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Converting Regional Anaesthesia Database into Publication: A Step-based Approach

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Abstract

The article discusses the benefits of regional anaesthesia (RA) and the role of point-of-care ultrasound (POCUS) in enhancing its safety and efficacy. Conducting randomized controlled trials (RCTs) to establish the efficacy of RA remains a challenge due to resource constraints and ethical considerations. The author suggests that focusing solely on RCTs can be counterproductive and advocates for the importance of other forms of research, such as case series, practice audits, and prospective observational cohort studies. These forms of research can provide a background and rationale for designing future RCTs and can help broaden the scope of research beyond the idealistic RCT paradigm. The passage also includes a table highlighting the pros and cons of different study designs. Overall, the article emphasizes the importance of expanding the scope of research to improve the safety and efficacy of RA.

Keywords: Regional anaesthesia, Point-of-care ultrasound, Randomized controlled trials, Case series, Practice audits, Prospective observational cohort studies, Efficacy, Safety

The benefits of regional anaesthesia (RA) in terms of reduced postoperative pain, reduced surgical stress response, early mobilization, improved functional outcomes and reduced length of hospital stay are time-honored and doctrinal even for a naive anaesthesiologist [1]. The advent and widespread availability of point-of-care ultrasound (POCUS) has proved to be an unparalleled boon and tool in the armamentarium of a RA enthusiast [2, 3]. Apart from improving the safety and efficacy of customary blocks; sono visualization of nerves, plexuses and facial planes alongside real-time visualization of needle advancement and drug distribution has opened a Pandora's box full of never ending newer techniques [4]. Though shown to be effective and safe within the closed boundaries of an operation suite, translating their clinical observation into evidence remains a dream of innovators and connoisseurs of RA techniques. No denying the fact that well-conducted randomized controlled trials (RCT) provide the highest level of evidence; the time, resources and training required to undertake a RCT make them out of reach of most, especially in resource poor and stand-alone facilities [5]. The ethical conundrum of subjecting a subset of patients to a placebo group creates another roadblock in securing ethical clearance for a RA RCT: To illustrate with an example, ethics committee of an institute recently raised a concern over subjecting a group of patients to sham block in a RCT aiming to evaluate the analgesic efficacy of serratus anterior plane block for postoperative pain in patients undergoing breast surgeries under general anaesthesia.

Keeping a tunnel vision and synonymizing research with an RCT hence makes research forbidden waters for many; contributing to a dearth of RA research especially from resource constrained settings. On the contrary, what's important is to broaden one's horizon to focus upon the less-shiny but non-invaluable treasure base upon which the crown gem of RCT rests (Figure 1). Case resorts, case series (usually three or more cases), practice audits and prospective observational cohort studies are time-immemorial and well recognized forms of peer-reviewed literature which have brought many

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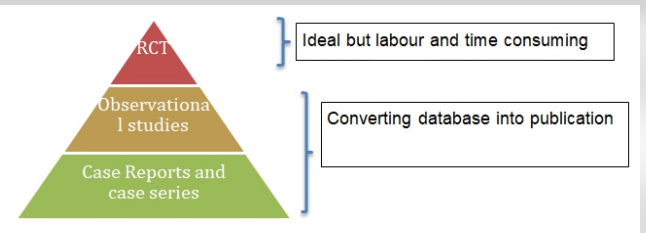

Figure 1: Hierarchy of evidence

quintessential scientific discoveries into limelight. This not only shifts the focus from what's ideal to what's achievable and available but also provides a background, rationale and hypothesis on which to design future RCTs. Another way to address above concern is to design research in a way to include either a control arm that only includes general anaesthesia or a comparison of two different regional anaesthesia techniques. Table 1 highlights some of the pros and cons of above study designs [6].

Below are some of useful pointers to reflect upon when preparing the manuscript:

- Indication: Unbacked by the bias-control processes inherent to a RCT, novelty and transparency are the hallmark of these non-experimental designs. A novel procedure or novel indication, consideration or approach to an established procedure are usual indications which fall under the purview of these designs.
- Prospective, systematic and transparent record of findings: What's come in handy is the researcher's zeal to document each and every finding prospectively and recognize the emerging trends [7]. The academy of regional anaesthesia of India (AORA) (https://www.aoraindia.com/downloads.php) provides a list of useful resources and downloads ranging from pre-procedure checklist, consent form, and a logbook template, with later two coming in handy when converting a database into a publication. A uniform format such as one promoted by AORA ensures prospective, systematic, transparent and complete real time recording of findings brushing away the evils of recall and reporting bias.
- Reporting guidelines: Reporting guidelines provide a structured format and checklist of important elements of a manuscript and where to document. The EQUATOR (Enhancing the Quality and Transparency of health research) network website (https://www.equator-network.org/) maintained by the Centre for Statistics in Medicine, University of Oxford offers a one-stop reference point for various study designs and reporting guidelines to be adhered to for each of them. Table 2 highlights various study designs, recommended reporting guidelines and a link to each of them.
- Selecting Journal: It is important to ensure that the manuscript is in line with the aims and scope of a journal. A 2021 bibliometric analyses of RA research across major biomedical databases provides a list of top 50 journals with major focus of RA; top ones being Anaesthesia and analgesia, Acta Anaesthesiologica Scandinavica, Anaesthesiology, British Journal of Pain and Regional Anaesthesia and Pain Medicine [8]. Besides, recent times have seen the emergence of a number of journals dedicated solely for case reports with acceptance rates higher than that of other journals [9, 10].
- Clinical images: Clinical images depicting fluoro-or sono-anatomy, needle trajectory, drug distribution supplement the theoretical description and help the readers to visualize and contextualize what the authors observed and want to depict. It is critical for all images to be anonymized, untampered and respectful to the and consented for by the patients [14].
- The following datasets are required for research in regional anaesthesia and are available on AORA website ("https://www.aoraindia.com/downloads.php"https://www.aoraindia.com/downloads.php).

Table 1: Pros and Cons of converting database into practice

Pros	Cons
Depict findings in real-world setting compared to controlled environment of a RCT	No control
Requires less time	Cannot be used to make practice or policy recommendations
Ethics clearance usually not required for case reports and case series (although institutional practices might differ)	Subject to reporting bias. Prospective Observational or retrospective studies need ethical approval and CTRI registration as well
Less resource intensive	Selection bias
Helps in generating research questions and hypothesis for future RCT	Low acceptance rate by high impact factor journals
Good starting point for novice researchers	Might not be accepted by institutions for promotions and appraisals

Table 2: Study designs and reporting guidelines

Study design	Reporting guideline	Link to checklist
Case Report and case Series	CARE (Consensus- Based Clinical Case Reporting) guidelines [11]	https://static1.squarespace.com/static/5db7b349364ff063a6c58ab8/t/5db7bf175f869e5812fd4293/1572323098501/CARE-checklist-English-2013.pdf
Observational studies	STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement [12]	https://www.equator-network.org/wp-content/uploads/2015/10/STROBE_checklist_v4_combined.pdf
Randomized trials	CONSORT statement [13]	https://www.elsevier.com/__data/promis_misc/CONSORT-2010-Checklist.pdf

Must Have	Good to have	Nice to have
1) Demographic details with procedural consent	BMI(Body mass index)	Point of LA deposition: intraneural/subparaneural/ Fascial plane/circumneural
2) Diagnosis with Anaesthesia care plan	Contact number to follow up for complications	Innervation of the surgical area
3) Approach to target nerves: Landmark/Peripheral nerve stimulator guided/USG guided	Sono-anatomy of target area: expected/Actual	Procedural sedation Drug/Dose/Concentration
4) Procedural data: Drug/Volume/concentration Single shot/continuous catheter	Needle used: Gauge/Length/Stimulating/ echogenic	Duration of surgery
5) Targeted nerves/spared nerves	Patient position	Equipment settings
6) Onset and Duration of sensor/motor blockade	Rescue block/Analgesia/alternate anaesthesia technique	Aseptic precaution details Skin/probe/coupling medium
7) Block-related complications; immediate/LAST/delayed	The extent of surgical stimuli: Skin/Muscle/Bone	Comorbidities

Conclusion:

The advent of ultrasonography has led to an unprecedented advent of new and new RA techniques and procedures everyday. Although RCTs provide highest level of evidence required to make policy and practice recommendations; the time, resources, training and ethical requirements make them out of reach of many especially in stand-alone, resource constrained settings. The need of the hour for all RA enthusiasts is to maintain a prospective, transparent and systematic record of their findings to translate the same into non-experimental study designs like case reports, case series and observational studies. To achieve the same, open-access resources and guidelines are available from a number of professional organisations like AORA and EQUATOR network. This not only provides an opportunity to naives to hone their writing skills but also provides rationale, hypothesis and training-on-the go to conduct RCTs later on.

References

[1] Hutton M, Brull R, Macfarlane AJR. Regional anaesthesia and outcomes. BJA Educ. 2018 Feb;18(2):52-56.

[2] Chin KJ, Mariano E, El-Boghdadly KE. Advancing towards the next frontier in regional anaesthesia. Anaesthesia 2021; 76(S1): 3–7.

[3] Shelley BG, Anderson KJ, Macfarlane AJR. Regional anaesthesia for thoracic surgery: what is the PROSPECT that fascial plane blocks are the answer? Anaesthesia 2022; 77(3): 252–256.

[4] Kearns RJ, Womack J, Macfarlane AJ. Regional anaesthesia research - where to now? Br J Pain. 2022 Apr;16(2):132-135.

[5] Dohlman LE, Kwikiriza A, Ehie O. Benefits and Barriers to Increasing Regional Anesthesia in Resource-Limited Settings. Local Reg Anesth. 2020 Oct 22;13:147-158.

[6] von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol. 2008 Apr;61(4):344-9.

[7] Carey TS, Boden SD. A critical guide to case series reports. Spine (Phila Pa 1976). 2003 Aug 1;28(15):1631-4.

[8] Kayir S, Kisa A. The evolution of the regional anesthesia: a holistic investigation of global outputs with bibliometric analysis between 1980-2019. Korean J Pain. 2021 Jan 1;34(1):82-93.

[9] New journals for publishing medical case reports. Akers KG. J Med Libr Assoc. 2016;104:146–149.

[10] Sayre JW, Toklu HZ, Ye F, Mazza J, Yale S. Case Reports, Case Series - From Clinical Practice to Evidence-Based Medicine in Graduate Medical Education. Cureus. 2017 Aug 7;9(8):e1546.

[11] Gagnier JJ, Kienle G, Altman DG, Moher D, Sox H, Riley D; CARE Group*. The CARE Guidelines: Consensus-based Clinical Case Reporting Guideline Development. Glob Adv Health Med. 2013 Sep;2(5):38-43.

[12] von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol. 2008 Apr;61(4):344-9.

[13] Butcher NJ, Monsour A, Mew EJ, Chan AW, Moher D, Mayo-Wilson E, Terwee CB, Chee-A-Tow A, Baba A, Gavin F, Grimshaw JM, Kelly LE, Saeed L, Thabane L, Askie L, Smith M, Farid-Kapadia M, Williamson PR, Szatmari P, Tugwell P, Golub RM, Monga S, Vohra S, Marlin S, Ungar WJ, Offringa M. Guidelines for Reporting Outcomes in Trial Reports: The CONSORT-Outcomes 2022 Extension. JAMA. 2022;328(22):2252-2264.

[14] Sayre JW, Toklu HZ, Ye F, Mazza J, Yale S. Case Reports, Case Series - From Clinical Practice to Evidence-Based Medicine in Graduate Medical Education. Cureus. 2017 Aug 7;9(8):e1546.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his/her consent for his/her images and other clinical information to be reported in the Journal. The patient understands that his/her name and initials will not be published, and due efforts will be made to conceal his/her identity, but anonymity cannot be guaranteed.

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