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DISCUSSION

# Off-label use of baclofen: A response to Kattula

**FLORIAN NAUDET, ALAIN BRAILLON**

***Abstract***

*The "discussion" on our commentary about baclofen use in India perpetuates misconceptions. We want to: a) highlight the flood of overlapping and conflicting meta-analyses that obscure rather than clarify baclofen's effects; b) stress the importance of pivotal trials which support hypothetico-deductive reasoning and provide the basis for regulatory decisions. Such trials use only high-dose baclofen without proven benefit but serious safety concerns, including mortality. Practitioner enthusiasm, lived experience, or off-label consensus — whether in the global North or recycled in the global South — cannot replace rigorous trial evidence. We call for careful evaluation of pivotal evidence and robust research.*

***Keywords:*** *Off-label medication, baclofen, ethics, drug regulation, alcohol use disorder*

The publication of a "discussion" [1] on our "commentary" [2] was a welcome surprise, as stimulating debate is always valuable. The work of reviewers certainly deserves recognition, and making reviews accessible is an excellent initiative. However, we believe Dr Kattula's response [1] perpetuates serious misconceptions that we are eager to address in this response.

## Ignoring the latest evidence?

First, on the issue of meta-analyses, Dr Kattula suggests that we are cherry-picking evidence. We are happy to clarify this point, since the implication of cherry-picking is dishonesty, something we reject.

We cited the network meta-analysis by Palpacuer et al in support of our statement: "indeed, as for other treatments, meta-analyses fail to show any convincing benefit from baclofen in harm reduction." That reference supports two key points: comparative effectiveness and lack of evidence for harm reduction. Indeed, as for other medications, no evidence exists that baclofen reduces alcohol-related harm.

To our knowledge, no new meta-analysis contradicts this point.

In contrast, the reference proposed by Agabio et al [3] provides no evidence on these two points. It is not a network meta-analysis — thus making no comparisons with other treatments — and it does not examine harm reduction (ie, reduction in alcohol-related risks). Instead, it focuses on various consumption outcomes. While these drugs are often proposed as harm-reduction agents, the evidence shows only modest effects on consumption and not true harm reduction. We do not deny that baclofen may yield small reductions in consumption, but these need to be considered alongside its overall safety profile in alcohol use disorders, which we discuss below.

Kattula's comments also open an important perspective: the problem of overlapping and conflicting meta-analyses on the same topic. A PubMed search for "((baclofen) AND (alcohol)) AND (meta-analysis)" retrieves about 15 meta-analyses (as of 19 Sep 2025): nearly one per primary study. This ratio shrinks further when only low risk-of-bias trials are considered.

This flood of meta-analyses is difficult to navigate. In fact, citing anyone without conducting an umbrella review could be construed as cherry-picking. Dr Kattula did not cite all 15 either. We therefore suggest that the real issue is not selective citation, but rather the redundancy, overlap, and inconsistency of these reviews. Meta-analyses are often retrospective, malleable exercises [4], small changes in trial selection or outcome definition can yield very different estimates, a phenomenon known as "vibration of effects." [5]

In alcohol use disorders, we have previously demonstrated that inclusion/exclusion criteria in a meta-analysis could produce entirely opposite results when comparing nalmefene with naltrexone [6]. The same "vibration" exists for baclofen: some meta-analyses report an effect, others do not. For example, a 2018 review of 14 randomised controlled trials (RCTs) (or four low-risk trials) found no significant effect of baclofen over placebo [7]. In contrast, the recent meta-analysis by Agabio et al [3] included the complete results of the BACLOVILLE trial [8] (whereas the previous one only covered partial findings presented at a conference), making this analysis in appearance more inclusive of available data. Yet it failed to consider serious methodological issues with that study. Regarding risk of bias, the BACLOVILLE trial was rated as "low risk of bias" for all items except for selective reporting, assessed as "unclear risk" because the protocol was allegedly unavailable. In fact, the protocol was available with the publication and showed changes to the primary outcome as we previously detailed [9]. Moreover, the trial cannot reasonably be considered at low risk of bias for blinding or incomplete outcome data: many patients switched to open-label baclofen, disproportionately in the placebo group. These breaches undermine the reliability of the data. When we requested individual patient data from the sponsor, the Paris Public Hospitals Authority, access was denied.

Another argument by Dr Kattula concerns baclofen's effectiveness in specific populations, such as patients with anxiety disorders. This claim rests on a subgroup meta-analysis by Agabio et al [10], which excluded the pivotal ALPADIR trial [11], a negative study that provided relevant abstinence and anxiety outcomes, on questionable grounds: the study — whose primary goal was maintenance of abstinence — was excluded because it did not provide information on a very specific outcome "rate of abstinence day" but Hospital Anxiety and Depression scores were available. At baseline they were 11.6 (± 4.0) and 11.9 (± 3.8) for the placebo and baclofen group, respectively, very similar to the BACLOVILLE study with 10.6 (± 4.6) and 10.4 (± 4.4) for baclofen. While the ALPADIR trial randomised 158 patients to baclofen and 162 to placebo, the meta-analysis relied heavily on small trials, particularly in the "low anxiety" subgroup, making it highly vulnerable to small-study effects. Furthermore, it is a post hoc analysis of subgroups via meta-regression. When based on aggregated data, meta-regressions are prone to many pitfalls including ecological fallacy [12] — ie assuming that a relationship observed at the group level automatically applies to individuals — rendering conclusions speculative, individual data being unavailable. Taken together, these issues suggest weak and biased evidence rather than true benefit in anxious patients. Post hoc-analyses can only generate hypotheses to be confirmed by prospective trials.

When meta-analyses add more confusion than clarity, we believe it is more rigorous to return to pivotal trials, an approach adopted by health authorities and consistent with a hypothetico-deductive framework. This leads us to the next critique.

## A distrust of regulators?

Dr Kattula suggests we distrust regulators. On the contrary, we trust them on this occasion, which is why we emphasise that most regulators worldwide have not approved baclofen. France's medicine agency remains the lone exception. It is noteworthy that this is a repetition of the benfluorex (Mediator) scandal [13].

Regulators operate under clear principles: they base their decisions on pivotal trials, not on a patchwork of meta-analyses. That is why we focused on ALPADIR and BACLOVILLE, the two largest studies, just as the French regulator's own scientific committee did when concluding that baclofen carries an unfavorable risk/benefit profile [14]. ALPADIR was unequivocally negative [11]. As for BACLOVILLE [8], we have outlined its major limitations above. Its publication prompted an *NEJM Journal Watch* news story that directly questioned baclofen's harm/benefit balance and highlighted its safety concerns [15].

Moreover, baclofen is not approved in France in high doses, but only up to 80 mg. While these lower doses may be less toxic, their efficacy remains unproven [15]. Importantly, the

French decision came in the unique context of widespread off-label use, making withdrawal practically impossible. Approval was therefore driven by misplaced pragmatism, not strong evidence. In countries without such off-label use, regulators have not even considered approval.

## A distrust of practitioners?

Dr Kattula also suggests that we distrust practitioners. We do not. But clinical enthusiasm should not dictate regulatory approval. Medical history is replete with reversals, treatments widely embraced by clinicians later overturned by solid evidence [16]. At best, ineffective therapies waste resources; at worst, they expose patients to unjustified risks.

We are also accused of promoting a "one-size-fits-all" approach, at odds with the lived experiences of clinicians and patients, especially in India. But should baclofen be largely prescribed merely on the basis of such experiences? It seems that the narrative of baclofen as a cheap, repurposed drug ignored by pharma for lack of profitability originated in the global North and is now recycled in the global South. In our opinion, that is why regulators exist: to separate rhetoric from reliable data, and wishful thinking from patient safety. Lastly, could treatment with a cheap product, repeatedly shown to lack benefit on clinically relevant outcomes, be an alternative in the global South to more costly products with somewhat more robust evidence for benefit? This seems like a very slippery slope.

As for the Indian studies cited by Dr Kattula, we regret that none provide strong evidence of safety or efficacy. Among the three references, the only randomised trial compared baclofen with topiramate in an open-label design, reporting a difference in consumption outcomes at one week that was no longer evidence at one month [17]. In the absence of a clear strategy for handling multiple testing, this hardly demonstrates efficacy. Moreover, such a short-term effect cannot be considered clinically relevant in a chronic condition like alcohol use disorder.

## Misrepresentation of safety profile?

Dr Kattula further suggests that the tone of our article aimed to "create fear." We leave that judgement to readers. What we presented is not fearmongering but evidence. Concerns about high-dose baclofen are mounting. A large pharmacoepidemiological study of 165,334 patients in France found a dose-dependent increase in mortality [18], echoing the two-fold mortality increase observed in the BACLOVILLE trial [8]. Furthermore, in a well-conducted randomised trial under intensive monitoring, baclofen was associated with serious safety issues, including prolonged ventilation, delayed awakening, and extended hospitalization [19].

## Lacking nuance in ethics?

Dr Kattula argues we lack nuance when discussing ethics. He also cites the Cagliari Statement [20] as evidence of an international consensus supporting off-label baclofen. Yet the Cagliari group itself explicitly states that it does not promote off-label use [21]. Rather, it acknowledges that such use occurs and provides guidance for clinicians when it does. It cannot reasonably be invoked as an argument for off-label prescribing.

Dr Kattula states that older drugs such as baclofen may have safety advantages, as their long-term use has provided more information about potential safety issues that can be addressed when considering them for new indications. In our opinion, this is simplistic and misleading. Safety profiles depend on context: risks can differ across populations and indications. Baclofen use in multiple sclerosis involves lower doses (typical range of 30 to 80 mg/day) than the high dose typically used in alcohol use disorders, and patients are advised against alcohol consumption. One cannot simply infer safety in a new context.

With baclofen, the evidence now accumulated points to an unfavourable benefit/harm profile in AUD. What is urgently needed, in both the global South and North, is rigorous research on the added value of combining psychosocial and pharmacological interventions compared with psychosocial care alone. High variability, risk of bias, and insufficient evidence reduce confidence in existing findings [22]. This is not a call for "salvage pilling" with a doubtful drug, but for serious evidence. It looks like a fairly ethical option.

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## DISCUSSION

# Response to "Israeli academia during the genocide: supporting the state through words and silences"

**RONIT CALDERON-MARGALIT, A MARK CLARFIELD, HAGIT HOCHNER, MAUREEN MALOWANY, YEHUDA NEUMARK, SHIRA NANAVATI, ORA PALTIEL**

***Abstract***

*This is a response to Dr Panchal's opinion piece that accused us, teachers, directors and staff of the programme he participated in, of not discussing or protesting against the situation in Gaza during the academic year of 2023-24. We find this accusation to be utterly wrong and incorrect. Beyond taking care of the safety of our students, the School facilitated discussion in class regarding the situation. Furthermore, some of the authors participated in protests and publicly advocated for the wellbeing and health of the Gazan population starting already in the early days of this war. Finally, we find it unethical that Dr Panchal did not approach us on this issue, either during his stay in Israel or before or after he chose to publish his opinion.*

***Keywords:*** *Gaza, ethics, discussion, teachers-students relationship*

We read with concern Dr Vidit Panchal's opinion piece [1], which reached us only recently via social media. In standard academic discourse, he or the editor would have sought our comment before publication.

As teachers at the Hebrew University-Hadassah Braun School of Public Health, we take pride in Dr Panchal and our more than 1,100 alumni from over 100 countries who, since 1971, have participated in our International Master of Public Health (IMPH) programme[1] and have gone on to contribute meaningfully to global public health. We therefore feel compelled to respond to this tendentious portrayal of an academic year lived in wartime, and Dr Panchal's mischaracterisation of our institution and its activities — both within and outside the programme.

Dr Panchal's studies coincided with the tragic onset of the war in Gaza following the October 7 Hamas-led massacres. In his account, he writes that *"Soon after the events of October 7, Israeli universities actively sought to gather international support for the country during its military operations".* A more accurate depiction would have acknowledged that