(total volume of 20 ml) or 0.5%bupivacainewithfentanyl100µg(totalvolumeof20ml)dependingonstudygroupBBorBF.Intheperiooperativeper iodthefollowingparameterswereobserved:

1. Vital parameters- heart rate, Spo_2, blood pressure and respiratoryrate
2. Onsetandcompletionofanalgesia
3. Qualityofanalgesia
4. Durationofanalgesia
5. Sedatonscore
6. Sideeffects

In the postoperative period, intensity ofpain was assessedusingLinearVisualanalogscale.

Demographicprofile(age,sex)wascomparablein bothgroups.

INTRAOPERATIVEHEMODYNAMICS:
Themeanarterialbloodpressureingroup BBwas83.4mmHg± 1.26(S.D)andingroupBFwas81.3mmHg±1.05(S.D).

The mean pulse rate in Group BB was 75.6±1.35(S.D.)/minutes andin GroupBFwas74.67±0.92(S.D.)/minutes
Themean respiratory rateingroupBB was12.6± 1.32(S.D.)/minand in group BF was 12.9±0.98(S.D.)/min. The statistical study showed nosignificant difference in the mean arterial blood pressure,mean pulse rate,meanrespiratoryratebetween the2groups.
Oxygen saturation (SPO_2) maintained between 97-98% in both thegroups.Noneofthepatientsinboththegroupsshoweddesaturation(SPO_2<95%).

Onsetandcompletionofanalgesia:
InBBgroupmeanonsetofanalgesiawas5-9minsandcompletionof analgesia occurredearlier(9-14 mins, mean 10.10 mins).In BF groupalsothe onset ofanalgesia wasrapid(5-10mins;mean 5.95mins) andcompletion of analgesia occured in (9-15mins;mean 10.96 mins). But therewasnostatisticallysignificantdifferencebetweenthetwogroups.
Durationofanalgesia:Thedurationofanalgesiawaslongerinbutorphanol group which ranged from5to8hours with a mean of 7.6hours compared to fentanyl group which ranged from 3 to 7 hours with amean of5.8hours.Thiswasclinicallyandstatisticallysignificant($p<0.001$).

Quality of analgesia:Thequality of analgesiawas goodin both BB andBFgroup.Therewasnostatisticalsignificancebetweenboththegroups.

Sedationscore:
The mean value of subjective sedation score was 1.00±0.06 in groupBFand3.0±0.64ingroupBB.Thiswasstatisticallysignificant($p<0.001$).

Sideeffects
The frequency of pruritis, nausea and vomiting was more in fentanylgroup when compared to butorphanol group but this was not statisticallysignificant.Respiratorydepressionwasnot reportedinboththegroups.

VII. Conclusion

It can be concluded from the above study that epidural butorphanolprovides a longer duration ofgood quality of analgesia with fewer sideeffects like sedation which are statistically significant when compared toepiduralfentanyl.

In view of itssafety profile, epidural butorphanol can be routinelyemployed as an adjuvant to bupivacaine in epidural anaesthesia for goodintraoperative and postoperative analgesiafor various surgical procedures.Howevermorestudieswithdifferentdosagesanddifferenttechniques(epidural bolus andinfusion) of both thestudy drugs shouldbe conductedtoevaluatetheefficiencyandtoconcludetheabovefacts.

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