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ORIGINAL RESEARCH

A double blind, prospective, comparative study of 0.25% bupivacaine and dexamethasone with 0.25% bupivacaine alone in ultrasound guided transversus abdominis plane block

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Abstract

Aim: To evaluate the effects of adding 4 mg dexamethasone to 20 ml of 0.25% bupivacaine on each side in TAP block (total volume 40+2 ml) versus 20 ml of 0.25% bupivacaine alone on each side (total volume 40 ml + 2ml normal saline) with regard to postoperative analgesia, postoperative pain scores, requirement of postoperative analgesia and side effects.

Materials and methods:It is a double blind, prospective, comparative study done in Sixty pregnant females who were to undergo either elective or emergency LSCS between 18 – 45 years of age were randomly allocated for study into two groups.Group TAP B+D : 20 ml of 0.25% Bupivacaine + 4 mg Dexamethasone on each side (total volume 42 ml)Group TAP B : 20 ml of 0.25% Bupivacaine + 2ml of normal saline on each side (total volume 42ml)

Results: Both the groups were comparable with regard to age, sex, height, weight distribution and ASA grading and emergency or elective procedure.The mean duration of effective analgesia (first pain medication) in group TAP B+D was 658.66±147.85 min and in group TAP B was 371.06±80.40 min which was statistically significant ($p<0.05$).Results concludes that the pain score at 2, 4, 6, 12 and 24 hours are much lower in group TAP B+D as compared to group B and showing statistically significance. In group TAP B+D, 83.3% of patients required a cumulative analgesia of 100mg only in a 24 hours duration, 16.7% of study population required 100mg of tramadol during a period of 24 hours and no patient required tramadol 100 mg thrice whereas in group TAP B 16.7% of patients required tramadol 100mg only in a 24 hour duration, 40% of patients required tramadol 200mg and 43.3% of patients required tramadol 300mg in a 24 hour postoperative period which implies that TAP B+D group has a lesser requirement of postoperative analgesics than

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group TAP B and is statistically significant. No side effects related to TAP Block.
Conclusions: Compared to TAP block with Bupivacaine alone TAP block with Bupivacaine + Dexamethasone providedincrease in duration of effective analgesia, lower postoperative pain scores, less postoperative analgesic requirement.
Keywords: Bupivacaine, Dexamethasone, pain scores,postoperative analgesic

Introduction

Caesarean section is one of the most common major surgical procedures in the world. Pain severity after caesarean section has been ranked 7th out of 179 surgical procedures.[1]with moderate to severe pain in 7 percent of women. Worldwide there is a gradual increase in the number of caesarean section deliveries in the last decade, and this number keeps on increasing.Inadequate analgesia following caesarean sections is a very frequent and medically important issue. Relieving pain is one of the most important physician functions second probably only to life and limb saving functions. These functions become important when it comes to postoperative pain because for whatever reasons this pain has been created by physicians themselves. Caesarean delivery with lower abdominal incision causes severe pain especially in first two days after surgery. This delays ambulation and breast feeding. Postpartum depression and chronic pain may follow the severe pain following the childbirth.For caesarean section performed under spinal anesthesia, the pain relief lasts till the neuraxial blockade is present and later on opioid analgesia is required to produce adequate analgesia, this produces the side effects of opioids e.g. nausea, vomiting, respiratory depression and hyperalgesia and also has a risk of transmission to baby across breast milk.Therefore a multimodal approach is required to enhance the analgesia and decrease the side effects, i.e. an alternative method for pain relief like epidural analgesia, wound infiltration and nerve block are used.[2,3]

If the postoperative pain is managed by regional anesthesia, Epidural analgesia is a good alternative for postoperative pain relief, but the gravid uterus, increases the chances of dural and vascular puncture. It may not be preferred in case of emergency caesarean section. Infiltration of local anaesthetic is also used to provide pain relief, but it is not effective for prolonged analgesia .Transversus Abdominis muscle plane block has been demonstrated to be effective in reducing postoperative pain scores and side effects of opioids in individual trials after caesarean section and lower abdominal surgeries.TAP block is a regional anesthetic technique that blocks abdominal wall neural afferents T7 to L1 and significantly reduces pain associated with lower abdominal surgeries .TAP block was originally described by Rafi in 2001 through landmark technique. Although landmark technique is effective, it is associated with difficulties like anatomical variations of triangle of petit, difficulty in palpation of patients angle in obese patients, and complications like liver injury, nerve injury, and unpredictable spread of local anaesthetics therefore ultrasound guided technique has been advocated.[4,5]

Bupivacaine hydrochloride is used as a local anaesthetic and is available as sterile isotonic solution for injection via local infiltration, peripheral nerve block, caudal, lumbar plexus block and TAP block.Various adjuvants such as opioids, tramadol, neostigmine, and clonidine have been used in the past to prolong the action of analgesia in peripheral nerve blocks. The analgesic effects of spinal and systemic corticosteroids in combination with local anaesthetics have been approved in human studies. Methyl prednisolone addition to local anesthetic has increased the duration of axillary brachial plexus block whereas Dexamethasone microspores have increased the block duration in both human and animal studies. Dexamethasone, through its anti-inflammatory and blocking effects on neural discharge, and nociceptor C fibers transmission could be used as local anaesthetic adjuvant.[6]

Further Dexamethasone is a long and efficient glucocorticoid structure and also offers anti

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inflammatory properties when added to local anesthetic as an adjuvant in peripheral blocks, it increases the action time, therefore it may also prolong analgesia time and contribute to TAP block .Several studies investigating the analgesic efficacy of dexamethasone added to local anesthetic agents have shown promising resultsThe addition of dexamethasone to 0.15% ropivacaine for caudal block has been shown significantly improve analgesic efficacy in children undergoing orchiopexyx.Various adjuvants have been tried to bupivacaine in TAP block, several studies showing the promising effects of dexamethasone added to bupivacaine, therefore the present double blind prospective study is aimed to assess the effect of adding dexamethasone to bupivacaine on the quality and duration of TAP block.

Materials and methods

It is a double blind, prospective, comparative study done in pregnant women more than 18 years to 45 year old posted for elective and emergency caesarean section in Department of Anesthesia.After approval from the institutional ethical committee and written informed patients consent 60 parturient were included in the study with 30 in each group.

The power analysis performed based on postoperative VAS score for pain with two sided Mann-Whitneytest with alpha =0.05 and 1-Beta=0.90 taking into consideration to detect 25% difference in VAS score with effect size =1 was taken. Estimated total study population is of 48 that is 24 in each group. However taking in to consideration of drop out of cases during the period of study 30 in each group were taken(115).

t tests - Means: Wilcoxon-Mann-Whitney test (two groups)

Inclusion Criteria

Pregnant women undergoing caesarean section under subarachnoid block both elective and emergency, ASA grade II parturient.

Exclusion Criteria

Allergy to opioids, amide group of local anaesthetic and nonsteroidal anti- inflammatory drugs, Coagulation derangement or bleeding disorders, Infection at the site of block, Patients with cardiovascular, pulmonary or neurological diseases, who received epidural analgesia, BMI >30kg/$m^{2.}$**,** TAP plane >6cm from the skin.

Randomized sampling techniqueSimple randomization is done by computer developed table such as random number sequence A, B, B, B, A, A etc.,

Group TAP B: TAP Block with 0.25% Bupivacaine 20 ml plus 2ml saline each side.

Group TAP B+D: TAP Block with 0.25% Bupivacaine 20 ml plus 4mg Dexamethasone each side.

After getting clearance from preoperative clinic, routine investigations like haemoglobin percentage, blood grouping and typing, urine examination, blood sugars, blood urea, serum creatinine, viral serology, checked and patients with investigations in normal range were taken up in the study. The procedure of TAP block was explained to the patient and consent taken.On arrival in the operating room, intravenous line was secured using 18 G canula and Ringers lactate solution was started. The patientswere monitored for vital data.Patients were given subarachnoid block with 2 ml of injection 0.5% hyperbaric bupivacaine at L3-L4 interspace using 25 G Quincke Babcock spinal needle.At the end of the surgical procedure, patients received USG guided transverse abdominis plane block.Study medication was prepared by anaesthetistnot performing the block and blinded to the person involved in care and monitoring of the patient. All observations were carried out by a single investigator who was blinded to drugs used in the block.

Patient placed in the supine position. After preparation of skin with povidone iodine, sterile drapes applied. A high frequency linear array LOGIQ e(GE healthcare) USG probe (6-12

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MHz) in sterile coverings was placed on the anterolateral abdominal wall, just cephalad to the iliac crest level where the 3 muscle layers (External Oblique, Internal Oblique and Transverse Abdominis) are most distinct. After identification of TAP neurofascial plane between internal oblique and transversus abdominis, probe is moved postero-laterally to lie between costal margin and iliac crest across mid-axillary line. Appropriate depth and frequency are adjusted to optimize the image of the abdominal wall muscle and underlying peritoneal cavity. The target is the fascial plane between the internal oblique and the transversus abdominis muscles. The 23 gauge Quincke Babcock needle introduced "in plane" of the ultrasound probe directly under the probe in the anterior axillary line, and the needle tip advanced until it reached the fascial plane between the internal oblique and transversus abdominis muscles approximately in the midaxillary line and the drug was administered.

The following parameters will be observed as duration of effective analgesia is defined as the time from initiation of TAP block to request of pain by the patient for the first time; the duration will be noted and recorded as time for first request analgesia(TFA).

Pain scores are assessed through visual analogue score. Visual analogue score is recorded at 0, 2, 6, 12, 24 hours and tabulated.The cumulative dose of analgesic given is recorded over 24 hours.Side effects if any were noted.

Inj.Tramadol 2mg/kg as a rescue analgesia if VAS score >4/10. Time for the first rescue analgesia noted when VAS score is more than 4. If pain is not subsided even after tramadol is given, then iv formulation Diclofenac 75 mgwas to be given. Outcomes were assessed in terms of visual analogue score for pain at interval of 0, 2,4, 6, 12, 24 hours. Data obtained from the study of cases will be tabulated, compared and analyzed through Microsoft Excel sheet and was analyzed through an independent statistician.

Results

The results obtained in our study are as follows:

Table 1: Demographic profile in the study group

Groups		Mean	Std. Deviation	P Value
Age (Years)	**B + D**	24.0000	3.00574	0.720
	B	23.7000	3.42556	
Weight (KGs)	**B + D**	59.5667	5.75765	0.125
	B	61.7000	4.80050	
Height (CMs)	**B + D**	155.7667	4.24007	0.609
	B	156.3333	4.30183	

$P < 0.05$ are Statistically Significant

The mean age of patient in group B+D was 24 ±3.00574 and in group B was 23.70 ±3.42556. The mean height of patient in group B+D was 155.7667 ± 4.24007 and in group B 156.3333 ± 4.30183. The mean weight of patient in group B+D was 59.5667± 5.75765 and in group B 61.7000 ± 4.80050.

In the present study it was observed that there was no statistically significant difference in the mean Age, Height and weight between study groups ($p > 0.05$).

In the present study in group TAP B+D, 20 patients were of ASA I and 10 patients were in ASA II and in group TAP B 20 patients were of ASA I and 10 patients were in ASA II.

In the present study it was observed that there was no statistically significant difference between two groups in terms of distribution of patients depending on ASA grade.

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Table-2: Distribution of patients based on surgery

Groups		Surgery		Total
		Elective LSCS	Emergency LSCS	
B + D	Count	12	18	30
	%	40.0%	60.0%	100.0%
B	Count	12	18	30
	%	40.0%	60.0%	100.0%
Total	Count	24	36	60
	% within Groups	40.0%	60.0%	100.0%

P = 1.0

Chi square test

In groupTAP B+D in a total of 30 patients posted for caesarean section , 12 were elective LSCS and 18 were emergency LSCS and in group TAP B , in a total of 30 patients posted for caesarean section , 12 were elective LSCS and 18 were emergency LSCS and both were comparable and there was no statisticalsignificance.

Table-3: Duration of effective analgesia

Groups		Mean	Std. Deviation	P Value
Duration Of Effective Analgesia (In Minutes)	**B + D**	658.6667	147.85205	0.000
	B	371.0667	80.40541	
P < 0.05 are Statistically Significant				

Independent Samples t-Test

The mean duration of effective analgesia (time of first analgesia) in group B+D was 658.66±147.85 min and in group B was 371.06±80.40 min which was statistically significant (p<0.05).

Figure-1: VAS at 2hours

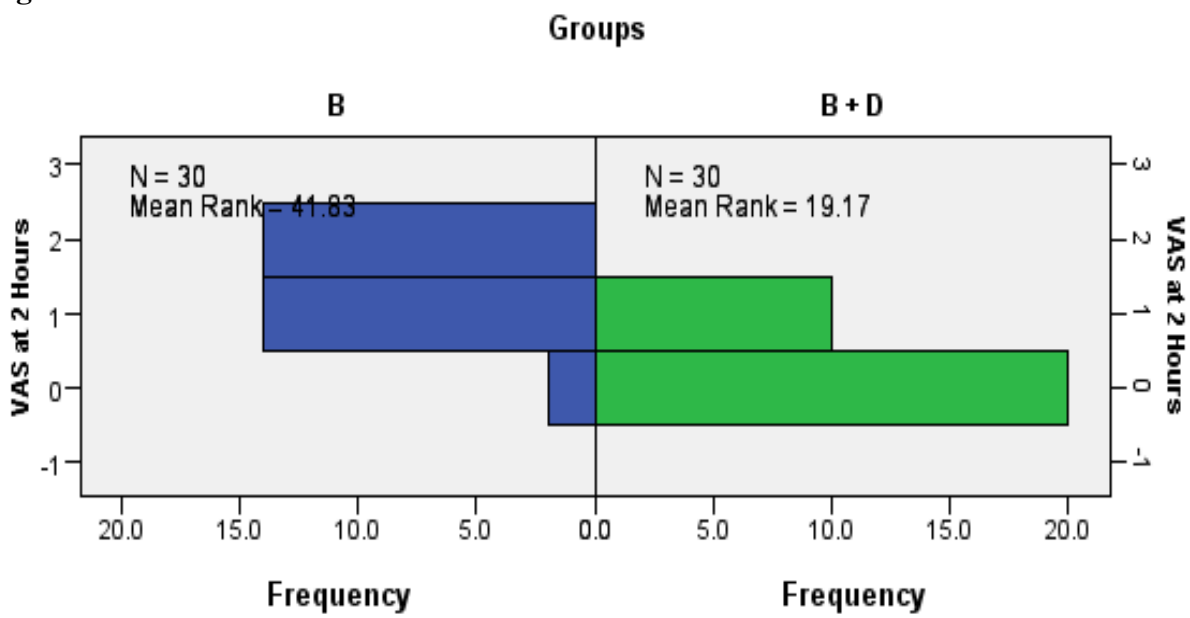

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Figure-2: VAS at 7 hours

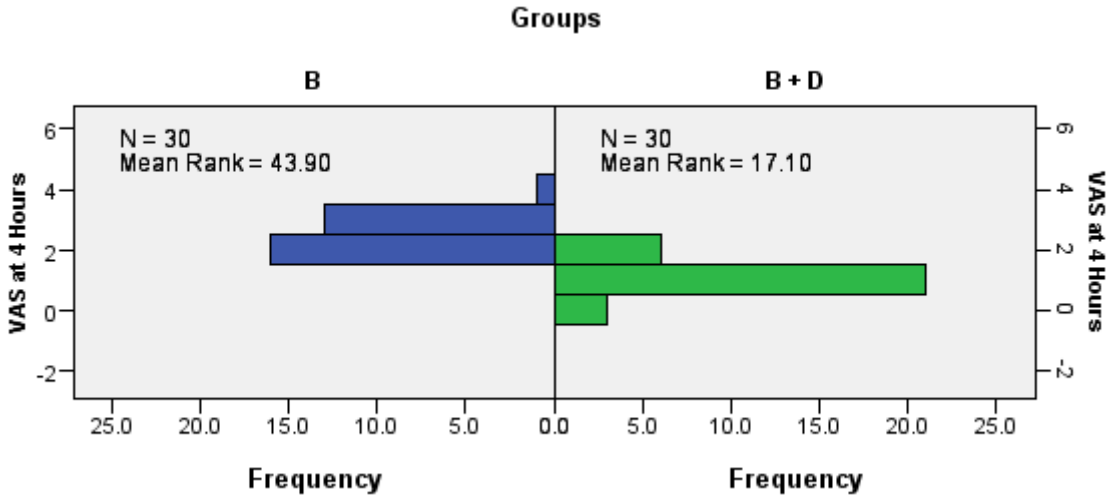

Figure-3: VAS at 6 hours

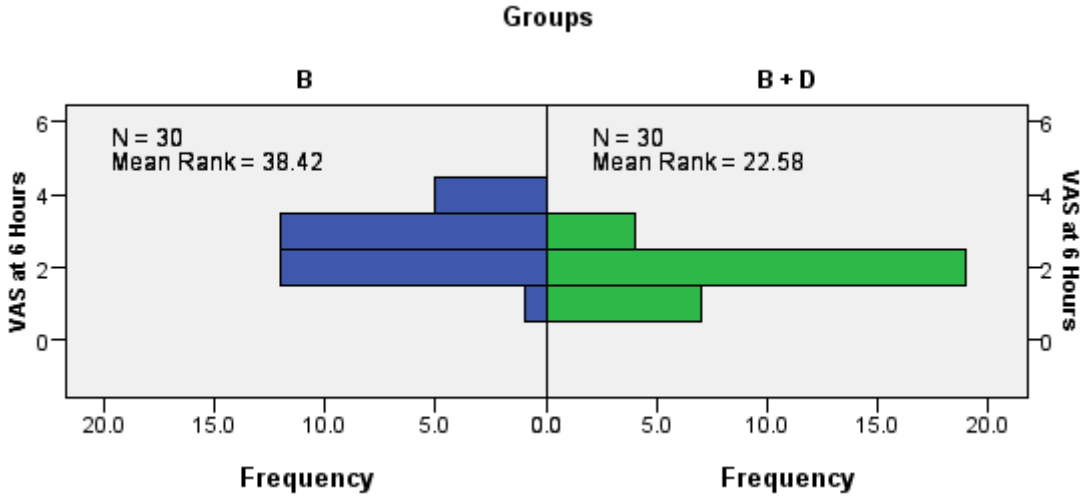

Figure-4: VAS at 12 hours

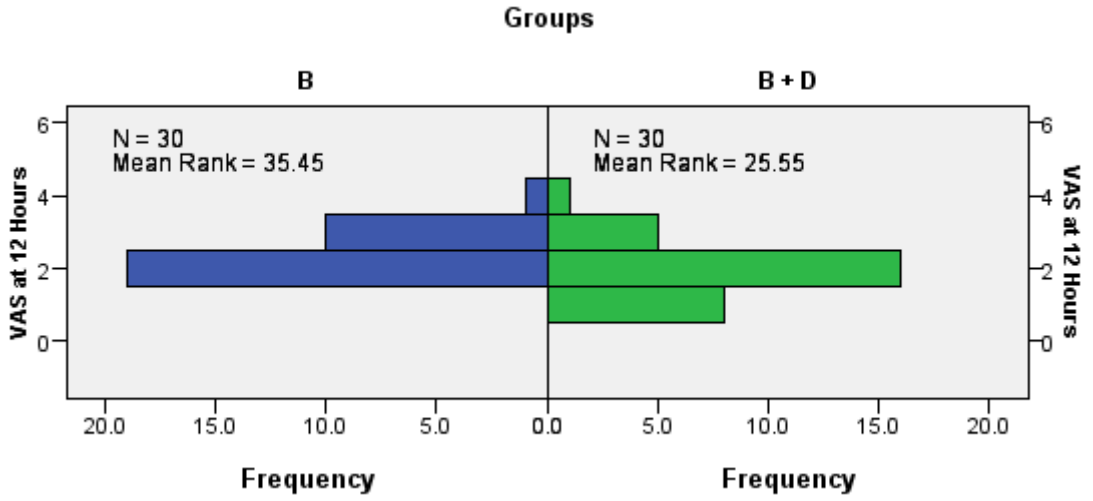

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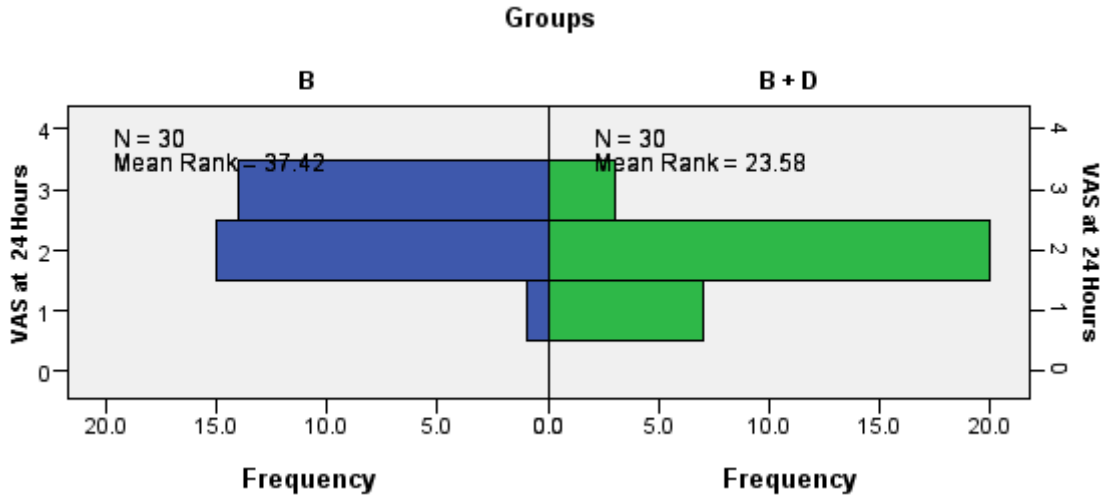
Figure-5: VAS at 24 hours



Findings shows that statistically significant difference has been seen in the pain scores (visual analogue scale) between the group TAP B+D and group TAP B. Results concludes that the pain score at 2, 4, 6, 12 and 24 hours are much lower in group TAP B+D as compared to group TAP B and showing statistically significance, there by concluding that group TAP B+D provides effective post operative analgesia for first 24 hours when compared to group TAP B.

Table-4: Cumulative analgesia in postoperative period

Groups		cumulative Analgesia			Total
		Tramadol 100 mg	Tramadol 200 mg	Tramadol 300 mg	
B + D	Count	25	5	0	30
	%	83.3%	16.7%	0.0%	100.0%
B	Count	5	12	13	30
	%	16.7%	40.0%	43.3%	100.0%
Total	Count	30	17	13	60
	%	50.0%	28.3%	21.7%	100.0%

P = 0.000
Chi-Square test

In group TAP B+D, 83.3% of patients requiredacumulative analgesia of 100mg only in a 24 hours duration, 16.7% of study population required 200mg of tramadol during a period of 24 hours and no patient required tramadol 100 mg thrice whereas in group TAP B 16.7% of patients required tramadol 100mg only in a 24 hour duration, 40% of patients required tramadol 200mg and 43.3% of patients required tramadol 300mg in a 24 hour postoperative period which implies that TAP B+D group has a lesser requirement of postoperative analgesics than group TAP B and is statistically significant.

Discussion

TAP block has been practiced for wide variety of abdominal procedures including open or laparoscopic appendectomy, laparotomies, caesarean section, total abdominal hysterectomy, laparoscopic cholecystectomy, open prostatectomy, abdominoplasty with or without liposuction, renal transplantations, and iliac crest bone graft. TAP block is a recently established and efficient peripheral nerve block implicating the nerves of the anterior

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abdominal wall for lower abdominal surgical procedure. Medical ultrasound has been used for more than 40years, but its use in anaesthesia has developed only recently.[7]

The present study assesses the efficacy of postoperative analgesia of TAP block for caesarean section, this sort of analgesic method is carried out after the surgical procedure. The method itself impedes the abdominal wall neural afferents by instituting analgesic into neurofascial plane amid the internal oblique and transverses abdominis muscles. The main objective of this method is to evaluate the duration of effective analgesia following TAP block with Dexamethasone and Bupivacaine. A number of researches have been carried out in order to define the analgesic power of TAP block in diverse ailments of abdominal surgical procedures, general anesthetic, dosages and intensities of medications and stretch of block. The findings of the current randomized research exhibited that TAP blockade takes care of an extra advantage to multimodal pain control in patient going through lower segment caesarean section. The patients who received TAP block required less postoperative analgesia.

The mean duration of effective analgesia in group TAP B+D group was 658.66±147.85 minutes and in groupTAP B was 371.06±80.40 minutes showing statistically significant increase in duration of effective analgesia in TAP B+D group. Ammar and Mahmoud[8] studied sixty adult patients undergoing elective open abdominal hysterectomy were randomly allocated to receive TAP block using 20 mL of bupivacaine hydrochloride 0.25% + 2 mL saline 0.9% (control group, *n*=30) or 20 mL of bupivacaine hydrochloride 0.25% + 2 mL dexamethasone “8 mg” (dexamethasone group, *n*=30). Furthermore, Time for First Analgesia was significantly longer in the dexamethasone group (459.8 vs. 325.4 min, *P*=0.002), with lesser morphine requirements in the postoperative 48 h (4.9 vs. 21.2 mg, *P*=0.003) and lower incidence of nausea and vomiting (6 vs.14, *P*=0.03). No complications attributed to the block were recorded.Several mechanisms have been suggested to explain the analgesic effect of corticosteroids. A direct effect on nerve membrane rather than an antiinflammatory action has been suggested as the corticosteroids were able to inhibit ectopic neural discharge originating in experimental neuromas. Modulation of pain signals in the spinal cord has been suggested as intrathecal betamethasone produced rapid analgesia for pelvic and perineal cancer pain that lasted for 5 days.Triggering vasoconstriction and antiallergic activity of topical steroids have been suggested through action on specific glucocorticoid receptors. It should be emphasized that a blockade is not produced if steroids are used alone for regional blocks, but steroids may potentiatethe action of local anesthetics through modulation of the function of potassium channels in the excitable cells.[9]

In comparison to our study this study found the additional benefit of decrease in the incidence of nausea and vomiting.

Falia MD et al[10] conducted a study in 104 patients undergoing LSCS. The average duration of analgesia with TAP bock for the overall study population was 316.15 minutes. The duration of analgesia was 151 minutes longer in the first group who received dexamethasone TAP. In majority of the patients (84%) who received clonidine TAP, the analgesia persisted for 2-4 hours. While in patients who received dexamethasone addition, the analgesia persisted for 6-8 hours in 37%. Fouad et al.,[11] carried out a study showed time of First Analgesia(TFA) was significantly longer in the dexamethasone group (438.2 ± 24.95 min vs. 272.04 ± 37.51 min, P=0.002), with lesser nalbuphine requirements in the postoperative24 h (15.20 ± 4.16 vs. 24 ± 4.16 mg nalbuphine, P <0.001) and lower incidence of nausea and vomiting (2 vs. 8, P=0.034). Naveen, et al[2] studied one hundred and forty patients who were to undergo LSCS. The mean time to first analgesic rescue was significantly prolonged in Group TAP as compared to Group CONT using unpaired *t* test. Mean time to rescue analgesia was 88.02 ± 21.62 min and 525.27 ± 114.52 min ($P < 0.001$) in groups CONT and TAP, respectively.

Our study correlates with the above mentioned studies and has exhibited that there is

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analytically important variance has been observed in the duration of effective analgesia amid the bupivacaine TAP B group and bupivacaine and dexamethasone group TAP B+D.
The VAS scores for the patients at 2 hours , 4 hours, 6 hours, 12 hours and 24 hours were lower in bupivacine and dexamethasone group TAP B+D group when compared to bupivacaine alone group , TAP B group.
Ammar and Mahmoud [8] in their study concluded that the pain VAS score was significantly lower at the postoperative 2 h (4.9 vs. 28.1, *P*=0.01), 4 h (12.2 vs. 31.1, *P*=0.01) and 12 h (15.7 vs. 25.4,*P*=0.02).[41]In study of Falia MD *et al*[10] the average VAS score in patients who received TAP with dexamethasone was 1.50 which is significantly lower than those who received clonidine (1.95) (P value-0.0001).[48]In study of Fouad et al[11] pain VAS score was lower at the postoperative 4 h (4.72± 0.84vs. 2.96 ± 0.45, P=<0.001), 8h (5.0 ± 0.58vs. 3.56 ± 0.65, P=0.001), 12 h (5.20vs. 4.24 ± 0.83, P=0.001), 16h (5.32 ± 0.69vs. 4.84 ± 0.55, P=0.009) and20 (5.40 ± 0.76vs. 4.96± 0.61, P=0.037) in dexamethasone group.[49]In study of Naveen, *et al*[2]Mann–Whitney U test was used to assess the mean painscores as noted at various time intervals in postoperative period. Mean pain scores were persistently low in group TAP (*P* < 0.001).
In our study in group B+D, 83.3% of patients required a cumulative analgesia of 100mg only in a 24 hours duration, 16.7% of study population required 200mg of tramadol during a period of 24 hours and no patient required tramadol 300 mg whereas in group B 16.7% of patients required tramadol 100mg only in a 24 hour duration, 40% of patients required tramadol 200mg and 43.3% of patients required tramadol 300mg in a 24 hour postoperative period which implies that B+D group has a lesser requirement of postoperative analgesics than group B and is statistically significant.Ammar and Mahmoud[8] in their study concluded that Time of First Analgesia was significantly longer in the dexamethasone group (459.8 vs. 325.4 min, *P*=0.002), with lesser morphine requirements in the postoperative 48 h which was statistically significant (4.9 vs. 21.2 mg, *P*=0.003). In study of *Fouad et al*[11] concluded that dexamethasone group lesser nalbuphine requirements in the postoperative24 h (15.20 ± 4.16 vs. 24 ± 4.16 mg nalbuphine, P <0.001) and lower incidence of nausea and vomiting (2 vs. 8, P=0.034).[49]Naveen, *et al*[2] reported opioid consumption in Groups TAP and CONT was 14.29 mg versus 166.95 mg (*P* < 0.001) in 48 h. concluded that the dexamethasone group(TAP group) required lesser opioid consumption compared to control group and is statistically significant.[4]
In our study, we did not encounter any complications/side effects related to TAP Block. However, there were few studies and case reports regarding complications of TAP Block. Though direct intravascular injection of local anesthetics is very unlikely with TAP blocks, studies do suggest that systemic toxicity is possible, and, as such, caution should be exercised throughout drug delivery. Likelihood of needle placement misadventures may be minimized with the proper use of ultrasound guidance.
Farooq and Carey described a liver laceration after a landmark-based TAP block. Upon laparotomy, the patient was subsequently found to have an enlarged liver that extended down to the iliac crest. As a consequence, the authors recommended routine palpation of the liver edge prior to landmark-based right-sided TAP blocks.[12]Lancaster and Chadwick also reported a liver laceration after ultrasound-guided TAP block, which was likely as a result of failure to adequately visualize the needle during the procedure.[13]

Limitations of the study

- The serum concentration of the drug administered in the TAP block was not estimated as facility for evaluation was notavailable.
- Pain score on coughing was notevaluated.
- Assessment was limited to only 24 hours post operatively.

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Conclusion

We conclude that in patients undergoing emergency or elective LSCS, when compared to TAP block with Bupivacaine alone TAP block with Bupivacaine + Dexamethasone providedincreasein duration of effective analgesia, lower postoperative pain scores, less postoperative analgesic requirement. No side effects/ complications of the procedures or drugs were found in both the groups of TAP blocks.

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