Dissertation writing in post graduate medical education

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ABSTRACT

A dissertation is a practical exercise that educates students about basics of research methodology, promotes scientific writing and encourages critical thinking. The National Medical Commission (India) regulations make assessment of a dissertation by a minimum of three examiners mandatory. The candidate can appear for the final examination only after acceptance of the dissertation. An important role in a dissertation is that of the guide who has to guide his protégés through the process. This manuscript aims to assist students and guides on the basics of conduct of a dissertation and writing the dissertation. For students who will ultimately become researchers, a dissertation serves as an early exercise. Even for people who may never do research after their degree, a dissertation will help them discern the merits of new treatment options available in literature for the benefit of their patients.

Key words: Academic dissertations as topic, ethics committee, registries, research design, students, writing

INTRODUCTION

The zenith of clinical residency is the completion of the Master's Dissertation, a document formulating the result of research conducted by the student under the guidance of a guide and presenting and publishing the research work. Writing a proper dissertation is most important to present the research findings in an acceptable format. It is also reviewed by the examiners to determine a part of the criteria for the candidate to pass the Masters' Degree Examination.

The predominant role in a dissertation is that of the guide who has to mentor his protégés through the process by educating them on research methodology, by: (i) identifying a pertinent and topical research question, (ii) formulating the "type" of study and the study design, (iii) selecting the sample population, (iv) collecting and collating the research data accurately, (v) analysing the data, (vi) concluding the research by distilling the outcome, and last but not the least (vii) make the findings known by publication in an acceptable, peer-reviewed journal.[1] The co-guide could be a co-investigator from another department related to the study topic, and she/he will play an equivalent role in guiding the student.

Research is a creative and systematic work undertaken to increase the stock of knowledge.[2] This work, known as a study may be broadly classified into two groups in a clinical setting:
a. Trials: Here the researcher intervenes to either prevent a disease or to treat it.
b. Observational studies: Wherein the investigator makes no active intervention and merely observes the patients or subjects allocated the treatment based on clinical decisions.[3]

The research which is described in a dissertation needs to be presented under the following headings:

Introduction, Aim of the Study, Description of devices if any or pharmacology of drugs, Review of Literature, Material and Methods, Observations and Results, Discussion, Conclusions, Limitations of the study, Bibliography, Proforma, Master chart. Some necessary certificates from the guide and the institute are a requirement in certain universities. The students often add an acknowledgement page before the details of their dissertation proper. It is their expression of gratitude to all of those who they feel have been directly or indirectly helpful in conduct of the study, data analysis, and finally construction of the dissertation.

Framing the research question (RQ)
It is the duty of the teacher to suggest suitable research topics to the residents, based on resources available, feasibility and ease of conduct at the centre. Using the FINER criteria, the acronym for feasibility, topical interest, novelty, ethicality and relevance would be an excellent way to create a correct RQ.[4]

The PICOT method which describes the patient, intervention, comparison, outcome and time, would help us narrow down to a specific and well-formulated RQ.[5,6] A good RQ leads to the derivation of a research hypothesis, which is an assumption or prediction of the outcome that will be tested by the research. The research topic could be chosen from among the routine clinical work regarding clinical management, use of drugs e.g., vasopressors to prevent hypotension or equipment such as high flow nasal oxygen to avoid ventilation.

Review of literature
To gather this information may be a difficult task for a fresh trainee however, a good review of the available literature is a tool to identify and narrow down a good RQ and generate a hypothesis. Literature sources could be primary (clinical trials, case reports), secondary (reviews, meta-analyses) or tertiary (e.g., reference books, compilations). Methods of searching literature could be manual (journals) or electronic (online databases), by looking up references or listed citations in existing articles. Electronic database searches are made through the various search engines available online e.g., scholar.google.com, National Library of Medicine (NLM) website, clinical key app and many more. Advanced searches options may help narrow down the search results to those that are relevant for the student. This could be based on synthesising keywords from the RQ, or by searching for phrases, Boolean operators, or utilising filters.

After choosing the topic, an apt and accurate title has to be chosen. This should be guided by the use of Medical Subject Headings (MeSH) terminology from the NLM, which is used for indexing, cataloguing, and searching of biomedical and health-related information.[7] The dissertation requires a detailed title which may include the objective of the study, key words and even the PICOT components. One may add the study design in the title e.g. "a randomised cross over study" or "an observational analytical study" etc.

Aim and the objectives
The Aims and the Objectives of the research study have to be listed clearly, before initiating the study.[8] "Gaps" or deficiencies in existing knowledge should be clearly cited. The Aim by definition is a statement of the expected outcome, while the Objectives (which might be further classed into primary and secondary based on importance) should be specific, measurable, achievable, realistic or relevant, time-bound and challenging; in short, "SMART!" To simplify, the aim is a statement of intent, in terms of what we hope to achieve at the end of the project. Objectives are specific, positive statements of measurable outcomes, and are a list of steps that will be taken to achieve the outcome.[9] Aim of a dissertation, for example, could be to know which of two nerve block techniques is better. To realise this aim, comparing the duration of postoperative analgesia after administration of the block by any measurable criteria, could be an objective, such as the time to use of first rescue analgesic drug. Similarly, total postoperative analgesic drug consumption may form a secondary outcome variable as it is also measurable. These will generate data that may be used for analysis to realise the main aim of the study.

Inclusion and exclusions
The important aspect to consider after detailing when and how the objectives will be measured is documenting the eligibility criteria for inclusion of participants. The exclusion criteria must be from among the included population/patients only. e.g., If only American Society of Anesthesiologists (ASA) I and II are included, then ASA III and IV cannot be considered as exclusion criteria, since they were never a part of the study. The protocol must also delineate the setting of the study, locations where data would be collected, and specify duration of conduct of the dissertation. A written informed consent after explaining the aim, objectives and methodology of the study is legally mandatory before embarking upon

any human study. The study should explicitly clarify whether it is a retrospective or a prospective study, where the study is conducted and the duration of the study.

Sample size: The sample subjects in the study should be representative of the population upon whom the inference has to be drawn. Sampling is the process of selecting a group of representative people from a larger population and subjecting them for the research.[10] The sample size represents a number, beyond which the addition of population is unlikely to change the conclusion of the study. The sample size is calculated taking into consideration the primary outcome criteria, confidence interval (CI), power of the study, and the effect size the researcher wishes to observe in the primary objective of the study. Hence a typical sample size statement can be - "Assuming a duration of analgesia of 150 min and standard deviation (SD) of 15 min in first group, keeping power at 80% and CIs at 95% (alpha error at 0.05), a sample of 26 patients would be required to detect a minimum difference (effect size) of 30% in the duration of analgesia between the two groups. Information regarding the different sampling methods and sample size calculations may be found in the Supplementary file 1.

Any one research question may be answered using a number of research designs.[11] Research designs are often described as either observational or experimental. The various research designs may be depicted graphically as shown in Figure 1.

The observational studies lack "the three cornerstones of experimentation" – controls, randomisation, and replication. In an experimental study on the other hand, in order to assess the effect of treatment intervention on a participant, it is important to compare it with subjects similar to each other but who have not been given the studied treatment. This group, also called the control group, may help distinguish the effect of the chosen intervention on outcomes from effects caused by other factors, such as the natural history of disease, placebo effects, or observer or patient expectations.

All the proposed dissertations must be submitted to the scientific committee for any suggestion regarding the correct methodology to be followed, before seeking ethical committee approval.

Ethical considerations

Ethical concerns are an important part of the research project, right from selection of the topic to the dissertation writing. It must be remembered, that the purpose of a dissertation given to a post-graduate student is to guide him/her through the process by educating them on the very basics of research methodology. It is therefore not imperative that the protégés undertake a complicated or risky project. If research involves human or animal subjects, drugs or procedures, research ethics guidelines as well as drug control approvals have to be obtained before tabling the proposal to the Institutional Ethics Committee (IEC). The roles, responsibilities and composition of the Ethics Committee has been specified by the Directorate General of Health Services, Government of India. Documented approval of the Ethics committee is mandatory before any subject can be enroled for any dissertation in India. Even retrospective studies require approval from the IEC. Details of this document is available at: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadEthicsRegistration/Applmhrcrr.pdf.

The candidate and the guide are called to present their proposal before the committee. The ethical implications, risks and management, subjects' rights and responsibilities, informed consent, monetary aspects, the research and analysis methods are all discussed. The patient safety is a topmost priority and any doubts of the ethical committee members should be explained in medically layman's terms. The dissertation topics should be listed as "Academic clinical trials" and must involve only those drugs which are already approved by the Drugs Controller General of India. More commonly, the Committee suggests rectifications, and then the researchers have to resubmit the modified proposal after incorporating the suggestions, at the next sitting of the committee or seek online approval, as required. At the conclusion of the research project, the ethics committee has to be updated with the findings and conclusions, as well as when it is submitted for publication. Any deviation from the approved timeline, as well as the research parameters has to be brought to the attention of the IEC immediately, and re-approval sought.

Clinical trial registration

Clinical Trial Registry of India (CTRI) is a free online searchable system for prospective registration of all clinical studies conducted in India. It is owned
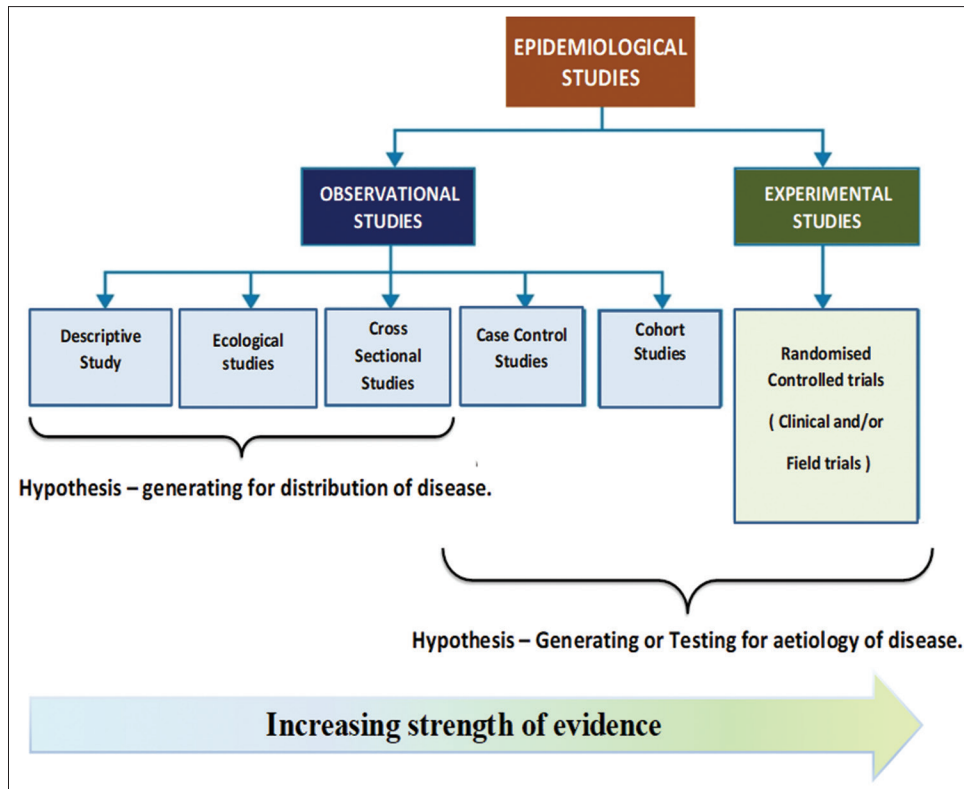
Figure 1: Graphical description of available research designs

and managed by the National Institute of Medical Statistics, a division of Indian Council of Medical Research, Government of India. Registration of clinical trials will ensure transparency, accountability and accessibility of trials and their results to all potential beneficiaries.

After the dissertation proposal is passed by the scientific committee and IEC, it may be submitted for approval of trial registration to the CTRI. The student has to create a login at the CTRI website, and submit all the required data with the help of the guides. After submission, CTRI may ask for corrections, clarifications or changes. Subject enrolment and the actual trial should begin only after the CTRI approval.

Randomisation
In an experimental study design, the method of randomisation gives every subject an equal chance to get selected in any group by preventing bias. Primarily, three basic types employed in post-graduate medical dissertations are simple randomisation, block randomisation and stratified randomisation. Simple randomisation is based upon a single sequence of random assignments such as flipping a coin, rolling of dice (above 3 or below 3), shuffling of cards

(odd or even) to allocate into two groups. Some students use a random number table found in books or use computer-generated random numbers. There are many random number generators, randomisation programs as well as randomisation services available online too. (https://www-users.york.ac.uk/~mb55/guide/randsery.htm).

There are many applications which generate random number sequences and a research student may use such computer-generated random numbers [Figure 2]. Simple randomisation has higher chances of unequal distribution into the two groups, especially when sample sizes are low (<100) and thus block randomisation may be preferred. Details of how to do randomisation along with methods of allocation concealment may be found in Supplementary file 2.

Allocation concealment
If it is important in a study to generate a random sequence of intervention, it is also important for this sequence to be concealed from all stake-holders to prevent any scope of bias.[12] Allocation concealment refers to the technique used to implement a random sequence for allocation of intervention, and not to generate it.[13] In an Indian post-graduate dissertation, the sequentially numbered, opaque, sealed envelopes
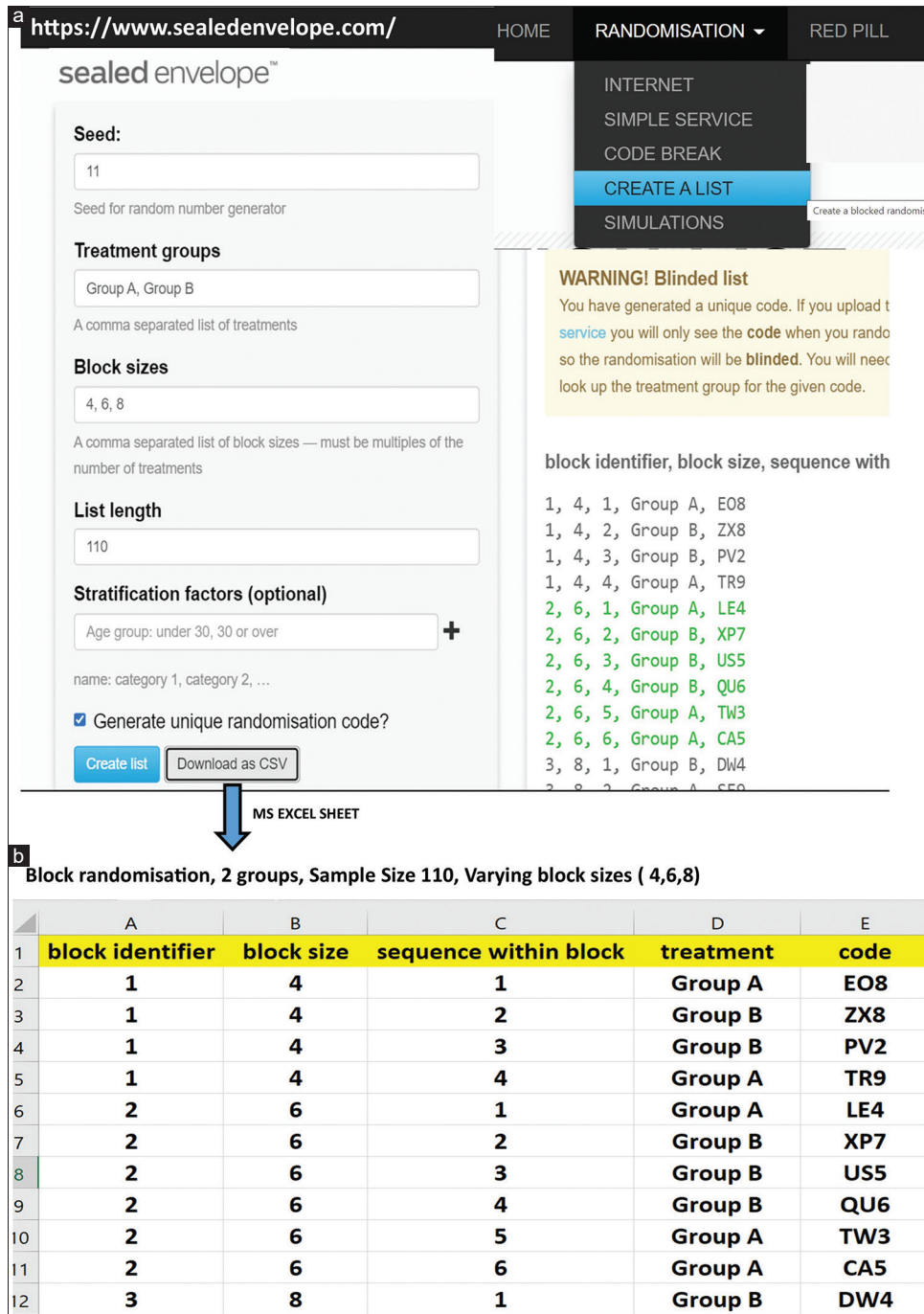
Figure 2: Figure depicting how to do block randomisation using online resources. (a) generation of a random list (b) transfer of the list to an MS excel file

(SNOSE) technique is commonly used [Supplementary file 2].

Blinding

To minimise the chances of differential treatment allocation or assessments of outcomes, it is important to blind as many individuals as possible in the trial. Blinding is not an all-or-none phenomenon. Thus, it is very desirable to explicitly state in the dissertation, which individuals were blinded, how they achieved blinding and whether they tested the success of blinding.

Commonly used terms for blinding are

- Single blinding: Masks the participants from knowing which intervention has been given.
- Double blinding: Blinds both the participants as well as researchers to the treatment allocation.
- Triple blinding: By withholding allocation information from the subjects, researchers,

as well as data analysts. The specific roles of researchers involved in randomisation, allocation concealment and blinding should be stated clearly in the dissertation.

Data which can be measured as numbers are called quantitative data [Table 1]. Studies which emphasise objective measurements to generate numerical data and then apply statistical and mathematical analysis constitute quantitative research. Qualitative research on the other hand focuses on understanding people's beliefs, experiences, attitudes, behaviours and thus these generate non-numerical data called qualitative data, also known as categorical data, descriptive data or frequency counts. Importance of differentiating data into qualitative and quantitative lies in the fact that statistical analysis as well as the graphical representation may be very different.

In order to obtain data from the outcome variable for the purpose of analysis, we need to design a study which would give us the most valid information. A valid data or measurement tool, is the degree to which the tool measures what it claims to measure. For example, appearance of end tidal carbon dioxide waveform is a more valid measurement to assess correct endotracheal tube placement than auscultation of breath sounds on chest inflation.

The compilation of all data in a 'Master Chart' is a necessary step for planning, facilitating and appropriate preparation and processing of the data for analysis. It is a complete set of raw research data arranged in a systematic manner forming a well-structured and formatted, computable data matrix/database of the research to facilitate data analysis. The master chart is prepared as a Microsoft Excel sheet with the appropriate number of columns depicting the variable parameters for each individual subjects/respondents enlisted in the rows.

Statistical analysis

The detailed statistical methodology applied to analyse the data must be stated in the text under the subheading of *statistical analysis* in the *Methods* section.The statistician should be involved in the study during the initial planning stage itself. Following four steps have to be addressed while planning, performing and text writing of the statistical analysis part in this section.

Step 1. How many study groups are present? Whether analysis is for an unpaired or paired situation?

Whether the recorded data contains repeated measurements? Unpaired or paired situations decide again on the choice of a test. The latter describes before and after situations for collected data (e.g. Heart rate data 'before' and 'after' spinal anaesthesia for a single group). Further, data should be checked to find out whether they are from repeated measurements (e.g., Mean blood pressure at 0, 1st, 2nd, 5th, 10th minutes and so on) for a group. Different types of data are commonly encountered in a dissertation [Supplementary file 3A].

Step 2. Does the data follow a normal distribution?[14]

Each study group as well as every parameter has to be checked for distribution analysis.This step will confirm whether the data of a particular group is normally distributed (parametric data) or does not follow the normal distribution (non-parametric data); subsequent statistical test selection mainly depends on the results of the distribution analysis. For example, one may choose the Student's' test instead of the 'Mann-Whitney U' for non-parametric data, which may be incorrect. Each study group as well as every parameter has to be checked for distribution analysis [Supplementary File 3B].

Step 3. Calculation of measures of central tendency and measures of variability.

Measures of central tendency mainly include mean, median and mode whereas measures of variability include range, interquartile range (IQR), SD or variance *not* standard error of mean. Depending on Step 2 findings, one needs to make the appropriate choice. Mean and SD/variance are more often for normally distributed and median with IQR are the best measure for not normal (skewed) distribution. Proportions are used to describe the data whenever the sample size is ≥100. For a small sample size, especially when it is approximately 25-30, describe the data as 5/25 instead of 20%. Software used for statistical analysis automatically calculates the listed step 3 measures and thus makes the job easy.

Step 4. Which statistical test do I choose for necessary analysis?

Choosing a particular test [Figure 3] is based on orderly placed questions which are addressed in the dissertation.[15]

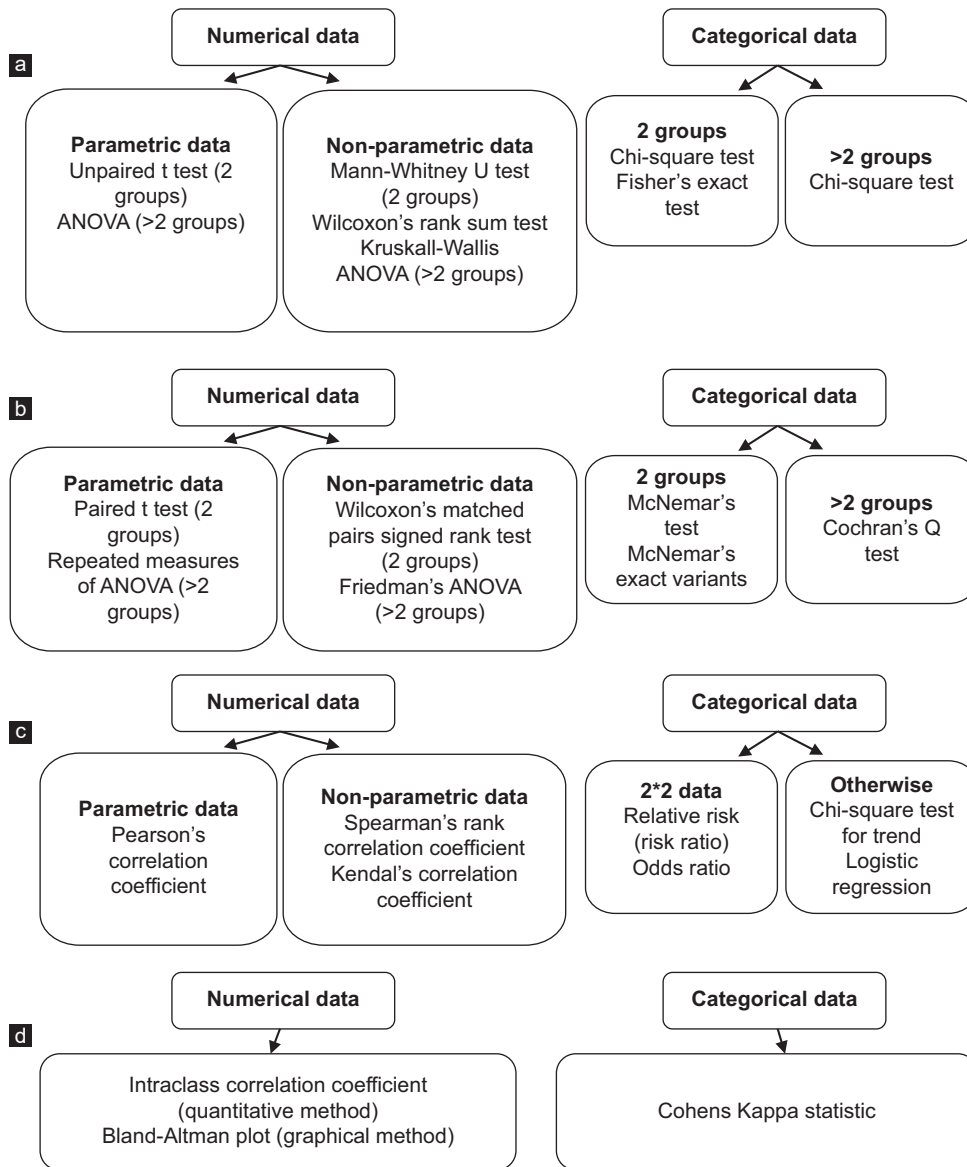A. Is there a difference between the groups of unpaired situations?

Figure 3: Chosing a statistical test, (a). to find a difference between the groups of unpaired situations, (b). to find a difference between the groups of paired situations, (c). to find any association between the variables, (d). to find any agreement between the assessment techniques. ANOVA: Analysis of Variance. Reproduced with permission from Editor of Indian Journal of Ophthalmology, and the author, Dr Barun Nayak[15]

B. Is there a difference between the groups of paired situations?
C. Is there any association between the variables?
D. Is there any agreement between the assessment techniques?

Perform necessary analysis using user-friendly software such as GraphPad Prism, Minitab or MedCalc,etc. Once the analysis is complete, appropriate writing in the text form is equally essential. Specific test names used to examine each part of the results have to be described.Simple listing of series of tests should not be done. A typical write-up can be seen in the subsequent sections of the

supplementary files [Supplementary files 3C-E]. One needs to state the level of significance and software details also.

Role of a statistician in dissertation and data analysis

Involving a statistician before planning a study design, prior to data collection, after data have been collected, and while data are analysed is desirable when conducting a dissertation. On the contrary, it is also true that self-learning of statistical analysis reduces the need for statisticians' help and will improve the quality of research. A statistician is best compared to a mechanic of a car which we drive; he knows each element of the car, but it is we who have

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to drive it. Sometimes the statisticians may not be available for a student in an institute. Self-learning software tools, user-friendly statistical software for basic statistical analysis thus gain importance for students as well as guides. The statistician will design processes for data collection, gather numerical data, collect, analyse, and interpret data, identify the trends and relationships in data, perform statistical analysis and its interpretation, and finally assist in final conclusion writing.

Results

Results are an important component of the dissertation and should follow clearly from the study objectives. Results (sometimes described as observations that are made by the researcher) should be presented after correct analysis of data, in an appropriate combination of text, charts, tables, graphs or diagrams. Decision has to be taken on each outcome; which outcome has to be presented in what format, at the beginning of writing itself. These should be statistically interpreted, but statistics should not surpass the dissertation results. The observations should always be described accurately and with factual or realistic values in results section, but should not be interpreted in the results section.

While writing, classification and reporting of the *Results* has to be done under five section paragraphs-population data, data distribution analysis, results of the primary outcome, results of secondary outcomes, any additional observations made such as a rare adverse event or a side effect (intended or unintended) or of any additional analysis that may have been done, such as subgroup analysis.

At each level, one may either encounter qualitative (n/N and %) or quantitative data (mean [SD], median [IQR] and so on.

In the first paragraph of *Results* while describing the population data, one has to write about included and excluded patients. One needs to cite the Consolidated Standards of Reporting Trials (CONSORT) flow chart to the text, at this stage. Subsequently, highlighting of age, sex, height, body mass index (BMI) and other study characteristics referring to the first table of 'patients data' should be considered. It is not desirable to detail all values and their comparison *P* values in the text again in population data as long as they are presented in a cited table. An example of this pattern can be seen in Supplementary file 3D.

In the second paragraph, one needs to explain how the data is distributed. It should be noted that, this is not a comparison between the study groups but represents data distribution for the individual study groups (Group A or Group B, separately) [Supplementary file 3E].

In the subsequent paragraph of *Results*, focused writing on results of the primary outcomes is very important. It should be attempted to mention most of the data outputs related to the primary outcomes as the study is concluded based on the results of this outcome analysis. The measures of central tendency and dispersion (Mean or median and SD or IQR etc., respectively), alongside the CIs, sample number and *P* values need to be mentioned. It should be noted that the CIs can be for the mean as well as for the mean difference and should not be interchanged. An example of this pattern can be seen in Supplementary file 3F.

A large number of the dissertations are guided for single primary outcome analysis, and also the results of multiple secondary outcomes are needed to be written. The primary outcome should be presented in detail, and secondary outcomes can be presented in tables or graphs only. This will help in avoiding a possible evaluator's fatigue. An example of this pattern can be seen in Supplementary file 3G.

In the last paragraph of the Results, mention any additional observations, such as a rare adverse event or side effect or describe the unexpected results. The results of any additional analysis (subgroup analysis) then need to be described too. An example of this pattern can be seen in Supplementary file 3H.

The most common error observed in the *Results* text is duplication of the data and analytical outputs. While using the text for summarising the results, at each level, it should not be forgotten to cite the table or graph but the information presented in a table should not be repeated in the text. Further, results should not be given to a greater degree of accuracy than that of the measurement. For example, mean (SD) age need to be presented as 34.5 (11.3) years instead of 34.5634 (11.349). The latter does not carry any additional information and is unnecessary. The actual *P* values need to be mentioned. The *P* value should not be simply stated as '*P* < 0.05'; *P* value should be written with the actual numbers, such as '*P* = 0.021'. The symbol '<' should be used only when actual *P* value is <0.001 or <0.0001. One should try avoiding % calculations for a small sample

especially when n < 100. The sample size calculation is a part of the methodology and should not be mentioned in the *Results* section.

Tables

The use of tables will help present actual data values especially when in large numbers. The data and their relationships can be easily understood by an appropriate table and one should avoid overwriting of results in the text format. All values of sample size, central tendency, dispersions, CIs and *P* value are to be presented in appropriate columns and rows. Preparing a dummy table for all outcomes on a rough paper before proceeding to Microsoft Excel may be contemplated. Appropriate title heading (e.g., Table 1. Study Characteristics), Column Headings (e.g., Parameter studied, *P* values) should be presented. A footnote should be added whenever necessary. For outputs, where statistically significant *P* values are recorded, the same should be highlighted using an asterisk (*) symbol and the same *symbol should be cited in the footnote describing its value (e.g., *P* < 0.001) which is self-explanatory for statistically significance. One should not use abbreviations such as 'NS' or 'Sig' for describing (non-) significance. Abbreviations should be described for all presented tables. A typical example of a table can be seen in Figure 4.

Graphical images

Similar to tables, the graphs and diagrams give a bird's-eye view of the entire data and therefore may easily be understood. bar diagrams (simple, multiple or component), pie charts, line diagrams, pictograms and spot maps suit qualitative data more whereas the histograms, frequency polygons, cumulative frequency, polygon scatter diagram, box and whisker plots and correlation diagrams are used to depict quantitative data. Too much presentation of graphs and images, selection of inappropriate or interchanging of graphs, unnecessary representation of three-dimensional graph for one-dimensional graphs, disproportionate sizes of length and width and incorrect scale and labelling of an axis should be avoided. All graphs should contain legends, abbreviation descriptions and a footnote. Appropriate labelling of the *x*- and the *y*-axis is also essential. Priori decided scale for axis data should be considered. The 'error bar' represents SDs or IQRs in the graphs and should be used irrespective of whether they are bar charts or line graphs. Not showing error bars in a graphical image is a gross mistake. An error bar can be shown on only one side of the line graph to keep it simple. A typical

example of a graphical image can be seen in Figure 5. The number of subjects (sample) is to be mentioned for each time point on the *x*-axis. An asterisk (*) needs to be put for data comparisons having statistically significant *P* value in the graph itself and they are self-explanatory with a 'stand-alone' graph.

Discussion

Once the results have been adequately analysed and described, the next step is to draw conclusions from the data and study. The main goal is to defend the work by staging a constructive debate with the literature.[16] Generally, the length of the '*Discussion*' section should not exceed the sum of other sections (introduction, material and methods, and results).[17] Here the interpretation, importance/

Table 1: Data collection types	
Quantitative Data Collection	**Qualitative Data Collection**
1. Experiments	1. In-depth interviews
2. Surveys	2. Observation methods
3. Interviews	3. Document review
Telephone interviews	Focus groups
Face-to-face interviews	Longitudinal studies
Computer Assisted Personal Interview (CAPI)	Case studies
4. Questionnaires	
Mail questionnaires	
Web-based questionnaires	

Table 1. Comparison of observations of analgesic and side effects between study groups.

Parameter		Group A (n = 30)	Group B (n=30)	P-value
Type of prosthesis	Ligament-preserving	16 (53%)	15 (50%)	>.99
	Posterior stabilised	14 (47%)	15 (50%)	
Sensory block in femoral nerve territory	POD1	3 (10%)	30 (100%)	<.0001*
	POD2	2 (6%)	26 (87%)	<.0001*
Pain at rest (VAS)	preoperative	0.3 [0.0-3.0]	0.0 [0.0-2.0]	0.673
	POD1	5.3 [4.0-6.4]	3.7 [2.0-4.4]	0.002*
	POD2	4.0 [2.7-5.7]	3.0 [1.3-4.4]	0.104
Opioid consumption (mg)	POD1	34 (10)	22 (8)	0.012*
	POD2	30 (10)	27 (11)	0.432
Number of patients with side effects	nausea/emesis POD1	22 (73%)	26 (87%)	0.654
	pruritus POD1	16 (53%)	19 (63%)	0.231

Footnote: Values are reported as mean (SD) or medians with 25th and 75th percentile values in square brackets, number of patients with percentage In brackets. Proportions are compared with Fisher-exact tests. Mean (SD) are compared with student 't' test. Medians are compared with Mann-Whitney U tests. Abbreviations: n = number of patients; POD = postoperative day; SD = standard deviation; VAS = visual analogue score. *P < 0.05 and statistically significant.

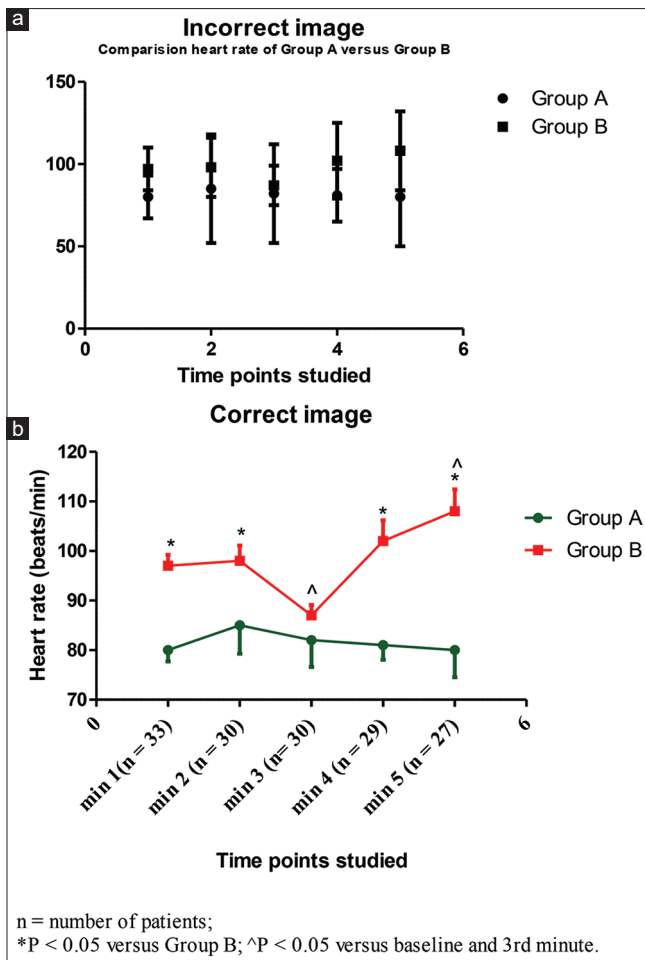**Figure 4:** Example of presenting a table

Figure 5: Example of an incorrect (a) and correct (b) image

implications, relevance, limitations of the results are elaborated and should end in recommendations.

It is advisable to start by mentioning the RQ precisely, summarising the main findings without repeating the entire data or results again. The emphasis should be on how the results correlate with the RQ and the implications of these results, with the relevant review of literature (ROL). Do the results coincide with and add anything to the prevalent knowledge? If not, why not? It should justify the differences with plausible explanation. Ultimately it should be made clear, if the study has been successful in making some contribution to the existing evidence. The new results should not be introduced and any exaggerated deductions which cannot be corroborated by the outcomes should not be made.

The discussion should terminate with limitations of the study,[17] mentioned magnanimously. Indicating limitations of the study reflects objectivity of the authors. It should not enlist any errors, but should acknowledge the constraints and choices in designing,

planning methodology or unanticipated challenges that may have cropped up during the actual conduct of the study. However, after listing the limitations, the validity of results pertaining to the RQ may be emphasised again.

Conclusion

This section should convey the precise and concise message as the take home message. The work carried out should be summarised and the answer found to the RQ should be succinctly highlighted. One should not start dwelling on the specific results but mention the overall gain or insights from the observations, especially, whether it fills the gap in the existing knowledge if any. The impact, it may have on the existing knowledge and practices needs to be reiterated.

What to do when we get a negative result?

Sometimes, despite the best research framework, the results obtained are inconclusive or may even challenge a few accepted assumptions.[18] These are frequently, but inappropriately, termed as negative results and the data as negative data. Students must believe that if the study design is robust and valid, if the confounders have been carefully neutralised and the outcome parameters measure what they are intended to, then no result is a negative result. In fact, such results force us to critically re-evaluate our current understanding of concepts and knowledge thereby helping in better decision making. Studies showing lack of prolongation of the apnoea desaturation safety periods at lower oxygen flows strengthened belief in the difficult airway guidelines which recommend nasal insufflations with at least 15 L/min oxygen.[19-21]

Publishing the dissertation work

There are many reporting guidelines based upon the design of research. These are a checklist, flow diagram, or structured text to guide authors in reporting a specific type of research, developed using explicit methodology. The CONSORT[22] and Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) initiatives,[23] both included in the Enhancing the Quality and Transparency of Health Research (EQUATOR) international network, have elaborated appropriate suggestions to improve the transparency, clarity and completeness of scientific literature [Figure 6].

All authors are advised to follow the CONSORT/STROBE checklist attached as Supplementary file 4, when writing and reporting their dissertation.
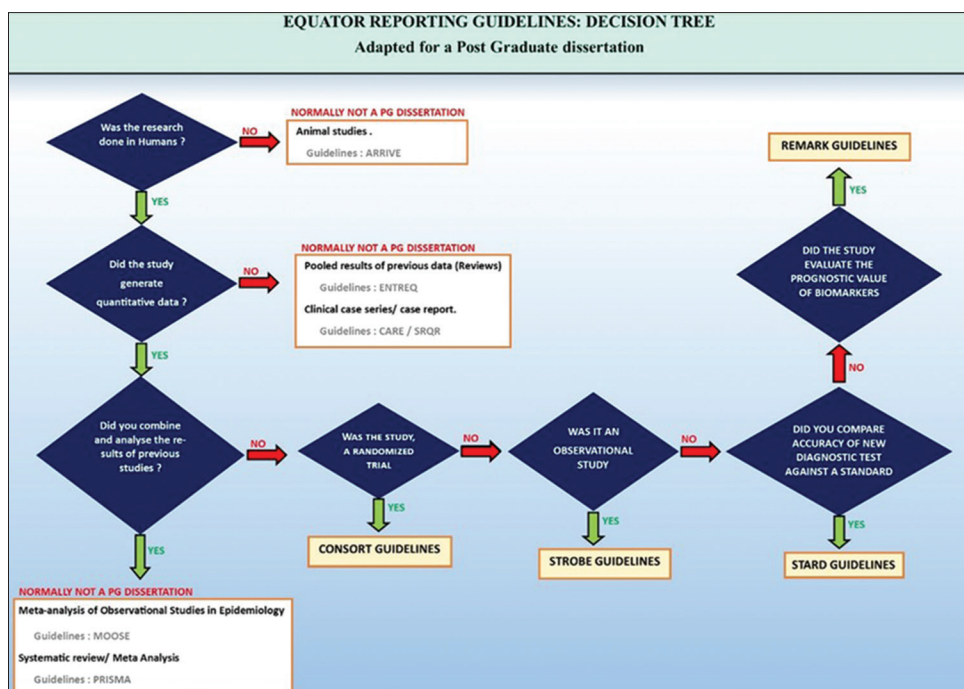
Figure 6: Equator publishing tree

For most dissertations in Anaesthesiology, the CONSORT, STROBE, Standards for Reporting Diagnostic accuracy studies (STARD) or REporting recommendations for tumour MARKer prognostic studies (REMARK) guidelines would suffice.

Abstract and Summary
These two are the essential sections of a dissertation.

Abstract
It should be at the beginning of the manuscript, after the title page and acknowledgments, but before the table of contents. The preparation varies as per the University guidelines, but generally ranges between 150 to 300 words. Although it comes at the very beginning of the thesis, it is the last part one writes. It must not be a 'copy-paste job' from the main manuscript, but well thought out miniaturisation, giving the overview of the entire text. As a rule, there should be no citation of references here.

Logically, it would have four components starting with aims, methods, results, and conclusion. One should begin the abstract with the research question/objectives precisely, avoiding excessive background information. Adjectives like, evaluate, investigate, test, compare raise the curiosity quotient of the reader. This is followed by a brief methodology highlighting only the core steps used. There is no need of mentioning the challenges, corrections, or modifications, if any. Finally,

important results, which may be restricted to fulfilment (or not), of the primary objective should be mentioned. Abstracts end with the main conclusion stating whether a specific answer to the RQ was found/not found. Then recommendations as a policy statement or utility may be made taking care that it is implementable.

Keywords may be included in the abstract, as per the recommendations of the concerned university. The keywords are primarily useful as markers for future searches. Lastly, the random reader using any search engine may use these, and the identifiability is increased.

Summary
The summary most often, is either the last part of the Discussion or commonly, associated with the conclusions (Summary and Conclusions). Repetition of introduction, whole methodology, and all the results should be avoided. Summary, if individually written, should not be more than 150 to 300 words. It highlights the research question, methods used to investigate it, the outcomes/fallouts of these, and then the conclusion part may start.

References/bibliography
Writing References serves mainly two purposes. It is the tacit acknowledgement of the fact that someone else's written words or their ideas or their intellectual property (IP) are used, in part or *in toto*, to avoid any blame of plagiarism. It is to emphasise the

circumspective and thorough literature search that has been carried out in preparation of the work.

Vancouver style for referencing is commonly used in biomedical dissertation writing. A reference list contains details of the works cited in the text of the document. (e.g. book, journal article, pamphlet, government reports, conference material, internet site). These details must include sufficient details so that others may locate and access those references.[24]

How much older the references can be cited, depends upon the university protocol. Conventionally accepted rule is anywhere between 5-10 years. About 85% of references should be dispersed in this time range. Remaining 15%, which may include older ones if they deal with theories, historical aspects, and any other factual content. Rather than citing an entire book, it is prudent to concentrate on the chapter or subsection of the text. There are subjective variations between universities on this matter. But, by and large, these are quoted as and when deemed necessary and with correct citation.

Bibliography is a separate list from the reference list and should be arranged alphabetically by writing name of the 'author or title' (where no author name is given) in the Vancouver style.

There are different aspects of writing the references.[24]

Citing the reference in the form of a number in the text. The work of other authors referred in the manuscript should be given a unique number and quoted. This is done in the order of their appearance in the text in chronological order by using Arabic numerals. The multiple publications of same author shall be written individually. If a reference article has more than six authors, all six names should be written, followed by "*et al.*" to be used in lieu of other author names. It is desirable to write the names of the journals in abbreviations as per the NLM catalogue. Examples of writing references from the various sources may be found in the Supplementary file 5.

Both the guide and the student have to work closely while searching the topic initially and also while finalising the submission of the dissertation. But the role of the guide in perusing the document in detail, and guiding the candidate through the required corrections by periodic updates and discussions cannot be over-emphasised.

Assessment of dissertations

Rarely, examiners might reject a dissertation for failure to choose a contemporary topic, a poor review of literature, defective methodology, biased analysis or incorrect conclusions. If these cannot be corrected satisfactorily, it will then be back to the drawing board for the researchers, who would have to start from scratch to redesign the study, keeping the deficiencies in mind this time.

Before submission, dissertation has to be run through "plagiarism detector" software, such as Turnitin or Grammarly to ensure that plagiarism does not happen even unwittingly. Informal guidelines state that the percentage plagiarism picked up by these tools should be <10%.

No work of art is devoid of mistakes/errors. Logically, a dissertation, being no exception, may also have errors. Our aim, is to minimise them.

SUMMARY

The dissertation is an integral part in the professional journey of any medical post-graduate student. It is also an important responsibility for a guide to educate his protégé, the basics of research methodology through the process. Searching for a gap in literature and identification of a pertinent research question is the initial step. Careful planning of the study design is a vitally important aspect. After the conduct of study, writing the dissertation is an art for which the student often needs guidance. A good dissertation is a good description of a meticulously conducted study under the different headings described, utilising the various reporting guidelines. By avoiding some common errors as discussed in this manuscript, a good dissertation can result in a very fruitful addition to medical literature.

Conflicts of interest
There are no conflicts of interest.

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Supplementary file 1. Details of sampling methods.

The sample subjects in the study should be representative of the population upon whom the inference has to be drawn and be in adequate numbers to detect a valid difference, should one exist. Sample size calculation is often performed after a pilot study or may be guided by outcomes measured in a previous similar study, called the index or parent article. When basing the sample size calculations on a parent article, students must ensure that the outcome variables under consideration are exactly the same as the primary outcome variable of the current thesis. Scientifically speaking, sample size should be calculated for primary as well as important secondary objectives. Many online sample size calculators are available which are easy to use e.g. clincalc.com, statulator.com, raosoft.com, openepi.com which also guide operators on how to calculate the sample size based upon their research design. Some common errors noted in dissertations with respect to sample size calculations include:

- Not mentioning the basis of sample size calculations at all. Mere mention of the sample size is not adequate.
- Many students consider an outcome variable of the parent article which is significantly different from outcome variables of the current project for calculation of power of the study.
- Some students document faulty or unrealistic assumptions in order to bring down sample size to manageable proportions
- Very commonly students draw conclusions on objectives even though the sample size is underpowered to detect a significant difference for the particular objective being discussed. It is of concern when this is the primary objective of their study.

Normally a study should have minimum power of 80%, and after primary analysis of data, various post hoc power analysis methods can measure it. These may be found on the websites which students use for sample size calculations in the first place. Higher the sample size, more will be the power of the study to answer the research question and more reliable will be the result. Study participants in excessive numbers may make the study more expensive and a waste of resources.

There are different ways of picking up subjects from a population for purpose of research which is called sampling. There are mainly two types of sampling methods.

Probability sampling involves random selection of subjects, but in a manner that every individual of the population has some known probability of inclusion in the sample. This sample is also likely to resemble the population from which it is drawn.

Probability sampling may be,

- Simple random sampling: This is easy to apply when small numbers are involved but needs a full list of members of the target population.
- Cluster sampling: The entire population is divided into clusters or groups and then all individuals in one cluster may be taken as the sample.
- Systematic sampling: This method fixes an interval to select members from a sampling frame, e.g. every 10th member may be chosen.
- Stratified random sampling: Involves subgrouping the population into non-overlapping groups or strata from which the sample is obtained.

Non-probability sampling: Here the chances of a subject of being selected is unknown and this may therefore result in a selection bias. However, practically for many thesis projects, probability sampling is not practical, feasible, or ethical therefore non probability sampling techniques are employed.

- Convenience sampling: As the name suggests, it is as per convenience of the investigator. It is commonly used in clinical thesis research where patients as and when meet the inclusion criteria, are recruited into the study.
- Purposive sampling: This is similar to convenience sampling but here researchers rely on their own judgment when choosing members of the population for their survey/study.
- Snowball sampling: The initial respondents are chosen by any sampling method but then the additional subjects are obtained by information provided by the initial respondents.
- Quota sampling: The investigator may desire a certain composition and mix of his population. This method ensures that the characteristics of his sample will be representative of the population to the exact extent as the investigator desires.
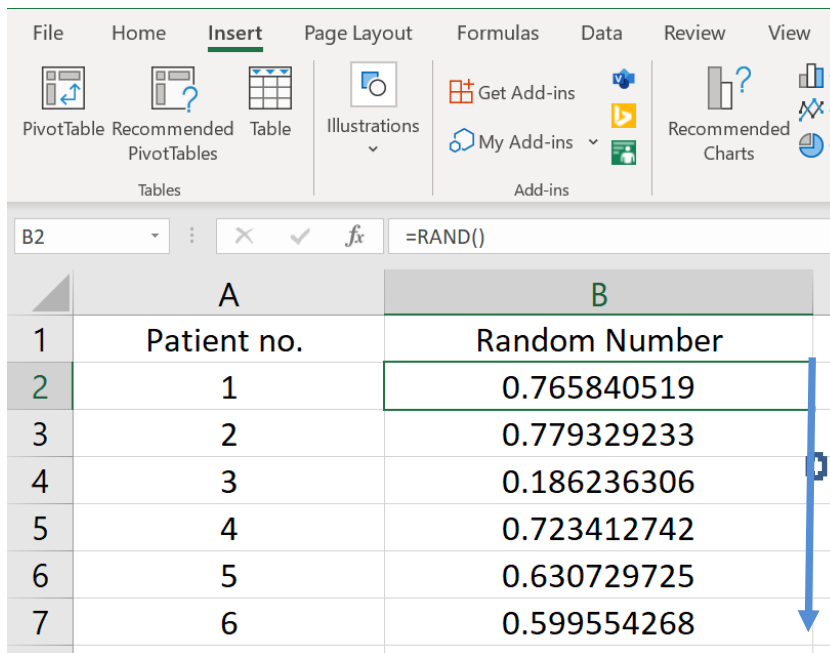
Interim analysis and stopping rule

Interim analysis is usually not very relevant for a post graduate thesis however if some trial recruits subjects over a long period of time or if an intervention is resulting in particularly adverse or favourable outcomes, an interim analysis is mandated. The study may need to be terminated early for ethical reasons in such cases. The analysis will help keep the trial free of any conflicts of interest. Considerations of cost, resource utilisation, and meaningfulness of the study are often answered after an interim analysis. An interim power analysis may suggest changes in sample size or even the study design. When reporting an interim analysis in the thesis, authors report whether the analysis was sought by the data monitoring committee or it was a self-initiated analysis. Frequency of data monitoring by researchers and what reasons triggered the interim analysis or whether such an analysis was planned in the protocol itself, before the start of the trial. They should mention the statistical tools used. This will be important if any formal stopping rule is applied. When an interim analysis is performed on initial or limited data, the implementation of the stopping rule requires more stringent P values, as compared to later analyses. The later the analysis, the stopping P values may be nearer to the nominal levels of significance. Although rarely performed in a dissertation, this information is often not included even in published trials that report stopping earlier than planned.

Supplementary file 2. Details of randomisation and allocation concealment

The simplest method of randomisation is by using computer generated random numbers. This may be performed in the Microsoft excel program by using the function =RAND() which has been entered in a cell e.g. B2 in the Figure 1(SF 2). This function generates random numbers greater than 0 but less than 1. In the figure the numbers may be seen in column B. Once a value is obtained for the function =RAND(), students can pull the right lower corner of the cell (highlighted as a blue square) to include as many random numbers as desired. The total number of random numbers desired would be equal to the sample size of the study. All cells in the column B from the 2nd row will thus have some number between 0 and 1.

Step 1.
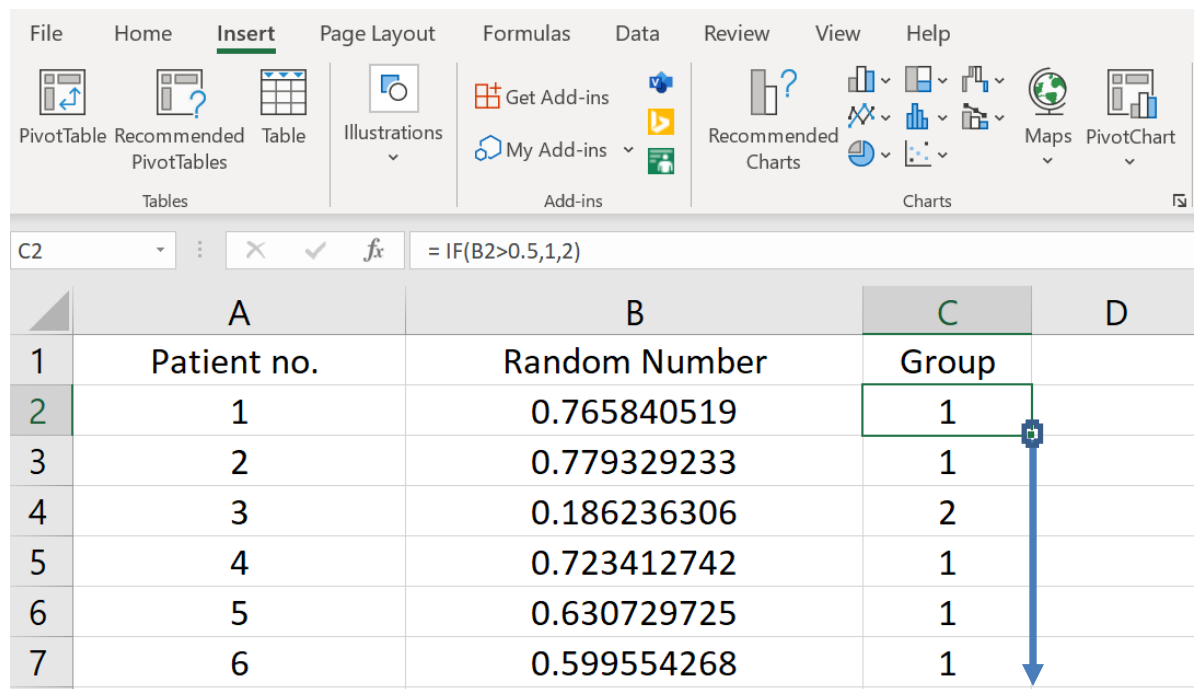
Figure 1(SF 2): Function: =RAND()

Once the random numbers have been generated, we need to allocate groups based upon these randomly generated numbers. We can decide that all numbers greater than 0.5 will be allocated group 1 and those below 0.5 will be given group 2. To segregate on this basis, we need to put in another formula in Step 2.

Step 2

By entering formula function: =IF(B2>0.5,1,2) in the cell C2, we may allot number 1 if the value of the random number in B2 is greater than 0.5, else the number allotted is 2 [Figure 2 (SF2)]. This may serve as groups 1 and 2 which can later be labelled as per the study name eg Lignocaine group and Bupivacaine group.

Figure 2(SF 2): Function =IF(B2>0.5,1,2)

There are drawbacks to this technique as chances of allocation to the two treatment arms are likely to be significantly different when the sample size is small (less than 100). It is thus preferable to use block randomisation.

Block Randomisation: This method allocates subjects into groups or blocks that result in a probability that each arm will contain an equal number of individuals by sequencing participant assignments by block. The block size must be divisible by the number of study groups. A disadvantage of block randomisation is that the allocation of participants may be predictable and result in selection bias when the study groups are unmasked.

Stratified Randomisation: Tries to address the need to control and balance the influence of covariates. Stratified randomisation is achieved by generating a separate block for each combination of covariates, and subjects are assigned to the appropriate block of covariates.

An example of a source which can serve most of the purposes of randomisation, is a website www.sealedenvelope.com. Although there are many sources of randomisation and treatment allocation online, authors have chosen this website solely as an example and it is not to endorse that this is the best available resource.

Once the website is reached, there is a drop-down tab for "RANDOMISATION" on the top panel. From this drop-down menu, "CREATE A LIST" tab has to be clicked where all details need to be filled as may be noted from Figure 3(SF2).

As an example of a study enroling 130 subjects, to utilise the service to block randomise them into two treatment groups with varying block sizes of 4,6 and 8, all the values can be fed at the desired place as may be seen in the Figure 3(SF2). There is an optional feature of stratification of the randomisation based upon factors such as age if it is likely to cause confounding. Certain surgeries like a laparoscopic cholecystectomy are more likely in females around forty. Guidance for entry of values is also provided alongside the tabs. All entire are made as may be seen with a unique Seed number which will help generate the similar sequence if re-entered.

Figure 3(SF 2). Details to be entered for creation of a block randomisation list.

Once the values have been fed as shown, the list has to be downloaded as an Excel style **CSV** format. A snapshot of the downloaded file may be seen as Figure 4(SF2). The excel sheet has columns for block identifier, block size, sequence within the block, treatment group allocated and unique randomisation code. It should be noted that patient number column is not generated by the website and the column containing patient number has been added in this [Figure 4(SF2)]. This unique list shall be available with a statistician or any other person not involved with the study. Even the statistician may be shielded from knowing the identity of treatment group.

Figure 4(SF2)

Output Excel sheet for block randomisation using online web site sealedenvelope.com

Patient No.	block identifier	block size	sequence within block	treatment	code
1	1	8	1	Group A	JX9
2	1	8	2	Group B	MN2
3	1	8	3	Group B	VL0
4	1	8	4	Group B	HM6
5	1	8	5	Group A	LL6
6	1	8	6	Group A	NT7
7	1	8	7	Group B	TQ5
8	1	8	8	Group A	AE7
9	2	8	1	Group B	NK6
10	2	8	2	Group B	KK7
11	2	8	3	Group A	LS8
12	2	8	4	Group A	OD9
13	2	8	5	Group B	GC3
14	2	8	6	Group A	IL8
15	2	8	7	Group B	PL3
16	2	8	8	Group A	CP8
17	3	4	1	Group B	JR1
18	3	4	2	Group A	LA5
19	3	4	3	Group B	VY6
20	3	4	4	Group A	FO2

Allocation concealment

The interventions (even medicines) are sometimes sealed in sequentially numbered identical envelopes/containers according to the allocation sequence.

Thus, in this case, 130 envelopes with have to be made. The paper should be reasonably thick to ensure that nothing can be read through them even after flashing light behind it. Aluminium foil inside the envelope has been used to render the envelope impermeable to light. The treatment group allocated i.e. Group A/ Group B, needs to be placed inside the envelope and the paper containing the treatment allocation group should be folded to prevent being read through the envelope. Some authors may put the unique randomisation code along with the treatment allocation e.g. Group A, JX9 inside the envelope. This envelope needs to be sealed with only the enroled patient number mentioned on the front of the envelope. The envelopes are then sequentially placed as per the enroled patient number. As and when the patients are recruited, top-most sealed envelope goes to the researcher who allots the treatment and ensures blinding. e.g. person preparing the identical drug infusions. To ensure sanctity of the process of the allocation sequence, the name and unique detail e.g. inpatient ID or birth date of the participant may be written on the envelope. Though a video tape may also be made of the sealed envelope with participant details visible, it is almost never practised for post graduate thesis work. Some authors place a carbon paper inside the envelope such that patient information is transferred onto the allocation card placed inside the envelope. An independent second researcher may later verify the sanctity of process by viewing the video tapes to ensure the envelopes were still sealed at the time of participants' names being entered on them. To ensure a fair distribution, containers should be opened sequentially and only after the subject's identification and other details are documented at all the appropriate proformas and places.

Some other methods used are: numbered or coded containers; pharmacy controlled; on-site computer systems, secure computer-assisted method where allocations are held in a locked unreadable electronic file. These criteria establish minimum methodological standards, yet they are met by only about a quarter of trials.

It is important to document who generated the allocation sequence, who enroled the participants, and who assigned participants to the interventions. This will vary with all studies, however an example of how this may be entered into the thesis is: "Simple randomisation was performed using computer generated random number list prepared using

Microsoft Excel 365 (2019) by a researcher not involved in this study. After generating the random numbers and allotment of the treatments, chits with group allocations, were sequentially placed inside an opaque envelope, sealed by the researcher and numbered. These envelopes were kept with him. After a post graduate student obtained an enroled patient's consent, he telephoned this researcher who noted all details and opened the sealed envelope. As per sequence, he directed another anaesthesiologist involved in the study but independent of the recruitment process, for allocation consignment."

Supplementary file 3A: Data classification.

Data can be classified in 3 ways,

1. **Based on variable**

```
                      ┌─────────────────────┐
                      │   Data or variable   │
                      └─────────────────────┘
                        ↙                 ↘
┌──────────────────────────┐      ┌──────────────────────────┐
│   Quantitative data      │      │    Qualitative data      │
│   (Numerical data)       │      │    (Categorical data)    │
│  Consists of numerical   │      │ Consists of attributes,  │
│  measurements and counts │      │ labels or non-numerical  │
└──────────────────────────┘      │ data                     │
        ↙          ↘              │ E.g., Mild, moderate,    │
┌────────────┐ ┌────────────┐     │ severe                   │
│  Discrete  │ │ Continuous │     │ Gender,                  │
│ E.g.,      │ │ E.g.,      │     │ Yes or no                │
│ number     │ │ Weight     │     └──────────────────────────┘
│ of patients│ │ of patients│
│ developing │ │            │
│ hypotension│ │            │
└────────────┘ └────────────┘
```
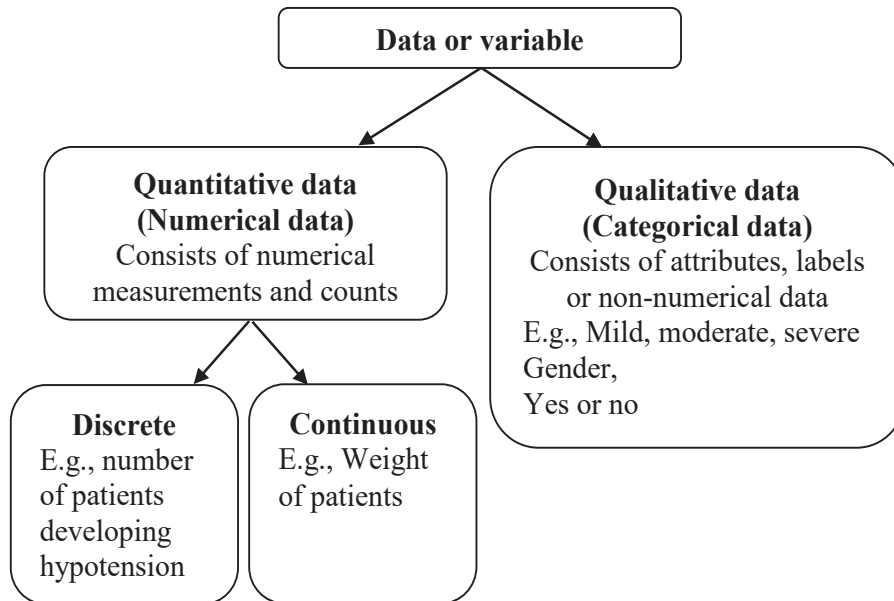
2. **Based on levels of data measurement**

Nominal	Ordinal	Interval	Ratio
E.g., name of the procedure or anaesthesia	(numerical/ non-numerical E.g., verbal rating pain scores (e.g. no pain, 0; mild pain, 1; moderate pain, 2; severe pain, 3)	E.g., Temperature measurements before and after general anaesthesia, using Celsius or Fahrenheit	E.g., The Kelvin scale: 100 K is twice as hot as 50 K
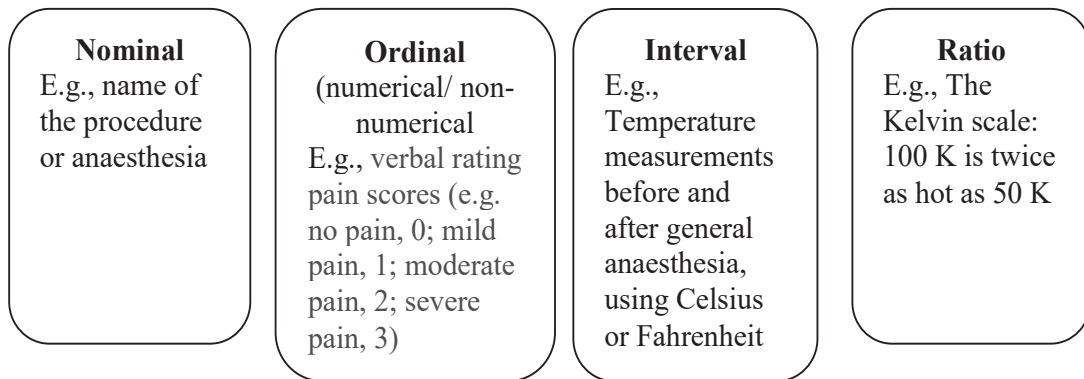
3. **Other types of classifications**
   Interval and categorical data

   Interval data: continuous and quantitative; a subtype of interval data is integer data.
   Categorical data: discrete and qualitative; comprise two subtypes: nominal and ordinal.

Supplementary File 3B: Distribution Analysis

There are different ways to inspect the data; use of frequency distribution table, use of a scatter plot etc. By visualising the plots, one can check for skewed data or an outlier that exists. The data can be normally distributed or may follow a skewed pattern. Though it is required to check and report the distribution for every parameter and outcome of

the respective group, the findings can be made concise. For example, one can write as '*all demographic data and baseline vitals were analysed for distribution using Shapiro-Wilk test and found normally distributed*'. If a specific parameter recorded data is abnormally distributed, one can consider a graph to depict it and cite it in the text, as '*all demographic data and baseline vitals were analysed for distribution using Shapiro-Wilk test and found normally distributed'; however, a skewed distribution for opioid use is observed (Shapiro Wilk test, P = 0.003, Figure 1).*'The commonly used normality tests are the Kolmogorov Smirnov test, Anderson-Darling test, D'Agostino and Pearson omnibus test or Shapiro-Wilk test. The *P*-values for each group are noted and decision on parametricity is taken.

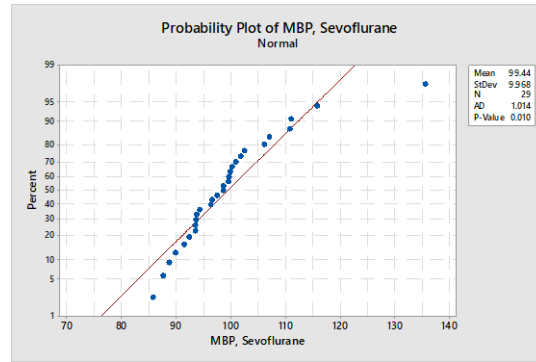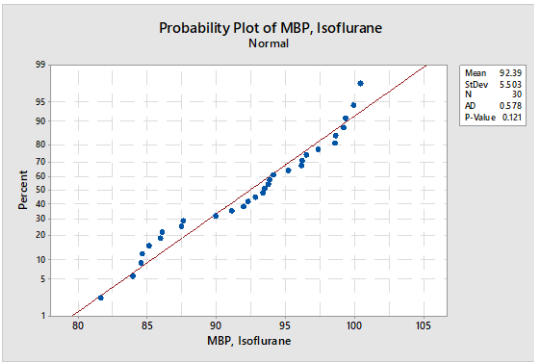**Supplementary file 3C. The pattern example for writing statistical methods used in thesis section 'Methods'.**

'The investigated parameters were assessed for normality of distribution using Shapiro-Wilk test. Data are expressed as mean (SD), median (IQR) and in proportions (%). Numerical data such as age, weight, BMI, MBP are compared between the groups, using independent sample 't' test. Categorical data such as gender distribution, type of surgery, incidence of nausea and vomiting are analysed using test of proportions or Chi-square test. For non-parametric data of any parameter studied, appropriate non-parametric test (here, Mann-Whitney U instead of t test) is used. Statistical significance was set at P < 0.05 (2-tailed). All statistical analysis were performed using Prism 5, Version 5.03, GraphPad Software, Inc. USA.'

Supplementary file 3D. The pattern example for writing text description of 'Results' section, in the first paragraph.

'Of 63 patients who underwent shoulder arthroscopic surgeries, 1 patient who refused interscalene block on operative table did not meet the inclusion criteria. Five patients who had a different operating team were excluded prior to randomisation. The remaining 57 were analysed as per protocol (CONSORT flow diagram). The groups did not differ by age, sex, weight, and pre-induction opioid use. Baseline vitals were comparable. Both groups received similar anaesthetic techniques with respect to regional or general anaesthesia. Surgical details with respect to type of surgical procedures, induction–incision time, surgical duration, initial pump pressures, and flows were comparable between the groups, Table 1.'

Supplementary file 3E. The example of a figure (and its presentation) showing distribution analysis of data. . In the presented figure, a skewed data of baseline mean blood pressure readings for sevoflurane patients is observed.

Data distribution analysis for mean blood pressure of isoflurane and sevoflurane subjects. Anderson darling test was used for analysis for each group. x-axis represent the mean blood pressure (mm of Hg). y- axis represent the percent of population. Note the outliers in second image and its P-value, which is statistically significant. Abbreviations: AD = Anderson Darling test; MBP = mean blood pressure; N = number of patients per group; StDev = standard deviation.

Supplementary file 3F. The pattern example for writing text description of 'Results' section, in the subsequent paragraph, especially for primary outcomes. Different patterns can be chosen accordingly.

Before AVP administration, (but post-induction baseline), jugular venous oxygen saturation did not differ between groups (mean difference −5.0%, 95% confidence interval [CI], −13.1% to 3.1%; P = 0.26, Table 1)

Pain scores did not differ at 6 hours with rest (mean ± SD, n; Group A, 2.0 ± 1.1, 57 vs Group P, 2.1 ± 1.2, 53; mean difference [95% CI of mean difference], 0.1 [-0.33 to 0.53]; P = 0.649) and with movement (Group A 1.6 ± 0.6, 57 vs Group P 1.5 ± 0.8, 53; 0.1 [-0.37 to 0.17]; P = 0.458, Table 1)

The primary outcome, the number of subjects requiring additional uterotonics, was similar in patients who received the oxytocin bolus (29%) compared with patients receiving the saline bolus (40%),(P = 0.11 ; odds ratio 1.65, 95% confidence interval [CI] 0.82–3.31, Table 3).

The primary end point of pain scores with active knee flexion in the operated knee at 24 h after surgery was significantly reduced in Group A compared with Group B (3 [IQR, 2.75–4.25, n = 55] vs 5 [IQR, 4–6, n = 58], P < 0.001), (Table 2).

Supplementary file 3G. The pattern example for writing text description of 'Results' section, in the subsequent paragraph, especially for secondary outcomes.

'The time until breakthrough pain (NRS > 3) was significantly longer in Group A than that in Group B (18.5 [IQR, 4–46] hours (n = 44) vs 10.0 [IQR, 3–24] hours, n = 45, P = 0.002) (Table 2).

After writing important secondary outcomes, subsequent presentation can be as follows for unimportant ones, when many secondary outcomes has to be presented in text.

'In addition, NRS pain scores at rest and with movement at 8, 12, 24 and 48 hours after surgery (Figures 2 and 3), and rate of patients with NRS > 3 with movement within 24 and 48 hours postoperatively were significantly lower in Group A than in Group B (P = 0.01, Table 2).'

Supplementary file 3H. The pattern example for writing text description of 'Results' section, in the subsequent paragraph, especially for secondary outcomes and subgroup analysis.

1. 'There was no difference between the groups in cumulative opioid consumption (milligrams of morphine equivalents) at 3, 6, 10, or 12 hours or the time to the first analgesic. The incidence of nausea was significantly higher in the A group at 6 hours, but there were no other differences in the incidence of opioid-related side effects. ; two patients out of 52 developed an episode of headache.'

2. Subgroup analyses of rest and movement pain for only patients who received a femoral nerve block are depicted in Figures 1 and 2, respectively. These analyses found that the A and B groups reported an equivalent rest and movement pain scores for all-time intervals'

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and	2a	Scientific background and explanation of rationale	
objectives	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	
Methods			
Study design	4	Present key elements of study design early in the paper	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	
		Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	
		Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed	
		Case-control study—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed	
		Case-control study—If applicable, explain how matching of cases and controls was addressed	
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	

	Item No	Recommendation	Page No
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	

Supplementary file 5. Writing the references from various sources

1. **Journals**

   Print Journals

   i. Number of authors between 1-6

       All the authors' names are listed with authors' surname up to two initials, separating each author's name with a comma. The article title with only the first letter of the article is capitalised. The title of the journal is abbreviated as per the NLM nomenclature followed by date of publication with year with all 4 numerals and first three letters of the month and date followed by volume number with issue number in the bracket, and lastly followed by page numbers in an abbreviated form.

       e.g., Panditrao MM, Panditrao MM, Fernandes AJ, Gill GS. A study of psycho-behavioral patterns in patients emerging from general anesthesia using sevoflurane, propofol and their combination in early, intermediate, and late post-operative period: A randomized controlled trial. Anesth Essays Res 2013 May; 7(2):257-62.

   ii. Number of Authors more than 6

       Everything as above with an addition of *et al* after the 6th name..

       e.g., Avasthi A, Basu D, Subodh B, Gupta P, Sidhu B, Gargi P, et al. Epidemiology of substance use and dependence in the state of Punjab, India: Results of a household survey on a statewide representative sample. Asian J Psychiatr 2018; 33:18–29. DOI: 10.1016/

   e Journals

   i. Digital Object Identifier (DOI): It is a unique identifier. It should be included wherever possible and available. Generally this alphanumeric string is included on the first page of the article in all the e journal articles. There are two ways of writing 10.25259/AUJMSR_32_2020 or http://dx.doi.org/1015259/a0024996

   ii. Everything just like print journal except the word [Internet] to be inserted after the name of the journal and the date on which this is being cited to be written after the date of publication.

Both of these to be written in square brackets [….]. the URL (web address) at the end of the reference to be written as available from URL, just before writing the DOI.

e.g., Panditrao MM, Panditrao MM. National Education Policy 2020: What is in it for a student, a parent, a teacher, or us, as a Higher Education Institution/University? Adesh Univ J Med Sci Res [Internet] 2020[cited 2021 Dec.10];2(2):70-9.Available from https://aujmsr.com/issue/2020-2-2/DOI: 10.25259/AUJMSR_32_2020

e.g., For more than 6 authors exactly same as above with names of the first 6 authors followed by *et al* to be written.

2. **Books/ Book Chapters**

Print Books: Entire Book

i. Name of the editor/s, followed by the title of the book in *italics*, number of the edition, place of publication, year of publication, page numbers in an abbreviated form.

e.g., Cousins MJ, Bridenbaugh PO (eds). Neural Blockade in Clinical Anaesthesia and Management of Pain, Philadelphia, PA: Lippincott–Raven, 1998;1113

Print Book Chapters

i. Author's surname and two initials. If more than 6 authors, then write names of the first 6 authors followed by *et al*. The editor/s name to be written followed by the title of the book in *italics*, number of the edition, place of Publication, year of publication, page numbers in an abbreviated form.

e.g., Panditrao MM, Panditrao MM. Obstetric Analgesia and Anaesthesia in High-Risk Pregnancies. In: Hemant Deshpande (Ed) High Risk Pregnancy& Delivery. 2nd ed. New Delhi, London, JayPee Brothers Medical Publishers, 2021; 340-349.

eBooks

i. Author's or editor's name/s, title of the web page followed by [Internet], place of publication, publisher of the website, year of publication [year mon date] number of the pages, Available at URL, lastly DOI.

    ii.   The rules for 1-6 names or more than 6 names, do apply here also.

        e.g., Halpen-Felsher BL, Morrell HE. Preventing and reducing tobacco use. In: Berlan ED, Bravender T, eitors. Adolescent medicine today: a guide to caring for the adolescent patient[Internet]. Singapore: World Scientific Publishing Co.; 2012 [Cited 2021 Dec 10]. Chapter 18. Available from http://www.worldscientific.com/doi/pdf/10.1142/978914324496_18

3. Government/ Corporates/ other Reports

    i.   Same rules for Name/s of authors (6 or more than 6) to be followed. In case only editor/s, their names.

    ii.   When name of the author is an organisation, government or corporate, then the name is written without 'The' preceding the name. followed by the first 2 letters of the country of origin in round brackets (..).

    iii.   Rest of the rules for books/ e books apply here.

        e.g., Rowe IL, Carson NE. Medical manpower in Victoria. East Bentleigh (AU): Monash University, Department of Community Practice; 1981. 35 p. Report No.: 4.

4. Internet

    i.   Name of the author in the order as on the website. name of the homepage as is evident on the screen. Place title followed by [internet]. The place of publication follows this. If [place unknown], then written in a square bracket. The owner of the home page is placed next along with date of publication, year followed by the date on which was cited. Lastly, Available from URL, where the endpoint is either slash (/) if there, otherwise with no full stop.

        e.g., Diabetes Australia. Diabetes globally [Internet]. Canberra ACT: Diabetes Australia; 2012 [updated 2012 June 15; cited 2012 Nov 5]. Available from: http://www.diabetesaustralia.com.au/en/ Understanding-Diabetes/Diabetes-Globally/

    ii.   In case of an image from the internet, author/organisation followed by the title of the image if known, if not, to be constructed with words followed by [image on Internet], rest as mentioned above.

5. **Dictionaries/ Encyclopaedias/ online reference site**

   i. Title of the dictionary/ encyclopaedia, followed by [Internet], place of publication, publisher, year, title of the article[updated year mon date, cited year mon date] number of page/s, Available from URL

   e.g., A.D.A.M. medical encyclopaedia [Internet]. Atlanta (Ga): A.D.A.M., INC.; c2005. Ear barotrauma; [updated2006 Oct 20; cited 2o21 Dec 10 Available from http://www.nlm.nih.gov/medlineplus/ency/article/001064.htm

6. **Audio-visual media/ web video files/ other media**

   i. Author name/s, Title[format],place of publication, year of description. Description of the item.

   e.g., Subbarao M. Tough cases of carotid stenting [DVD], Woodbury (CT); Cine-Med Inc; 2003, 1 DVD, colour, 43/4 in.

7. **Conferences/ CMEs/ Association meetings**

   i. Author/s, Title of the conference paper followed by In: editor/organisation. Title in italics, place, publisher/organiser, year, page numbers using p before the number.