

# Comparision of Intermittent Bolus versus Continuous Infusion of Epidural Labour Analgesia by 0.15% Ropivacaine and Fentanyl: A Randomised Clinical Study

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## ABSTRACT

**Introduction:** Epidural labour analgesia is considered to be the most effective method to produce pain relief during labour. Programmed Intermittent Epidural Bolus (PIEB) has been observed to have many advantages over Continuous Epidural Infusion (CEI) like reduced incidence of breakthrough pain, local anaesthetic usage, instrumental delivery, shorter second stage of labour and more maternal satisfaction. Administration of local anaesthetic solution as PIEB at regular intervals has shown to spread more extensively in the epidural space compared to CEI, possibly enabling greater efficacy.

**Aim:** To compare the intermittent bolus versus continuous infusion of epidural labour analgesia with the primary objective to measure the total local anaesthetic consumption of 0.15% ropivacaine and fentanyl.

**Materials and Methods:** The randomised double blind study was carried out on parturient in Obstetrics and Gynaecology Department at Fortis Hospital, Bengaluru, Karnataka, India from June 2014 to June 2015. The present study compared 60 primiparous females (divided into two groups of 30 each). Labour analgesia was provided by bolus of 12 mL of 0.15% ropivacaine and 2 µg/mL fentanyl, after one hour of the initial

bolus dose, group I parturients received 8 mL of 0.15% ropivacaine with fentanyl 2 µg/mL hourly and group C parturients received same solution as continuous infusion immediately. If patient complained of pain or Visual Analog Scale (VAS) score  $\geq 4$ , additional 8 mL of the same solution was given. Total dose of 0.15% ropivacaine, number of rescue doses, pain scores, motor block and second stage of labour were compared.

**Results:** The mean age in group I was  $27.93 \pm 1.14$  and in group C was  $27.87 \pm 1.28$  years. Total dose of ropivacaine in group I was  $41.45 \pm 14.62$  mg and in group C was  $59.20 \pm 21.12$  mg ( $p$ -value=0.0004). In group C, at 2<sup>nd</sup> hour, VAS score ( $3.03 \pm 1.88$ ) was more compared to intermittent bolus group ( $1.40 \pm 2.02$ ), which was statistically significant ( $p$ -value=0.002). No motor block was observed in group I, but two parturients in group C had modified Bromage score of 4. Second stage of labour was significantly reduced in group I compared to group C ( $p$ -value <0.001). Less instrumental delivery and more maternal satisfaction was observed in group I.

**Conclusion:** Intermittent bolus group required less rescue doses hence, less total local anaesthetic dose with better analgesic efficacy.

**Keywords:** Local anaesthetic, Maternal satisfaction, Motor block, Visual analog scale

## INTRODUCTION

Labour has been illustrated as the most painful and life threatening episode in a woman's life. Continuous effort has been made by obstetricians and obstetric anaesthesiologists to alleviate the labour pain by using pharmacological, non pharmacological methods with variable efficacy. An ideal method to provide labour analgesia which is safe, effective and free of side effects is a continuing challenge for the anaesthetist [1]. Epidural analgesia has been considered as gold standard due to its authentic efficacy, flexibility and greater maternal satisfaction. Many techniques have been evolved for maintenance of epidural labour analgesia like intermittent top ups, Continuous Epidural Infusion (CEI), Patient Controlled Epidural Analgesia (PCEA), Computer Integrated Patient Controlled Epidural Analgesia (CIPCEA) and Programmed Intermittent Epidural Bolus (PIEB) techniques. Intermittent top-up technique has disadvantages like regression of analgesia, requires frequent provider intervention and high score of motor blockade after each bolus dose [2].

Continuous epidural infusion technique provides smooth and adequate analgesia and haemodynamic stability but requires larger doses of local anaesthetics, which may result in increased rate of instrumental deliveries due to impaired bear down during second stage of labour [3]. The PIEB technique used for the maintenance of epidural labour analgesia is currently in practice, in which bolus

of epidural analgesic mixture is administered at timed intervals [4]. Recent randomised controlled studies concluded that PIEB had similar analgesic effect with less motor blockade, reduced consumption of local anaesthetics dose, less need for rescue boluses and higher maternal satisfaction compared with the CEI [5,6]. Labour analgesia has grown from chloroform in the 19<sup>th</sup> century [7] to automated central neuraxial delivery devices of the 21<sup>st</sup> century [8].

Intermittent boluses of solution at regular intervals are more efficacious because these spread more extensively in the epidural space as against continuous infusion. The present study compared the efficacy of both the techniques using 0.15% ropivacaine and fentanyl with regard to total local anesthetic dose requirement as a primary outcome and secondary outcomes, like number of rescue boluses required, pain relief by Visual Analog Scale (VAS) score, motor block, effect on obstetric and neonatal outcome and maternal satisfaction.

## MATERIALS AND METHODS

This randomised double blind study was carried out on 60 parturient in Obstetrics and Gynaecology Department at Fortis Hospital, Bannerghatta road, Bengaluru, Karnataka, India from June 2014 to June 2015. Institutional Ethical Committee approval was taken (Ref. No./NBE/152037/2015/8124-25). All of parturients were briefed about the procedure and written informed consent obtained.

**Inclusion criteria:** American Society of Anesthesiologists (ASA) II parturients, aged 18-35 years, admitted with term gestation for safe confinement in active labour were included. Also primiparturients with singleton pregnancy, term gestation, cephalic presentation in active first stage of labour willing for epidural analgesia, cervical dilatation >3 cm and <5 cm, aged 18-35 years, height >145 cm, and Body Mass Index (BMI) 18-25 kg/m<sup>2</sup> were included in the study.

**Exclusion criteria:** Parturients who were unwilling, had medical disorders and pregnancy associated disorders, spine abnormalities and local skin infections, coagulopathies, preterm gestation, non reassuring non stress test, pregnant women with preterm labour or false labour pains, parturients in whom epidural analgesia was inadequate even after 45 minutes of initial bolus, parturients who experience unilateral block, parturients with blood tap during epidural and those with accidental dural puncture were excluded from the study.

**Sample size calculation:** According to the study by Fettes PDW et al., mean±SD ropivacaine dose consumption in intermittent and continuous infusion was 104.7±29.2 mg and 124.2±17.9 mg, at 95% confidence interval, and at 90% power [9]. Hence, the calculated sample size in each group was 30.

## Procedure

Baseline parameters of all the parturients like pulse rate, blood pressure, temperature and VAS score were noted. An intravenous line was secured with an 18G cannula on the non dominant hand and a preloading with 500 mL of ringer's lactate solution was done. Epidural technique was performed by experienced anaesthetist when the patient was in first stage of labour with 3-5 cm of cervical dilatation, in sitting position at L3-L4 interspinous space with 18G Tuohy's epidural needle. Epidural space was identified by loss of resistance to saline technique. Test dose of 3 mL of 2% lignocaine with adrenaline was given. After the confirmation of the epidural space, catheter was placed with 3-4 cm inside the epidural space. A 12 mL of 0.15% ropivacaine with fentanyl 50 µg was deposited through the catheter in increments over 10 minutes. After the injection, the parturients were turned to supine position. The parturients were monitored for target sensory level of T10 to achieve. If T10 not achieved in 30 minutes, additional 5 mL of ropivacaine 0.15% with fentanyl 2 µg/mL was given.

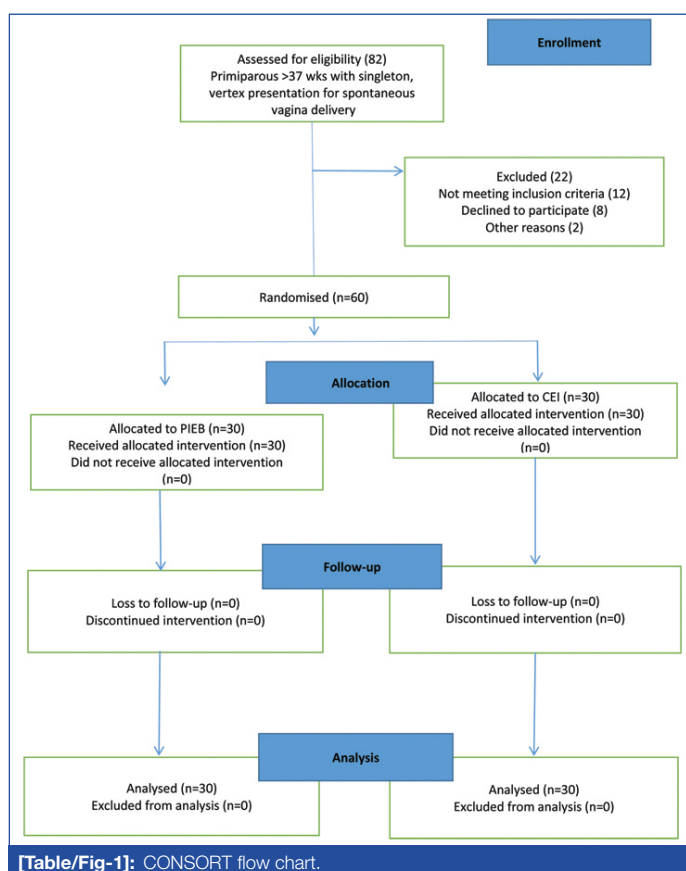
The parturients were then randomly assigned, using sealed envelope method, to one of the two groups to receive the drug combination of 0.15% ropivacaine with 2 µg/mL of fentanyl. After one hour of the initial bolus dose,

- Group I (PIEB) parturients received 8 mL of 0.15% ropivacaine with fentanyl 2 µg/mL hourly.
- Group C (CEI) parturients received same solution as continuous infusion immediately.
- Breakthrough pain was treated with 8 mL of 0.15% ropivacaine with fentanyl 2 µg/mL in both the groups. Parturients' vital parameters, progress of labour, VAS score and foetal well-being were monitored in co-ordination with the attending obstetrician. Maintenance fluid, Ringer Lactate (RL) was given at the rate of 100 mL/hr. Observations were made by an assessor 'blind' to the mode of drug administration. The attending anaesthesiologist was informed whenever pain recurred (VAS ≥4) and additional top-ups of the study drug were given. Sensory level was assessed for all parturients using gauze piece soaked with spirit after 10 minutes of initiation of labour epidural analgesia.

Pain relief was assessed by VAS scale. Zero (0) represents no pain, 1-3 mild pain, 4-6 moderate pain, and 7-10 severe pain. Motor block was assessed by modified Bromage score [10]: 1=Almost complete block (able to move feet only); 2=Partial block (just able to move knees); 3=Detectable weakness of hip flexion while supine (full flexion of knee); 4=Complete block (unable to move feet and knees);

5=No detectable weakness of hip flexion while supine; 6=Able to perform partial knee bend. Maternal heart rate and arterial pressure were recorded. Maternal hypotension is defined as a decrease in systolic Blood Pressure (BP) of ≥20% of the basal or <90 mmHg. Hypotension was treated with increased i.v. fluid administration and/or injection ephedrine, intravenously, 6 mg boluses as required.

Overall maternal satisfaction was recorded 24 hours after the delivery based on quality of analgesia, experience of child birth and incidences of nausea and shivering. It was graded as excellent, good and average depending upon parturient's subjective feeling. Uterine contraction and fetal well-being were recorded continuously by contraction stress test. Number of rescue doses required were noted. Duration of second stage of labour and duration of labour analgesia were noted. Mode of delivery as spontaneous vaginal, instrumental or operative delivery and indication for the same were noted. Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) score was assessed at 1 and 5 minutes following delivery. In the event of technical failure, the study number was re-allocated to the next patient, and blinding was maintained [Table/Fig-1].



[Table/Fig-1]: CONSORT flow chart.

## STATISTICAL ANALYSIS

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean±SD and results on categorical measurements are presented in number (%). Significance is assessed at 5% level of significance. Student t-test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (inter group analysis) on metric parameters. Levene's test for homogeneity of variance has been performed to assess the homogeneity of variance. Student t-test (two tailed, dependent) has been used to find the significance of study parameters on continuous scale within each group. Chi-square and Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups. Data were recorded as Mean±SD and percentages. The p-value <0.05 was considered statistically significant. The statistical software SAS 9.2, Statistical Package for the Social Sciences (SPSS) version 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment version 2.11.1 were used for the analysis of the data.

## RESULTS

Demographic and maternal characteristics like age, height, weight, gestational age and cervical dilatation were comparable in both the groups [Table/Fig-2]. The haemodynamic parameters were similar in both the groups [Table/Fig-3].

Variables	Group I Mean±SD	Group C Mean±SD	p-value
Age (years)	27.93±1.14	27.87±1.28	0.832
Weight (kg)	64.73±1.84	65.27±1.82	0.263
Height (cm)	159.03±3.14	157.83±3.06	0.141
Gestational age (weeks)	39.32±1.4	39.02±1.3	0.393
Cervical dilatation (cm)	3.56±0.62	3.58±0.64	0.902

**[Table/Fig-2]:** Demographic and maternal parameters. p-value <0.05 was considered statistically significant (calculated using Student t-test)

Variables	Group I	Group C	Independent t-test	p-value
	Mean±SD	Mean±SD		
Pulse rate (beats per minutes)	80.73±7.129	77.67±8.612	1.502	0.138
Mean arterial pressure (mmHg)	88.17±5.018	88.73±4.982	-0.439	0.662

**[Table/Fig-3]:** Haemodynamic parameters. p-value <0.05 was considered statistically significant

Parameters observed during epidural labour analgesia are given in [Table/Fig-4]. Level of sensory block at T10 (20 vs 21) and at T8 (10 vs 9) was comparable in both groups. None of the parturients in the intermittent group had any motor blockade. However, two parturients in the continuous group had modified Bromage score of 4, although the difference was not statistically significant. Regarding rescue analgesic doses in group I, 19 parturients required 1 rescue dose, and 2 parturients required 2 rescue doses, whereas 9 parturients did not require extra dose of analgesia. In continuous group, 8 parturients experienced no breakthrough pain, whereas 7 parturients required 1 rescue dose and 15 parturients required 2 rescue doses. Total dose of ropivacaine consumption in group I was less compared to group C (41.45±14.62 mg vs 59.20±21.12 mg) at p-value=0.0004. Duration of epidural analgesia was comparable in both groups, which was statistically not significant. Regarding maternal satisfaction, more parturients in group I expressed greater satisfaction than in group C (25 vs 20).

Variables	Group I	Group C	p-value
<b>Sensory block</b>			
T10	20	21	0.781 (Fisher-exact test)
T8	10	9	
<b>Modified Bromage score</b>			
6	30	28	0.492 (Fisher-exact test)
4	0	2	
<b>No. of rescue doses required</b>			
0	9 (30%)	8 (26.7%)	0.004 (Student t-test)
1	19 (63.3%)	7 (23.3%)	
2	2 (15%)	15 (5%)	
Ropivacaine dose consumed (mg)	41.45±14.62	59.20±21.12	0.004 (Student t-test)
Duration of epidural (minutes)	261.33±51.74	273.16±63.19	0.43 (Fisher exact test)
<b>Maternal satisfaction</b>			
Excellent	25 (83.3)	20 (66.7%)	0.233 (Fisher-exact test)
Good	5 (16.7%)	9 (30%)	
Average	0 (0%)	1 (3.3%)	

**[Table/Fig-4]:** Characteristics of epidural labour analgesia and maternal satisfaction. p-value <0.05 was considered statistically significant

Pain scores were assessed by VAS scale [Table/Fig-5]. Complete pain relief (VAS score=0) was achieved at 30 minutes after epidural analgesia in both groups. In continuous group, at second hour VAS

score was more compared to intermittent bolus group, which was statistically significant.

Time	Visual Analog Scale (VAS)		p-value
	Group I Mean±SD	Group C Mean±SD	
Before epidural	6.80±1.32	7.06±1.24	1.000
5 min	6.80±1.19	6.80±1.19	1.000
10 min	3.90±0.76	3.90±0.76	1.000
15 min	1.63±0.49	1.60±0.45	1.000
30 min	0	0	-
1 hr	0	0	-
2 hr	1.40±2.02	3.03±1.88	0.002**
3 hr	1.80±2.04	2.10±2.09	0.576

**[Table/Fig-5]:** VAS Score in two groups of parturients studied. \*\*p-value <0.05 was considered statistically significant (calculated using student t-test)

Maternal and neonatal outcomes were compared [Table/Fig-6] in both groups, 3 parturients in intermittent group had positive contraction stress test, 10 parturients in continuous group had positive contraction stress test (p-value <0.028). Mode of delivery in both groups was similar. In group I, 22 parturients and 15 parturients in continuous group had normal vaginal delivery. Instrumental delivery was required in three parturients in group I and one patient in group C. Eight parturients in group C and five parturients in group I had lower segment caesarean section (p-value=0.468). Second stage of labour was significantly less in intermittent bolus group than in group C (p-value <0.001). APGAR scores at one minute and five minutes were similar in both the groups. There was no significant effect of mode of drug delivery on neonatal outcome.

Variables	Group I	Group C	p-value
<b>Contraction stress test</b>			
Negative	27 (90%)	20 (66.7%)	0.028 (Chi-square test)
Positive	3 (10%)	10 (33.3%)	
<b>Type of delivery</b>			
Instrumental delivery	3 (10%)	1 (3.3%)	0.468 (Chi-square test)
Caesarean section	5 (16.7%)	7 (23.3%)	
Vaginal delivery	22 (73.3%)	17 (56.7%)	
<b>Second stage of labour (min)</b>			
<20 min	2	0	p≤0.001 (Fisher Exact test)
20-40 min	23	12	
>40-60 min	0	7	
>60 min	0	4	
<b>APGAR score at</b>			
1 min	8.7±1.3	8.6±1.2	1.000
5 min	9.5±0.4	9.4±0.3	1.000 (Fisher Exact or Chi-square test)

**[Table/Fig-6]:** Obstetric and foetal outcome parameters. p-value <0.05 was considered statistically significant

## DISCUSSION

Labour analgesia is a challenging journey with gratifying end points. Labour analgesia has grown from chloroform in the 19<sup>th</sup> century [7] to automated central neuraxial delivery devices of the 21<sup>st</sup> century [8]. The search for an ideal technique or drug continues as it has to produce effective pain control to the mother without any adverse physiological effect to the foetus. Primiparous females have longer duration of labour and more intense pain than multiparous females. Also, rate of cervical dilatation, neonatal weight, time of epidural catheter placement are predictors of breakthrough pain in labour analgesia [11]. To avoid these confounding factors, present study included only primiparous females in first stage of labour and placed the epidural catheter when cervical dilatation was between 3-5 cm. The study included 60 primiparous females (30 in each group).

Demographic and maternal characters were comparable in both the groups, and were statistically not significant. All the parturients in both groups were haemodynamically stable throughout the labour analgesia as all of them were preloaded with intravenous bolus of Ringer's lactate. Also, parturients were suggested to lie down in lateral position intermittently.

The main observation in this study was less consumption of local anaesthetic, reduced request for rescue analgesic bolus doses, no motor block, shorter second stage of labour in group I compared to group C. Efficacy of labour analgesia was similar in both groups except at second hour with less VAS score in PIEB group than in CEI group. Less parturients required top up doses in PIEB group as compared to CEI group. Total ropivacaine dose in PIEB was significantly less ( $47.45 \pm 18.62$  mg) compared to CEI group ( $59.20 \pm 21.12$  mg). The study found no significant difference in pain scores except at 2 hours after epidural administration, and less requirement of top ups in intermittent group than in continuous group.

Different mechanisms were proposed, both in cadaveric and experimental studies, to explain superior quality of analgesia in intermittent epidural bolus than continuous epidural infusion. Kaynar and Shankar demonstrated, using methylene blue dye and white semi-absorbent paper, that intermittent boluses through multiorifice epidural catheter have a greater spread of dye distribution than continuous infusion [12]. It has been attributed that superior local anaesthetic spread with bolus dose is due to generation of higher pressures compared to CEI [12]. Examination of cryomicrotome section in a cadaveric study revealed that when injection is made with high pressure, solution spreads preferentially along the nerve root sheath through the intervertebral foramina rather than a unified front [13].

Study by Fettes PD et al., they compared 0.2% ropivacaine and 2 µg/mL of fentanyl for PIEB and CEI. They found less total local anaesthetic dose ( $104.79 \pm 29.2$  vs  $124.2 \pm 17.9$ ) which was statistically significant ( $p$ -value=0.02) with minimal top up requirements with equivalent pain scores. They observed continuous group parturients required over three times more epidural boluses compared with the intermittent group to maintain pain relief. They also found incidence of motor block in both the groups but no significant difference in motor block. This may be due to the use of high concentration as well as high volume (0.2% ropivacaine) in their hospitals [14]. In another study, total dose of ropivacaine received in CEI group was almost double than the programmed intermittent bolus group (CEI vs PIEB group  $72.5 \pm 43.0$  vs  $40.4 \pm 23.8$  mg), which was statistically significant ( $p$ -value <0.001). They also found markedly reduced incidence of motor block, significantly reduced second stage of labour and no significant difference in the instrumental delivery in intermittent group compared to continuous group [15]. Capogna G et al., in their study compared epidural labour analgesia using levobupivacaine 0.0625% with sufentanil 0.5 µg/mL found less consumption of levobupivacaine 31 (25-38) mg in PIEB group compared to 37 (31-44) mg in CEI group [4]. They also found less motor block and less incidence of instrumental delivery in intermittent group compared to continuous group.

In the present study, no motor blockade was observed in intermittent group, but 2 parturients (6%) in the continuous group had detectable weakness of hip flexion while in supine position. Parturients were allowed to be ambulatory under supervision. Less motor block was assumed to be due to low concentration as well as reduction of total dose of local anaesthetic solution used. Ojo OA et al., observed significantly less motor block in intermittent group compared to continuous infusion group (Bromage score <5, 27.5% vs 50%;  $p=0.03$ ) without any difference in the hourly requirement of local anaesthetic. They also concluded that no statistically significant difference in the instrumental delivery, LSCS and maternal satisfaction [16]. In CEI, the high incidence of motor block has been attributed to

the existence of constantly higher concentration of local anaesthetic in the extradural space to diffuse readily into the intraneural space to produce block. When low concentrations of local anaesthetics are used as intermittent boluses, total amount of drug inside the nerve is inadequate to produce motor block.

In the present study, it was observed that duration of second stage of labour was lesser in intermittent group compared to continuous group. A significant reduction in the duration of the second stage of labour by 25.4 min from 108.2 to 79.4 min ( $p$ -value<0.002) was observed in primiparous females in a recent study by Bullingham A et al., [15]. In a study by Choudhary R et al., the authors had compared 0.0625% Levobupivacaine and 1µg/ml fentanyl 10 mL every hour as intermittent bolus and continuous infusion following 20 mL of bolus [17]. They found less total amount of local anaesthetic, less rescue doses and shorter second stage of labour in intermittent bolus group compared to continuous group. In a meta-analysis, the authors concluded that in intermittent bolus group second stage of labour was less compared to continuous group [18]. In the present study, prolongation of 2<sup>nd</sup> stage of labour in continuous group was probably because of more local anaesthetic drug required for labour analgesia. We were unable to find significant difference regarding instrumental or caesarean delivery in both the groups. APGAR scores recorded at one minute and five minutes were similar in both the groups, though more incidence of CST positive was observed in continuous group. In a review article, the authors did not find difference in the maternal and fetal outcome between intermittent bolus and continuous infusion group [19]. Mothers were interviewed the day following their delivery by an independent observer and asked about their perception of pain relief. Maternal satisfaction was similar, and no significant difference was found in both the groups.

### Limitation(s)

Parturients were not provided any extra analgesia for the second stage of labour. Observations were recorded by trained nursing staff, hence possibility of observer bias. Experience of obstetrician was not taken into consideration, hence maternal outcome may vary.

### CONCLUSION(S)

The study concludes that programmed intermittent epidural bolus technique for labour analgesia required less total local anaesthetic consumption with less rescue doses compared to CEI technique, shortened second stage of labour and no motor block representing a better mode of analgesia. Hence, the study recommends intermittent bolus technique as a better mode of analgesia for parturients in labour.

**Authors' contributions:** KNR and RC were responsible for conception and design of the study. PB and NK helped in acquisition and interpretation of data. Manuscript writing, history collection was done by RC and all the co-authors contributed revising the manuscript critically and approved the final version.

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#### PLAGIARISM CHECKING METHODS: (Jain H et al.)

- Plagiarism X-checker: Aug 23, 2021
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- iThenticate Software: Oct 25, 2021 (21%)

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