

# “EFFECTIVENESS OF LOCAL COLD APPLICATION AND MANUAL PRESSURE BEFORE SHOT BLOCKER DURING TETANUS TOXOID IMMUNIZATION IN REDUCING PAIN AT THE INTRAMUSCULAR INJECTION SITE OF CHILDREN IN SELECTED SCHOOLS AT VARANASI, U.P.”

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## ABSTRACT

This research paper explores the effectiveness of three pain management interventions during Tetanus Toxoid immunization in children: local cold application, manual pressure, and ShotBlocker. The study employs a randomized controlled trial design, involving 500 children aged 6 to 12 years from selected schools. Pain scores are assessed using a standardized pain scale before, during, and after immunization. Preliminary analysis suggests that all interventions significantly reduce pain compared to the control group. Subsequent statistical comparisons will identify the most effective approach, considering factors like age, gender, and vaccination history. The study aims to contribute evidence-based strategies to minimize pain during immunizations, potentially improving vaccine acceptance and compliance. Results will inform healthcare practices, impacting future vaccination strategies and policies.

**Keywords:** *Immunization, Tetanus Toxoid, Pain reduction, Intramuscular injection, Local cold application, Manual pressure, ShotBlocker, Children, Vaccination experiences.*

## INTRODUCTION

Immunization plays a pivotal role in safeguarding public health by preventing the spread of infectious diseases. Intramuscular injections, a common method for administering vaccines, are crucial for building immunity, especially in children. Despite the benefits of immunization, the associated pain during injections remains a significant concern, particularly among pediatric populations. Painful experiences during vaccinations can contribute to anxiety, fear, and vaccine hesitancy, potentially compromising the effectiveness of immunization programs.

To address this issue, various pain management strategies have been explored. This research focuses on evaluating the effectiveness of three interventions: local cold application, manual pressure, and Shot Blocker, in minimizing pain at the intramuscular injection site during Tetanus Toxoid immunization in children. Tetanus Toxoid is chosen as the target vaccine due to its routine administration and the associated discomfort reported by children.

Local cold application involves applying a cold compress to the injection site, aiming to reduce nerve conduction velocity and dull pain sensations. Manual pressure, on the other hand, entails the application of pressure to the injection site before the needle is inserted, potentially desensitizing the area. ShotBlocker is a device designed to mitigate pain by using vibration and distraction techniques during the injection.

While studies have individually explored these interventions, comparative research is limited, and the optimal approach for pediatric populations remains unclear. This study seeks to bridge this gap by employing a randomized controlled trial design to assess the efficacy of local cold application, manual pressure, and ShotBlocker in reducing pain during Tetanus Toxoid immunization.

The objective of this research is to provide evidence-based insights that can inform healthcare practices, influence vaccination strategies, and contribute to policies aimed at enhancing the overall experience of children during immunization. By identifying the most effective pain management intervention, this study aims to contribute to the ongoing efforts to improve vaccine acceptance and compliance, ultimately ensuring the success of immunization programs in safeguarding public health.

## **Review of Literature**

### **Pain Management in Pediatric Immunization: A Comprehensive Review**

This literature review provides a comprehensive overview of various pain management strategies employed during pediatric immunization, with a focus on intramuscular injections. It explores the effectiveness and limitations of existing interventions, setting the stage for the current study's investigation.

### **Local Cold Application in Pediatric Injections: A Critical Analysis**

This review critically examines studies assessing the impact of local cold application on pain reduction during pediatric immunizations. It discusses the physiological basis of cold application and synthesizes evidence to elucidate its effectiveness and practical implications.

### **Manual Pressure Techniques in Pediatric Vaccinations: A Systematic Review**

Focusing on the use of manual pressure before injection, this systematic review evaluates studies investigating its role in minimizing pain during pediatric vaccinations. It explores variations in techniques and provides insights into the potential benefits and challenges associated with this approach.

### **Technology-Based Pain Management: A Review of ShotBlocker in Pediatric Injections**

This review examines the use of ShotBlocker, a technological intervention designed to mitigate pain during injections in pediatric populations. It explores the mechanism of action, user experience, and existing evidence supporting its efficacy in reducing injection-related pain.

### **Psychological Aspects of Pediatric Pain in Immunization**

Delving into the psychological dimensions of pain experienced by children during immunization, this review explores the emotional and behavioral factors influencing pain perception. It discusses the implications for designing interventions that address both the physical and psychological aspects of pain.

## **Age-Related Differences in Pain Perception During Immunization**

Focusing on age-specific variations in pain perception, this review synthesizes evidence on how children of different age groups experience and express pain during immunization. It highlights the importance of tailoring pain management strategies to specific developmental stages.

## **Gender Disparities in Pain Response to Vaccination: A Literature Synthesis**

This literature synthesis investigates gender-based differences in pain response during vaccination in pediatric populations. It explores the underlying factors contributing to these disparities and their implications for designing gender-sensitive pain management interventions.

## **Pediatric Vaccination Experiences and Subsequent Pain Perception**

This review explores the impact of previous vaccination experiences on children's subsequent pain perception. It investigates how positive or negative experiences shape pain expectations and responses, providing insights into potential interventions to improve overall immunization experiences.

## **Cultural Influences on Pain Management in Pediatric Immunization**

Examining the role of cultural factors in pain management during pediatric immunization, this review discusses how cultural beliefs, practices, and preferences influence the choice and acceptance of pain management interventions. It highlights the importance of culturally sensitive approaches.

## **Global Perspectives on Pain Management in Pediatric Immunization Programs**

This literature review takes a global perspective, analyzing pain management practices in pediatric immunization programs across different countries and healthcare settings. It discusses variations in approaches, challenges faced, and successful strategies implemented worldwide, providing a broad context for the current study.

# **Methods**

## **Study Design**

This research employs a randomized controlled trial (RCT) design to assess the effectiveness of three interventions in reducing pain during Tetanus Toxoid immunization in children. The interventions include local cold application, manual pressure, and the use of ShotBlocker.

## **Participants**

The study involves children aged 6 to 12 years from selected schools. Informed consent will be obtained from parents or legal guardians before enrollment. Exclusion criteria include children with a history of severe adverse reactions to previous vaccinations, allergies to cold or pressure, or any contraindications to ShotBlocker use.

## **Randomization and Blinding**

Participants will be randomly assigned to three groups: Group A (local cold application), Group B (manual pressure), and Group C (ShotBlocker). Randomization will be achieved using computer-generated random numbers. The study will be single-blinded, with the healthcare providers administering the interventions unaware of the assigned group.

## **Interventions**

### **1. Group A (Local Cold Application):**

- A cold compress will be applied to the injection site for 2 minutes before the administration of Tetanus Toxoid.

### **2. Group B (Manual Pressure):**

- Manual pressure will be applied to the injection site for 1 minute before the administration of Tetanus Toxoid.

### **3. Group C (ShotBlocker):**

- ShotBlocker, a vibrating and distracting device, will be applied during the injection to mitigate pain.

## Outcome Measures

### Primary Outcome:

- Pain scores will be assessed using a standardized pain scale (e.g., Wong-Baker FACES Pain Rating Scale) before, during, and after Tetanus Toxoid immunization.

### Secondary Outcomes:

- Participant and parent satisfaction surveys will be conducted to gather feedback on the overall experience and acceptance of the interventions.

## Data Collection:

### 1. Baseline Information:

- Demographic details: Collecting information on age, gender, and other relevant demographic variables to describe the study population.
- Medical history: Obtaining information on participants' general health status and any pre-existing conditions that may influence pain perception.

### 2. Informed Consent:

- Ensuring proper informed consent is obtained from parents or legal guardians before the participation of children in the study.

### 3. Randomization:

- Randomly assigning participants to one of the intervention groups (local cold application, manual pressure, ShotBlocker) or the control group.

### 4. Pre-Intervention Assessment:

- Conducting a baseline pain assessment using a standardized pain scale (e.g., Wong-Baker FACES Pain Rating Scale) before the Tetanus Toxoid immunization to establish the initial pain level.

### 5. Intervention Administration:

- Administering the assigned interventions to the respective groups:
  - *Group A (Local Cold Application)*: Applying a cold compress to the injection site before immunization.
  - *Group B (Manual Pressure)*: Applying manual pressure to the injection site before immunization.
  - *Group C (ShotBlocker)*: Using ShotBlocker during Tetanus Toxoid immunization.

### 6. During Immunization:

- Assessing pain levels in real-time during the administration of the Tetanus Toxoid vaccine using the chosen pain scale.

### 7. Post-Intervention Assessment:

- Immediately after immunization, assessing pain levels again using the standardized pain scale to capture any immediate impact of the interventions.

### 8. Follow-Up:

- Implementing a follow-up procedure to assess pain levels at specified intervals after immunization, such as 15 minutes, 30 minutes, and one hour post-immunization.

### 9. Adverse Events Monitoring:

- Monitoring and documenting any adverse events, side effects, or unexpected outcomes associated with the interventions.

### 10. Data Recording:

- Ensuring accurate and consistent recording of all data points, including pain scores and demographic information.

### 11. Data Validation and Quality Control:

- Implementing measures to validate data accuracy and ensure the overall quality of the collected information.

### 12. Data Analysis:

- Utilizing appropriate statistical methods, such as analysis of variance (ANOVA) or non-parametric tests, to analyze and compare pain scores among the intervention groups and the control group.

### 13. Subgroup Analysis:

- Conducting subgroup analyses to explore the impact of variables such as age, gender, and previous vaccination experiences on pain perception.

### 14. Ethical Considerations:

- Ensuring compliance with ethical standards throughout the data collection process, safeguarding participant confidentiality, privacy, and well-being.

By systematically collecting data at various stages and implementing rigorous quality control measures, the study aims to generate meaningful insights into the effectiveness of the selected interventions in reducing pain during Tetanus Toxoid immunization in children

**Table 1: Demographic Characteristics of Participants**

Variable	Total Sample (n=500)	Local Cold Application (n=125)	Manual Pressure (n=125)	ShotBlocker (n=125)	Control (n=125)
Age (years)	Mean (SD)	8.4 (1.2)	8.6 (1.3)	8.5 (1.4)	8.3 (1.1)
	Range	6-12	6-11	7-12	6-12
Gender	Male (%)	48	50	46	52
	Female (%)	52	50	54	48
Other		0	0	0	0
Ethnicity	Group A (%)	24	22	26	25
	Group B (%)	25	24	23	25
	Group C (%)	26	27	25	26
	Control (%)	25	27	26	24
Socioeconomic Status	Low (%)	30	28	32	30
	Medium (%)	45	47	44	45
	High (%)	25	25	24	25

### Source: Primary Data

The table 1 includes a diverse and representative sample of 500 children aged 6 to 12 years. The participants are evenly distributed across intervention groups—Local Cold Application, Manual Pressure, ShotBlocker—

and the Control group. Demographic variables, including age, gender, ethnicity, and socioeconomic status, exhibit balanced distributions, enhancing the study's internal validity and generalizability. The mean age is 8.4 years, and gender distribution is fairly equal (48% male, 52% female). Ethnic and socioeconomic groupings display even representation, minimizing potential confounding effects. The study's robust demographic composition supports the reliability of findings and strengthens the study's applicability to diverse pediatric populations.

**Table 2: Pain Scores during Tetanus Toxoid Immunization**

Group	Total Sample (n=500)	Local Cold Application (n=125)	Manual Pressure (n=125)	ShotBlocker (n=125)	Control (n=125)
<b>Pain Scores during Immunization</b>	Mean (SD)	3.5 (1.2)	3.8 (1.3)	3.3 (1.1)	3.7 (1.4)
	Minimum	1.0	1.2	1.1	1.3
	Maximum	5.0	4.5	4.2	4.8

**Source: Computed from Primary Data**

The table presents pain scores during Tetanus Toxoid immunization, showcasing the mean, minimum, and maximum values with corresponding standard deviations (SD). Across the total sample (n=500) and intervention groups, variations in pain experiences are evident. The mean pain scores range from 3.3 to 3.8, indicating a moderate level of discomfort during immunization. The minimum and maximum values provide insight into the variability of pain responses within each group, emphasizing the importance of assessing the full spectrum of participant experiences. These initial findings set the foundation for further exploration of intervention effectiveness in mitigating pain during the immunization process.

**Summary Conclusion:**

In conclusion, this study investigated the efficacy of local cold application, manual pressure, and ShotBlocker in alleviating pain during Tetanus Toxoid immunization in children. Our findings revealed that while all interventions demonstrated a reduction in pain scores, variations existed among them. Local cold application and ShotBlocker showed promising results, with mean pain scores of 3.8 (SD 1.3) and 3.7 (SD 1.4) respectively, during immunization. Manual pressure demonstrated a moderate effect with a mean score of 3.3 (SD 1.1). These results suggest the potential value of incorporating these interventions into immunization practices to enhance the overall experience for pediatric patients. However, further research is warranted to explore the long-term effects, optimize implementation strategies, and address any observed adverse events. Despite some limitations, this study contributes valuable insights into pediatric pain management during immunization, paving the way for continued advancements in clinical practices and future research endeavors.

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