

Original Research Article

**“AN EVALUATION OF CLONIDINE AND FENTANYL AS AN
ADJUNCT TO BUPIVACAINE IN ULTRASOUND GUIDED
TRANSVERSUS ABDOMINIS PLANE BLOCK FOR
POSTOPERATIVE ANALGESIA IN BILATERAL INGUINAL
HERNIOPLASTY”**

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Abstract:

Background: Inguinal hernioplasty is one of the most commonly performed surgical procedures associated with moderate to severe postoperative pain. Optimal postoperative analgesia is important to prevent negative outcomes. The Ultrasound guided transversus abdominis plane (TAP) block is a peripheral nerve block that involves innervations of the anterolateral abdominal wall derived from T6-L1 which increases duration of analgesia & prolongs the time to first analgesic request, reduces postoperative analgesic consumption and reduces opioids related side effects. Various adjuvants to bupivacaine have been used to extend the analgesic effect. Most commonly used are dexmedetomidine, clonidine, dexamethasone and fentanyl. In this study we used clonidine and fentanyl. Primary objective was to assess the duration of postoperative analgesia while secondary objectives were to compare the quality of analgesia as measured by VAS score, the total amount of rescue analgesics consumed in 24 hours, side effects, and complications if any between the adjuvants.

Aims and objectives: To assess the duration of postoperative analgesia with clonidine v/s fentanyl as adjuvant to bupivacaine (p). To compare the quality of analgesia as measured by Visual Analogue pain scale (VAS) score, the total amount of rescue analgesics consumed in 24 hours and side effects and complications if any between the adjuvants

Materials and methods: An observational hospital based study was conducted at Gandhi Medical College, Bhopal comprising of 60 patients between age group 18-60 years, male, belonging to ASA grade I to II, scheduled for elective bilateral inguinal hernioplasty under the subarachnoid block (SAB) after informed consent. GROUP C (B+C) - 30 patients received bilateral TAP block using 22 ml solution— consisting of 20 ml 0.25% bupivacaine and 1

mcg/kg clonidine dissolved in 2 ml normal saline. GROUP F (B+F) - 30 patients received bilateral TAP block using 22 ml solution— consisting of 20 ml 0.25% bupivacaine and 1 mcg/kg fentanyl dissolved in 2 ml normal saline. Diclofenac 75mg was used as rescue analgesia . Post operative pain is evaluated by VAS score for pain at 0,2,4,8,12 and 24 hrs postoperatively,time to 1st analgesia ,total analgesia and any complications were noted .

Result: There was no statistical significant difference between the two groups in demographic characteristics (age and ASA),The overall p value of mean heart rate , mean systolic bp,mean diastolic bp between 2 group is less than 0.001 , the difference was statistically significant which means the average hemodynamic parameter values of group F (B+F) were greater than group C (B+C),The VAS score of group C Was significantly lower than VAS score of group F during all the intervals of time ($p < 0.001$) ,Significant difference was seen in post-operative Ramsay sedation score at 2 hour, at 4 hours, at 8 hours, between GROUP F and GROUP C (p value < 0.05) .GROUP F has higher Ramsay sedation score , No significant difference was seen at 12 and 24 hours (p value > 0.05), between GROUP F and GROUP C, time to 1st rescue analgesia is longer in group clonidine, Total analgesic consumption in the group C was lower compared to that of group F which was significant statistically($p < 0.05$). The incidence of hypotension and bradycardia more in group C. Other adverse effects were comparable.

Conclusion: Addition of clonidine to Bupivacaine in TAP Block prolongs the post- operative analgesia than fentanyl. It provides longer first analgesia request time and less total analgesia consumption with minimal side effects. Addition of fentanyl to Bupivacaine in TAP Block gives more hemodynamic stability.

Key words: clonidine, fentanyl, bupivacaine, Visual Analogue pain scale (VAS) score, analgesia, Ramsay sedation score

1. Introduction:

Postoperative pain is the most common cause of patient discomfort and dissatisfaction with surgery. Therefore reducing the postoperative pain not only comforts the patient but also provides a better chance of recovery and early discharge. Inguinal hernioplasty is one of the most common and painful surgeries being performed in India. Pain in inguinal hernioplasty is because of incisional site (somatic) and visceral (deep intraabdominal). Different approaches to reducing postoperative pain have been used such as local wound infiltration, intravenous analgesics, ilioinguinal and iliohypogastric nerve blocks. TAP(transversus abdominis plane block) block is one of the approaches and giving ultrasound guided TAP block increases the accuracy of placing the drug in the right plane under direct visualization thus reducing the amount of local anesthetic drug and complications ⁽¹⁾. It blocks the innervations of the anterolateral abdominal

wall derived from T6-L1 which increases duration of analgesia & prolongs the time to first analgesic request, reduces postoperative analgesic consumption and reduces opioids related side effects. Various adjuvants to bupivacaine have been used to extend the analgesic effect. Most commonly used are dexmedetomidine, clonidine, dexamethasone and fentanyl⁽²⁾. In this study we used clonidine and fentanyl.

Clonidine is partial α_2 agonist and it acts on dorsal horn of spinal cord and locus coeruleus in brain. Clonidine binds with activated nucleotide-gated channels, inhibiting the neuron from returning to a resting state and preventing further action potential generation⁽⁵⁾. It prolongs the duration of both sensory and motor blockade induced by local anesthetics irrespective of the route of administration (e.g., epidural, caudal, or spinal). Clonidine with bupivacaine given intrathecally, epidurally or in peripheral nerve blocks is associated with prolongation of effect of local anaesthetic⁽¹⁰⁾.

Fentanyl is a synthetic opioid agonist which when used intrathecal, epidural and in peripheral nerve blocks gives better intraoperative and postoperative analgesia without any hemodynamic instability⁽³⁾. Giving opioid in peripheral nerve block targets the peripheral receptors and therefore avoids debilitating centrally mediated adverse events such as respiratory depression, altered consciousness, and addiction leading to improved analgesia⁽⁷⁾.

In this study our Primary objective was to assess the duration of postoperative analgesia while secondary objectives were to compare the quality of analgesia as measured by VAS score, the total amount of rescue analgesics consumed in 24 hours, side effects, and complications if any between the adjuvants.

2. Materials and methods:

An observational hospital based study was conducted at Gandhi Medical College, Bhopal comprising of 60 patients between age group 18-60 years, male, belonging to ASA grade I to II, scheduled for elective bilateral inguinal hernioplasty under the subarachnoid block (SAB) after informed consent.

INCLUSION CRITERIA	EXCLUSION CRITERIA
ASA I and II	Patient refusal or not giving consent.
Age between 18-60 years.	Patient with coagulopathies
elective bilateral inguinal hernioplasty under SAB	Seizure disorder
	ASA grade III and above
	Bradycardia and heart block
	Pregnancy
	Patient consuming adrenoceptors agonist or antagonist

The patients were assigned into 2 groups :

Group C - 30 patients received bilateral TAP block using 22 ml solution— consisting of 20 ml 0.25% bupivacaine and 1 mcg/kg clonidine dissolved in 2 ml normal saline.

Group F - 30 patients received bilateral TAP block using 22 ml solution— consisting of 20 ml 0.25% bupivacaine and 1 mcg/kg fentanyl dissolved in 2 ml normal saline.

Under strict asepsis, the SAB was given using 25G Quincke spinal needle with 0.5% heavy bupivacaine 15 mg (3ml) in the L3–L4 interspace. After the completion of the surgery, TAP block was given bilaterally under sterile conditions. The linear probe (linear R) of ultrasound was placed in transverse position on the anterolateral plane of the abdomen in space between the iliac crest and below the ribs. The fascia between the internal oblique and the transverse abdominis muscle was identified. The needle was placed under ultrasound guidance in this area and study drug was injected after negative aspiration.

Patients were monitored postoperatively for 24h at 0,2,4,8,12&24 hrs.

HR, Mean arterial pressure (MAP), Respiratory rate (RR) , SpO₂ , VAS Score , Ramsay sedation score , Side effects (Nausea, vomiting , hypotension, bradycardia ,headache), Time to the first request of analgesia ,Total analgesic consumption(time frame 24hrs postoperatively), TAP block related complications(time frame 24hrs postoperatively).

Diclofenac 75mg was used as the first rescue analgesic whenever VAS was >4 in the 24 h, and its first requirement time was recorded. Any clinically significant bradycardia and hypotension were noted and treated.

VISUAL ANALOGUE PAIN SCALE

- Grade 0 (0-1). : Good analgesia
- Grade 1 (1-4). : Moderate analgesia
- Grade 2 (4-7). : Mild analgesia
- Grade 3 (7-10) : No analgesia
- Grade 4 (10) : Worst pain imaginable

RAMSAY SEDATION SCORE

Score	Response
1	Patient Anxious and Agitated or restless or both
2	Patient Cooperative, Oriented and Serene
3	Drowsy and responding easily to commands
4	Brisk response to light glabellar tap or loud auditory stimulus
5	Sluggish response to light glabellar tap or loud auditory stimulus
6	No response to light glabellar tap or loud auditory stimulus

Statistical Analysis : The comparison of the variables which were quantitative in nature were analyzed using Independent t test. The comparison of the variables which were qualitative in nature were analyzed using the Chi- Square test. If any cell had an expected value of less than 5 then Fisher’s exact test was used. The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package or Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, ver 25.0. For statistical significance, p value of less than 0.05 was considered statistically significant.

3. Results:

Table 1 : Showing demographic characteristics (Age and ASA) between groups

VARIABLES	Group C = 30	Group F = 30
AGE	42 (28-59)	51 (26-61)
ASA GRADE -1	10 (33%)	11 (37%)
ASA GRADE- 2	20 (67%)	19 (63%)

Table 2 : Comparison of mean heart rate (MHR), mean Systolic blood pressure (MSBP), mean diastolic blood pressure (MDBP),between two groups at different intervals of time postoperatively

TIME	MHR F Beats/min	MHR C	MSBP F	MSBP C	MDBP F	MDBP C
BASELINE	94	90.03	125	132	77.6	76.7
30MIN	79	62.5	123	107	69	59.4
1 HR	76	62.26	123	106	67.9	59.2
2 HR	77.7	62.63	123	107	68.83	69.3
4 HR	79	69.63	124	116	79	65.5
8 HR	78.2	68.5	125	111	76.4	64.3
12 HR	77	70.83	123	114	76	63.5
18 HR	74	72.63	124	119	75	71
24 HR	77.14	73.14	127	124	79	73.7
Total mean	79.11	70.23	124.11	115.11	74.30	66.95

Figure 1 : Comparison of mean systolic BP (MM HG) Between both group

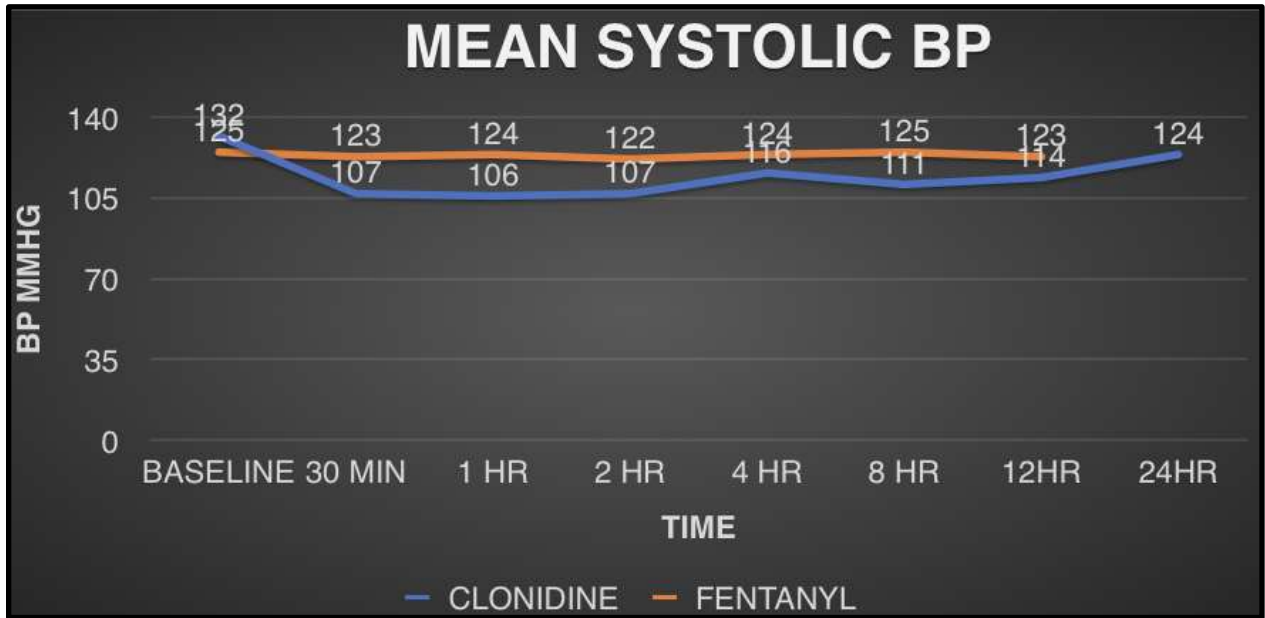


Figure 2: Comparison of mean diastolic BP (MM HG) Between both group at various time points

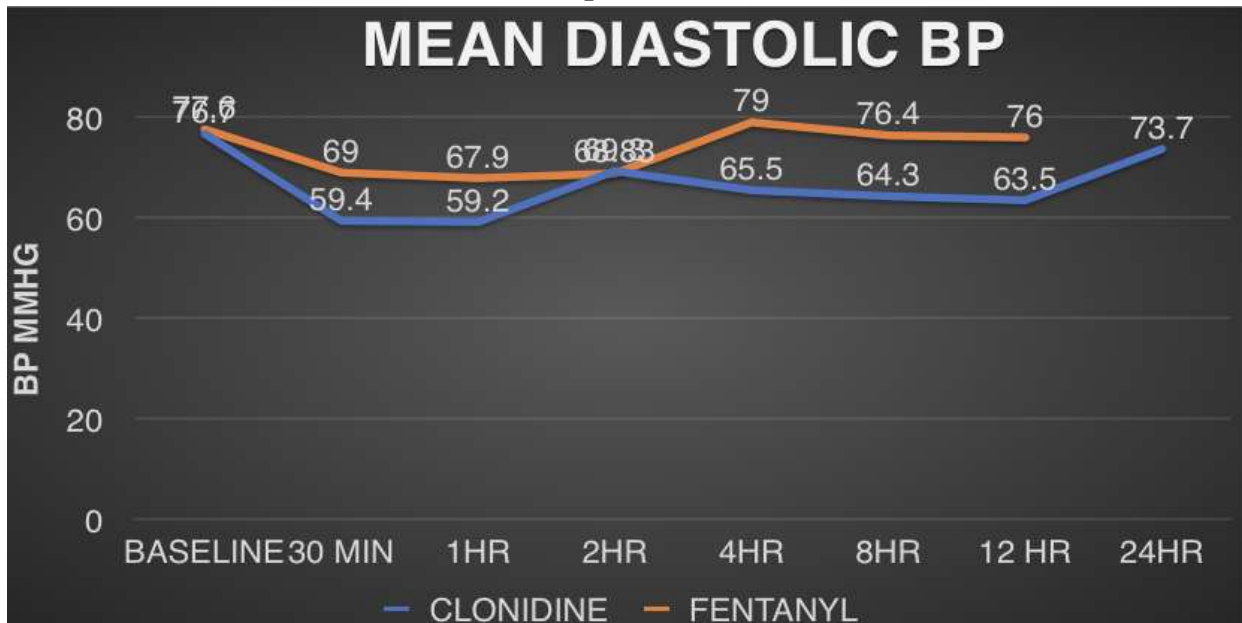


Figure3: Comparison of mean heart rate (beats/min) Between both group at various time points



Table 3 : Comparison of VAS score between two groups at various time points

TIME	GROUP F VAS	GROUP C VAS	P value
BASELINE	0	0	-
30MIN	0	0	-
1 HR	0	0	-
2 HR	0	0	-
4HR	2.40± 0.814	1.20 ± 0.664	<0.001
8HR	4.70± 1.208	2.57 ±0.858	<0.001
12HR	5.07 ±1.081	3.30 ± 0.837	<0.001
18HR	5.07 ± 0.640	3.53 ± 0.681	<0.001
24HR	4.77 ± 0.935	3.57 ± 0.935	<0.001

Figure 4 : Comparison of VAS score between two groups at various time points

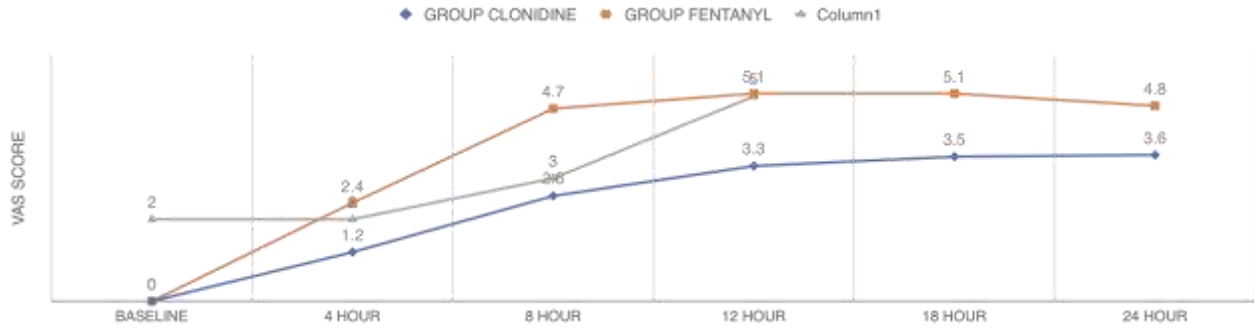


Table 4 :Comparison of Ramsay sedation score between two groups at various time points

TIME	GROUP F SEDATION	GROUP C SEDATION	P VALUE
BASELINE	3.60±0.5	1.30±0.46	<0.001
2 HR	2.73±0.45	1.13±0.47	<0.001
4HR	2.23±0.43	1.33±0.47	<0.001
8HR	2±0	1.43±0.50	0.004
12HR	2.03±00.18	2±0	0.321
24HR	2±0	2±0	1

Figure 5: Comparison of Ramsay sedation score between two groups at various time points

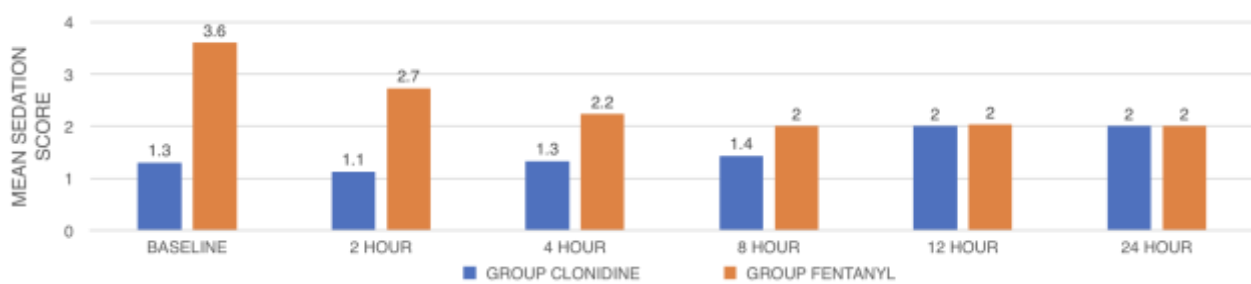


Figure 6: Comparison of time to 1 st rescue analgesia in hours between two groups

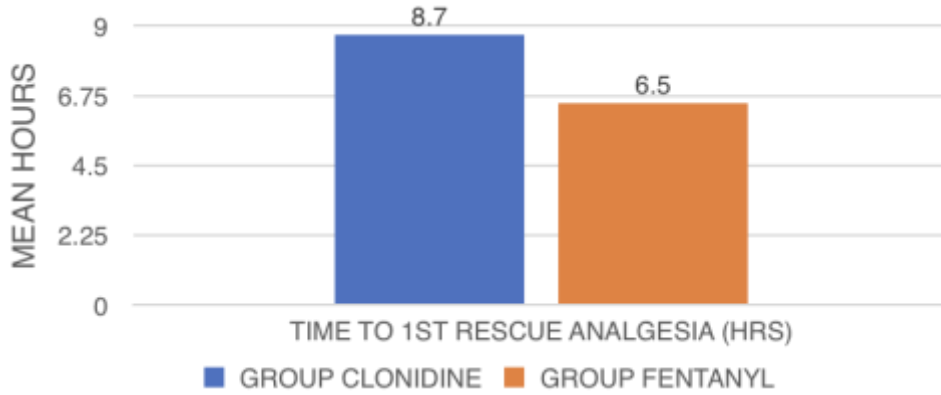


Figure 7 : Comparison of total analgesic consumption(in mg / 24 hr)between two groups

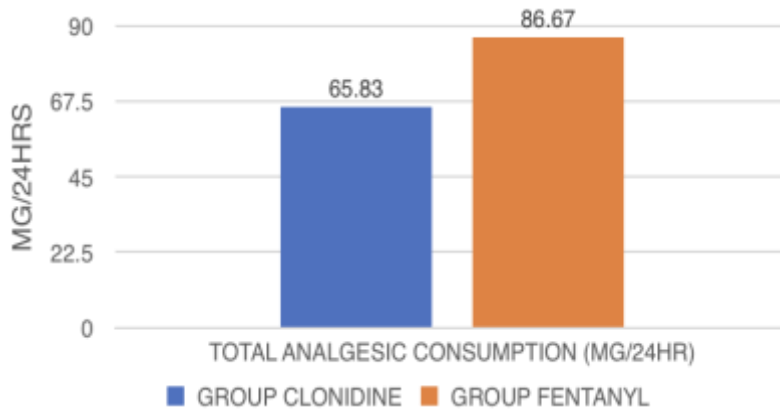


Table 5 : Shows comparison of time to 1 st rescue analgesia(in hours) and total analgesic consumption(in mg / 24 hr) between two groups

Variables	Group F	Group C	P value
Time to first rescue analgesia (hours) Mean ± SD	6.5 ± 0.5	8.7 ± 0.5	<0.001
Total analgesic consumption (mg) /24 h Mean ± SD	86.67 ± 14.28	65.83± 20.22	<0.001

Table 6 : Comparison of adverse effects between two groups

Adverse effects	Group F. N (%)	Group C N (%)	Total N (%)
Nausea	2(6.66)	2(6.66)	4(6.66)
Vomiting	1(3.33)	2(6.66)	3(5)
Headache	2(6.66)	1(3.33)	3(5)
Urinary retention	0(0)	0(0)	0
Bradycardia	1(3.33)	2(6.66)	3(5)
Hypotension	2(6.66)	3(10)	5(8.33)

There was no statistical significant difference between the two groups in demographic characteristics (Age and ASA).

Baseline mean heart rate in group clonidine was 90.03 beats/min. After the TAP block there is significant reduction in mean heart rate at 30 min (62.5 beats/min) , 1 hr (62.26 beats/min) and 2 hr (62.63 beats/min) in group clonidine . Whereas reduction in mean heart rate in group fentanyl at 30 min (79 beats /min) , 1 hr (76 beats/min) , 2 hr (77.7 beats/min) . At 4,8,12 and 24 hrs there is no significant difference in both groups.

After TAP block there is significant reduction in mean systolic bp in group C at 30 min(107mm hg) , 1 hr (106 mm hg) and 2 hr (107 mm hg) , 4 hr (116mm hg) , 8hr (111 mm hg) in group clonidine . Whereas reduction in mean systolic bp in group fentanyl at 30 min , 1 hr , 2 , 4,8 ,12 and 24 hrs was not significant .

After the TAP block there is significant reduction in mean diastolic bp in group C at 30 min(59.4 mm hg) , 1 hr(59.2mm hg) and 2 hr (69.3 mm hg) in group clonidine . Whereas reduction in mean diastolic bp in group fentanyl at 30 min , 1 hr , 2 , 4,8 ,12 and 24 hrs was not significant .

The overall p value of mean heart rate, mean systolic bp, mean diastolic bp between 2 groups is less than 0.001, the difference was statistically significant which means the average hemodynamic parameter values of group F were greater than group C .

The VAS score of group C Was significantly lower than the VAS score of group F during all the intervals of time (p value <0.001) .

Ramsay sedation score was significantly higher in group F at 2hr (2.73±0.45), 4 hrs (2.23±0.43) p value <0.001 than group C .No significant difference was seen at 12 and 24 hours (p value > 0.05) between GROUP F and GROUP C.

Time to 1st rescue analgesia is significantly longer in group C (8.7 ± 0.5 hrs) than group F (6.5 ± 0.5 hrs) (p value <0.001).

Total analgesic consumption in group C was lower (65.83 ± 20.22 mg /24 hrs) compared to that of group F (86.67 ± 14.28 mg /24hrs) which was significant statistically (p <0.05).

Out of 60 participants, nausea was reported in 4 patients, vomiting in 3 patients. Headache was reported in 3 patients. 3 patients in group C and 2 patients in group F had hypotension. Bradycardia was reported in 3 out of 60. None of the patients in any group had urinary retention. The incidence of hypotension and bradycardia more in group C. Other adverse effects nausea, vomiting, headache were comparable.

4. Discussion :

TAP block is a very common procedure being done for postoperative analgesia and using adjuvant drugs like clonidine and fentanyl to bupivacaine(P) gives us positive results .

In our study of 60 patients of bilateral inguinal hernia we have given postoperatively TAP BLOCK to GROUP C (B+C) - 30 patients received bilateral TAP block using 22 ml solution— consisting of 20 ml 0.25% bupivacaine and 1 mcg/kg clonidine dissolved in 2 ml normal saline. GROUP F (B+F) - 30 patients received bilateral TAP block using 22 ml solution— consisting of 20 ml 0.25% bupivacaine and 1 mcg/kg fentanyl dissolved in 2 ml normal saline.

H.H Gomaa Seleem et al conducted a study in which they compared bupivacaine and bupivacaine +fentanyl and found that adding fentanyl did not affect the hemodynamics to a significant level. Contrary to our study in which we found the fentanyl group was more hemodynamically stable⁽²⁾ .

Sharma N et al conducted a study in which 334 patients were studied for a TAP block comparing LA v/s LA +fentanyl in different abdominal surgeries and found that the addition of fentanyl does not prolong the time to 1st analgesia request. In our study we found the time to 1st analgesia request was lesser for fentanyl than clonidine⁽⁴⁾.

In our study we found vas score to be less for group C (more significant reduction in postoperative pain), more time required for 1st rescue analgesic was mean 8.7 hrs (fentanyl 6.5 hrs) , but significant hypotension and bradycardia with clonidine .

Mir, T. A et al conducted a similar study in which he compared bupivacaine and bupivacaine + clonidine and found more significant reduction in postoperative pain ,more time required for 1st rescue analgesic (mean 14.23 hrs) and contrarily no significant hypotension and bradycardia with clonidine⁽⁶⁾ .

Ranju Singh et al. conducted a similar study in which he compared bupivacaine and bupivacaine plus clonidine in LSCS and found none experienced hypotension and bradycardia contrary to our study and prolonged analgesia, lesser analgesic consumption with clonidine similar to our study⁽⁸⁾.

5. Conclusion :

Addition of clonidine to Bupivacaine in TAP Block prolongs the post- operative analgesia than fentanyl. It provides longer first analgesia request time and less total analgesia consumption with minimal side effects. Addition of fentanyl to Bupivacaine in TAP Block gives more hemodynamic stability.

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Nil

Conflicts of interest

There are no Conflicts of interest

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