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## ***Titles Should reflect findings, not manipulated for Citation***

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It was with great interest that I read the paper, “Single-Shot Liposomal Bupivacaine Reduces Postoperative Narcotic Use Following Outpatient Rotator Cuff Repair” by Baessler AM, Moor M, Conrad DJ, Creighton J, Badman BL. As there are multiple papers that found liposomal bupivacaine has no advantage over other strategies, this paper’s title implies a game changing study.

Prior studies have found the clinical efficacy of liposomal bupivacaine of no benefit. A systemic review of this product using a gold standard of randomized trials concluded, “Current prospective, randomized controlled trials in patients undergoing orthopaedic surgery fail to support the routine use of liposomal bupivacaine compared with other local injectable analgesics”. As such the paper by Baessler, et. al, directly contradicts the conclusions of this systemic review. (1)

After reading the article, there are several issues with both the paper, the title, and the conclusions.

Of concern is the following:

- 1.) The conclusions of the authors were using a combination of liposomal bupivacaine and bupivacaine. This combination strategy is not noted in the title.
- 2.) The study failed to evaluate a comparison of bupivacaine without dexamethasone with that of liposomal bupivacaine and bupivacaine without dexamethasone.
- 3.) The VAS pain scores are noted to be “adjusted for age and number of anchors”. This is never explained nor is there any evidence that VAS needed to be adjusted as the age and demographics of each cohort are similar.  
Such adjustments need detailed explanation and referenced to a paper that shows such adjustments are statistically acceptable and valid.
- 4.) Although there is a difference between VAS scores, the difference was only one point between all groups on each post op day and no difference on PO 3.
- 5.) The total use of narcotics across all groups is less than and average of 1.5 pills per day. When looking

at the SD in each group, the difference between the LB group is greatest on POD 2, but this is the equivalent of two Percocet. And their pain is better in the control than LB on day 4.

6.) The difference in VAS did NOT reach clinical significance on any PO day. (2) (3)

7.) The cost quoted of liposomal bupivacaine is not the cost to the patient. Most hospitals have a standard 300% cost markup. The cost to the patient is typically \$800-\$900 dollars.

Most critical of all is the conclusion. What this study shows is not the efficacy of liposomal bupivacaine. The study is a comparison of the effect of dexamethasone on pain control. It clearly finds that the addition of dexamethasone does not significantly improve or potentiate the effects of bupivacaine or liposomal bupivacaine alone. There is no analysis of the effects of liposomal bupivacaine and bupivacaine.

In summary, the title does not reflect the study. The conclusions are based on findings that that are, 1.) not significant and 2.) manipulated in an unknown way.

This paper demands a revision of the title, the data analysis and the conclusions with recommendations..

Disclaimer: e-Letters represent the opinions of the individual authors and are not copy-edited or verified by JBJS.

## References

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Conflict of Interest: None Declared

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## Article Author Response

2 December 2020

### *Article Author(s) to Letter Writer(s)*

It was with interest I read your critiques and comments. I thank you kindly for your remarks and I currently offer our rebuttal.

The title is appropriately named. This paper has zero financial bias – it was unfunded. The goal of the study at the onset was to assess what we felt we were seeing anecdotally with less pain and longer duration of the nerve block when liposomal bupivacaine was utilized. Our early level 5 assessment was that when steroid was mixed with the LB it seemed to potentiate the effect of the block. At our institution, the addition of steroid (dexamethasone) is standard of care for our anesthesiologists as it has been shown to prolong the efficacy and duration. I offer again our references that support this and were noted in the manuscript(1-4). We, therefore, had zero intention to ever study a block with bupivacaine alone as this is not the standard at our institution and would provide absolutely no measure for a control. The control, as such, was bupivacaine with dexamethasone. For the active comparator groups we wanted to then assess if (1) adding LB to bupivacaine prolonged the analgesic effect, and (2) if adding steroid to LB blocks had any impact. In effect, the other two arms consisted of addition of LB alone and LB with dexamethasone. The study was properly powered to assess for differences.

Generalized estimating equations were used for statistical analysis, as appropriate for a longitudinal study. Age and tear complexity (measured by number of anchors) can impact the physiologic process of healing; thus; adjustments were made to control for any variability that these factors may have had on the outcomes of VAS pain and narcotic use. This was briefly explained in the discussion of the paper. Moreover, study findings did not waver in showing a significant reduction in narcotic pain pills within the first three postoperative days with similar VAS pain scores across groups.

The crux of our findings demonstrated no significant differences with regard to the addition of steroid to the LB group. While it trended in this direction it was not significant. More importantly, blocks with LB without steroid required fewer postoperative narcotics. As to your comment on VAS pain, I would counter that pain is a very subjective measure. What I may call a “2”, you may call a “10”. Using pain as the fifth vital sign is one of the primary reasons we are now faced with the opioid crisis prompting other measures, as this paper offers. We included morphine milligram equivalent units as a measure, as we believe this offers a better objective means to understand the level of pain a patient is experiencing. As we had expected, VAS pain scores were not overly different between the groups. We do not state that there

were significant differences in pain scores. What was statistically significant, once again, was patients receiving LB and LBD blocks took fewer pain pills by day 3 cumulatively. As the discussion states, pain scores stayed similar between groups, however the total amount of narcotic ingested was decreased in the LB groups, implying that patients in those groups had less overall pain.

Regarding your interpretation of the amount of Percocet reduction, your assessment is correct but looking at this as a simply miniscule amount is a dangerous and irresponsible vantage. Orthopedic surgeons are one of the leading prescribers of narcotics and we as a group have some ownership in the crisis at hand. According to Shah, among patients prescribed one day of opioids, the risk of continued opioid use at one year was 6% (5). The authors also note the risk of long term use increases most sharply in the initial days of therapy, and if prescribed narcotics longer than 8 days the risk of long term addiction more than doubles. So, while two Percocet per day may not seem like a lot in your opinion, the cumulative dosing of 6 fewer Percocets in the first 3 days of surgery is, in fact, significant.

The reviews you referenced are recent, and have been referenced for the most part within our manuscript. The JBJS review looked at papers assessing the use of LB in a periarticular or local injection method. We agree, in this manner, the literature does not support its use as being overly different. This is not the method that we utilized. With regard to the JSES review, once again, not all referenced papers used LB in an interscalene block with only two referenced articles (Vandepitte and Shariat) as an equal comparison to our study. Of these two, Shariat was the only article that would be a similar comparison as only rotator cuff patients were studied. The other article included total shoulder patients as well, which in my opinion is a flaw of that paper. Thus, narrowing the meta-analysis of two papers you submit as counter evidence and comparing our findings to the only other paper that is similar in comparison, our findings also support those of Shariat, in that less narcotics were necessary within the first 3 days following rotator cuff surgery when LB was used in the interscalene injection.

Finally, regarding cost, different centers bill differently but at our institution payment for rotator cuff surgery is typically bundled and a contracted rate. The added cost is not passed on to the patient but it is assumed in the cost of care and effectively becomes less profit for the institution and center. Less profit for me per case is worth the benefit of potentially reducing the issue of long-term narcotic use in my patients. I am only doing my part to improve the status quo and not continue to negate.

In conclusion, your comments have been noted, the title is appropriate, our findings are significant, and I am proud of the work rendered by my co-authors. I thank JBJS for the opportunity to publish our manuscript.

## References

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