Original Research

THE EFFECT OF DEXMEDETOMIDINE AS AN ADJUVANT TO ROPIVACAINE FOR WOUND INFILTRATION IN PROVIDING POSTOPERATIVE ANALGESIA FOR OPEN ABDOMINAL SURGERIES

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ABSTRACT

Background: Wound infiltration with local anaesthetics is one of the multimodal approach to control post-operative pain after open abdominal surgeries.

Aim and Objectives: The aim of the study is to evaluate the efficacy of wound infiltration with two different doses of dexmedetomidine added to ropivacaine on postoperative analgesia in patients undergoing open abdominal surgeries. Primary outcomes were magnitude of pain assessed by Numerical Rating Scale (NRS) at 0, 2, 4, 6, 12, 24 hours after surgery, time to first request of analgesia, analgesic requirement in the postoperative period over 24hours.

Methods: 99 patients posted for elective open abdominal surgeries were randomly assigned to three groups. Group R received 30ml of 0.75% ropivacaine, GroupRD1 received 30ml of 0.75%ropivacaine with dexmedetomidine 0.5mcg/kg, GroupRD2 received 30ml of 0.75% ropivacaine with dexmedetomidine 1mcg/kg. Study drugs were made into equal volume of 60ml each by adding 0.9% normal saline and the study drug was infiltrated into the edges of the wound at the end of surgery.

Results: The NRS scores for pain intensity did not show any statistical significance at any of the predefined time points. Time to first request of analgesia was longer in groupRD2 (136.2 +114.4 minutes) when compared to other groups (R, 66.06 + 58.5 minutes; RD1, 103.2+ 48.8 minutes; $P < 0.05$). Total amount of rescue fentanyl consumed in group RD2 (280.4 + 140.7 micrograms) was less when compared to RD1 (306.6 +133.8micrograms) R (331.8+ 99.2 micrograms); P=0.262).

Conclusions: We conclude that wound infiltration with dexmedetomidine at both the doses (0.5mcg/kg and1mcg/kg) provides extended postoperative pain relief when administered along with 30ml of ropivacaine (0.75%). The pain relief provided by dexmedetomidine (1mcg/kg) appears to be superior to both dexmedetomidine (0.5mcg/kg) and plain ropivacaine.

Keywords: Laparotomy, Local Anaesthetics, Analgesia, Ropivacaine, Dexmedetomidine, Postoperative Pain.

INTRODUCTION

Intensive pain caused by abdominal laparotomy may influence postoperative recovery, prolong hospitalization, causes stress response.

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[1,] Wound infiltration with local anaesthetics is one of the multimodal approach to control post-operative pain after open abdominal surgeries.[2] Ropivacaine is a long acting amide– local anaesthetic, used for postoperative pain relief.[3] Ropivacaine has slightly prolonged duration of action than bupivacaine with less cardiotoxic effects and, is associated with a low incidence of motor block.[4] Dexmedetomidine is a strong and highly selective α2-adrenoreceptor agonist enhances the analgesic efficacy of local anaesthetics when added

as an adjuvant for wound infiltration.[5] We undertook this prospective randomised trial to compare two different doses of dexmedetomidine as an adjuvant to local ropivacaine wound infiltration after abdominal surgery.

METHODS

This is a prospective, randomised, double blind study. Study participants were recruited after obtaining approval from Institute Ethics Committee. Written informed consent obtained from all patients screened to participate in the study. The study was registered in the Clinical Trials Registry(CTRI/2019/02/017736).Study population included patients who has undergone open abdominal sureries belonging to American Society of Anaesthesiologists (ASA) Physical status 1,2 aged between 18 and 65 years. Exclusion criteria were patient refusal to participate in the study, severe hepatic/cardiac/renal disorders, pre-existing neurological deficits/psychiatric illness/metabolic disorders, allergic reaction to the study drugs, history of chronic analgesic usage(on oral analgesics for more than one month),pregnant and lactating mothers, patients who cannot understand and interpret numerical rating scale(NRS)to indicate pain perception level.

The estimated sample size 28 per each group was based on a study by Saikat Mitra et al, [6]where amount of fentanyl consumed in mcg in 24 hours in group-1 is 90.4,group-2 is 85,and group-3 is 79.2 with a standard deviation of 7,with type-1 error at 5% level of significance and 80% power of the study, we used sample size calculation for 3 groups. We enrolled 99 patients and distributed randomy into 3 groups (Group R, RD1 and RD2)

Group R (n = 33):30 ml of 0.75% ropivacaine along with 30 ml of normal saline (total volume=60ml) infiltrated into the edges of the wound at the end of surgery.

Group RD_1(n = 33): 30 ml of 0.75% ropivacaine along with 0.5mcg/kg Dexmedetomidine diluted to 60 ml with NS infiltrated into the edges of the wound at the end of surgery.

Group RD_2(n = 33): 30 ml of 0.75% ropivacaine along with 1mcg/kg Dexmedetomidine diluted to 60 ml with NS infiltrated into the edges of the wound at the end of surgery.

Randomization was done before recruiting the participants to the study by computer generated random number table and with sealed opaque envelope technique. Both assessor and patient were blinded to the study protocols.

All the patients underwent a thorough preoperative evaluation and were explained about the study protocol and how to use numerical rating scale to indicate their pain perception by identifying zero as no pain and ten as worst imaginable pain. Patients were premedicated with oral alprazolam 0.5mg and oral ranitidine 150mg on the night before the day of surgery and also in the morning on the day of surgery.

On arrival to the operating room a peripheral 18 G intravenous cannula under local anaesthesia was secured and monitoring of heart rate, noninvasive blood pressure, oxygen saturation started and baseline values recorded and any significant alterations in haemodynamics noted. Preoxygenation done for 3 min with 100 % oxygen. General anaesthesia induced with IV fentanyl 2 µg / kg, titrated propofol 1-2 mg/ kg and sevoflurane 2-6% with 40%oxygen in air. Tracheal intubation was facilitated with bolus dose of Inj vecuronium 0.1 mg/kg. Anaesthesia maintained with intermittent boluses of vecuronium and seoflurane 2-4%.

The prepared study drug as per group allocated infiltrated by the surgeon into the surgical wound edges at the end of surgery. For reversal of residual neuromuscular blockade inj. neostigmine 0.05mg/kg and inj. glycopyrrolate 0.01mg/kg given. Patients were extubated after standard criteria for extubation are met. After extubation, patients were transferred to the post anaesthesia care unit for further observations.

In postoperative period, the intensity of pain recorded for all patients using numerical rating scale at 0, 2, 4, 6, 12, 24 hours after surgery, total cumulative analgesic requirement recorded for the first 24hours after infiltration of the drug. The duration of analgesia was defined as the time from infiltration of the drug to the time for first analgesic given.If NRS score>4,patients were offered inj.tramadol 2mg/kg IV followed by additional doses if requested by patient after an interval of 12 hours and pain between two doses of tramadol treated with fentanyl 0.5mcg/kg IV.

All collected data was double checked to exclude any clerical errors. Statistical analysis was performed using a computer programme SPSS, version 20[IBM Inc. Chicago IL, USA, 2010]. Data collected was evaluated for normality using the Shapiro wilk test. Quantitative data like age, weight, BMI, duration of surgery and anesthesia, time to first request of analgesia and total amount of rescue analgesic given, overall NRS scores over 24hrs were expressed as mean +/-standard deviation or median (inter quartile range 25-75%) and were analyzed with one way ANOVA (for normally distributed data) or Kruskal–Wallis H test (for non-normally distributed data) as appropriate along with Bonferrani post hoc test to find out significance between the pairs. The qualitative data like gender, ASA physical status grade, and post-operative adverse effects were expressed as frequency or percentage and were compared by Chi-Square test or Fisher's exact test. P value < 0.05 was considered as significant.

RESULTS

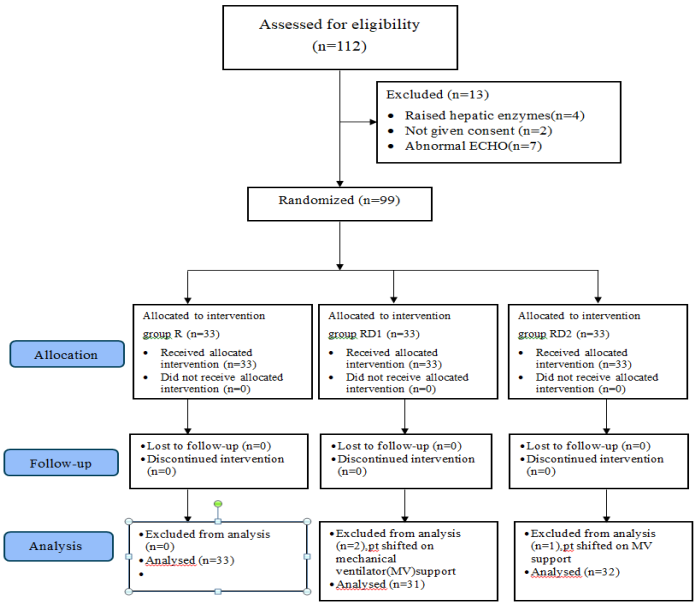

Table 1: Demographic Comparison of Study Groups

	Group R (N =33) Mean ±S.D	**Group RD_1 (N = 31) Mean ±S.D**	**Group RD_2 (N = 32) Mean ±S.D**	**P Value**
Age (Years)	48.7± 12.9	48.3±12.6	49.09 ± 11.8	0.900
Sex (M/F)	14/19	15/16	15/17	0.882
ASA(I/II)	19/14	23/8	24/8	0.231
Weight(kg)	62.4 ±4.38	63.06±7.3	63.09 ±6.96	0.900
BMI(kg/m^2)	28.4 ±4,96	26.8 ±1.47	27.5 ±2.52	0.152

Data represented as mean± S.D; n= number of subjects in each group; F = female; M = male; ASA PS = American society of anaesthesiologists physical status; BMI = body mass index; Group R=Ropivacaine or control group; Group RD_1=Dexmedetomidine 0.5mcg/kg group; Group RD_2= Dexmedetomidine 1mcg/kg group and $p < 0.05$ is considered significant.

Ninety-six patients of either sex participated in this study .There were no statistically significant differences between the groups with respect to socio demographic variables and ASA PS grading.

Table 2: Post-Operative Nrs Scores in 24 Hours

TIME(HR)	**Group R (N =33) Mean +S.D**	**Group RD_1 (N = 31) Mean +S.D**	**Group RD_2 (N = 32) Mean +S.D**	**P Value**
0	2.48 ± 1.00	2.74 ±0.63	2.43 ±1.07	0.379
2	3.48 ± 1.20	3.90 ±0.74	3.43 ±1.24	0.182
4	3.21 ± 1.13	3.16 ±1.09	3.12 ±1.21	0.954
6	3.60 ± 1.02	3.45± 1.08	3.46 ±1.10	0.802
12	3.33 ±0.98	3.61 ±0.98	3.21 ±1.00	0.277
24	3.30 ±1.01	3.54 ±0.96	2.93 ±0.80	0.036

Table 2 reflects postoperative NRS scores in 24 hours among the groups

NRS: Numerical Rating Score for pain

The NRS score at extubation was 2.48 ± 1.00 in group R, 2.74 ±0.63 in group RD_1 and 2.43 ±1.07 in group RD_2 with no statistical significance between the groups. The post hoc analysis between the groups did not show any statistical significance.

Table 3: Time to First Analgesic Request in Minutes

	Group R (33) Mean ±S.D	Group RD_1 (31) Mean ±S.D	Group RD_2(32) Mean±S.D	P Value
Time to first request of analgesia(minutes)	66.06 ± 58.5	103.2± 48.8	136.2 ±114.4	0.003

Table 3 reflects time to first analgesic request .Time to the first request of analgesia in minutes in group R is 66.06 ±58.5,in group RD_1 103.2± 48.8,in group RD_2 is 136.2 ±114.4 with statistical significance with p value of 0.003 between the groups. The post hoc analysis between the groups R, RD_1 showed statistical significance of 0.002, between the groups RD_1, RD_2 showed statistical significance of 0.002

Table 4: Total Amount of Fentanyl Consumed In Mcg in 24 Hours

	Group R (33) Mean ±S.D	Group RD_1 (31) Mean ±S.D	Group RD_2(32) Mean±S.D	P Value
Total amount of fentanyl received in mcg	331.8± 99.2	306.6 ± 133.8	280.4 ± 140.7	0.262

Table 4 reflects total amount of fentanyl consumed in mcg in 24hours.Total amount of fentanyl consumed in mcg in group R is 331.8±99.2, in group RD_1 is 306.6 ± 133.8, in group RD_2 is 280.4 ± 140.7 with no statistical significance between the groups. Post hoc analysis between the groups did not show statistical significance.

Table 5: Incidence of Adverse Events Postoperatively

Adverse Events (%)	Group R (N=33)	Group RD1 (N=31)	Group RD2 (N=32)	P Value
Nausea	0	0	0	_
Vomiting	0	0	0	_
Bradycardia	0	0	0	_
Tachycardia.	2	2	0	0.351
Hypotension.	0	0	0	_
Hypertension.	0	0	0	_
Fall in respiratory rate < 8 breaths/min.	0	0	0	_
SpO2 < 95 % with O2 mask @6 lit/min.	No	No	No	_

Table 4 reflects incidence of postoperative adverse events in the participants among the three groups. Postoperatively 2 patients in group R,2 patients in group RD_1 had tachycardia with no statistical significance between the groups. No nausea, vomiting, bradycardia, hypotension, hypertension, fall in respiratory rate <8 breaths/min, SpO_2<95% on O_2 mask at 6L/min noted

DISCUSSION

Local anaesthetic wound infiltration is one of the modalities to extend the duration of pain free postoperative period. It was developed to improve postoperative analgesia, reduce opioid consumption and hasten patient recovery. It is hoped that this extra-analgesic use will have benefits on outcomes, such as reduction of postoperative organ dysfunctions and enhanced recovery when integrated into multimodal rehabilitation programs, patient safety, quality of life and health economics.[7]In the recent years, wound infiltration analgesia has become an important part of multimodal analgesia. [8,9]

Almost all LAs can be effectively used for wound infiltration, but long acting and less toxic LAs are preferred. We have chosen ropivacaine over other local anaesthetics because of its ability for differential block, duration of action is comparable to the conventional long-acting bupivacaine with significant reduced cardiotoxicity. The intrinsic vasoconstrictive property of ropivacaine makes it more attractive with lesser systemic absorption and lower risk for local anaesthetic systemic toxicity and adverse cardiovascular events.[4] More over addition of dexmedetomidine which has more α2 selective vasoconstriction property when compared to clonidine brings down further the risk of local anaesthetic systemic toxicity.[10] We have infiltrated 225 mg of ropivacaine which remains well below the maximum safe dose of 300 mg.[11,12]

We have analysed data from 96 patients who completed the study protocol. The demographic data of patients from all the three groups are comparable.The major findings from our study are Dexmedetomidine in both the doses (0.5mcg/kg, 1mcg/kg) extends the duration of first analgesic request significantly when used as an adjuvant to

0.75% ropivacaine wound infiltration after open abdominal surgeries. Addition of demedetomidine could reduce the magnitude of pain significantly only at 24th hour postoperatively in comparison to control group. However, our study did not reveal any significant difference in consumption of rescue fentanyl over 24 hours in the post-operative period.

Bamigboye et al in their placebo-controlled study used 30 ml of 0.75 % ropivacaine for wound infiltration and part of the study drug was used in spraying peritoneum in obstetric population undergoing elective lower segment caesarean section under general anaesthesia. Their study results revealed that 94% of the patients from the ropivacaine wound infiltration group did not require any analgesia in the first post-operative hour compared to 52% in the control group.[11] In our study too, the duration of post-operative pain free period is about 66 minutes in plain ropivacaine group. However, in our study we also observed that addition of dexmedetomidine to ropivacaine increased the pain free period to 103 minutes in RD1 group to 136 minutes in RD2 group.

Jing-Xian Sun et al[13] has studied efficacy of ropivacaine wound infiltration in 56 patients undergoing open hepatectomy. They have used much smaller dose compared to our study (20 ml of 0.75% ropivacaine, 150 mg) wound infiltration. They concluded that ropivacaine wound infiltration decreases the magnitude of pain scores compared to control group up to 24 hours. They have also observed that the mean arterial pressure and heart rate were significantly lower in ropivacaine group when compared to control group but not resulted in any major adverse events However we have not observed any adverse cardiovascular events despite the use of higher ropivacaine dose similar to other studies for bolus wound infiltration (225 mg).[12,8] Literature suggests maximum amount of ropivacaine that can be used for wound infiltration is 300 mg.[12] The cardiac depressant effect of ropivacaine is more pronounced in Jing-Xian Sun et al study could be because of impaired hepatic function in their study participants (all study participants underwent open hepatectomy) unlike our study participants where we have taken only ASA grade I and II patients without any hepatic disorders.[13]

Addition of adjuvant to local anaesthetic with presumed additive or synergistic effect is a popular practice in regional anaesthesia for extending the pain free time in the post-operative period. Various regimens of additives to local anaesthetic wound infiltration after abdominal surgeries have been evaluated. [15,16,17,18]

Chander et al used bupivacaine plus fentanyl for wound infiltration after abdominal surgeries and concluded the superiority of fentanyl addition over plain bupivacaine.[18] The addition of opioids to local anaesthetics is advantageous in extending postoperative pain free period with low pain score due to its peripherally mediated antinociception through delta, kappa receptors located on primary afferent nerves however, sometimes opioid addition may result in certain opioid related central adverse effects as the primary clinical effects of fentanyl may be related to the central opioid receptors and thus can occur at a very small dose, particularly elderly population.

Recently there has been a interest developing among anaesthesiologists to go for opioid free anaesthesia and analgesia and thus we have chosen dexmedetomidine as an adjuvant to our local anaesthetic for wound infiltration analgesia.[18]α2 agonists have unique property of providing both sleep and analgesia to the recipient because of reduction in central sympathetic flow. Both clonidine and dexmedetomidine are in use as adjuvant to local infiltrative analgesia.[7,8,17,18]Various animal studies have proven both safety and efficacy of dexmedetomidine as an local anaesthetic adjuvant during peripheral nerve block.[19,20] The mechanism underlying antinociceptive effects of α2 agonists includes a direct effect on peripheral nerve activity[21] or blockade of hyperpolarization activated cation current or through inhibition of α2 mediated release of norepinephrine from presynaptic junction and peripheral α2A adrenoreceptors.[22] The release of norepinephrine because of α2 mediated stimulation is supposed to have a facilitatory effect on pain signal pathway after cutaneous injury.

In the present study, patients who received ropivacaine plus dexmedetomidine mixture wound infiltration for abdominal surgeries not only had reduced postoperative pain scores but also had reduced consumption of rescue analgesics in first 24 hours when compared to control group however this has not reached statistical significance level.

Abdelnaim et al has compared post-operative analgesia using wound infiltration with bupivacaine plus dexmedetomidine or bupivacaine plus magnesium sulfate mixture versus bupivacaine plus saline in patients undergoing herniorrhaphy. They concluded that continuous wound infiltration with bupivacaine plus magnesium sulfate produced effective analgesia and reduced postoperative patient controlled analgesic requirement delivered through a PCA pump. In their study the time to first request of analgesia was almost double in dexmedetomidine group compared to magnesium sulfate group and least in saline group: The postoperative opioid consumption was significantly lower in dexmedetomidine group than in other two groups. Also, no other reported complications in their study cohort.[23]

Kim and Kang opined that preemptive infiltration of ropivacaine dexmedetomidine mixture not only

reduces the postoperative pain but also postoperative fentanyl consumption after peri anal surgery. One of the mechanism by which dexmedetomidine produces peripheral analgesic action is by reducing the inflammatory mediators of pain at the surgical incision site.[24]Thus a preemptive infiltration might have attenuated the release of cytokines in their cohort. In contrast we have infiltrated the wound at the end of the surgery and yet we had similar results. This could be because dexmedetomidine not only inhibit cytokine release but also block the nociceptive stimulus by blocking the primary afferents carrying pain sensation(C fibre).

Our results are consistent with several other investigators, though lower pain scores in dexmedetomidine group has not reached statistical significance level at all time points except at 24th hour.Similarly Our study failed to demonstrate any statistical significant difference in rescue fentanyl consumption over first 24 hours among the three groups. This could be because most of the researchers used a PCA pump to deliver the rescue analgesics which are more precise and better indicator for postoperative analgesic requirement. Secondly the pain reporting efficacy has a great subjective variability. Neverthless our patients from dexmedetomidine group had a significantly longer pain free period compared to plain ropivacaine control group.

There are some concerns that addition of dexmedetomidine may give rise to certain adverse cardiovascular events because of its supraspinal action secondary to the absorption into systemic circulation.[14] However, no significant adverse cardiovascular events were observed in our study. Other studies using mixture of ropivacaine-dexmedetomidine also have not reported any adverse events with dexmedetomidine addition in comparision to control group.[7,8,14]

Strengths: Presence of a placebo control group in our study. It is a Prospective randomized double blind study. Adequately powered to detect the difference between the groups. Post Hoc comparision has been done to best understand the result. All the NRS measurements were carried out by single investigator to eliminate any inter investigator variability.

Limitations: Surgeries conducted by different surgical teams thus causing difference in tissue handling and local anaesthetic infiltration. Blood levels of ropivacaine and dexmedetomidine were not measured. The study has been done only in ASA grade I and II patients, the results cannot be generalized to patients with comorbidities. Patients satisfaction has not been measured in our study.

CONCLUSIONS

We conclude that wound infiltration with dexmedetomidine at both the doses (0.5mcg/kg and 1mcg/kg) provides extended postoperative pain relief when administered along with 30ml of ropivacaine (0.75%). The pain relief provided by dexmedetomidine (1mcg/kg) appears to be superior to both dexmedetomidine (0.5mcg/kg) and plain ropivacaine.

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