Original Article

Major neurological complications following central neuraxial blockade – A multicentre pilot study in Aurangabad city (MGMA CNB Study)

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ABSTRACT

Background and Aims: Incidence of major neurological complications following central neuraxial blockade (CNB) in India is not known. This information is essential for explaining risk preoperatively to patients and for medico-legal purposes. This study was undertaken to assess feasibility (recruitment process, protocol adherence, resources mobilisation, data management and evaluation of scientific outcome) for planning multicentric studies on major neurological complications following CNB at state/national level. **Methods:** This was a hospital-based, multicentre pilot study, with cross-sectional and follow-up components. Patients receiving CNB either perioperatively or during acute/chronic pain management were included in the study. Thirty-six randomly selected tertiary and nontertiary care institutes were included.Details of demographic information, CNB procedure and major neurological complications were collected anonymously via online tools. Feedback about study feasibility was collected from participating anaesthesiologists and study team. **Results:** Selected institutes continued participation throughout study period. About 99.98% of eligible patients were enroled. Complete data collection of 8053 patients and analysis was possible. Regular reminders from study coordinators helped to optimise data collection. Tertiary care institutes contributed to 74.50% of data.About 64.96% patients were females. Spinal anaesthesia was the most frequently used neuraxial block (93.41%). Bupivacaine and adjuvant were used in 95.53% and 16.5% patients, respectively. Two patients developed cardiac arrest and cause-effect relationship with CNB was established. Participants' recruitment, protocol adherence, resources mobilisation, data management and evaluation of scientific outcomes were feasible. **Conclusion:** A multicentre state/nationwide study can be conducted based on this first-of-its-kind pilot study in India.

Key words: Complications, feasibility study, multicentre study, neuraxial anaesthesia, neurological manifestations, pilot study

INTRODUCTION

Central neuraxial blocks (CNBs) are widely practised in India and have a strong safety record. However, minor, transient, permanent or life-threatening complications may be observed following the procedure.

Incidence of major neurological complications ranges from 1:1000 to 1:100,000 CNBs according to available western literature.[1] One must know this to explain the risk of CNB and also to deal with medico-legal problems. Also, country-specific safety guidelines can be formulated if this data are available. Most of the available information is from studies conducted

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abroad and may not apply to Indian scenarios because of divergent anaesthetic practices, hospital settings, training programs and resources in the operation theatre.[1-4]

Indian data regarding nature, incidence and outcome of neurological complications following CNB is not available. It is not possible to collect retrospective data as there is no national board to report complications following anaesthesia in India. Estimation based on case reports or retrospective studies may underestimate incidence of major neurological complications.

Major neurological complications following CNB are rare. Large patient data from prospective multicentric studies are needed to find out the incidence, and problems might be encountered during conduct of the studies.[5,6] With this background, a pilot study is an essential prerequisite to assess feasibility of a large study.[7]

A multicentre pilot study was conducted with the primary objective to assess the feasibility to conduct a multicentre nationwide study related to neurological complications following CNB (recruitment process, protocol adherence, resources mobilisation, data management and evaluation of scientific outcome; with special emphasis on cause and effect relationship of neurological complications with CNB).

The secondary objectives were to find out i) indications, types and frequency of CNB ii) types of local anaesthetics and adjuvants used iii) drugs used for sedation andanalgesia during CNB.

METHODS

Investigators followed the methodology based on CONSORT 2010 extension guidelines, for this study.[8,9] It was a hospital-based study involving tertiary care institutes (TCI) and non-tertiary care institutes (NTCI) in the city with facilities for CNB and representing infrastructure and practice diversity. The study was coordinated by Department of Emergency Medicine of MGM medical college. Administrative permissions and ethical clearance were obtained. Written informed consent and nondisclosure agreement was obtained from institutional heads, study team and participating anaesthesiologists. Patient's consent was obtained as per standard procedure.

This was a period-based, observational, multicentre, external pilot study having two components. Component I, related to CNB profile, was a cross-sectional study. Component II, related to follow-up of complications was a prospective study. Study duration was from January 2019 to December 2020, including preplanning to report-writing period. Apart from investigators, study team comprised 22 faculty members and five advisors[Annexure 1].

Data of the patients receiving CNB were collected by anaesthesiologists from the participating institutes. Anaesthesiologists, enroled in the Indian Society of Anaesthsiologists city branch, were approached telephonically and the study purpose was explained. Details of study were e-mailed to seek willingness to participate. 50% of willing TCIs and NTCIs were selected using simple random sampling (sealed envelope method) by coordinators. A meeting was organised at the coordinating site to explain study procedure. Multilingual patient information brochures and consent forms were provided. Study coordinators allotted code numbers to institutes to collect data anonymously. Anaesthesiologists explained the purpose of study before obtaining consent from patients. In addition, an information brochure was provided to patients.

Inclusion criteria were Indian patients willing to participate by giving written informed consent, from all age groups (including paediatric age group), genders and receiving CNB (spinal, epidural, combined spinal/epidural, caudal block) during perioperative period, for acute and chronic pain management, for obstetric analgesia or obstetric analgesia and anaesthesia.

Patients receiving intravenous (I.V.) analgesics, narcotics, anxiolytics, or ketamine in analgesic doses (up to 0.5 mg/kg) during CNB and patients receiving repeat spinal/epidural anaesthesia were included in the study.

Exclusion criteria were patients receiving CNB combined with general anaesthesia. Patients in whom neuraxial block could not be administered due to technical difficulty or general anaesthesia was administered for failed block were also excluded.

This study was not intended to calculate sample size for future large-scale studies and to test any hypothesis. Sample size was not calculated for this pilot study.[7] This was a period-based observational study. Data of 8053 patients were collected over 7 months from May 1 to November 30, 2019.

Investigators and coordinators had unanimously agreed to collect data till the desired endpoints were achieved - a) reporting of at least one major neurological complication and its follow-up period along with audit committee analysis period.b) Data uploading by more than 90% of anaesthesiologists without repeated reminders.

There were three tools for CNB profile, feasibility and suggestions.

CNB profile tool (Tool I) included three Google forms (A, B, C).Form 'A' was for collecting coded information regarding patient demographics, type and indication of CNB, local anaesthetics, adjuvant, I.V. analgesics/sedatives used.Form 'B' was for reporting neurological complication. Form 'C' was for monthly follow-up of patient developing a complication till 6 months or till death, whichever was earlier. Tools for feasibility assessment (Tool II) included semi-structured feeback collected anonymously by principal investigator from participants to assess feasibility of study protocol and data uploading (patient recruitment, time required and convenience) via online pretested questionnaire.Tools III was for collecting suggestions from participating anaesthesiologists and study team members.

Data were collected online. Anaesthesiologists were instructed to upload data through Google forms link provided by investigators. Weekly reminders were sent to anaesthesiologists from coordinators. Data operators sent defaulters' information to coordinators for additional reminders. The anaesthesiologists who required repeated reminders (four or more personal calls/month) were noted by coordinators. Anaesthesiologists were requested to communicate the number of eligible patients refusing to answer the coordinator. If a patient had any major neurological complication, the concerned anaesthesiologist requested coordinator for forms 'B' and 'C'. These coded forms were forwarded to the principal investigator, who directed them to audit committee. The audit committee submitted complication analysis to the principal investigator.

Data were stored in an encrypted computer located in Emergency Medicine department. Consent forms and data would be preserved as per statutory guidelines.

Clinical outcome and feasibility criteria were defined *a priori* for a large study. Major neurological complications included were epidural abscess, bacterial meningitis, vertebral canal haematoma, paraplegia/quadriplegia, major neuropathy, wrong drug/route administration, cardiac arrest where anaesthetic/analgesic procedure was responsible for arrest as defined by Cook *et al*.[1] Neurological injury was labeled as permanent when neurological symptoms persisted beyond 6 months.[1]

A large study would be possible if study protocols were adhered to:≥70% of all eligible patients could be recruited, ≥90% of anaesthesiologists uploaded data without repeated reminders and complete data uploading of ≥90% of all recruited subjects. Reporting and analysis of all patients developing complications and their follow-up should be possible in 95% of patients for 95% of the predecided follow-up period.[10,11] Financial and human resources feasibility problems could be identified from feedbacks.

Data were extracted from Google forms in the form of MS Excel 2010. It was cleaned, coded and analysed using Statistical Package for the Social Sciences version 25 (International Business Machines USA, 2020). Quantitative data were reported as absolute numbers and percentages. Means and standard deviations were calculated wherever necessary.Chi-square test was applied and P value < 0.05 was considered significant. The feasibility and audit data were analysed separately.

The measures adopted for quality assurance of the present study were the consultation with subject experts from and outside India; legal advice by advocate; appointment of 22 study team members [Annexure 1], blinding of investigators and audit committee members; anonymous data entry and regular reminders by coordinators [Annexure 2].

RESULTS

Anaesthesiologists from all TCIs (06) and NTCIs (89) were approached. About 23 (25.85%) anaesthesiologists from NTCIs were not willing to participate for various reasons. All anaesthesiologists from 06 TCI and 66 anaesthesiologists (74.15%) from NTCI were willing to participate. As there was no similar study conducted in India, considering assumption of response distribution of 50%, anaesthesiologists from 03 TCI and 33 NTCI were selected for the study. All anaesthesiologists continued participation throughout the study period. TCI and NTCI contributed for mean 2002 and 61 patients respectively. (TCI:NTCI enrolment proportion was

32.81:1 and the difference was not statistically significant, $P = 0.15$). The feasibility assessment was analysed. About 8087 (99.98%) eligible patients were enroled.Excluding patients receiving general anaesthesia (34 patients), data of 8053 patients were analysed [Figure 1].

Investigators adhered to the study protocol.Daily data uploading was feasible but 16.2% of the participants uploaded data only after repeated reminders, due to unavoidable reasons and the large patient load of TCIs, at times. Hence, all anaesthesiologists were permitted to upload data at any time in that particular week. However, the coordinator's timely reminders were sent to ensure feasibility target.Six anaesthesiologists were allowed to upload backdated data of the previous month as they had technical or health-related problems. Apart from these minor modifications, the study protocol was strictly adhered to. Financial grant was approved by the sponsoring university. Infrastructure was provided by the coordinating institute.

A robust study team of 22 faculty members could conduct the study smoothly. However, anaesthesiologists from TCI requested additional manpower for data entry.

Feasibility feedback from anaesthesiologists, investigators, coordinators and auditors was analysed [Table 1]. Complete data of all recruited patients (100%) was uploaded, stored and analysed. TCI contributed to 74.50% of patient data in which 64.96% of the total participants were female. Out of 8053 patients, 3836 (47.63%) were females in the age group of 21-40 years and 12.56% patients were in the age group of 0–20 years [Table 2].CNB was administered in 93.63% of patients for perioperative procedures. Acute pain management in the form of obstetric analgesia alone and analgesia converted to obstetric anaesthesia was used more in NTCI patients than TCI patients.Epidural block was used for chronic pain management in 0.13% of patients [Annexure 3].

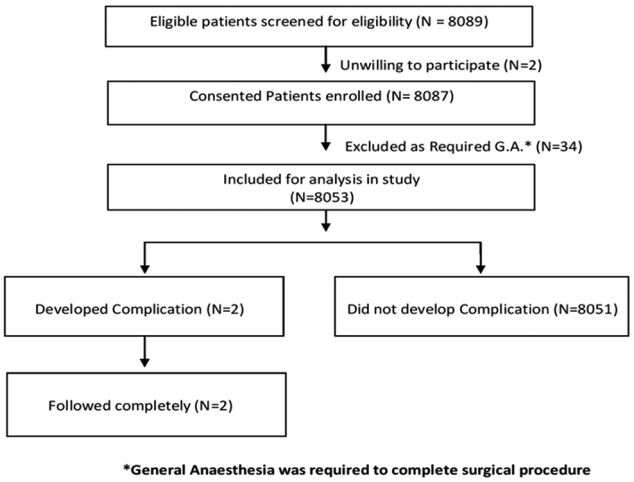

Figure 1: Flow chart of patients through the pilot study

Spinal anaesthesia was the most frequently (93.41%) used CNB in TCI and NTCI. Combined spinal-epidural was used in more patients from TCI (391 patients) and caudal was practised only from NTCI [Table 3]. Bupivacaine was used in 95.53% of patients.Five percent lignocaine was used (75-100 mg) by six anaesthesiologists. Newer local anaesthetics like ropivacaine, chloroprocaine and L-bupivacaine were used less frequently than lignocaine [Table 4]. Adjuvant was not used in 78.88% patients. Fentanyl was used most frequently.Adrenaline was used in 3 patients[Annexure 4].

About 66.93% patients (57.06% TCI and 9.87% NTCI) did not receive any I.V. supplementary drug. Midazolam (15.49%) and fentanyl (2.50%) were commonly administered. Diazepam, phenergan, tramadol, pentazocine, nalbuphine, ketamine, diclofenac and dexmedetomidine were also used.

Two patients had cardiac arrest related to CNB and were followed till death. As the second complication occurred during study period, it was also analysed. Audit committee members unanimously opined about cause–effect relationship with CNB in both events [Table 5].

DISCUSSION

Our study is the first of its kind in India, demonstrating that a large multicentre study of major neurological complications following CNB is feasible. It was successfully conducted in 36 institutes having divergent anaesthetic practices, hospital settings and resources available in the operation theatre; hence it truly represented the CNB scenario practised in the city.

We could adhere to the study protocol with minor deviations. We were able to collect online data with the help of timely reminders by the coordinators. Anaesthesiologists uploaded complete data of all recruited patients (100%). Our online tools were user-friendly and structured in such a way that all

Table 1: Feasibility Criteria and Feasibility of a Large Scale Study

Feasibility criteria	Expected	Results of the pilot study	Large scale study Feasibility
1 Recruitment			
Participation of Institutes/ Anaesthesiologists	70%	100% TCI* and 76.41% NTCI† Anaesthesiologists	Feasible
Recruitment of eligible patients	70%	99.98%	Feasible
2 Data Management			
Complete Data uploading	90%	100%	Feasible with timely reminders
Data uploading was user friendly	90%	97.3%	Feasible
Time taken for uploading information/patient	3 minutes‡	3-5 min. Time consuming for large data of TCI	Feasible. Data entry operator is needed for TCI
Data uploading complications, analysis and follow-up	Reporting 100%, follow-up 90% patients	100%	Feasible
3 Resources			
Financial and infrastructure resources	Funds for computer and payment for Data operator may not be generated for a pilot study.	Financial aid Feasible	Feasible
Additional Human Resources	Coordinators and Different study committee members are essential.	Teamwork and Coordinators played a vital role	Feasible
4. Management			
Participants (Anaesthesiologists)	90% of anaesthesiologists will upload data	97.3%, Contribution of Anaesthesiologists practicing Super speciality was less	Feasible
Reporting complications by participants, follow-up and analysis,	Skeptical about complication reporting and analysis with online tools.	All patients developing Complications were reported, followed, and analysed by audit committee members	Feasible (complication reporting, follow-up and Analysis)
5. Scientific Outcome			
Adequacy of data collection and analysis	Skeptical about collecting sufficient evidence to demonstrate the feasibility and cause-effect relationship of CNB complication	Data of 8053 patients' CNB profile and two major complications were collected. Analysis of complications was possible	Large scale study is Feasible

*TCI: Tertiary care institutes, †NTCI: Non-tertiary care institutes, ‡This was an observation of the protocol review committee, CNB: Central neuraxial block

Table 2: Demographic Data of Patients

Age Group	Female (Number of patients)			Male (Number of patients)			Total number and % of Patients
Years	TCI	NTCI	Total	TCI	NTCI	Total	
0-10	6	4	10	12	25	37	47 (0.58%)
11-20	626	66	692	225	48	273	965 (11.98%)
21-30	2315	852	3167	416	105	521	3688 (45.79%)
31-40	389	280	669	413	111	524	1193 (14.81%)
41-50	177	88	265	333	101	434	699 (8.6%)
51-60	120	38	158	266	93	359	517 (6.41%)
61-70	141	41	182	332	95	427	609 (8.67%)
Above 70	67	22	89	159	87	246	335 (4.15%)
Total (%)	3841 (47.69%)	1391 (17.27%)	5232 (64.96%)	2160 (26.82%)	661 (8.22%)	2821 (35.04%)	8053 (100.00%)

TCI: Tertiary care institutes, NTCI: Non-tertiary care institutes

information was mandatory for data uploading. Statistical analysis can be biased when more than 10% of data is missing. Anaesthesiologists did not hesitate to report the complications as data collection was anonymous. Follow-up of patients who developed cardiac arrest and establishment of cause–effect relationship with CNB was possible. We also generated financial and human resources. In the past, pilot studies were completed with limited or no funding.[12] We were able to convince the sponsoring agency for financial grant about the importance of the pilot study.

Quantitative data analysis revealed that out of 8053 patients, 47.7% females were in the age group of 21-40 years and this might have been because CNB was administered frequently for caesarean section.[13,14] About 12.45% patients less than 20 years

Table 3: Age Group and Type of CNB

Age Group	Caudal Anaesthesia			Epidural Anaesthesia			Spinal Anaesthesia			Combined Spinal Epidural Anaesthesia			Total Number (%)
	TCI	NTCI	Total	TCI	NTCI	Total	TCI	NTCI	Total	TCI	NTCI	Total	
0-10	0	14	14	0	0	0	22	11	33	0	0	0	47 (0.58)
11-20	0	0	0	6	3	9	817	111	928	28	0	28	965 (11.98)
21-30	0	0	0	14	30	44	2655	926	3581	62	1	63	3688 (45.80)
31-40	0	0	0	11	2	13	700	387	1087	91	2	93	1193 (14.81)
41-50	0	0	0	9	3	12	435	181	616	66	5	71	699 (8.68)
51-60	0	0	0	4	3	7	339	123	462	43	5	48	517 (6.41)
61-70	0	0	0	7	2	9	394	129	523	72	5	77	609 (7.56)
Above 70	0	0	0	9	1	10	188	104	292	29	4	33	335 (4.15)
Total (%)	0	14 (0.17%)	14 (0.17%)	60 (0.74%)	44 (0.54%)	104 (1.30%)	5550 (68.91%)	1972 (24.48%)	7522 (93.41%)	391 (4.85%)	22 (0.27%)	413 (5.12)	8053 (100%)

TCI: Tertiary care institutes, NTCI: Non-tertiary care institutes, CNB: Central neuraxial block

Table 4: Local Anaesthetic Agents used in Tertiary Care Institutes and Non-Tertiary Care Institutes*

Local Anaesthetic	TCI (No. of patients)	NTCI (No. of patients)	Total (No. of patients)
Bupivacaine	5702 (70.80%)	1991 (24.72%)	7693 (95.53%)
Bupivacaine and lignocaine	273 (3.39%)	30 (0.37%)	303 (3.77%)
Lignocaine (5% Hyperbaric)	13 (0.16%)	14 (0.17%)	27 (0.33%)
Chloroprocaine	1 (0.012%)	10 (0.12%)	11 (0.13%)
L-Bupivacaine	8 (0.099%)	6 (0.074%)	14 (0.19%)
Ropivacaine	3 (0.037%)	1 (0.012%)	4 (0.050%)
L-Bupivacaine and lignocaine	1 (0.012%)	0 (0%)	1 (0.012%)
Total no. of Patients	6001 (74.52%)	2052 (25.48%)	8053 (100%)

*Percentages were calculated column-wise. TCI: Tertiary care institutes, NTCI: Non-tertiary care institutes

Table 5: Major neurological complications analysed by the Audit Committee

Complication observed	*Cause and effect relation with CNB	Measures suggested for prevention
Cardiac arrest after repeat spinal anaesthesia	Event: Total spinal anaesthesia resulted after repeat spinal anaesthesia as dose of local anaesthetic exceeded the recommended dose. There was delay in recognition of total spinal anaesthesia. Outcome: Patient had cardiac arrest and hypoxic cerebral injury. Expired on 13th day due to ventilator-associated pneumonia. CNB was responsible for cardiac arrest	Possibility of total spinal anaesthesia after repeat spinal anaesthesia should be anticipated. Early recognition of total spinal anaesthesia by continuous and vigilant monitoring of vital signs including altered consciousness and immediate treatment with head-low position, administration of fluids and vasopressors along with ventilation with 100% Oxygen can prevent cardiac arrest
Cardiac arrest after combined Spinal- epidural anaesthesia (ASA II)*	Event: Large epidural bolus dose of local anaesthetic for maintenance of anaesthesia during combined spinal- epidural anaesthesia was responsible for severe hypotension. Adequacy of oxygenation could not be assessed in the patient in lateral position. Pulse Oximeter readings were not of help due to hypotension. Patient had cardiac arrest. Outcome: The patient was revived but again arrested in the intensive care unit after 40 min. CNB was responsible for cardiac arrest	Titrate level of the block by giving small incremental doses of epidural rather than administering a large bolus during maintenance with epidural anaesthesia during combined spinal-epidural block. Immediate treatment with vasopressors, fluids and adequate oxygenation can be life saving

CNB: Central neuraxial blockade, ASA: American Society of Anaesthesiologists * This patient (52 years) had a well controlled hypertension and was receiving atenolol 50 mg and amlodipine 5 mg BD. Electrocardiogram and Echocardiogram of the patient were normal

of age received CNB. Inexperience in paediatric CNB and misconceptions might be the reason for the less numbers.[15,16] Spinal anaesthesia was the most commonly administered CNB. Bupivacaine was administered in 95.53% patients and fentanyl was the adjuvant of choice as observed in other studies.[1,17] Five per cent lignocaine (75-100 mg) was used more frequently than ropivacaine, chloroprocaine and L-bupivacaine. Awareness about the use of safer agents for spinal anaesthesia needs to be reinforced.[18] Persuasion by anaesthesiologists is essential for availability of safer local anaesthetic agents in the institutes. Obstetric analgesia and anaesthesia were used in more NTCI patients than TCI as also observed by Narayanappa *et al*.[19]

Our pilot study demonstrated that a large multicentre study is feasible as all the feasibility criteria were

satisfied and we could analyse the quantitative data.Yeung *et al*.[11] followed similar feasibility criteria and concluded that a large study related to paravertebral and epidural block was possible.Choi *et al*.[10] in their study could not satisfy feasibility criteria related to perioperative effects of epidural blockade and concluded that a large study would not be feasible.

In a pilot feasibility study related to supraglottic airway assisted fibreoptic intubation, the authors assessed only the success criteria but participants' acceptability for study protocol was not assessed.[20] Feasibility criteria were not decided *a priori*. These parameters are mandatory for planning a large study[21,22] and were considered in the current pilot study.

In the present study, two patients had cardiac arrest. The details of cause–effect relationship of complication and CNB are explained in Table 5. Cardiac arrest due to total spinal anaesthesia is preventable. Extra vigilance is required when repeat spinal anaesthesia is administered, as there is an increased risk of high spinal anaesthesia.[23] Early recognition and treatment are essential.[24] Epidural top-ups of local anaesthetic should be given in small incremental doses.[25]

Coordinated teamwork was the key factor for smooth conduct of the current study. Pilot studies help to increase the validity and reliability of a future large study.[26,27] It will not be appropriate to estimate the incidence of complications from our study as major neurological complications following CNB are rare and large sample size is needed for the same.[27] Data of patients developing complications might be missed if the patient did not report to the anaesthesiologist. This is a limitation of our study.

CONCLUSIONS

We conclude that it is possible to conduct a nationwide study using our pilot study protocol, with close monitoring of data uploading. A large multicentre study is required to find out the incidence and outcome of major neurological complications following CNB. This nationwide data can be used to prepare Indian guidelines for safer use of CNB and to address medico-legal issues following complications. Information of true risk associated with the use of CNB will help patients to make an informed choice of anaesthesia.

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The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Cook TM, Counsell D, Wildsmith JAW, Royal College of Anaesthetists Third National Audit Project. Major complications of central neuraxial block: Report on the Third National Audit Project of the Royal College of Anaesthetists. Br J Anaesth 2009;102:179–90.
2. Adekola OO, Desalu I, Adekunle MO, Asiyanbi GK, Irurhe NK. Complications and outcomes following central neuraxial anesthesia in a sub-Saharan Tertiary Hospital: The legal implication. Egypt J Anaesth 2015;31:189–95.
3. Pitkänen MT, Aromaa U, Cozanitis DA, Förster JG. Serious complications associated with spinal and epidural anaesthesia in Finland from 2000 to 2009: Complications associated with neuraxial anaesthesia. Acta Anaesthesiol Scand 2013;57:553–64.
4. Toledano R, Wlody D. Serious neurologic complications of neuraxial anaesthesia procedures in obstetric patients. Available from: https://www.uptodate.com/contents/serious-neurologic-complications-of-neuraxial-anesthesia-procedures-in-obstetric-patients. [Last accessed on 2021 Sep 13].
5. Scott DB, Hibbard BM. Serious non-fatal complications associated with extradural block in obstetric practice. Br J Anaesth 1990;64:537–41.
6. Agarwal A, Kishore K. Complications and controversies of regional anaesthesia: A review. Indian J Anaesth 2009;53:543-53.
7. In J. Introduction of a pilot study. Korean J Anesthesiol 2017;70:601–5.
8. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, *et al*. CONSORT 2010 statement: Extension to randomised pilot and feasibility trials. Pilot Feasibility Stud 2016;2:64.
9. Eldridge SM, Lancaster GA, Campbell MJ, Thabane L, Hopewell S, Coleman CL, *et al*. Defining feasibility and

pilot studies in preparation for randomised controlled trials: Development of a conceptual framework. PLoS One 2016;11:e0150205.
10. Choi PT, Beattie WS, Bryson GL, Paul JE, Yang H. Effects of neuraxial blockade may be difficult to study using large randomized controlled trials: The PeriOperative Epidural Trial (POET) pilot study. PLoS One 2009;4:e4644.
11. Yeung J, Middleton L, Tryposkiadis K, Kerr A, Daniels J, Naidu B, *et al*. Randomised controlled trial to investigate the effectiveness of thoracic epidural and paravertebral blockade in reducing chronic post-thoracotomy pain (TOPIC): A pilot study to assess feasibility of a large multicentre trial. BMJ Open 2019;9:e023679.
12. Story DA, Leslie K, French C. Feasibility and pilot studies: Small steps before giant leaps. Anaesth Intensive Care 2018;46:11–2.
13. Gandhi KA, Jain K. Management of anaesthesia for elective, low-risk (Category 4) caesarean section. Indian J Anaesth 2018;62:667–74.
14. Dongare PA, Nataraj MS. Anaesthetic management of obstetric emergencies. Indian J Anaesth 2018;62:704-9.
15. Parthasarathy S, Senthilkumar T. Age-based local anaesthetic dosing in pediatric spinal anesthesia: Evaluation of a new formula - A pilot study in Indian patients. Anesth Essays Res 2017;11:627–9.
16. Bule SS, Sungandh RN, Irkhede KG, Sugandh SR. A study of spinal anaesthesia in paediatric patients of aged 2-8 years. Available from: https://jmscr.igmpublication.org/home/index.php/archive/136-volume-05-issue-03-march-2017/1988-a-study-of-spinal-anaesthesia-in-paediatric-patients-of-aged-2-8-years.[Last accessed on 2021 Jun 26].
17. Swain A, Nag DS, Sahu S, Samaddar DP. Adjuvants to local anaesthetics: Current understanding and future trends. World J Clin Cases 2017;5:307–23.
18. Chin A, Zundert AV.Spinal anesthesia – NYSORA. Available from: https://www.nysora.com/techniques/neuraxial-and-perineuraxial-techniques/spinal-anesthesia/. [Last accessed on 2021 May 05].
19. Narayanappa A, Gurulingaswamy S, Prabhakaraiah U, Kempegowda K, Hanumantharayappa NB. Practice of labour analgesia amongst anaesthesiologists across India: Cross-sectional study. Anesth Essays Res 2018;12:651–6.
20. Lim WY, Fook-Chong S, Wong P. Comparison of glottic visualisation through supraglottic airway device (SAD) using bronchoscope in the ramped versus supine "sniffing air" position: A pilot feasibility study. Indian J Anaesth 2020;64:681–7.
21. Mbuagbaw L, Kosa SD, Lawson DO, Stalteri R, Olaiya OR, Alotaibi A, *et al*. The reporting of progression criteria in protocols of pilot trials designed to assess the feasibility of main trials is insufficient: A meta-epidemiological study. Pilot Feasibility Stud 2019;5:120.
22. Jones TA, Olds TS, Currow DC, Williams MT. Feasibility and pilot studies in palliative care research: A systematic review. J Pain Symptom Manage 2017;54:139-51.
23. Parikh KS, Seetharamaiah S. Approach to failed spinal anaesthesia for caesarean section. Indian J Anaesth 2018;62:691–7.
24. Sivanandan S, Surendran A. Management of total spinal block in obstetrics. Available from: https://resources.wfsahq.org/wp-content/uploads/uia34-Management-of-total-spinal-block-in-obstetrics.pdf. [Lastaccessed on 2021 Jun 25].
25. Ranasinghe JS, Elyad Davidson E, and Birnbach DJ. Combined spinal-epidural anesthesia- NYSORA. Available from: https://www.nysora.com/regional-anesthesia-for-specific-surgical-procedures/abdomen/combined-spinal-epidural-anesthesia/. [Last accessed on 2021 Jun 21].
26. Malmqvist J, Hellberg K, Möllås G, Rose R, Shevlin M. Conducting the pilot study: A neglected part of the research process? Methodological findings supporting the importance of piloting in qualitative research studies. Int J Qual Methods 2019;8.doi: 10.1177/1609406919878341.
27. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, *et al*. A tutorial on pilot studies: the what, why and how. BMC Med Res Methodol 2010; 10:1.

CNB STUDY (ANNEXURE 1)

Study Team Members

MGMA CNB Study Team Members (Annexure 1)

Advisors:

Name	Designation	Institute
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Dr. Nithya Gogtay	Professor, Department of Clinical Pharmacology	Seth GS Medical College and KEM Hospital, Mumbai
Dr. Sudhir Kulkarni	Professor and Head, Department of Nephrology	MGM Medical College, Aurangabad
Dr. Avinash Ratnaparkhi	Consultant in Intensive Care	Darlington Memorial Hospital, UK
Adv. Sanjay Hivarekar	Senior Advocate	High Court, Aurangabad

Protocol Evaluation Committee Members:

Name of expert	Designation	Institute
Dr. Shobhana J. Baride	Professor, Anaesthesiology	P. Vikhe Patil Medical College, Ahmednagar
Dr. Seema A. Pandhare	Senior Anathesiologist	Dr. Hedgewar Hospital, Aurangabad
Dr. Renu M. Chauhan	Senior Anathesiologists	Dr. Hedgewar Hospital, Aurangabad
Dr. Pramod V. Bhale	Professor, Anaesthesiology	MGM Medical College, Aurangabad
Dr. Shubhada A. Patil	Assoc. Professor, Anaesthesiology	IIMSR, Badnapur, Jalna
Dr. Madhuri P. Lonikar	Assoc. Professor, Anaesthesiology	IIMSR, Badnapur, Jalna
Dr. Sonal A. Chaudhari	Assoc. Professor, Anaesthesiology	Govt. Medical College & Cancer Hospital Aurangabad

Study Coordinators:

Name	Designation	Institute
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Dr. Samiksha V. Kapre	Clinical Assistant, Department of Emergency Medicine	MGM Medical College and Hospital, Aurangabad
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Audit Committee Members:

Name	Designation	Institute
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Dr. Makarand M. Kanjalkar	Chief Neurologist	Manik Hospital & Research Centre Aurangabad
Dr. Deepak S. Bhosle	Professor & Head, Clinical Pharmacology & Therapeutics	MGM Medical College, Aurangabad
Dr. Surekha S. Shinde	Professor & Head, Anaesthesiology	Govt. Medical College & Cancer Hospital Aurangabad
Dr Ishtyaque A. Ansari	Professor of Neuro-surgery	MGM Medical College, Aurangabad
Dr. Shubhangi V. Shetkar	Senior Radiologist	Mangal Medi Centre, Aurangabad

Adjudication Committee Members:

Name	Designation	Institute
Dr. Anirudha D. Gulanikar	Professor, Dermatology	MGM Medical College, Aurangabad
Dr. Sachin S. Kale	Professor and Head, Pathology	MGM Medical College, Aurangabad
Dr. Sangita R. Phatale	Professor, Physiology	MGM Medical College, Aurangabad
Dr. Deepali M. Vaishnav	Professor, Biochemistry	MGM Medical College, Aurangabad
Dr. Bhavna P. Joshi	Assistant Professor, Community Medicine	MGM Medical College, Aurangabad

Study Assistant:

Name	Department	Institute
Mr. Syed Jafar	Sr. Clerk, Department of Emergency Medicine	MGM Medical College and Hospital, Aurangabad

CNB STUDY (ANNEXURE 2)

Quality Assurance Measures

1. Three research experts from India and two from other countries were consulted during study. Legal aspects were dealt by senior advocate.
2. Appointment of committees - Google forms were generated after approval by Protocol evaluation committee, comprising seven experienced anaesthesiologists from different institutes.Adjudication committee of six faculty members monitored the study process periodically. Audit committee comprising seven experts from Anaesthesiology, Neurology, Neurosurgery, Radiology, Surgery and Pharmacology analysed the complication and established cause–effect relationship with CNB.
3. Investigators adhered to protocol.
4. All study members except coordinators were blinded for data identification
5. Data Collection–Data was collected anonymously. Timely reminders and follow-up of defaulters improved data collection.
6. Data Reporting – All information in the form was mandatory. This assured complete data reporting.
7. No hesitation in reporting of the complications because of data anonymity.
8. Involvement of three study coordinators helped insmooth conduct of project.

CNB STUDY (ANNEXURE 3)

Indications for Central neuraxial block (CNB)

Obstetric analgesia and obstetric analgesia extended to anaesthesia was used in more patients of TCI than NTCI. This was the only modality of acute pain management.

Indications of Central Neuraxial Blocks				
Type	**TCI**	**NTCI**	**Number of patients**	**Percentage of patients***
Perioperative CNB	5825	1715	7540	93.63%
Obstetric analgesia	90	69	159	1.97%
Obstetric analgesia and anaesthesia	78	264	342	4.24%
Chronic pain management	8	4	12	0.13%
Total	6001	2052	8053	100%

*Percentages are calculated column-wise.

- TCI: Tertiary Care Institute; NTCI: Non-Tertiary Care Institute

CNB STUDY (ANNEXURE 4)

Adjuvant was used more in patients of TCI whereas Buprenorphine was used more in NTCI patients. Adrenaline was used in only three patients.

Adjuvant used during CNB

Adjuvant used with Local Anesthetic	**TCI**	**NTCI**	**Total number of patients**	**Total percentage of patients**
Not received any adjuvant	4624	1730	6353	78.88%
Fentanyl	1082	253	1335	16.5%
Clonidine	260	46	306	3.9%
Buprenorphine	29	23	52	0.65%
Adrenaline	3	0	3	0.037%
Triamcinolone*	3	0	4	0.037%
Total	6001	2052	8053	100%

*Triamcinolone was used with Bupivacaine for Chronic backache management