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Indian study confirms,
Safety and Efficacy of Fixed dose Paracetamol & Lignocaine

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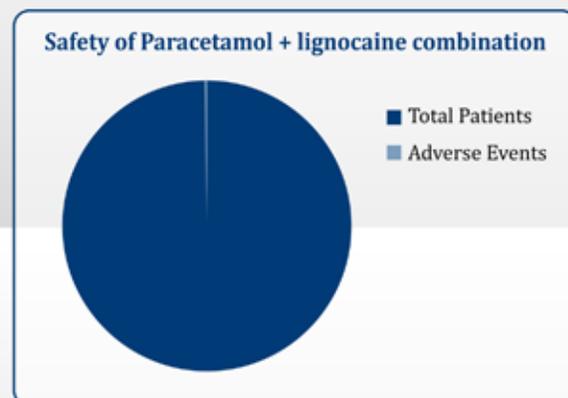
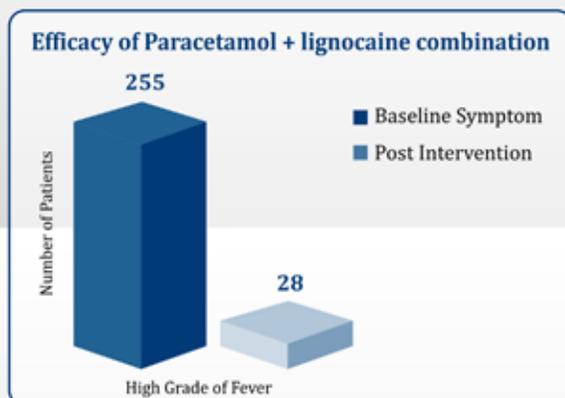
The Most Trusted Paracetamol



- Absolutely safe in combination with Lignocaine through IV/IM route¹
- Effective resolution of Pain seen on VAS score¹
- Significant analgesia observed at the site of injection²

Patient Response after Paracetamol + Lignocaine Injection

- 89% patients showed resolution of Fever¹
- It was well tolerated in 99.7% patients, proves overall safety of this combination.¹



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2. HayatM, Afshan G, Nasir M, AsgharS, Monem M. 2020 Feb,10 (cited 2022 Jan21); 12 (2)

Safety and Efficacy of Paracetamol + Lignocaine Injection in Patients with High-grade Fever: A Prospective Analysis

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ABSTRACT

High-grade fever is a common presenting symptom in various infectious and inflammatory conditions, requiring prompt and effective management. Paracetamol (acetaminophen) is a widely used antipyretic agent, while lignocaine possesses analgesic and anti-inflammatory properties. This prospective study evaluated and established the safety and efficacy of paracetamol + lignocaine injection in patients with high-grade fever. The study outcomes revealed that after administering paracetamol and lignocaine injections, 89% of patients experienced a reduction in high fever, while 68.6% of patients reported no or mild pain at the injection site. Based on these findings, the authors recommend that health care professionals consider the potential benefits of using paracetamol and lignocaine injections for patients suffering from severe fever accompanied by pain and discomfort.

Keywords: Fever, antipyretic, analgesic, anti-inflammatory

BACKGROUND

Elevated body temperature exceeding 38.3°C (100.4°F), known as fever, is a commonly observed abnormal physical sign in ill patients, often associated with systemic inflammatory response syndrome (SIRS) or infections. Fever has been linked to prolonged hospital stays in general intensive care unit (ICU) patients and unfavorable outcomes in specific patient populations.¹ To address fever, antipyretic therapy is typically initiated, which involves administering antipyretic medications or applying external cooling methods. The primary rationale behind such interventions includes enhancing patient comfort, reducing cardiovascular strain and preventing excessive oxygen consumption.¹ Prompt management of fever alleviates patient

discomfort, minimizes complications and optimizes patient outcomes.²

In clinical settings (community health care settings and hospitals), fever is frequently managed by administering acetaminophen (paracetamol) to reduce body temperature. Even in the ICU, using acetaminophen to treat fever in patients with infection is a common practice, driven by the rationale that fever places additional physiological stress on patients who are already critically ill.³

Additionally, lignocaine is also famed for its analgesic, anesthetic and anti-inflammatory properties,⁴ which can effectively reduce pain at the injection site and improve patient compliance. The combination of paracetamol and lignocaine has emerged as a promising therapeutic option owing to their complementary pharmacological properties.⁵

Given the significance of effective fever management in patients with high temperatures, it is crucial to examine the safety and efficacy of acetaminophen injection as a treatment for high fever.³

AIM

This study aims to evaluate the outcomes surrounding the administration of paracetamol + lignocaine injection in patients with high-grade fever. This research aims to provide insights into the safety and effectiveness

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CLINICAL STUDY

associated with this common practice by analyzing the obtained data.

METHODS

The study included:

- Patients who were 18 years or older.
- Experiencing high-grade fever ($>102^{\circ}\text{F}$).

Patients with serious underlying conditions such as acquired immunodeficiency syndrome (AIDS), cancer and renal or hepatic dysfunction were excluded.

Upon enrollment, the patients underwent measurement of initial body temperature and documented any associated symptoms. The patients received either intravenous (IV) or intramuscular (IM) administration of paracetamol + lignocaine injection, and their feedback regarding pain score (at the injection site) was recorded using a visual analog scale (VAS). Temperature readings and observations of any changes in associated symptoms were noted 15 to 30 minutes after administration. The occurrence of side effects, such as skin rashes, nausea, vomiting, etc., was monitored in the patients.

Written consent was obtained from all participants after providing them with comprehensive information about the study, the use of the medication in their condition, and the potential side effects. Data were collected anonymously, and the responses were analyzed using simple percentage calculations.

RESULTS

The study sample consisted of 349 patients, with 160 females and 189 males. Two hundred fifty-five patients initially presented with a baseline fever exceeding 102°F , while all the participants had some degree of fever. Among all the enrolled patients, 320 reported pain as an associated symptom, including 12 patients with joint pain, 6 with associated injury and 1 with severe arthralgia, abdominal pain and chest pain.

Following the administration of parenteral paracetamol + lignocaine injection, within a span of 30 minutes, 89% of patients experienced a reduction in high fever. Notably, 68.6% of patients reported no or only mild pain at the injection site (based on VAS score). Figure 1 depicts the baseline and post-intervention data of the patients regarding the efficacy of paracetamol + lignocaine injection in terms of fever resolution.

Furthermore, the parenteral administration of paracetamol + lignocaine injection demonstrated excellent

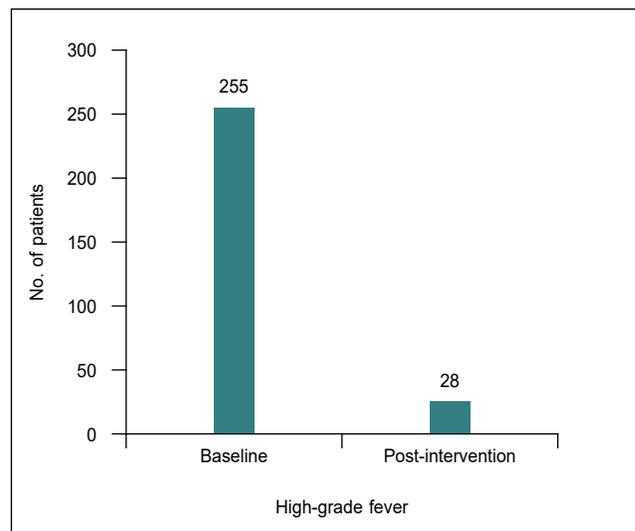


Figure 1. The reduction in the number of fever patients post-intervention.

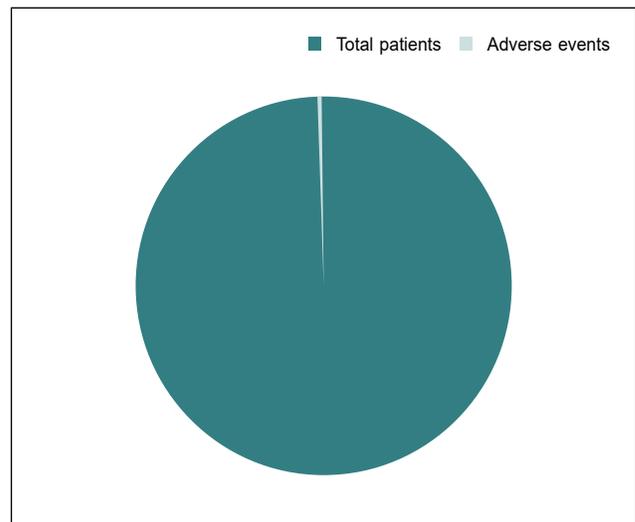


Figure 2. The post-intervention data regarding the safety of paracetamol + lignocaine combination.

tolerance in 99.7% of the patients, which proves the safety of this combination. Figure 2 depicts the post-intervention data of the patients regarding its safety.

These observations highlight the positive impact of the parenteral paracetamol + lignocaine combination in managing fever and pain in patients with high-grade fever.

DISCUSSION

Paracetamol (acetaminophen) is unquestionably a highly prevalent medication utilized globally. As an easily accessible over-the-counter drug, paracetamol is widely recognized as the primary and initial choice for treating fever and acute pain.⁶

Young et al in 2015 evaluated the effectiveness of acetaminophen in managing fever and probable infection and found that patients who received acetaminophen exhibited a lower mean daily peak body temperature, a lower mean daily average body temperature, and sustained resolution of fever compared to the placebo group. They also found that the occurrence of adverse events was not significantly different between the acetaminophen group and the placebo group. Overall, these findings demonstrate a modest antipyretic effect of parenteral paracetamol (acetaminophen) in patients with fever and probable infection.³ These findings align with our study as most of the patients (89%) receiving paracetamol + lignocaine injection experienced sustained resolution of fever without any adverse effects.

The combination of lignocaine and paracetamol is highly effective in reducing pain at the injection site and improving patient compliance. Recent studies have demonstrated that when lignocaine is administered alongside IV paracetamol, the occurrence of pain is dramatically reduced to a mere 2%, thereby increasing the overall acceptance of this particular formulation among patients.⁷ This result is even evident in our study, where paracetamol + lignocaine injection significantly decreased the pain at the injection site, as evident by the lowered VAS scores in the majority of the patients (68.6%).

Furthermore, clinical studies have shown a high level of tolerability, with extremely rare adverse reactions,⁸ which is also evident in our study and thus proves parenteral paracetamol to be desirable and safe.

CONCLUSION

Our study highlights the effectiveness of IV administration of a combination of paracetamol and lignocaine, which results in a rapid onset of action within 15 to 30 minutes. This treatment approach offers several favorable outcomes, including the absence of adverse effects, effective reduction of associated signs and a prolonged duration of action. Paracetamol + lignocaine injection ensures painless administration at the injection site, which enhances convenience for health care professionals. This injection's dual mechanism of action provides both antipyretic and analgesic benefits, making it a valuable choice for fever management.

These findings support the clinical rationale of utilizing paracetamol + lignocaine injection for short term

management of moderate pain and fever. It is recommended that physicians consider integrating this approach into their patient care strategies for individuals experiencing fever and related discomfort or pain.

Indian studies prove the safety and efficacy of a fixed-dose combination of paracetamol and lignocaine in managing high-grade fever and pain.

The combination of paracetamol and lignocaine:

- Is entirely safe when administered through the IM or IV route in patients.
- Effectively reduce pain at the injection site, as evidenced by a favorable VAS score.
- Significantly decreases body temperature in most patients indicating the effectiveness of the paracetamol and lignocaine combination.

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