Sham block in a randomised controlled trial: Is it ethical?

Sir,

When a new fascial plane block technique or a novel approach to an established block is described, its analgesic efficacy is validated in the form of a case series, radio-opaque contrast study and cadaveric dissections. However, the most appropriate way to analyse this is by conducting a well-designed, adequately powered randomised controlled trial (RCT). In an RCT, a new technique is compared with either an established standard of care, by offering no intervention to the other group or by performing a sham block. In a sham block, the same intervention is performed, i.e., the block under investigation but instead of local anaesthetic (LA) or a pharmacologically active substance, a placebo (usually normal saline) is used.[1] Over half of the published RCTs use sham blocks in their methodology; in fact, a manuscript submitted for review involving regional anaesthesia (RA) technique could suffer rejection if the editor or reviewer thinks so. The paper in such a situation must mention explicitly the reason for not performing a sham block.

Sham block is advocated by many researchers to increase the internal validity of a study by reducing the bias. The concept of using a placebo which is usually a sugar pill for oral medications and normal saline for injections is to minimise the bias by using something inert via same route. In an attempt to standardise the interventions in methodology, researchers usually perform an injection or deposit the LA and normal saline near the plexus or fascial planes. Placebo is an inert substance that does not have any therapeutic effect. When a sham block is performed, the patient gets exposed to an intervention that has no therapeutic benefit but could lead to serious harm. Other adverse events with a placebo block could be vascular puncture, bowel injury during transversus abdominis plane (TAP)/quadratus lumborum (QLB)/ilioinguinal/iliohypogastric blocks, organ damage (liver, spleen, kidney during subcostal TAP/rectus sheath/QLB blocks), pneumothorax (erector spinae plane/, paravertebral/serratus anterior plane/pectoralis blocks) and nerve injury.[2,3]

Some researchers feel that sham intervention is essential to answer the research question, i.e., if the intervention in question needs LA to produce an effect, even a placebo could work if injected in the same volume at the target area.[4]

However, Cyna *et al*. argue against venturing into a placebo intervention performed in RCTs in RA and pain medicine.[5] They suggest painting/draping the site of intervention, scanning with ultrasonography and marking the site of needle entry with a blunt needle but do not recommend sham interventions. Some say that eliminating a sham block can reduce overall procedural time.

In 2011, McGuirk *et al*. described Serious Harm and Morbidity (SHAM) scale with examples to assess the risks involved in placebo interventions by reviewing 59 RCTs.[6] On analysis, they found that more than half of the RCT designs involved interventions that could lead to risks of serious or irreversible harm to patients in control groups. Based on this, they described 4 grades: grade 0- no placebo intervention, grade 1- non-invasive placebo with minimal risk of harm, grade 2- minimally invasive placebo with the risk of minor complications, grade 3a- invasive placebo intervention with the risk of moderate complications but no placebo drug administered, grade 3b- invasive placebo with the risk of moderate complications and a placebo drug administered and grade 4- invasive placebo procedure with the risk of major complications. The role of ethics committee members in such situations cannot be overemphasised. Even if the researcher produces references describing the safety of a RA technique in question, the ethical team must carefully analyse the complexity and potential harm caused by an intervention if a sham block is part of the study methodology.

In our opinion, we feel that researchers should avoid using a sham block of any grade to avoid unwanted complications in the recruited patient. Instead of this, the block under investigation can be compared with an established standard of care technique.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Abhijit Nair, Sandeep Diwan[1]

Department of Anaesthesiology, Basavatarakam Indo-American Cancer Hospital and Research Institute, Hyderabad, Telangana, [1]Department of Anaesthesia, Sancheti Hospital, Pune, Maharashtra, India

Address for correspondence:
Dr. Abhijit Nair,
Department of Anaesthesiology, Basavatarakam Indo-American Cancer Hospital and Research Institute, Hyderabad - 500 034, Telangana, India.
E-mail: abhijitnair95@rediffmail.com

Submitted: 24-Jun-2020
Revised: 13-Jul-2020
Accepted: 27-Aug-2020
Published: 12-Dec-2020

REFERENCES

1. Mankikar MG, Sardesai SP, Ghodki PS. Ultrasound-guided transversus abdominis plane block for post-operative analgesia in patients undergoing caesarean section. Indian J Anaesth 2016;60:253-7.
2. Jeng CL, Torrillo TM, Rosenblatt MA. Complications of peripheral nerve blocks. Br J Anaesth 2010;105(Suppl 1):i97-107.
3. Salhotra R. Ultrasound-guided truncal/plane blocks: Are they safe in anticoagulated patients? J Anaesthesiol Clin Pharmacol 2020;36:118-20.
4. Kallmes DF, Buchbinder R, Miller FG. Viewpoint: Randomised controlled trials using invasive control interventions should be included in Cochrane Reviews. Cochrane Database Syst Rev 2011:ED000030. doi: 10.1002/14651858.ED000030.
5. Cyna AM, Costi D, Middleton P. Viewpoint: Randomised controlled trials using invasive 'placebo' controls are unethical and should be excluded from Cochrane Reviews. Cochrane Database Syst Rev 2011:ED000029. doi: 10.1002/14651858.ED000029.
6. McGuirk S, Fahy C, Costi D, Cyna AM. Use of invasive placebos in research on local anaesthetic interventions. Anaesthesia 2011;66:84-91.

Access this article online	
Quick response code	Website: www.ijaweb.org
	DOI: 10.4103/ija.IJA_836_20

How to cite this article: Nair A, Diwan S. Sham block in a randomised controlled trial: Is it ethical? Indian J Anaesth 2020;64:1082-3.