

Letter to the Editor

Intra-articular Drain versus No Drain after Arthroscopic Anterior Cruciate Ligament Reconstruction: A Randomized Prospective Clinical Trial

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Dr Jaffar Al Bareeq
Chief Editor,
Bahrain Medical Bulletin

Dear Sir

I read with interest the publication, Intra-articular drain versus no drain after arthroscopic anterior cruciate ligament reconstruction: a randomized prospective clinical trial (Bahrain Medical Bulletin. 2008; 30(1):9-11). It is uncertain how this study (El Khalifa et al., 2008) with its methodological limitations and inconsistencies is able to contribute to the evidence-base for this intervention, or indeed build on the trial that it mirrors (McCormack 2006).

The careful design, conduct and analysis of a randomized controlled trial should seek to minimize bias such that any differences observed between participants may, apart from random error, be attributed to the intervention. Systematic bias resulting from a lack of recognition of these significant aspects of methodological quality can lead to serious over or under estimation of treatment effect sizes in clinical trials, and ultimately distort the results in systematic reviews.

In the El Khalifa et al., study the alternate or open assignment of participants to treatment arms, a form of quasi-randomization, is unlikely to have provided every participant with an equal chance of receiving one or other intervention which, together with the inadequate concealment of the allocation sequence, equates to a potential and significant source of selection bias.

The nature of the intervention and control and the difficulty of blinding participants and investigators coupled with the probability of biased outcomes assessment were some of the other challenges faced in this trial.

El Khalifa et al, indicated that “the results were evaluated through pain assessment (assessed pain) scores and analgesic counts” but “pain” was reported (Table 3) solely as ‘pills count’, whilst the assessment of its severity was unreported.

Pain severity and relief of pain are discrete, not linearly correlated, but interdependent items, which can be usefully combined to provide a valid global pain score. The investigators in this trial provided no information on the type and dosage of medication used by the participants, other than “patients’ need for analgesics”, and only reported sparse data as ‘pill counts’. Pill counts, although invaluable as measures of pain relief, are only considered proxy measures of pain severity and the absence of

pain severity assessment in this trial has compromised the precision of any data presented as pain outcomes.

Patient reported outcomes to measure pain severity should be supported by a validated and internationally recognized pain scale that has the discriminatory capacity in terms of both bandwidth and fidelity and is appropriate for this type of intervention as was used in the McCormack study¹. The value of these patient reported outcomes, if used, could then have been further enhanced if El Khalifa et al had provided more comprehensive details about the analgesics used to control and relieve pain.

Whilst the trialists are to be congratulated on undertaking this trial, aspects of selection, performance and detection bias are likely to have compromised and reduced the internal validity of the study and consequently the generalisability of its results.

It is important; therefore, that any further trials should be robust well designed, and conducted and reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement (<http://www.consortstatement.org/>).

Yours Sincerely
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31 March 2008

REFERENCE

1. McCormack RG, Greenhow RJ, Fogagnolo F, et al. Intra-articular Drain versus no Drain after Arthroscopic Anterior Cruciate Ligament Reconstruction: a Randomized Prospective Clinical Trial. *Arthroscopy* 2006; 22(8):889-93.

Dr Jaffar Al Bareeq
Chief Editor,
Bahrain Medical Bulletin

Dear Sir,

I read with interest the article by Drs Tarek El Khalifa, et al in the March issue of the journal¹. As I was reading through the table of contents, I was glad to find a randomized study being done and published in our country. However, I was a bit disappointed when I read the article, as a potentially excellent study was made mediocre by flaws in methodology and reporting.

Firstly, there was no mention of when the study was done, and over how long. Surgeries done a decade ago will likely have technical and procedural differences to surgeries performed nowadays. In addition, a recruitment period that is too long may affect the homogeneity of the subjects studied as well as the skill of the operating surgeon. It is not uncommon in surgical series that patients at the end of the recruitment period have better outcome than those recruited earlier.

Second, the authors did not mention whether informed consent was obtained from patients prior to enrollment, which is usually required by biomedical journal for research involving human subjects.

Third, the authors did not mention how randomization was made, and, whether there was any blinding?

Fourth, there was no description of the statistical methods used in the study.

Fifth, the authors state that there were no differences between the two groups regarding sex, activity levels, and time between rupture and reconstruction. However, in table 2, the mean time from injury to surgery was 22 versus 14 months. With no statistics reported, one wonders whether this was an important difference.

Sixth, while the numbers in table 3 seem convincing for the differences between the two groups, scientifically speaking this is inadequate to say there is a significant difference. Again, appropriate statistics for continuous and categorical variable have to be used in order to infer such a difference.

Again, I believe this study is potentially excellent, and I applaud the authors' efforts in carrying out this study. It may need to be rewritten to make full use of the material and data included.

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27 March 2008

REFERENCE

1. Khalifa T, Mahozi A, Dhaif B. Intra-articular Drain versus no Drain after Arthroscopic Anterior Cruciate Ligament Reconstruction: a Randomized Prospective Trial. Bahrain Medical Bulletin 2008; 30:9-11.