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.

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Letters to Editor

Indian Journal of Anaesthesia | Volume 64 | Issue 12 | December 2020

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Scapular surgery under combined thoracic paravertebral and interscalene blocks

Sir,

Scapular fractures are relatively rare (0.5-1%) and many of them are managed conservatively. Nowadays surgical fixation is preferred for better functional outcomes.

Usually general anaesthesia is required as the procedure involves extensive tissue dissection and prolonged uncomfortable positioning. We report a combined thoracic paravertebral (TPVB) and interscalene blocks (ISB) for scapular fixation. To the best of our knowledge this technique has not been reported in literature.

A 22-year-old man weighing 78 kg was posted for plate and screw fixation of a comminuted and displaced scapular body fracture. He had a run-over injury of his left chest 20 days back resulting in scapular and multiple rib fractures with left hemopneumothorax. An intercostal drain was placed which was subsequently removed. The patient was in considerable pain preoperatively. In the operation theatre intravenous access was secured and monitoring (Electrocardiogram, pulse oximetry, non-invasive blood pressure) was initiated. Ultrasound (Sonoray DS50 plus, Ultraserve systems, Chennai, India) guided TPVB was performed at T7-T8 level using a 16 G Tuohy needle (Romsons, India) on the left side in sitting position. After confirming pleural drop sign on ultrasound, a mixture of 6 ml 2% lignocaine with adrenaline, 8 ml 0.5% bupivacaine and 6 ml normal saline was injected. Subsequently a 16 G epidural catheter was introduced and fixed away from the surgical field. The patient was then turned supine and ultrasound guided interscalene block (ISB) was performed with 15 ml of 0.25% bupivacaine. After confirming absence of pain on deep palpation and skin hypoaesthesia over scapular region, the patient was positioned in right lateral with a slight anterior tilt aided by appropriate supports [Figure 1a]. The incision site was infiltrated with 10 ml of 1% lignocaine with adrenaline. Intraoperative sedation was administered with 50 \( \mu \)g of dexmedetomidine over 15 minutes followed by an infusion of 15 \( \mu \)g/hour. A bolus of 50 \( \mu \)g of fentanyl was administered as the patient complained of shivering. Open reduction and internal fixation of the scapula was done by the modified Judet posterior approach. Total blood loss was around 350 ml. The patient was arousable and comfortable throughout the surgery which lasted for 90 minutes. Position of the paravertebral catheter was confirmed postoperatively by injection of 2 ml of iohexol [Figure 1b]. A bolus of 8 ml of 0.125% bupivacaine through the catheter provided and should be excluded from Cochrane Reviews. Cochrane Database Syst Rev 2011:ED000029. doi: 10.1002/14651858.ED000029.

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