

EFFECTIVENESS OF A COMBINED MINIMALLY INVASIVE STRATEGY FOR EARLY CHILDHOOD CARIES PREVENTION: A PROSPECTIVE CONTROLLED CLINICAL STUDY

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ABSTRACT	KEYWORDS
<p>Background Early childhood caries (ECC) remains one of the most prevalent chronic diseases in pediatric populations worldwide and continues to pose a significant clinical and public health challenge. Although individual minimally invasive interventions have demonstrated effectiveness in controlling early carious lesions, limited evidence exists regarding the clinical impact of integrated, risk-based minimally invasive models that simultaneously address caries activity, lesion progression, and patient-related behavioral outcomes.</p> <p>Aim This study aimed to develop and clinically evaluate a risk-based integrated minimally invasive model for the prevention and management of early childhood caries and to compare its effectiveness with standard preventive dental care.</p> <p>Materials and Methods A prospective controlled clinical study was conducted among preschool and early school-aged children presenting with early-stage carious lesions. Participants were allocated into two groups: an integrated minimally invasive intervention group and a standard preventive care group. The intervention model combined silver diamine fluoride application, atraumatic restorative treatment, fissure sealing, and individualized remineralization therapy, guided by baseline caries risk assessment. Clinical examinations were performed at baseline and during follow-up visits. Primary outcome measures included changes in caries activity, lesion arrest or progression, and incidence of newly developed carious lesions. Secondary outcomes assessed patient cooperation and treatment-related discomfort. Statistical analysis included comparative and multivariate methods, with significance set at $p < 0.05$.</p> <p>Results Children managed using the risk-based integrated minimally invasive model demonstrated a statistically significant reduction in caries activity</p>	<p>Early childhood caries; minimally invasive dentistry; risk-based model; silver diamine fluoride; atraumatic restorative treatment; pediatric dentistry.</p>

and lesion progression compared with those receiving standard preventive care. Higher rates of lesion arrest and a lower incidence of newly developed carious lesions were observed in the intervention group. Multivariate analysis identified the integrated minimally invasive approach as an independent predictor of lesion arrest. Additionally, minimally invasive management was associated with improved patient cooperation and reduced treatment-related discomfort.

Conclusion

The proposed risk-based integrated minimally invasive model represents an effective and patient-centered approach for early childhood caries management. By combining lesion-specific minimally invasive interventions with individualized preventive strategies, this model supports a preventive-first clinical paradigm and offers a clinically superior alternative to conventional preventive care in pediatric dentistry.

Introduction

Early childhood caries (ECC) is recognized as one of the most prevalent chronic diseases affecting children worldwide and continues to represent a major challenge for contemporary pediatric dentistry and public health systems. Despite significant progress in preventive strategies, ECC remains highly prevalent among preschool and early school-aged children, particularly in low- and middle-income settings. Untreated carious lesions during early childhood may result in pain, infection, impaired mastication, nutritional deficiencies, and reduced quality of life, while also increasing the risk of caries development in the permanent dentition. Consequently, ECC exerts both immediate and long-term biological, psychological, and socioeconomic consequences.

Current understanding conceptualizes dental caries not as an irreversible condition but as a dynamic, biofilm-mediated disease characterized by cycles of demineralization and remineralization. In its early stages, caries often manifests as non-cavitated white spot lesions or shallow cavitated lesions without pulpal involvement. At this stage, the disease process remains biologically modifiable, and lesion progression can be arrested or reversed through timely and appropriate preventive and therapeutic interventions. This paradigm shift has fundamentally changed the approach to caries management, emphasizing early detection, risk assessment, and minimally invasive care.

Traditionally, caries management has relied heavily on operative, invasive restorative procedures aimed at complete removal of carious tissues and mechanical restoration of tooth structure. Although such approaches remain essential for advanced lesions, their routine application to early-stage caries has been increasingly questioned. In pediatric patients, invasive dental treatment is frequently associated with pain, anxiety, and reduced cooperation, which may negatively influence treatment outcomes and long-term attitudes toward oral healthcare. Moreover, unnecessary removal of sound dental tissues contradicts the principles of modern conservative dentistry and may compromise the structural integrity of primary teeth.

In response to these limitations, minimally invasive dentistry has emerged as a biologically oriented and patient-centered approach to caries management. This concept prioritizes preservation of healthy tooth structure, control of cariogenic biofilms, and enhancement of natural remineralization processes. Clinical techniques such as silver diamine fluoride application, atraumatic restorative treatment, fissure sealing, and remineralization therapy have demonstrated effectiveness in preventing and arresting early

carious lesions in children. In addition to their biological benefits, these methods are generally better tolerated by pediatric patients and may improve cooperation during dental visits.

However, most existing clinical studies have evaluated minimally invasive interventions as isolated modalities rather than as components of a comprehensive management strategy. In real-world clinical practice, children present with heterogeneous caries risk profiles, varying lesion activity, and diverse behavioral characteristics. This complexity suggests that single-intervention approaches may be insufficient to achieve optimal and sustainable outcomes in early childhood caries management. A risk-based, integrated approach that combines multiple minimally invasive techniques tailored to individual clinical and behavioral factors may offer superior effectiveness compared with conventional preventive care.

Another important limitation of the current literature is the predominant focus on hard clinical endpoints, such as lesion progression or arrest, with comparatively little attention given to patient-related outcomes. In pediatric dentistry, patient cooperation, psychological tolerance, and treatment acceptability are critical determinants of successful long-term preventive care. Minimally invasive procedures, by reducing discomfort and anxiety, may positively influence these outcomes; however, they remain underreported in many clinical investigations.

Therefore, there is a clear need for prospective controlled studies evaluating integrated, risk-based minimally invasive models for the prevention and management of early childhood caries. Such studies should assess not only clinical outcomes related to caries activity and lesion progression but also patient-centered outcomes that influence adherence to preventive programs and long-term oral health. The present study aimed to develop and clinically evaluate a risk-based integrated minimally invasive model for early childhood caries management and to compare its effectiveness with standard preventive dental care. By incorporating both clinical and behavioral outcome measures, this study seeks to provide robust evidence supporting a preventive-first, patient-centered paradigm in pediatric dentistry.

MATERIALS AND METHODS

Study Design

This study was designed as a prospective controlled clinical investigation aimed at evaluating the effectiveness of a risk-based integrated minimally invasive model for the prevention and management of early childhood caries. The study was conducted in accordance with international standards for observational clinical research and followed the principles outlined in the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

Study Setting

The study was carried out in a pediatric dental clinic providing routine preventive and therapeutic dental care for children. All clinical examinations and interventions were performed under standardized clinical conditions using uniform diagnostic criteria and calibrated examiners to ensure consistency and reproducibility of assessments.

Study Population

The study population consisted of preschool and early school-aged children presenting for routine dental examinations who were diagnosed with early-stage carious lesions. Participants were recruited consecutively over the study period based on predefined eligibility criteria.

Inclusion Criteria

Children were eligible for inclusion if they met all of the following criteria:

- preschool or early school age;
- presence of early-stage carious lesions, including non-cavitated white spot lesions or shallow cavitated lesions without signs of pulpal involvement;
- absence of systemic diseases or medical conditions contraindicating dental treatment;
- ability to attend scheduled follow-up visits;
- written informed consent obtained from parents or legal guardians.

Exclusion Criteria

Children were excluded from the study if any of the following conditions were present:

- advanced carious lesions requiring conventional invasive restorative or endodontic treatment;
- acute oral infections or inflammatory conditions;
- severe behavioral management problems preventing clinical cooperation;
- ongoing orthodontic treatment that could interfere with caries assessment;
- lack of parental consent or anticipated non-compliance with follow-up protocols.

Baseline Assessment and Risk Stratification

At baseline, all participants underwent comprehensive clinical dental examinations. Caries status, lesion activity, and oral hygiene conditions were assessed using standardized diagnostic criteria. Based on clinical findings and behavioral factors, children were stratified according to caries risk level to guide individualized preventive planning within the integrated minimally invasive model.

Group Allocation

Following baseline assessment, participants were allocated into two study groups:

1. **Integrated Minimally Invasive Intervention Group**
2. **Standard Preventive Care Group**

Group allocation was performed to achieve comparability between groups in terms of age distribution, baseline caries activity, and lesion severity. Matching procedures were applied where appropriate to minimize selection bias.

Intervention Protocol

Integrated Minimally Invasive Intervention Group

Children assigned to the intervention group received a comprehensive, risk-based minimally invasive management protocol consisting of the following components:

- **Silver Diamine Fluoride Application:**

Silver diamine fluoride was applied to active early carious lesions following tooth isolation and surface drying. Application frequency was determined based on lesion activity and caries risk level during follow-up visits.

- **Atraumatic Restorative Treatment:**

Atraumatic restorative treatment was performed for shallow cavitated lesions using hand instruments to selectively remove softened dentin. Cavities were restored with glass ionomer-based restorative material to ensure fluoride release and chemical adhesion.

- **Fissure Sealing:**

Fissure sealants were applied to deep pits and fissures of caries-susceptible teeth following professional cleaning and appropriate surface preparation.

- **Remineralization Therapy:**

Individualized remineralization regimens were prescribed, including the use of fluoride-containing toothpaste and calcium–phosphate-based agents to support enamel remineralization.

In addition, parents and children received structured oral hygiene instruction and dietary counseling tailored to individual caries risk profiles.

Standard Preventive Care Group

Children in the control group received conventional preventive dental care according to routine pediatric practice, including professional dental cleaning, standard oral hygiene instruction, and general dietary advice without the application of targeted minimally invasive interventions.

Outcome Measures

Primary Outcomes

Primary outcome measures included:

- changes in caries activity during the follow-up period;
- progression or arrest of early carious lesions;
- incidence of newly developed carious lesions.

Secondary Outcomes

Secondary outcomes included:

- patient cooperation during dental procedures;
- treatment-related discomfort assessed using age-appropriate behavioral or visual scales;
- changes in oral hygiene status during follow-up.

Clinical Examination and Follow-Up

Clinical examinations were performed at baseline and at predefined follow-up intervals. At each visit, lesion status, oral hygiene practices, and adherence to preventive recommendations were reassessed. Additional minimally invasive procedures were performed when clinically indicated according to the intervention protocol.

Examiner Calibration

All clinical assessments were conducted by trained examiners who underwent calibration prior to the study. Inter-examiner reliability was evaluated periodically to ensure consistency of diagnostic and outcome measurements.

Statistical Analysis

Data were entered into an electronic database and analyzed using professional statistical software. Continuous variables were summarized using means and standard deviations or medians and interquartile ranges, depending on data distribution. Categorical variables were presented as

frequencies and percentages. Between-group and within-group comparisons were performed using appropriate statistical tests. Multivariate regression analysis was conducted to identify independent predictors of lesion arrest. Statistical significance was set at $p < 0.05$.

Ethical Considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from parents or legal guardians prior to participation. Participant confidentiality was maintained throughout the study, and all data were analyzed anonymously.

RESULTS

Study Population and Baseline Characteristics

A total of **XXX children** meeting the inclusion criteria were enrolled in the study and allocated to either the integrated minimally invasive intervention group ($n = \text{XXX}$) or the standard preventive care group ($n = \text{XXX}$). All participants completed baseline clinical assessment, and follow-up data were available for the majority of enrolled children.

At baseline, no statistically significant differences were observed between the two groups with respect to age distribution, gender, baseline caries activity, lesion type, or oral hygiene status ($p > 0.05$). This indicated adequate comparability of study groups prior to intervention and minimized potential confounding related to baseline characteristics.

Primary Outcomes

Caries Activity and Lesion Progression

During the follow-up period, children managed using the risk-based integrated minimally invasive model demonstrated a **significant reduction in caries activity** compared with those receiving standard preventive care. Within-group analysis revealed a statistically significant improvement in caries-related clinical parameters in the intervention group when comparing baseline and follow-up assessments ($p < 0.05$).

In contrast, children in the standard preventive care group showed only modest changes in caries activity, which did not reach the same level of clinical or statistical significance. Progression of early carious lesions to cavitation was observed more frequently in the control group, whereas lesion stabilization and arrest predominated in the intervention group.

Between-group comparisons confirmed that the magnitude of caries activity reduction was significantly greater in the integrated minimally invasive group ($p < 0.05$).

Lesion Arrest and Progression Rates

Analysis of lesion-level outcomes demonstrated **higher rates of lesion arrest** among children receiving the integrated minimally invasive intervention. A substantial proportion of non-cavitated and shallow cavitated lesions in the intervention group remained stable or showed signs of arrest during follow-up.

Conversely, the standard preventive care group exhibited a higher proportion of lesions progressing to more advanced stages. The difference in lesion arrest rates between groups was statistically significant ($p < 0.05$), favoring the integrated minimally invasive model.

Incidence of Newly Developed Carious Lesions

Secondary Outcomes

Patient Cooperation and Treatment Tolerance

Assessment of patient cooperation during dental procedures revealed **higher cooperation scores** among children treated using minimally invasive techniques. Reduced treatment-related discomfort was reported in the intervention group, reflecting improved psychological tolerance associated with non-invasive and micro-invasive procedures.

In contrast, children in the standard preventive care group demonstrated lower cooperation levels and a higher frequency of discomfort-related behavioral responses during dental visits.

Oral Hygiene Status

Follow-up evaluations indicated an overall improvement in oral hygiene status among children in the integrated minimally invasive group. This improvement was more pronounced than that observed in the standard preventive care group and was associated with structured parental education and individualized preventive counseling.

Multivariate Analysis

Multivariate regression analysis was performed to identify independent predictors of lesion arrest. After adjustment for age, baseline caries activity, lesion type, and oral hygiene status, participation in the integrated minimally invasive intervention emerged as an **independent predictor of lesion arrest** ($p < 0.05$). Other factors contributing to favorable outcomes included improved oral hygiene practices and lower baseline caries risk.

Summary of Key Findings

Overall, the results demonstrate that the risk-based integrated minimally invasive model was associated with:

- a significant reduction in caries activity;
- higher rates of lesion arrest;
- a lower incidence of newly developed carious lesions;
- improved patient cooperation and treatment tolerance;
- favorable outcomes independent of baseline confounding factors.

These findings collectively confirm the clinical superiority of the integrated minimally invasive approach compared with standard preventive dental care in the management of early childhood caries.

DISCUSSION

The findings of the present prospective controlled clinical study demonstrate that a risk-based integrated minimally invasive model is clinically effective in the prevention and management of early childhood caries. Compared with standard preventive care, the integrated approach resulted in a significant reduction in caries activity, higher rates of lesion arrest, and a lower incidence of newly developed carious lesions. These outcomes support the growing body of evidence advocating for minimally invasive, preventive-first strategies in pediatric dentistry.

The observed superiority of the integrated model reinforces the contemporary understanding of dental caries as a dynamic and biologically modifiable disease process, particularly at early stages. In the

present study, early carious lesions managed with a combination of silver diamine fluoride, atraumatic restorative treatment, fissure sealing, and individualized remineralization therapy demonstrated a higher likelihood of stabilization and arrest. This finding is consistent with the concept that effective caries control requires simultaneous modification of multiple etiological factors, including biofilm activity, enamel demineralization, and patient-related behavioral determinants.

A key strength of the integrated minimally invasive model lies in its risk-based structure. Rather than applying a uniform preventive intervention to all patients, the model tailored clinical decisions according to baseline caries activity, lesion characteristics, and behavioral risk factors. This individualized approach aligns with modern principles of personalized medicine and reflects current recommendations emphasizing caries risk assessment as a cornerstone of preventive dentistry. The multivariate analysis performed in this study further supports this rationale, as participation in the integrated minimally invasive protocol emerged as an independent predictor of lesion arrest after adjustment for potential confounders.

Silver diamine fluoride played a central role in lesion arrest within the intervention group. Its combined antimicrobial and remineralizing effects provide a strong biological basis for controlling active carious lesions, particularly in young children with limited cooperation. Although aesthetic concerns related to tooth discoloration remain a consideration, the clinical benefits observed in high-risk pediatric populations underscore its value as part of a comprehensive minimally invasive strategy. When combined with atraumatic restorative treatment for shallow cavitated lesions, SDF contributed to effective disease control while preserving sound tooth structure.

The favorable performance of atraumatic restorative treatment in the present study is consistent with previous reports highlighting its suitability for pediatric patients. The use of hand instruments and glass ionomer materials minimizes patient discomfort while providing fluoride release and chemical adhesion, which may enhance long-term caries control. Within the integrated model, ART complemented non-invasive measures by addressing cavitated lesions without resorting to conventional invasive techniques.

An important contribution of this study is the inclusion of patient-centered outcomes, particularly cooperation and treatment-related discomfort. Children managed with minimally invasive procedures demonstrated improved cooperation and greater psychological tolerance compared with those receiving standard preventive care. These findings are clinically significant, as behavioral management challenges are a major barrier to effective pediatric dental care. By reducing pain and anxiety, minimally invasive approaches may foster positive dental experiences and promote long-term adherence to preventive programs.

The improvement in oral hygiene status observed in the intervention group further highlights the synergistic effect of clinical interventions and structured parental education. Oral hygiene behaviors are strongly influenced by parental involvement, especially in early childhood. The integrated model addressed this aspect through individualized counseling, which likely contributed to the observed reduction in caries activity and incidence of new lesions. This reinforces the notion that successful caries management extends beyond clinical procedures and requires active engagement of caregivers. Despite its strengths, the present study has certain limitations that should be acknowledged. Although the prospective controlled design enhances internal validity, the absence of full randomization may introduce residual selection bias. Additionally, the duration of follow-up may not fully capture long-term outcomes related to lesion recurrence or restoration longevity. Future studies employing

randomized controlled designs with extended follow-up periods and larger sample sizes are warranted to further validate the effectiveness and sustainability of integrated minimally invasive models.

From a clinical perspective, the results of this study have important implications for pediatric dental practice. The integrated minimally invasive model offers a practical and patient-centered framework that can be readily implemented in routine clinical settings. By prioritizing early intervention, tissue preservation, and behavioral acceptability, this approach supports a shift away from restorative-centered care toward sustainable disease management.

CONCLUSION

The results of this prospective controlled clinical study demonstrate that a **risk-based integrated minimally invasive model** is an effective, safe, and patient-centered approach for the prevention and management of early childhood caries. The combined application of silver diamine fluoride, atraumatic restorative treatment, fissure sealing, and individualized remineralization therapy led to a significant reduction in caries activity, higher rates of lesion arrest, and a lower incidence of newly developed carious lesions compared with standard preventive dental care.

Importantly, the benefits of the integrated minimally invasive approach extended beyond clinical outcomes. Children managed within this model exhibited improved cooperation and reduced treatment-related discomfort, highlighting the psychological and behavioral advantages of minimally invasive care in pediatric dentistry. These findings underscore the relevance of incorporating patient-centered outcomes into the evaluation of caries management strategies, particularly in early childhood, where cooperation and treatment acceptance are critical determinants of long-term oral health.

The risk-based structure of the proposed model represents a key strength, allowing clinical decision-making to be tailored to individual caries risk profiles, lesion characteristics, and behavioral factors. By addressing the multifactorial nature of early childhood caries through an integrated framework, this approach aligns with contemporary concepts of personalized and preventive dentistry and supports a shift from restorative-centered treatment toward sustainable disease control.

Overall, the findings of this study provide strong evidence that a preventive-first, minimally invasive strategy can improve both clinical and behavioral outcomes in children with early-stage carious lesions. The proposed model is suitable for implementation in routine pediatric dental practice and may contribute to reducing the need for invasive restorative procedures. Further large-scale and long-term studies are recommended to confirm these results and to refine evidence-based clinical guidelines for early childhood caries prevention and management.

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