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ORIGINAL ARTICLE

Comparison of effectiveness of combination of lidocaine-ketorolac vs lidocaine alone in biers block of upper limb surgery: Focus on intraoperative and post-op pain relief.

Sumara Tabassam[1], Neelam Ali[2], Tabinda Maqsood[3], Tayyab Riaz[4], Masooma Shafqat[5], Muhammad Talha Anjum[6]

ABSTRACT… Objective: To compare the effectiveness of a combination of Lidocaine and Ketorolac versus Lidocaine alone in Bier's Block for upper limb surgery, in terms of intraoperative and 12 hours postoperative pain score. **Study Design:** Randomized Controlled Trial (RCT). **Setting:** Department of Anesthesia, Aziz Fatima Hospital Faisalabad. **Period:** Six months (January to June'25). **Methods:** Following approval from the Institutional Ethical Review Committee and the College of Physicians and Surgeons Pakistan, this randomized controlled trial enrolled 100 patients fulfilling the inclusion criteria. Participants were equally divided into two groups. Group A received intravenous lidocaine 4 mg/kg after confirmation of proper tourniquet inflation and absence of distal pulse. Group B received intravenous lidocaine 4 mg/kg combined with ketorolac 30 mg under the same conditions. Postoperative assessment was initiated immediately after tourniquet release. **Results:** Most participants were aged 20–45 years (64%), with male predominance (76%) and majority classified as ASA-I. The lidocaine-ketorolac group demonstrated significantly lower intraoperative VAS scores at 5, 10, and 15 minutes compared with lidocaine alone ($p<0.001$). Postoperative pain scores at 1, 6, 12, and 24 hours were also significantly reduced in the combination group ($p<0.001$). Time to first analgesic request was significantly prolonged with ketorolac (163.26±32.63 vs. 87.54±24.36 minutes; $p<0.001$). Rescue analgesia requirement and adverse effects were numerically lower in the combination group. **Conclusion:** The addition of ketorolac with lidocaine increases the analgesic efficacy for both intraoperative and postoperatively in addition to extending analgesic duration for improving the effectiveness of IVRA.

Key words: Analgesia, Bier Block, Intravenous Regional Anesthesia, Ketorolac, Lidocaine, Postoperative Pain, Pain Measurement, Upper Extremity Surgery.

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INTRODUCTION

Upper extremity surgeries pose challenges for anesthesiologists and pain specialists due to persistent pain issues.[1] Utilizing regional anesthesia techniques targeting the brachial plexus is crucial for effective pain control in modern surgical practice, minimizing systemic side effects linked to general anesthesia.[2] The Bier's block, which is also known as intravenous regional anesthesia, is a method that is often used in order to achieve anesthesia in the upper limb.[3] Regional anesthesia's roots extend to ancient times, employing herbal remedies for surgical pain.[4] Modern principles emerged in the late 19th century, with Bier's block, pioneered by August Bier, a key advancement utilizing distal vein injection for localized anesthesia in upper limb surgeries.[5]

Regional anesthesia has advantages over general anesthesia, offering rapid recovery, enhanced postoperative pain control, and lower airway complication risks.[6] Despite its benefits, challenges exist, requiring expertise in anatomy, dosing, and managing complications like tourniquet pain and local anesthetic toxicity.[7] Therefore, it would be preferable to combine additives with local anesthetics in order to alleviate the IVRA disadvantages. Based on earlier studies, the adjuncts used are opioids, tramadol, nonsteroidal anti-inflammatory drugs (NSAIDs; ketorolac, tenoxicam, acetyl-salicylate), clonidine, muscle relaxants, alkalinization with sodium bicarbonate, potassium and temperature.[8]

Ketorolac is an injectable NSAID drug that has analgesic properties[9] and is effective in the short-term

1. MBBS, FCPS, Professor Anesthesia, Aziz Fatima Hospital, Faisalabad.
2. MBBS, PG Resident (Anesthesia), Aziz Fatima Hospital, Faisalabad.
3. MBBS, FCPS, Senior Registrar Anesthesia, Aziz Fatima Hospital, Faisalabad.
4. MBBS, FCPS, Assistant Professor Surgery, ABWA Hospital, Faisalabad.
5. MBBS, PGR, Anesthesia, Aziz Fatima Hospital Faisalabad.
6. MBBS, FCPS, Consultant Anesthesiologist, Mujahid Hospital, Faisalabad.

Correspondence Address:
Dr. Tayyab Riaz
Department of Surgery, ABWA Hospital, Faisalabad.
dr.tayyabch100@gmail.com

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control of moderate to severe postoperative pain approved by the US Food and Drug Administration for use in treating the mediated inflammatory response. It decreases the pain and increases the period of painlessness. Therefore, it is added to lidocaine in venous blocking for postoperative pain relief.[10-11]

Seyfi et al reported that the mean intra-operative pain scores were comparable at zero minute (2.8±0.7 vs 2.7±0.6 in lidocaine-alone vs lidocaine-ketorolac groups), but were significantly lower in the lidocaine-ketorolac group at subsequent intervals: 4.9±1.1 vs 3.1±0.9 at 5 minutes, 4.6±1.0 vs 2.8±0.8 at 10 minutes, and 4.3±0.9 vs 2.6±0.7 at 15 minutes ($p < 0.001$ for all), in the lidocaine-alone and lidocaine-ketorolac groups respectively.[12]

In post-operative period mean pain was 6.26±1.38 versus 1.9±0.44 at 1 hour, 1.9±0.44 versus 4.55±1.63 at 6 hours. 4.61±0.94 versus 3.9±1.51 at 12 hours and 3.83±0.83 versus 3.10±1.37 at 24 hours in Lidocaine alone and ketorolac-lidocaine respectively.[12]

Bier's block is a common and effective way to numb the arm for short surgeries, using a medicine called lidocaine. Lidocaine is the standard local anesthetic used in this procedure. Adding another medicine called ketorolac, helps to reduce pain. This study compares using lidocaine alone with using both lidocaine and ketorolac together to see which gives better pain relief. If the combination works better, it will be adopted as a regular method for upper limb surgeries to give longer pain relief. It will reduce the need for opioids, making recovery safer.

METHODS

This Randomized Controlled Trial(RCT) was carried out at Department of Anesthesia, Aziz Fatima Hospital Faisalabad during the period January to June'25 after getting approval from the Institutional Ethical Committee (Ref no: IEC-290-24, Dated: 27/09/2024). The sample size was estimation was performed with the help of open EPI by taking Power of the test= 80%, Level of significance= 5%, Anticipated Mean in Group A = 4.61±0.94[7], consequently, 100 patients were recruited, with 50 participants assigned to two groups.

The participants in this study were of both gender, aged 20-70 years, classified as ASA physical status I and II scheduled for surgery involving fractures of the hand, wrist, or forearm. Patients with known allergies to the study medications, contraindications to the drugs, and other co-morbidities like preexisting neurological diseases, prolonged surgeries exceeding one hour and conditions unsuitable for Bier's block including severe limb trauma, mental illness, psychological disorders, pregnant/breastfeeding women, were excluded from the study.

As Bier's block is administered in awake patients, intraoperative pain assessment was performed, therefore able to self-report pain intensity by using Visual Analog Scale (VAS) and Numeric Rating Scale (NRS).Patients were requested to cooperate by to scale their pain during the procedure at every 5-minute interval/ on demand by the assessor. The VAS ranged from 0 (no pain) to 10 (worst possible pain). Postoperative pain assessment was similarly performed at different intervals i.e. 1 hours, 6 hours, 12 hours and then finally on 24th hour of the procedure. We hypothesized that patients undergoing biers block with combination of Lidocaine-Ketorolac experience less intraoperative and post-operative pain than those with Lidocaine alone.

Due approval from the Institutional Ethical Review Committee and College of Physicians and Surgeons Pakistan was obtained before the start of this trial. Informed written consent was secured from the participants of the trial by explaining them detailed purpose and objective and they were also ensured for the confidentiality of their medial record. Patients planned for elective upper limb surgery under Bier's block intravenous regional anesthesia (IVRA) were evaluated for inclusion/exclusion criteria. Relevant baseline demographic information include age, gender, type of surgery, BMI were recorded before the start of the procedure.

The enrolled patients were randomly divided into two groups, Group A (Lidocaine alone) and Group B (Lidocaine with Ketorolac). Patients in Group A received intravenous lidocaine at a dose of 4 mg/kg after confirmation of proper tourniquet inflation

and absence of distal circulation as evidenced by loss of pulse.

Patients allocated to Group B received a dose of 4 mg/kg combined with ketorolac 30 mg was injected intravenously once confirmation of adequate tourniquet inflation and verification of loss of peripheral pulse. To minimize bias, both the patients and the outcome assessors were blinded to the treatment allocation throughout the trial. The intravenous regional anesthesia procedure was performed using a standard double tourniquet Bier's block technique. Assessment of intraoperative pain scores was done and recorded at 5-minute intervals just after the tourniquet inflation until the deflation was completed.

Patients were asked to quantify their pain on the Visual Analog Scale (VAS; 0–10). During each assessment interval, the occurrence of tourniquet pain was evaluated and documented, any additional fentanyl requirement was also noted along with the dose and timing of administration. These parameters were analyzed to record the analgesic efficacy for intraoperative pain management.

Postoperative assessment was initiated immediately after tourniquet is released. The return of sensory function in the operated limb and the duration until first analgesic demand were recorded. The intensity of pain was evaluated/documented on different intervals i.e. 1st, 6th, 12th, and 24th hour of the procedure. Further, the details regarding postoperative analgesic administration, in addition to type and total amount consumed during the first 24 hours was noted. Any adverse effects e.g. vomiting, nausea, allergic reactions, and dizziness were observed and recorded. All the collected data of our trial was entered for statistical analysis on SPSS-25.0. Quantitative variables were presented as mean ± standard deviation, while categorical variables were expressed as frequencies and percentages.

RESULTS

The present study enrolled 100 patients undergoing upper limb surgery by using Bier's block intravenous regional anesthesia with equal allocation into two groups. Of these, 50 patients receiving lidocaine alone and 50 were in lidocaine-ketorolac group. The age range of 20-45 years in both groups was in majority of the patients by calculating 64 (64.0%). Male patients were more common in both groups i.e. 67(76%), similarly, ASA-I classification was more common. Regarding BMI, both groups were comparable with over-weight cases were higher than normal weight patients. Similarly, BMI distribution and types of surgery were comparable between the two groups. No statistically significant differences were observed regarding age (p=1.000), gender (p=0.523), ASA status (p=0.420), BMI category (p=0.422), or type of surgery (p=0.983), indicating adequate baseline comparability between study groups. In terms of surgical procedures, wrist open reduction and internal fixation emerged most common surgical procedure consisting of 31(31%) of the cases, forearm tendon repair and hand fracture repair were also commonly performed accounting for 27(27%) and 23(23%) of the participants respectively, however, forearm fracture fixation was the least common surgical procedure performed in both groups by counting 19(19%) of the cases. (Table-I)

Table-II demonstrates the comparison of intraoperative pain intensity between both treatment groups. VAS at 5 minutes in Lidocaine alone group was recorded as 4.78+1.02 and 3.06 ± 0.87 in Lidocaine + Ketorolac group, (p=<0.001), it was 4.38 ± 1.10 at and 2.93 ± 0.76, (p=<0.001) at 10 minutes whereas 4.28 ± 0.91 and 2.41 ± 0.95 (p=<0.001) in both groups respectively.

Comparison of postoperative pain intensity between both treatment groups was done in Table-III where VAS at 1 hour in Lidocaine alone group was recorded as 6.37+1.35 and 2.03 ± 0.53 in Lidocaine + Ketorolac group, (p=<0.001), it was 4.77 ± 1.38 and 3.86 ± 1.19, (p=<0.001) at 6 hours, further, it was 4.70 ± 1.09 and 3.74 ± 1.02, (p=<0.001) at 12 hours, whereas 3.86 ± 0.94 and 2.99 ± 0.74 (p=<0.001) at 24th hour of the surgery in both groups respectively.

Comparison of time to first analgesic request was recorded at 87.54+24.36 minutes in Lidocaine alone group whereas 163.26+32.63 minutes in combination group, (p=<0.001). (Table-IV)

Comparison of rescue analgesia requirement was recorded in 24(48%) of the cases in Lidocaine alone group while 16(32%) in combination, group. (P=0.102) (Table-V)

Regarding comparison of adverse effects, it was found 14(28%) of the cases in Lidocaine alone group and 7(14%) in Lidocaine+Ketorolac group, p=0.086. (Table-VI)

TABLE-I

Baseline demographic and clinical characteristics of study participants (N=100)

Variable	Lidocaine Alone (n=50)	Lidocaine + Ketorolac (n=50)	Total (n=100)	P-Value
Age Group				
20–45 years	32 (64.0%)	32 (64.0%)	64 (64.0%)	1.000
46–70 years	18 (36.0%)	18 (36.0%)	36 (36.0%)	
Gender				
Male	32 (64.0%)	35 (70.0%)	67 (67.0%)	0.523
Female	18 (36.0%)	15 (30.0%)	33 (33.0%)	
ASA Status				
ASA-I	26 (52.0%)	30 (60.0%)	56 (56.0%)	0.420
ASA-II	24 (48.0%)	20 (40.0%)	44 (44.0%)	
BMI Category				
18–25 kg/m²	21 (42.0%)	25 (50.0%)	46 (46.0%)	0.422
>25 kg/m²	29 (58.0%)	25 (50.0%)	54 (54.0%)	
Type of Surgery				
Forearm Fracture Fixation	10 (20.0%)	9 (18.0%)	19 (19.0%)	0.983
Forearm Tendon Repair	13 (26.0%)	14 (28.0%)	27 (27.0%)	
Hand Fracture Repair	12 (24.0%)	11 (22.0%)	23 (23.0%)	
Wrist ORIF	15 (30.0%)	16 (32.0%)	31 (31.0%)	

* Statistical significance considered at p ≤0.05.

TABLE-II

Comparison of intraoperative pain scores between study groups

Variable	Lidocaine Alone Mean ± SD	Lidocaine + Ketorolac Mean ± SD	Mean Difference	P-Value
VAS at 5 min	4.78 ± 1.02	3.06 ± 0.87	1.72	<0.001*
VAS at 10 min	4.38 ± 1.10	2.93 ± 0.76	1.45	<0.001*
VAS at 15 min	4.28 ± 0.91	2.41 ± 0.95	1.87	<0.001*

* Statistical significance considered at p ≤0.05.

TABLE-III

Comparison of postoperative pain scores between study groups

Variable	Lidocaine Alone Mean ± SD	Lidocaine + Ketorolac Mean ± SD	Mean Difference	P-Value
VAS at 1 hour	6.37 ± 1.35	2.03 ± 0.53	4.34	<0.001*
VAS at 6 hours	4.77 ± 1.38	3.86 ± 1.19	0.91	0.001*
VAS at 12 hours	4.70 ± 1.09	3.74 ± 1.02	0.96	<0.001*
VAS at 24 hours	3.86 ± 0.94	2.99 ± 0.74	0.87	<0.001*

* Statistical significance considered at p ≤0.05.

TABLE-IV

Comparison of time to first analgesic request

Variable	Lidocaine Alone Mean ± SD	Lidocaine + Ketorolac Mean ± SD	Mean Difference	P-Value
Time to first analgesia (min)	87.54 ± 24.36	163.26 ± 32.63	-75.72	<0.001*

* Statistical significance considered at p ≤0.05.

TABLE-V

Comparison of rescue analgesia requirement

Rescue Analgesia	Lidocaine Alone	Lidocaine + Ketorolac	Total	P-Value
Yes	24 (48.0%)	16 (32.0%)	40 (40.0%)	0.102
No	26 (52.0%)	34 (68.0%)	60 (60.0%)	
Total	50 (100%)	50 (100%)	100 (100%)	

* Statistical significance considered at p ≤0.05.

TABLE-VI

Comparison of adverse effects

Adverse Effects	Lidocaine Alone	Lidocaine + Ketorolac	Total	P-Value
Yes	14 (28.0%)	7 (14.0%)	21 (21.0%)	0.086
No	36 (72.0%)	43 (86.0%)	79 (79.0%)	
Total	50 (100%)	50 (100%)	100 (100%)	

* Statistical significance considered at p ≤0.05.

DISCUSSION

In our study, we compared the efficacy of analgesic agent lidocaine alone and in combination with ketorolac during Bier's block intravenously in regional anesthesia while performing upper limb surgery. Our findings are evident that by adding ketorolac with lidocaine, it provides better analgesic effect than used alone on all evaluated intervals and even postoperative pain score upto 24 hours after surgery was better in addition to first analgesic request. Although ketorolac group had fewer patients required rescue analgesics or experienced any adverse effect, however, it did not show significant difference. These findings underscores that ketorolac enhances the analgesic effect of Bier's block anesthesia.

Various previous studies evaluated different adjunctive agents in combination with local anesthetics to optimize the efficacy and prolong analgesic duration for the control of pain. We recorded significant effect of addition of ketorolac to reduce intraoperative pain intensity on different intervals. It corroborates previous evidence supporting ketorolac as an effective adjunct when used in in Bier's block anesthesia. Similar findings by Seyfi et al showing significantly lower intraoperative pain score on different time intervals like 5, 10 and 15 minutes during the surgery in patients administered with lidocaine-ketorolac combination compared with those received lidocaine alone.[12] This consistency is observed in other studies by Ghori et al[13] and Rivera et al[14], who documented an improved postoperative analgesic requirement and improved pain control in patients receiving ketorolac in addition to lidocaine in Bier's block. It strengthens the results of our study. Consistent with the current findings, other trials suggested that adjuvant agents are beneficial for improving the quality and persistence of regional anesthesia.[15]

Ketorolac's enhanced analgesic advantage may be attributed to its strong peripheral cyclooxygenase inhibitory action, hereby reducing prostaglandin-mediated inflammatory pain sensitization at the surgical site. It may reduce pain through combined central and peripheral mechanisms that help suppress pain transmission following tissue injury. In IVRA, local accumulation of ketorolac within the isolated extremity may enhance peripheral analgesic activity and prolong postoperative analgesia following release of the tourniquet. The associated

reduction in inflammatory response may therefore explain the lower postoperative pain severity observed in the present study.

Comparable findings were reported in a study by Younas et al revealed that adding dexmedetomidine during IVRA reduces post-operative pain and delays its analgesic effect in patients selected for upper limb surgery.[15] Similarly, Nazeer and workers observed thatdexmedetomidine-containing Bier's block regimens resulted in faster onset of motor block and extended postoperative pain relief.[5] Supporting evidence from Amini et al observed superior postoperative analgesia and reduced recovery room pain intensity and delayed the need for opioid analgesics.[8] Such findings highlight the beneficial role of adjunctive agents in intravenous regional anesthesia.

Although, a reduced need for rescue analgesia was observed among patients receiving ketorolac, did not achieve statistical significance, may still hold important clinical implications suggesting a potentially meaningful improvement in perioperative pain outcomes. Similarly, adverse effects were observed less frequent, despite the absence of statistical significance. Furthermore, no serious complications associated with IVRA or ketorolac-related complications were identified, reinforcing a favorable safety profile of adjunctive analgesic agent.

The two study groups were comparable regarding clinical variables and baseline demographic profile, such as age, gender, BMI, ASA classification and surgical procedure type. Similarity between the two groups, extends the strength of the trial and reduces the any confusion. In both groups, we observed wrist open reduction and internal fixation as the most commonly performed surgical procedure followed by forearm tendon repair and fracture of hand repair. It further supports the reliability of comparisons outcome.

Being randomized control trial, our study has several important strengths. Blinding of the researchers and patients, equal allocation of participants, standardized anesthetic protocol, thereby improves internal validity and minimizing bias. We evaluated pain on multiple points (intraoperative/postoperatively), it provided extensive understanding of analgesic quality. In addition, by incorporating outcomes directly relevant to postoperative pain management, need for additional analgesia, and adverse effects, thereby increasing the practical applicability of the findings.

Despite various methodological strengths, certain limitations of the present trial should be acknowledged. The relatively limited sample size, a single-center trial, the external validity of the results may be limited. Long-term follow-up and assessment of patient satisfaction were not evaluated. Lastly, inflammatory and pharmacokinetic parameters were also not assessed. Future multicenter randomized trials are required to validate these findings.

CONCLUSION

The findings of the present study contribute to the increasing body of literature suggesting the use of adjunctive pharmacological agents for improving the effectiveness of IVRA. The addition of ketorolac with lidocaine increases the analgesic efficacy for both intraoperative and postoperatively in addition to extending analgesic duration.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Sumara Tabassam:** Conception, supervision.
2	**Neelam Ali:** Data collection, analysis, writing.
3	**Tabinda Maqsood:** Data collection, validation.
4	**Tayyab Riaz:** Visualization.
5	**Masooma Shafqat :** Literature view, editing.
6	**Muhammad Talha Anjum:** Critical revision.