Bone & Joint Research

Tahir M, Chaudhry EA, Zaffar Z, et al. Fixation of distal radius fractures using wide-awake local anaesthesia with no tourniquet (WALANT) technique. *Bone Joint Res*. 2020;9(7):429–439.

https://doi.org/10.1302/2046-3758.97.BJR-2019-0315.R1

11 March 2021

Sir,

We are writing to express our concerns regarding the study reported by Tahir et al.[1] We note that while the manuscript contains a Consolidated Standards of Reporting Trials (CONSORT) flow diagram, there is no statement about CONSORT.[2] We have referenced the CONSORT checklist items[2] for each of our points below. In preparing this letter, we have referenced the trial registration documents (Chinese Clinical Trial Registry ChiCTR1900026870).

The study is described as a randomized controlled study, but we have several concerns with this descriptor being used (CONSORT 1a). First, the allocation ratio is not reported (CONSORT 3a, 13a). Figure 1 makes clear that 77 patients were allocated to wide-awake local anaesthesia with no tourniquet (WALANT) and 134 to Bier's block or general anaesthesia. The reason for no allocation ratio being adhered to should be stated. The trial registry document states that the planned sample sizes were 55 for WALANT, 56 for GA, and 58 for Bier's block. However, trial registration was retrospective after the 'trial' had been completed, so "planned" appears neither accurate nor honest. The combination of unequal allocation and retrospective trial registration makes one ask whether this is genuinely a 'randomized controlled trial'?

There is no power calculation described in the manuscript or in the trial registry, although the manuscript states an 80% power (CONSORT 7a). Multiple hypotheses have been tested (for example 'cost-effectiveness', 'satisfaction', operative times, blood loss, recovery time, intraoperative visual analogue scale (VAS) score, VAS score at 24 hours, hospital stay, ICU stay, frequency of oral analgesics, physiotherapy sessions, and complications). No details of specific hypotheses, including a hypothesis for the primary outcome or timepoint of primary assessment are described. The type of trial is not described (equivalence, superiority, or inferiority), nor are specific group comparisons. A power calculation would require details of trial type and which groups are to be compared. Some *a priori* data would form the basis of such a sample size/power calculation, and this should be referenced, as well as the precise method of calculating the sample size/power.

Allowing for the uncertainty about the primary outcome, no specific hypothesis with an appropriate statistical test has been described for the primary outcome as stated in either the manuscript or the trial registry documents (CONSORT 12a). Again, the primary outcome has been changed from the trial registry to the final manuscript. The data distribution is not described. It is unclear whether continuous data were screened for normality. It is likely that several of the continuous data sets – for example the patient-reported outcome measures (PROMs), pain scores, hospital stay – were non-parametric. As such, Student's *t*-tests/analysis of variance (ANOVA) are inappropriate. We note

the data are not publicly available in a data repository. It is strange that the SD of the 'satisfaction' (presumably SF-12) data is considerably smaller in the WALANT group.

There are inadequate details on the generation of the random sequence (CONSORT 8a). There are several differences between the patient characteristics in the three intervention groups which are unexplained (CONSORT 15). For example, the general anaesthesia group was older, WALANT patients had a shorter time to surgery, and the American Society of Anesthesiologists (ASA) grade mix and fracture patterns were imbalanced between groups, with a higher proportion of more complex C3 fractures in the Bier's block and general anaesthesia groups. One would expect randomization to minimize baseline differences between groups. These significant confounding factors are not explained.

The study claims to be 'double-blinded' (CONSORT 11a) which is incorrect. Patients and operating surgeons clearly knew the type of anaesthesia used during surgery from the description of the perioperative period. Outcome assessment was performed by members of the surgical team and not by independent assessors blinded to the intervention. Thus, the study was not blinded.

The abstract, manuscript, and trial registration documents conflict in terms of the primary outcome measure. The primary outcome measure is unclear from either document (CONSORT 1b, 6a, 6b). The primary outcomes in the trial registration document are multiple PROMs (Disabilities of the Arm, Shoulder and Hand Score (QuickDASH), VAS, patient-rated wrist evaluation (PRWE), Mayo Wrist Score). In the manuscript, this appears to have changed to hospital costs, but elsewhere the manuscript lists numerous other primary outcomes. This is inappropriate. There should be a single primary outcome, and this should be clearly defined in a prospectively published trial registry.

'Cost-effectiveness' is described but cost-effectiveness has not overtly been calculated. This requires a formal cost-effectiveness analysis (CEA) which has not been described. Changes to the planned methodology should be described and justified in the manuscript (CONSORT 3b). Given the observed changes between the registration document and manuscript, we would expect justification of these differences in the manuscript or supplementary material.

According to the manuscript, the trial started in March 2016 and was completed by April 2019. The trial was not registered until after the study was completed (October 2019 registration date) (CONSORT 14a and 23). This retrospective registration is highly concerning. Trial registration is carried out prospectively so that a clear research question and the study's methodology including a clear single primary outcome can be predefined in order to reduce publication bias and selective reporting. Retrospective registration is pointless as it does nothing to address selective reporting or publication bias. It is also worrying that the trial recruited the first patient in March 2016 but the trial registry document states that ethical approval was not granted until February 2017, that is 11 months later. This needs urgent clarification. Does this mean that some patients were recruited without ethical approval?

The 12-Item Short Form Survey (SF-12) has been used to measure 'satisfaction' but is a recognized measure of quality of life (CONSORT 17a). We are unsure about the method of assessing satisfaction, as well as how the described scales (SF-12, QuickDASH, PRWE, Mayo Wrist Score, Pain VAS) were administered. The VAS requires participants to mark on a line (usually of 20 cm length) where they consider their pain, satisfaction, or health lies. It seems unlikely that patients marked on a line every ten minutes intraoperatively. How was this done in practice? Was the actual scale used a numerical rating scale (NRS)? We request that the authors clarify exactly which questionnaires have been used and how they were administered. The effect size should be estimated and this should be framed within the minimal clinically important difference for the SF-12 in the manuscript.

The limitations have been inadequately described (CONSORT 20). As detailed above, there are several aspects of this study which are consistent with an extremely high risk of bias which need to be made clear. The results of the study have been overinterpreted (CONSORT 22). The primary outcome as recorded in the trial registry is no different between groups. This should be described clearly in both the abstract and conclusions. The observed differences in outcome may or may not be related to the interventions, given the baseline differences between groups in terms of age, fracture type, ASA grade, and time to surgery. This also requires clarification in the manuscript. The trial protocol is not available and, given the above concerns, we feel that the trial protocol, ethical approval documents, and raw data should be made available to the Journal's editors (CONSORT 24).

In conclusion, we have grave concerns regarding this 'randomized controlled trial' and would appreciate urgent clarification from the authors as regards these raised concerns, and if they cannot be adequately addressed there is a strong case for retraction.

B. J. F. Dean,
Senior Research Fellow and Fellow,
R. W. Trickett,
University of Oxford,
Oxford, UK.

1. **Tahir M, Chaudhry EA, Zaffar Z, et al.** Fixation of distal radius fractures using wide-awake local anaesthesia with no tourniquet (WALANT) technique. *Bone Joint Res*. 2020;9(7):429–439.
2. **Schulz KF, Altman DG, Moher D, CONSORT Group.** CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340:c332. http://www.bmj.com/content/340/bmj.c332.abstract (date last accessed 7 September 2021).

Conflicts of Interest: None

==========

Editorial Note: The authors were invited to respond and have chosen not to do so.

==========