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Original Research Article

A Comparative Study of Intrathecal Tramadol with Intravenous Tramadol, as an Adjuvant to Intrathecal Bupivacaine for Post Operative Pain Relief in Gynaecological Procedures

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Abstract

Background: In this study, we wanted to compare the efficacy of intrathecal bupivacaine and intrathecal tramadol with intrathecal bupivacaine and intravenous tramadol in patients undergoing gynaecological procedures. The parameters studied include onset of sensory block, change in vital signs, adverse effects, and duration of post operative analgesia.

Materials and Methods: This prospective randomized double-blind study was conducted among 60 patients who were allocated randomly into two groups of 30 each. Group I received 3.5 ml of 0.5 % bupivacaine (heavy) and 0.5 mg/kg (preservative free) tramadol intrathecally. Group II received 3.5 ml of 0.5 % bupivacaine (heavy) and 0.5 ml saline intrathecally and 0.5 mg/kg tramadol (preservative free) intravenously. After obtaining written informed consent, Institutional Ethical Committee approval was taken.

Results: The most common study is that of postoperative pain which is unique by its transitory nature. Bupivacaine is the most widely used local anaesthetics for spinal anaesthesia. Whereas tramadol is a centrally acting analgesic with weak opioid agonistic properties. A combination of intrathecal tramadol with bupivacaine could be used for better postoperative analgesia with no major side effects like respiratory depression. From the present study, it can be concluded that intrathecal tramadol 0.5 mg/kg in combination with bupivacaine offers a simple, inexpensive and effective means of good quality post-operative analgesia.

Conclusion: A combination of intrathecal tramadol with bupivacaine could be used for better post operative analgesia with no major side effects like respiratory depression. Present study can be concluded that intrathecal tramadol 0.5 mg/kg in combination with bupivacaine offers a simple, inexpensive and effective means of good quality post operative analgesia.

Keywords: Intrathecal Tramadol, Intravenous Tramadol, Bupivacaine

Introduction

Post operative pain is a major concern of anaesthesiologist as well as surgeon. It has adverse physiological impact leading to increase post operative morbidity with cardiovascular and respiratory side effects.Post operative pain is unique by its transitory nature, which makes it more amendable to therapy. Several modalities are available with merits and demerits.

Regional anaesthesia especially spinal anaesthesia is one of the commonly used technique for gynaecological surgeries. Local anaesthetics are used to provide spinal anaesthesia. They produce motor, sensory and sympathetic blockade.

Following the initial reports in 1979 of the clinical efficacy of intrathecal opioids, these drugs have been used to control pain. Intrathecal opioids by themselves cannot produce motor blockade. So, a combination of intrathecal opioids with local anaesthetics, in which the former acts synergistically with local anaesthetics without increasing sympathetic block, would be advantageous and beneficial.

It is believed that injection of an opioid into the cerebrospinal fluid, a reservoir of drug is created that passively diffuses into the dorsal horn of spinal cord. There, it binds to the opioid receptors where it is presumed to inhibit the release of substance-P a neuro transmitter believed to be responsible for relaying the nociceptive information across the synapses.

Thus, it can be hypothesized that it is possible to achieve an adequate degree of spinal anaesthesia using combination of intrathecal opioids and local anaesthetics. The major advantage of this combination is prolonged excellent post operative analgesia with minimal side effects.

Bupivacaine is the most widely used local anaesthetics for spinal anaesthesia. It is an amide local anaesthetic. Local anaesthetic acts by preventing the generation and conduction of nerve impulses. It blocks conduction by preventing the large transient increase in permeability of excitable membrane to sodium ions that normally is produced by the depolarization of membrane.

Tramadol is a centrally acting analgesic with weak opioid agonistic properties and has effects on nor-adrenergic and serotonergic neuro transmission. It has six thousand fold less affinity for μ receptors compared to morphine, hence with less respiratory depression.

Tramadol has been extensively studied by extradural route, but not by intrathecal route. So, in patients for gynaecological procedures with traction and manipulations, intrathecal tramadol with its opioid and non-opioid actions could be a better intra operative and post operative analgesic with minimal side effects, compared to intrathecal bupivacaine alone.

Intravenous tramadol has also been studied and shown to have analgesic potency equal to pethidine with minimal adverse effects.

So, this randomized double-blind study was designed to evaluate and compare the efficacy of tramadol, considering the duration, quality of analgesia and side effects by two different routes (intrathecal and intravenous) as an adjuvant to intrathecal bupivacaine in patients undergoing gynaecological procedures.

Aims and Objectives

To compare the efficacy of intrathecal bupivacaine and intrathecal tramadol with intrathecal bupivacaine and intravenous tramadol in patients undergoing gynaecological procedures. The parameters studied include.

1. Onset of sensory block
2. Change in vital signs
3. Adverse effects
4. Duration of post-operative analgesia.

Materials and Methods

This prospective randomized double-blind study was conducted among 60 patients who were allocated randomly into two groups of 30 each. Group I received 3.5 ml of 0.5% bupivacaine (heavy) and 0.5 mg/kg (preservative free) tramadol intrathecally. Group II received 3.5 ml of 0.5% bupivacaine (heavy) and 0.5 ml saline intrathecally and 0.5 mg/kg tramadol (preservative free) intravenously. After obtaining written informed consent, Institutional Ethical Committee approval was taken.

Inclusion Criteria

All patients in the study were American Society of Anaesthesiologists (ASA) Grade I, aged 20 - 50 years undergoing elective gynaecological procedures. The type of surgery included, total abdominal hysterectomy, ovarian cyst excision, and ovarian tumour excision.

Exclusion Criteria

1. Patient not willing for spinal anaesthesia
2. Patient with coagulation abnormality
3. Patient with infection at the site of injection
4. Patient with hypertension, diabetes mellitus, ischemic heart disease, central nervous system disorders and other diseases.
5. Any allergy to tramadol/bupivacaine
6. Patient on MAO inhibitors

Pre operative evaluation

A thorough pre anaesthetic checkup was carried out. Detailed history was taken, relevant and routine investigations were done. Pulse, blood pressure and respiratory rate were noted. Body weight was recorded. Systems were examined.

Study Procedure

A prospective randomized double blind study was conducted. 60 patients were allocated randomly into two groups of 30 each. Group I Received. 3.5ml of 0.5% bupivacaine (heavy) and 0.5 mg/kg (preservative free) Tramadol Intrathecally. Group II Received. 3.5ml of 0.5% Bupivacaine (Heavy) and 0.5ml saline intrathecally and 0.5 mg/kg Tramadol (preservative free) intravenously. The intrathecal drug was prepared by the assistant and administered by the researcher who was blinded. The researcher was blinded to administration of intravenous tramadol. The researcher continued patient assessment and care.

Pre-Operative Preparation

All patients were kept fasting for 8hrs prior to surgery. Premedicated with.

T Ranitidine 150mg HS and 6am on day of surgery

T Alprazolam. 0.25mg HS and 6am on day of surgery

T. Metoclopramide 10mg HS and 6am on day of surgery,

Base line pulse rate, blood pressure and respiratory rate were recorded.

An intravenous line was established and patient preloaded with 20ml/Kg Ringer lactate in the premedication room.

Anaesthetic Technique

As the patient arrived in operating room, pulse rate, systolic and diastolic blood pressures were recorded as baseline. Monitors included Electrocardiogram (ECG), Non Invasive Blood Pressure· (NIBP) and Pulse Oximeter (SPO_2). The patient was placed in lateral decubitus position. The skin of the back was prepared, draped and was anaesthetised locally with two ml of 1% preservative free lignocaine at level of L_2 -L_3• Lumbar subarachnoid block was performed using 23G pencil point spinal needle with free flow of CSF was verified before and after injection. Needle was directed cranially. Group I received 3.5cc of 0.5% Bupivacaine heavy with 0. 5 mg/kg

preservative free Tramadol intrathecally. Group II Received 3.5cc of 0.5% Bupivacaine heavy with 0.5cc normal saline intrathecally. Intravenously 0. 5 mg/kg Tramadol was given once intrathecal drug was given. The time of administration of Tramadol intrathecally or intravenously was taken as zero hour. After the subarachnoid block, patients were turn to supine position. 0_2 was given by mask at a rate of 6 L/minute.

Sensory block and vital signs were monitored. Sensory level was assessed by pinprick in the midline every two minutes until T_6 level was obtained. Pulse rate, BP, Oxygen saturation and Respiratory rate were checked every two-minute for first fifteen minutes and then every 5 minute till completion of surgery. Ringer lactate solution was used as maintenance fluid.

Brady cardia (HR < SO/minute) was treated with Inj. Atropine 0.6 mg. IV as needed.

Hypotension (30% of fall from basal systolic blood pressure or systolic BP less than 80mm of Hg) was treated with Inj. Mephentermine 6mg intravenously and rapid infusions of ringer lactate.

Patient with nausea and vomiting were treated with inj. Metoclopramide 10 mg IV.

Respiratory depression was taken as Respiratory rate less than 10/minute.

No analgesics were given in the intraoperative period.

The total time of study was taken as 12 hours, including the average operative time of two hours. Patient was monitored every 15minute for 2 hours in the recovery room in the postoperative period; and hourly basis for 8 hours in the ward. Vitals and side effects were looked for.

No analgesics were given in the postoperative period except when the patient complained of discomfort with pain according to McGill classification pain score 2.

When the patient complained of pain for the first time, she was given Inj. Ketorolac 30mg intramuscular. If patient still complaint of pain after 4 hours another dose of Ketorolac was given. Even after 2 doses of Ketorolac or duration between the doses was less than 4 hours, Inj. Pethidine l mg/kg IM + Inj Promethazine 0.25 mg/kg IM was given. The duration of analgesia was calculated as the time interval between the time of intrathecal or intravenous administration of Tramadol and the time of first rescue analgesic. The numbers of rescue analgesics were noted in both groups. The incidences of side effects were closely watched into the postoperative period. Patients with Nausea/vomiting were treated with Inj. Metoclopramide l0 mg IV. Patient who were drowsy were checked whether they were arousable by verbal command. Patients who had pruritus were treated with intramuscular injection of Phentermine maleate. Urinary retention was not a problem in these patients as bladder catheterization is a routine practice in all-gynaecological procedures. The catheter is kept in situ for 24 hours postoperatively.

Statistical Methods

Statistical analysis of the observed parameters in both the groups was done under the guidance of a statistician to find out whether a significant difference exists between the two groups.

The following parameters were statistically analysed by student's 't' test, time taken for abolition of pinprick sensation at T_6 level and number of hours after which patient required analgesia. The following parameters were analysed by chi square test (Fisher's exact test)

1. Intra operative / post-operative bradycardia
2. Intra operative / post-operative hypotension

3. Intra operative / post-operative incidence of nausea/vomiting
4. Post-operative need of rescue analgesic.

Statistical analysis was done using software Statistical Package for Social Sciences (SPSS) 10.0 version and data was entered in Microsoft Excel. The arithmetic mean and standard deviation of various parameters were calculated. For finding out difference in mean, student 't' test was applied. The level of significance was put at 95%. To find out statistical significance of association, chi square test (Fisher's exact test) was used.

Results

Mean age in group I was 45.70 years with a standard deviation of 5.68 (95 % CL is 34.34 - 57.06 years). Mean age in study group II was 42.70 years with a standard deviation of 10.96 (95 % CL is 37.74 - 53.66 years). The mean weight of group I was 56.60 kg with standard deviation of 7.23 (95 % CL is 42.14 kg - 71.06 kg). Mean weight of group II was 52.40 kg with standard deviation of 4.85 (95 % CL is 42.7 kg to 62.1 kg).

The mean height of group I was 157.23 cm with standard deviation of 4.15 (95 % CL is 148.93 cm - 165.53 cm). The mean height of group II was 154.57 cms with standard deviation of 5.20 (95 % CL is 144.17 cm- 164.97 cm);

Table 1: Onset of Block up to T6 Level was Assessed by Abolition of Pinprick Sensation

Onset of block	Group I	Group II	't' value	P value
In minutes	4.57 + 1.26	3.53 + 1.02	7.023	< 0.01

Significance level was assessed by student's 't' test and t value was 7.023, so p is < 0.01 which is statistically significant. With the result addition of tramadol intrathecally delays the onset of block when compared to intravenous tramadol.

Table 2: Incidences of Side Effects

Side Effects	**Group I**	**Group II**
Bradycardia	10	1
Hypotension	2	3
Nausea and vomiting	17	11
Respiratory depression	0	0
Pruritis	0	0
Urinary retention	0	0

Table 3: Incidence of Bradycardia and Hypotension

	Yes		**No**		
	Number	**%**	**Number**	**%**	
Group 1	10	90.9	20	40.8	30
Group 2	1	9.1	29	59.2	30
Total	11		49		60
Incidence of Bradycardia					
		Yes		**No**	
Group1	2	40 %	28	50.97	
GroupII	3	60 %	27	49.1 %	
Total	5		55		
Incidence of Hypotension					

The incidence of bradycardia was compared between the two groups with chi square test (Fisher's exact test). Chi square test was applied with value 9.017 (b) and

degree of freedom one with significance value 0.003 i.e., < 0.01. So it is statistically significant. The addition of tramadol to bupivacaine intrathecally leads to bradycardia in comparison to giving tramadol by intravenous route. So, bradycardia (i.e. HR < 50/minute) was more in-group of patients who were given intrathecal tramadol in comparison to intravenous tramadol.

Incidence of hypotension was compared and statistically analysed between two groups using chi square test (Fisher's exact test). The chi square value was 0.218 with degree of freedom 1 and significance 0.5 i.e., p > 0.01 so this is not statistically significant. The incidence of hypotension is given in figure 2. Thus, there was no significant difference between the two groups with regard to fall in blood pressure.

Table 4: Incidence of Nausea / Vomiting

	Present		Absent		
Group 1	17	60.7 %	13	40.6 %	30
Group II	11	39.3 %	19	59.4 %	30
Total	28		32		60

The statistical significance of occurrence of nausea and vomiting was analyzed by chi square test (Fisher's exact test). The chi square value was 2.411 and the significance was 0.098 with a degree of freedom one. So, P > 0.01. Thus, there was no statistically significant difference in the occurrence of nausea/vomiting between the two groups i.e. group I intrathecal bupivacaine + intrathecal tramadol and group II intrathecal bupivacaine + intravenous tramadol.

Table 5: Duration of post operative analgesia

Duration in Hours	Group I	Group II	't' value	Significance level
	5.033 + 1.928	3.200 + 1.276	8.685	P < 0.01

The duration of post operative analgesia was statistically analysed using student 't' test. 't' value was 8.685 and p < 0.01 and it is highly significant.

So, the time at which the patients request analgesic were significantly longer in group I patients (intrathecal bupivacaine + intrathecal tramadol 0.5 mg/kg) when compared to group II patients (intrathecal bupivacaine + intravenous tramadol).

The mean duration in group I was 5.033 hours. The mean duration in group II was 3.200 hours (figure 4). The duration of analgesia of group I ranged from 3.5 hours to 7 hours. While that of group II was between 2.5 - 4.5 hours.

All the patients of group II required both ketorolac and pethidine while 3 patients of group I required only one dose of ketorolac, as post-op analgesic. This was analysed by chi square test but was not found to be statistically significant.

So to conclude, the results of addition of tramadol intrathecally to bupivacaine causes delay in the onset of block, but will lead to prolonged post operative analgesia when compared to giving tramadol by intravenous route.

Intrathecal tramadol also causes bradycardia, which is significantly more while compared to intravenous group. But all other side effects are comparable between two groups.

Discussion

The present study was undertaken to compare the efficacy of intrathecal tramadol with intravenous tramadol for postoperative pain relief and the side

effects. This was a prospective randomized double blind study of 60 patients of two groups of 30 patients each. The patients were evaluated for efficacy of analgesia using McGill Scoring system.

In this study, the mean duration of analgesia in Group I (3.5ml of 0.5% Bupivacaine and 0.% mg/kg Tramadol intrathecally) was 5.033 hrs. while the mean duration of analgesia in-group II (3.5ml of 0.5% Bupivacaine and 0.5 mg/kg Tramadol IV) was 3.200 hours. The difference in the duration of analgesia between the two groups was found to be statistically significant ($p < 0.01$).So this study demonstrated that 0.5 mg/kg intrathecal tramadol with Bupivacaine was more effective in relieving postoperative pain compared to 0.5 mg/kg intravenous tramadol with intrathecal Bupivacaine.

Brijesh Jain, Saraswath VK [1] has studied the efficacy of intrathecal tramadol for postoperative pain relief in cases of LSCS and gynecological surgeries. They found that addition of 25mg Tramadol intrathecally to Bupivacaine (0.5%) heavy prolonged the duration of postoperative analgesia. In their study there were 100 LSCS patients in-group one who received 1.3ml lignocaine (Heavy) and 25mg Tramadol.

In Group II 30 Gynaecology patients received 3.5ml 0.5% bupivacaine (heavy) and 25mg Tramadol. The mean duration of postoperative pain relief, In Group I was 8.00 + 2.54hrs only Group II was 8.47 + 3.27 hrs. The results of the study were not compared with a control group.[1] But results of this study agreed with our study prolonging duration of postoperative analgesia.

Alhashemi JA and Kaki MA[2] did another study of Intrathecal tramadol on patients undergoing transurethral resection of prostate. Here 64 patients were randomized to two groups and

Group I - 3ml of Bupivacaine 0.5% and 25 mg Tramadol

Group II - 3ml of Bupivacaine 0.5%- and 0.5-ml Saline was given

They concluded that 25mg Tramadol given intrathecally was ineffective in decreasing analgesia requirement after TURP surgery and attributed that to [2]

1. Low dose of tramadol
2. Decrease affinity of tramadol to μ receptors, which is the site of action of spinal opioids.
3. Due to lipophilic property of tramadol rapidly diffusion of drug out of subarachnoid space occurs.
4. Possibility of analgesic effect of tramadol disappeared before the spinal anaesthetic
5. Tramadol in a dose of 20mg may have antianalgesic effect that is mediated via, its systemic action or its effect on the spinal cord.

The ineffective analgesia could be due to the low amount of drug since mean weight of the group was 74.9kg and intrathecal tramadol group in our study was 56.6kg. So the dose given in the study by Alhashemi JA and Kaki MA i.e. tramadol 25mg was very less.

In our study we have adjusted it to 0.5 mg/kg according to body weight and this could be the reason for effective postoperative analgesia in our observations. Epidural tramadol has been studied for postoperative analgesia in different surgeries but are with varying results.

Siddik Sayyid S, Aouad Maroun M, Sleiman D, et al [3] compared post-operative analgesia with 100mg and 200mg Tramadol epidurally after lower segment cesarean section. They concluded that 100mg tramadol would be enough to produce postoperative analgesia without respiratory depression.

Baraka Anis; Jabbour Samar; Nader

Antoun et al [4] studied efficacy of 100 mg tramadol with 4 mg morphine for post operative analgesia in patients undergoing major abdominal surgery. They reported that 100 mg tramadol epidurally could provide adequate and prolonged postoperative analgesia without respiratory depression.

Delilkan AE; Vijayan R [5] compared 50mg tramadol, 100 mg tramadol and 10ml of 0.25% Bupivacaine epidurally for patients undergoing abdominal surgery. They noted that, there was no difference between 100 mg and 50 mg in duration of doses, but quality of analgesia was better with 100 mg Tramadol. They advocated 100 mg Tramadol for effective postoperative pain relief.

In the study titled "Ineffective analgesia after extradural tramadol hydrochloride in patients undergoing total knee replacement", Grace D and Fee JPH concluded that epidural tramadol even in 50mg or 100mg bolus doses followed by infusion was ineffective in relieving postoperative pain.

In our study, we observed longer duration of postoperative analgesia with intra thecal tramadol compared with intravenous route. Normal dose of intravenous tramadol is 0.5- lmg/kg. In our study we assessed the lower dose (0.5 mg/kg). This could be the reason for short duration of post op analgesia with intravenous tramadol.

We also studied the time of onset of block. The loss of pinprick sensation was taken as the onset of block. Onset of block at T6 was compared. Time taken for onset of block in Group I (3.5ml of 0.5%. Bupivacaine + 0.Srilg/kg Tramadol intrathecally) was 4.57 + 1.26 minute while in-group II (3.5ml of 0.5% Bupivacaine + 0.5 mg/kg Tramadol Intravenously) it was 3.53 + 1.02 minute. This was compared and found to be statistically significant.

Alhashemi JA and Kaki AM [2] did not study this parameter in their study, while Brijesh Jain and Saraswath VK [1] noted that addition of 25 mg tramadol to· lignocaine and Bupivacaine, intrathecally did not show any significant difference in time of onset of analgesia.

This variation could be due to a change in PH caused by addition of tramadol to bupivacaine and also due to the patient variation in personal threshold of pain, which varies with psychological attitude, mood, fatigue and fear.

In our study we could demonstrate that the fall in heart rate is significantly higher in Group I (3.5ml of 0.5% Bupivacaine + 0.5 mg/kg intrathecal tramadol) compared to Group II (3.5ml of 0.5% bupivacaine + 0.5ml normal saline + 0.5 mg/kg Tramadol IV). 10 patients in group I (33.3%) showed Bradycardia i.e. HR < SO/minute while only 1 patient showed bradycardia in group II (3.33%). Bradycardia was treated with Injection Atropine 0.6mg IV.

But in the study by Brijesh Jain and Saraswath VK [1] reported on 3.33% of Bradycardia in the study group of bupivacaine. They referred this bradycardia to central effect of local anaesthetic as w II as traction on the viscera by surgeon during surgery in subarachnoid block.

Alhashemi JA and Kaki AR [2] in their studies noticed a trend towards increased HR in patients who received intrathecal tramadol. But there was no clinically relevance when compared to other group. Other studies of epidural tramadol or IV tramadol have not noticed any significant change in heart rate.

The reduction in heart rate could be attributed to Bain Bridge reflex [6] Most patients under spinal anaesthesia exhibit brady cardia and it would appear that the Bain Bridge reflex predominates. In spinal anaesthesia, venous pooling in the periphery reduces stimulation of volume receptors there by diminishing the activity of the cardiac sympathetic nerves.

The result is vagal dominance and reduction in heart rate. So this could be given as an explanation to the brady cardia noted in our study. This fall in heart rate in our study could be attributed to the high level of block obtained, by the central effect of local anaesthetic, and the traction on the viscera by surgeon. [7]

In our study we noted hypotension (i.e. fall in systolic BP below 30% or fall below 80mm of Hg) for 2 patients in group I (6.66%) (3.5ml of 0.5% bupivacaine + 0. 5 mg/kg tramadol intrathecally) and 3 patients in group II(10%) (3.5ml of 0.5% bupivacaine intrathecally + 0.5ml saline + 0.5 mg/kg Tramadol intravenously) we could not demonstrate any significant difference in the occurrence of hypotension between the two groups. All these patients, who developed hypotension, were treated with IV fluids and Injection Mephentermine by IV boluses.

Alhashemi JA and Kaki AM [2] in their study, noted that the two groups were comparable with regard to blood pressure changes. Brijesh Jain and Saraswath VK [1] noticed fall in BP in 4 patients of the 30 people group receiving intrathecal tramadol + bupivacaine. The studies with epidural tramadol, noted no major fall in blood pressure. Only transient fall were noted which were treated with ephedrine and IV fluid. The less incidence of hypotension in our study could be due to the preloading of fluid before the block is attained. Hypotension could be due to high level of block.

In our study we noticed 17 patients developed nausea or vomiting in- group I (56.66%) (3.5ml of 0.5% bupivacaine + 0.5 mg/kg tramadol intrathecally). Out of 30 patients, while only 11 patients in the intravenous tramadol group (36.66%) developed nausea or vomiting. But we could not demonstrate any significant difference in the incidence of nausea and vomiting between groups. Nausea or vomiting was treated with injection. Metoclopramide 10mg IV as needed.

Delilkan AE, Vijayan R [5] reported incidence of nausea and vomiting in 50% of patients who received 100mg tramadol epidurally for abdominal surgery. Incidence was 26.3% in patients who received 50mg tramadol and 15% in patients who received 0.25% bupivacaine. The incidence of nausea and vomiting was statistically significant when 100mg tramadol was compared with bupivacaine group.

Conclusion

A combination of intrathecal tramadol with bupivacaine could be used for better post operative analgesia with no major side effects like respiratory depression. This technique is simple and inexpensive. Preservative free tramadol is easily available. So, from this study, it can be concluded that intrathecal tramadol 0.5 mg/kg in combination with bupivacaine offers a simple, inexpensive and effective means of good quality post operative analgesia.

Authors Contribution

Dr. Mohamed Hussain Sait - Concept and design of the work, Data collection, Data analysis and interpretation.

Dr. Neena Thomas - Drafting the article, Critical revision of the article, Final approval of the version to be published.

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