

LETTER TO EDITOR



Interventional Studies require Contextualised Controls: Hot Herbal Compression (*Chingdug*) compared to pure or mixed Diclofenac gel?

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Dear Editor,

We recently read with interest Dorji et al's randomised non-inferiority trial comparing the efficacy of Hot Herbal Compression therapy (*Chingdug*) with Diclofenac gel in the management of nonspecific low back pain [1]. We believe that it is important to grow the body of literature on traditional and complementary medicine to provide evidence on the efficacy of these Bhutanese Traditional Medicine practices [2,3].

However, we wish to highlight one potential shortcoming in the study design of Dorji et al's paper. The paper states that the control arm received a standard treatment of "Diclofenac 1% gel with an instruction to self-apply on the lumbosacral region, twice a day as recommended by a pharmacist or medical doctor for 2 weeks." One thing that the paper does not specify is whether the gel that was prescribed was a pure form where the active ingredient is only Diclofenac, or a mixed form where the active ingredients besides Diclofenac may include linseed oil, menthol, and methyl salicylate.

Clarifying this would be important for two reasons.

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First and more importantly, the majority of pharmacies in Thimphu (and we assume Bhutan) stock either a mixed form of Diclofenac gel or no Diclofenac at all. Private pharmacies typically import the mixed variety form from India, since they are more commonly available and better promoted and marketed by Indian manufacturers. Speaking with pharmacists at local private pharmacies, pure forms are accessible but are usually not stocked and require ordering. Further, Diclofenac gel is not in the National Essential Medicines List 2023, meaning that it is not available in any of the government hospitals (which include public pharmacies) and health centres, whether it be a pure form or a mixed form. If a pure 1% Diclofenac gel was indeed used in the trial, its applicability to real-world Bhutanese practice may be limited.

The second reason is that, unlike Bhutan, pharmacies in many contexts in the Global North typically supply only a pure gel form of Diclofenac; a mixed gel form would be considered unusual. When it is considered that most randomised controlled trials assessing the efficacy of Diclofenac gel have been conducted in these Global North contexts [4], it becomes unclear which type of Diclofenac gel was used in this study conducted in Bhutan.

Therefore, this study would have benefitted from providing clarity in the specific type of Diclofenac gel used:

- If indeed a pure 1% Diclofenac gel was used, the study would have benefitted from including a third arm, the mixed formula Diclofenac gel
- If a mixed formula Diclofenac gel was used, the study would have benefitted from specifying that this was the case

Since diclofenac gels are not listed in the public pharmacies' essential medicines list, the majority of patients in Bhutan using Diclofenac for musculoskeletal-related pain are accessing the Diclofenac gel in a mixed form. Future studies conducted in Bhutan that investigate the efficacy of a particular intervention compared with the standard treatment of Diclofenac gel should consider including a mixed gel form in their control arm. This would ensure greater contextualisation of such studies to the very setting where the intervention is most likely to be used. It goes without saying that this point about contextualising the research topic to the study setting is apropos for any future researcher intending to conduct research in Bhutan.

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Consent for publication

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