

Pain Assessment in Patients with Cyanotic Congenital Heart Disease Undergoing Phlebotomy for polycythemia in Tikur Anbessa Specialized Hospital: A Cross-Sectional Study

Investigator: Lensa Habtamu, MD.

Final Year Pediatric and Child Health Resident

Advisor: Henok Tadele, MD.

Associate Professor of Pediatrics and Child Health

Consultant Pediatrician and Pediatric Cardiologist

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SCHOOL OF MEDICINE

DEPARTMENT OF PEDIATRICS AND CHILD HEALTH

Name of investigator	Lensa Habtamu (MD, Pediatrics and Child Health Resident)
Name of advisors	Advisor: Henok Tadele, MD. Associate Professor of Pediatrics and Child Health Consultant Pediatrician and Pediatric Cardiologist
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Address of investigator	Tel: +251973021812 e-Mail: lensahberhanu@gmail.com

APPROVAL SHEET

ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF PEDIATRICS AND CHILD HEALTH

I, the undersigned pediatrics Resident, declared that I have submitted my original work on a title: "Pain Assessment in Patients with Cyanotic Congenital Heart Disease Undergoing Phlebotomy for polycythemia in Tikur Anbessa Specialized Hospital: A Cross-Sectional Study" for examination.

Submitted by:

Dr. Lensa Habtamu (MD, Pedatrics and Child Health Resident)

This thesis work has been submitted for examination with my approval as an advisor.

Approved by: Advisor: Henok Tadele, MD. _____

Associate Professor of Pediatrics and Child Health

Consultant Pediatrician and Pediatric Cardiologist

STATEMENT OF THE AUTHOR

By my signature below, I declare that this thesis is my own work. I followed the ethical guidelines while preparing the paper, collecting data and analyzing data. I declare that this thesis has not been submitted to any other institution for any academic degree, diploma, or certificate.

June, 2026
Addis Ababa, Ethiopia

Dr. Lensa Habtamu (MD, Pediatrics and Child health Resident)

Research Advisor:

Dr. Henok Tadele (MD, Associate Professor of Pediatrics and Child Health

Consultant Pediatrician and Pediatric Cardiologist)

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Acronyms and abbreviations

- TASH – Tikur Anbessa Specialized Hospital
- CHD – Congenital Heart Disease
- NRS – Numeric Rating Scale
- WBS – Wong–Baker Faces Pain Rating Scale
- SPSS – Statistical Package for Social Sciences
- TOF – Tetralogy of Fallot
- VAS- Visual Analog Scale,
- FPS-R – Faces Pain Scale–Revised
- FLACC – Face, Legs, Activity, Cry, Consolability

ABSTRACT

Background: Children with cyanotic congenital heart disease frequently undergo therapeutic phlebotomy to manage secondary polycythemia, yet procedural pain is rarely assessed or managed in Ethiopian healthcare settings. This study assessed the severity of phlebotomy-related pain and identified associated factors among children with cyanotic congenital heart disease at Tikur Anbessa Specialized Hospital.

Methods: A cross-sectional study was conducted from October 1, 2025 to March 1, 2026 among 118 children aged 4 to 16 years with echocardiography-confirmed cyanotic congenital heart disease undergoing therapeutic phlebotomy. Pain was assessed immediately post-procedure using validated age-appropriate tools: Wong-Baker Faces Pain Rating Scale for children aged 4 to 7 years and Numeric Rating Scale for older children. Pain scores were categorized as mild for scores of 2 to 3 versus moderate-to-severe for scores of 4 or higher. Data were analyzed using descriptive statistics, bivariate analysis, and binary logistic regression in SPSS version 27.

Results: Two-thirds of children experienced moderate-to-severe pain, with a mean pain score of 4.0 (SD 1.00) and a median of 4 (IQR 3–5), with scores ranging from 2 to 6. Preprocedural anxious children experienced moderate to severe pain, $p< 0.001$. Young children, less than 5 years of age, experienced moderate to severe phlebotomy pain, $p < 0.001$. Children with frequent phlebotomy attempts experienced moderate to severe pain, $p<0.0001$.

Conclusion: Two-third of children with cyanotic CHD undergoing therapeutic phlebotomy experienced moderate to severe procedural pain. Pre-procedural anxiety, young age, and frequency of phlebotomy attempts associated with moderate to severe phlebotomy pain. Therapeutic Phlebotomy pain needs to be assessed and managed. Systematic pre-procedural psychological preparation including the use of distraction techniques, and improving competency to improve first-attempt venipuncture success recommended particularly in young children with cyanotic CHD undergoing therapeutic phlebotomy.

Keywords: Cyanotic congenital heart disease, therapeutic phlebotomy, procedural pain, children, Ethiopia

1. INTRODUCTION

1.1. BACKGROUND

Cyanotic congenital heart disease is a group of birth defects that lower arterial oxygen and cause a bluish discoloration (cyanosis). It occurs when blood flow to the lungs is reduced or when oxygen-poor and oxygen-rich blood mix. [1]

Worldwide, more than 4.18 million children under five years were living with congenital heart disease in 2021, and although deaths have fallen since 1990, the burden remains concentrated in low- and lower-middle income regions; severe forms such as cyanotic defects contribute disproportionately to early mortality. [2] In Africa, TOF is the dominant cyanotic lesion, comprising about 10% of all pediatric CHD cases. [3]. In Ethiopia, the burden cyanotic CHD in neonates with face roughly 3.5-times higher mortality than those with non-cyanotic defects; overall in-hospital neonatal mortality was 9.9%**,** with an incidence of 11.9 per 1,000 person-days. [4]

Africa has limited cardiac surgical capacity, only ~22 centers regularly performing open-heart surgery in sub-Saharan Africa (out of 78 across the continent). [5] Ethiopia currently has four local centers providing cardiac surgery, and care pathways often depend on visiting missions or out-of-country referral leading to long waits and out-of-pocket costs. [6] Recent estimates suggest Africa can surgically treat <5% of annual congenital cases, underscoring severe access constraints. [7]

When cyanotic heart disease is not corrected, chronic low oxygen can lead to secondary erythrocytosis (polycythemia) and hyper viscosity with symptoms such as headaches, visual changes, and an increased risk of thrombosis and stroke. [8] In Ethiopia, hospital data show a high prevalence of polycythemia and thrombocytopenia among children with unoperated cyanotic heart disease, underscoring risks from an untreated course. [9]

Therapeutic phlebotomy in children with symptomatic polycythemia secondary to cyanotic congenital heart disease should be performed in a monitored clinical setting with appropriate fluid replacement, aiming to lower hematocrit below 65% while avoiding repeated procedures that may cause iron deficiency, in line with expert review guidance on the management of hyperviscosity in cyanotic patients.[10]

In many African settings, including Ethiopia, delayed diagnosis and limited access to cardiac surgery contribute to a higher proportion of children with cyanotic congenital heart disease remaining unoperated, placing them at increased risk of secondary polycythemia and its related complications. [9]

An Ethiopian hospital study of children with unoperated cyanotic defects reported a high prevalence of polycythemia and thrombocytopenia and variable use of iron therapy and phlebotomy, indicating the need for standardized supportive care. [9]

Comparative studies of the Visual Analog Scale, Faces Pain Scale–Revised, and Wong-Baker

Faces Scale in pediatric patients have demonstrated that all three instruments are highly reliable and comparable, highlighting the critical role of validated tools in accurately assessing pain in clinical practice. [11]

A systematic review in five Sub-Saharan African countries demonstrated that validated pediatric pain scales including the Faces Pain Scale–Revised, Numerical Rating Scale, and Visual Analog Scale are widely underutilized in clinical practice, highlighting persistent gaps in routine pain assessment for children. [12]

A hospital-based study in Northwest Ethiopia applied age-appropriate scales, using the revised FLACC for non-verbal children under five, the Faces Pain Scale–Revised for children aged 5–7, and the Numeric Rating Scale for older children to evaluate pain during admission. [13]

1.2. STATEMENT OF THE PROBLEM

Children with cyanotic congenital heart disease often need repeated phlebotomy, yet the pain from this procedure is not routinely assessed or managed. Venipuncture is among the most painful procedures for children and can cause anxiety, fear, and harmful physiologic stress. In Ethiopia, studies show major gaps in pediatric pain practice, with very few clinicians using validated pain scales and almost no documentation of pain scores in medical charts. As a result, the true burden of phlebotomy pain in cyanotic CHD patients remains unknown. Uncontrolled pain not only

worsens children's hospital experiences but also affects long-term trust in healthcare. This study aims to measure pain severity and identify related factors in patients with cyanotic CHD undergoing phlebotomy for polycythemia at Tikur Anbessa Specialized Hospital.

1.3. SIGNIFICANCE OF THE STUDY

The findings from this study will be important for several reasons:

- Provides baseline data on phlebotomy-related pain in children with cyanotic CHD undergoing phlebotomy for polycythemia at Tikur Anbessa Specialized Hospital.
- Identifies key patient, procedural, and environmental factors linked to pain severity.
- Promotes the use of validated pain assessment tools in routine pediatric cardiac care.
- Guides healthcare providers toward better pain management strategies and training.
- Serves as a foundation for future research and improved child-centered care in Ethiopia.

2. LITREATURE REVIEW

2.1. Pain in Pediatric Procedures

Venipuncture is one of the most frequently performed medical procedures in pediatric care and often causes significant pain and distress. Despite its prevalence, pain during venipuncture is frequently underestimated and inconsistently documented in clinical practice [14,15]. Research examining venipuncture pain in children with chronic diseases has demonstrated that these populations experience substantial procedural pain, with children suffering from chronic conditions reporting higher anticipatory anxiety and pain scores compared to healthy children undergoing first-time venipuncture [15]. This suggests that repeated procedures in the absence of adequate pain management create sensitization rather than habituation effects, a finding with direct relevance to children with cyanotic congenital heart disease requiring serial therapeutic phlebotomy.

Studies across diverse pediatric populations have documented that the simple insertion of a needle represents one of the most frightening and distressing medical procedures for hospitalized children [16]. The recognition and assessment of acute pain resulting from venipuncture remains inadequate in many clinical settings despite the availability of validated pain assessment tools and evidence-based interventions to reduce procedural pain [16]. Although no studies have specifically examined procedural pain in children with cyanotic congenital heart disease undergoing therapeutic phlebotomy, it is reasonable to expect that this population experiences similar or potentially greater pain given their repeated exposure to needle procedures and the larger volumes of blood typically removed during therapeutic phlebotomy compared to standard diagnostic venipuncture. This gap in the literature highlights the need for careful attention to pain assessment and management during routine hospital procedures in this vulnerable population.

2.2. Pain Assessment Tools in Children

Validated tools are essential for accurately assessing pain in children, particularly given the subjective nature of pain and developmental variations in children's ability to communicate pain intensity. The Wong-Baker FACES Pain Rating Scale is widely used for self-reporting pain in children and presents six faces ranging from a smiling face representing no pain to a crying face representing worst pain, with scores from 0 to 10 [20,21]. The scale has demonstrated strong

validity and reliability across diverse pediatric populations and clinical settings. Studies have shown that Wong-Baker scores correlate with both physiological indicators such as skin conductance fluctuations during venipuncture and with observer-rated pain assessments, supporting its use in routine clinical care and research applications [16].

A systematic review of faces scales for self-report of pain intensity in children examined the psychometric properties, clinical utility, and validity evidence for various faces scales including the Wong-Baker FACES, Faces Pain Scale-Revised, and other similar instruments [20]. The review concluded that faces scales demonstrate good to excellent reliability and validity when used in appropriate age groups, with the Wong-Baker FACES showing particularly strong evidence for use in children aged 4 years and older. The scale's visual representation of pain intensity through facial expressions allows young children who may not fully understand numeric concepts to reliably communicate their pain experience [20].

The Numeric Rating Scale represents an alternative approach for older children and adolescents who can conceptualize pain intensity on a numeric continuum from 0 representing no pain to 10 representing worst pain imaginable. Validation studies have confirmed that children aged 8 years and older can reliably use numeric rating scales to report pain intensity, with test-retest reliability and construct validity comparable to adult populations [21]. The choice between faces scales and numeric scales should be guided by the child's developmental level and cognitive ability, with faces scales preferred for younger children and numeric scales appropriate for older children and adolescents who demonstrate numeric competency.

The FLACC scale represents a behavioral assessment tool designed for children who cannot self-report pain, evaluating five parameters including Face, Legs, Activity, Cry, and Consolability. Studies have demonstrated strong reliability and validity of the FLACC scale in various clinical settings including vascular access procedures in preschoolers and children with cognitive impairment who cannot use self-report measures [17]. Recent systematic reviews continue to confirm that the Wong-Baker FACES, Numeric Rating Scale, FLACC, and related tools are reliable and feasible in clinical settings, ensuring accurate pain assessment and improving patient care when properly implemented [11,12,17].

2.3. Global Studies on Venipuncture Pain

Across countries and settings, a consistent pattern has been observed in pediatric venipuncture pain research. Without specific interventions, children's venipuncture pain often reaches moderate to severe levels on standard pain scales, with substantial proportions of children reporting pain scores indicating clinically significant distress [18]. However, controlled trials have demonstrated that age-appropriate psychological interventions including education, distraction, and anxiety-reduction strategies can significantly reduce pain scores, confirming that procedural pain is both measurable and modifiable with evidence-based, low-risk interventions [18,19].

A Cochrane systematic review of psychological interventions for needle-related procedural pain and distress in children and adolescents synthesized evidence from multiple randomized controlled trials examining interventions such as distraction, preparation and information provision, cognitive-behavioral approaches, hypnosis, and combined interventions [18]. The review found that distraction interventions demonstrated significant effects in reducing pain and distress during needle procedures across diverse pediatric populations and clinical settings. The evidence supported the routine implementation of psychological interventions as part of standard care for children undergoing needle procedures rather than as optional add-ons reserved for particularly distressed children.

A randomized clinical trial published in 2023 demonstrated that immersive virtual reality significantly lowered self-reported pain, observer-rated anxiety, and physiological stress markers including heart rate and salivary cortisol compared to standard care during pediatric venipuncture [19]. The intervention group showed effect sizes ranging from 0.4 to 0.8 across different

outcome measures, representing clinically meaningful reductions in pain and distress. Other controlled studies have reported similar benefits for video-based distraction, animated cartoons, and interactive activities during venipuncture, confirming that procedural pain can be substantially reduced through systematic implementation of evidence-based distraction strategies [14,19].

These findings from diverse international contexts underscore the importance of routine assessment and management of procedure-related pain in children. The evidence base demonstrates that pediatric venipuncture pain should not be dismissed as a minor, unavoidable discomfort but rather recognized as a clinically significant experience amenable to intervention through relatively simple, low-cost, and low-risk psychological and behavioral strategies that can be integrated into standard procedural protocols.

2.4. Studies from African Settings

Research from African pediatric populations provides important context for understanding venipuncture pain in settings with resource constraints and diverse cultural contexts. In Egypt, a descriptive study of preschool-age children undergoing venipuncture reported that most participants experienced severe pain according to the Wong-Baker FACES scale, with mean pain scores substantially higher than the moderate pain threshold [24]. The study documented statistically significant negative correlations between children's age and pain scores, with younger children reporting higher pain intensity than older children even within the narrow preschool age range. These findings highlight the substantial burden of needle-related pain in routine outpatient procedures similar to therapeutic phlebotomy in children with cyanotic congenital heart disease, demonstrating that venipuncture pain represents a significant clinical problem in African pediatric settings [24].

The Egyptian study also revealed that venipuncture pain was consistently underestimated by both mothers and nurses compared to children's self-reported pain scores, with healthcare providers assigning significantly lower pain ratings than children themselves [24]. This observation underscores the critical importance of using validated child self-report measures rather than relying solely on observer assessments, as adults may systematically underestimate pediatric procedural pain. The successful implementation of the Wong-Baker FACES scale in this

Egyptian setting demonstrated the feasibility and cultural appropriateness of faces-based pain assessment in African pediatric populations, providing validation for similar approaches in other Sub-Saharan African countries including Ethiopia.

Research from Sub-Saharan Africa examining the validation and reliability of pediatric self-report pain scales has confirmed that instruments including the Faces Pain Scale-Revised, Wong-Baker FACES, and Numeric Rating Scale demonstrate good psychometric properties when used in African pediatric populations [12]. A systematic review examining validation studies across five Sub-Saharan African countries found that these tools performed comparably to validation studies conducted in high-income settings, with children able to understand and reliably use faces scales to communicate their pain experience [12]. This evidence supports the use of validated self-report pain scales in African clinical and research contexts, confirming that cultural and linguistic diversity does not preclude effective pain assessment when tools are properly administered with age-appropriate instructions.

2.5. Studies from Ethiopian Settings

Ethiopian research on pediatric pain assessment and management reveals substantial gaps in knowledge, attitudes, and clinical practices that create barriers to adequate procedural pain control. At Tikur Anbessa Specialized Hospital, a descriptive cross-sectional study assessed the knowledge, attitude, and practice of pediatric and pediatric surgical residents regarding childhood pain assessment and management [22]. The study revealed significant deficiencies across all three domains, with residents achieving a mean knowledge score of only 14.56 out of 27 possible points, representing approximately 54 percent correct responses. Perhaps most concerning, 86.2 percent of residents reported not utilizing pain assessment tools in their clinical practice despite the availability of validated instruments and clinical practice guidelines recommending routine pain assessment [22].

The study identified specific knowledge gaps including limited understanding of pharmacological pain management principles, inadequate familiarity with available pain assessment tools appropriate for different developmental stages, and misconceptions about children's pain perception and expression [22]. Attitudinal barriers included concerns about time required for pain assessment in busy clinical settings, perceptions that pain assessment tools add

complexity without improving clinical decision-making, and beliefs that experienced clinicians can accurately estimate pain severity through clinical observation without need for formal measurement. These findings from the primary institution where the current study was conducted provide important context for interpreting patterns of pain management and assessment in the pediatric cardiac clinic setting.

Complementing this, a cross-sectional study conducted at St. Paul's Hospital Millennium Medical College's Neonatal Intensive Care Unit observed 1,352 painful procedures over a defined observation period, with venipuncture being the second most common painful procedure after heel stick [23]. The study documented that zero pain scores were recorded in medical records for any of these procedures, and no analgesic interventions including topical anesthetics or systemic analgesics were administered for procedural pain management despite hospital policies recommending pain assessment and treatment [23]. The complete absence of pain documentation and analgesic use for over one thousand painful procedures highlights systemic under-assessment and undertreatment of procedural pain in Ethiopian critical care settings, suggesting that the problem extends beyond knowledge deficits to include institutional culture and workflow barriers that prevent implementation of evidence-based pain management practices [23].

These Ethiopian studies reveal a concerning pattern where validated pain assessment tools exist and evidence-based pain management strategies are known, yet implementation in routine clinical practice remains minimal. The gap between knowledge and practice appears to stem from multiple factors including inadequate training in pain assessment and management during medical education, absence of institutional protocols mandating pain assessment as a vital sign, limited accountability mechanisms for pain documentation, time pressures in busy clinical settings, and potentially cultural factors affecting how healthcare providers conceptualize and prioritize pediatric procedural pain. Addressing these multilevel barriers will require coordinated interventions targeting individual provider knowledge and skills, institutional policies and protocols, and broader healthcare system structures that either facilitate or impede effective pain management.

We identified no published studies that specifically measured phlebotomy pain among children with cyanotic congenital heart disease undergoing therapeutic phlebotomy for polycythemia in Ethiopia or in broader global literature database searches. This represents a significant gap given the substantial and growing population of children with unoperated cyanotic heart disease requiring repeated palliative phlebotomy in settings with limited access to corrective cardiac surgery. The current study addresses this gap by providing the first systematic assessment of procedural pain during therapeutic phlebotomy in this vulnerable population, using validated pain assessment tools to quantify pain severity and identify modifiable factors that could inform evidence-based pain management protocols.

3. OBJECTIVE OF THE STUDY

3.1. General objective

- To determine the severity of phlebotomy pain and associated factors among cyanotic congenital heart disease patients undergoing phlebotomy for polycythemia at Tikur Anbessa Specialized Hospital.

3.2. Specific objective

- To determine the severity of phlebotomy-related pain using validated pediatric pain assessment tools.
- To identify patient-related, procedural, and environmental factors associated with pain severity during phlebotomy.

4. MATERIALS AND METHODS

4.1. Study Area and Setting

This study was conducted at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia. Tikur Anbessa Specialized Hospital is the largest tertiary referral and teaching hospital in the country, affiliated with Addis Ababa University College of Health Sciences. The hospital operates a dedicated pediatric cardiac clinic that provides comprehensive follow-up and treatment services for children with congenital and acquired heart diseases. The cardiac clinic is staffed by pediatric cardiologists, cardiac nurses, and support personnel, and serves as the main referral center for pediatric cardiac care in Ethiopia, receiving patients from across the country and neighboring regions.

The pediatric cardiac clinic operates five days per week in an outpatient setting, providing services including echocardiography, electrocardiography, medication management, pre-operative assessment for children awaiting cardiac surgery, and palliative management for children with inoperable or not-yet-operated cardiac conditions. Therapeutic phlebotomy for polycythemia in children with cyanotic congenital heart disease is performed in the cardiac clinic setting, with approximately two to three procedures conducted per day during regular clinic operations. The procedures are performed by experienced cardiac clinic nurses under the supervision of pediatric cardiologists, following institutional protocols for blood volume removal based on patient weight, baseline hematocrit, and clinical status.

4.2. Study Design and Period

An institution-based cross-sectional study design was employed to assess the severity of phlebotomy pain and associated factors among children with cyanotic congenital heart disease. Cross-sectional design was selected as appropriate for the study objectives, which focused on measuring pain prevalence and identifying correlates at a single point in time rather than examining changes over time or establishing causality. Data collection was conducted over a six-month period from October 1, 2025 to March 1, 2026. This timeframe was selected to allow adequate enrollment of the target population while accounting for seasonal variations in patient presentation and clinic operations.

4.3. Source and Study Population

The source population comprised all children with cyanotic congenital heart disease receiving ongoing follow-up care at the pediatric cardiac clinic of Tikur Anbessa Specialized Hospital. This included children with various forms of cyanotic congenital heart disease including but not limited to tetralogy of Fallot and its variants, tricuspid atresia, double outlet right ventricle, transposition of the great arteries, and other complex cyanotic lesions. Children in the source population attended regular follow-up visits ranging from monthly to quarterly intervals depending on disease severity and clinical status, with therapeutic phlebotomy performed as needed based on hematocrit monitoring and symptom assessment.

The study population was defined as children with echocardiography-confirmed cyanotic congenital heart disease who underwent therapeutic phlebotomy for polycythemia at Tikur Anbessa Specialized Hospital during the study period. Echocardiography confirmation was required to ensure diagnostic accuracy and exclude children with suspected but unconfirmed cyanotic heart disease. The indication for therapeutic phlebotomy was determined by treating physicians based on either laboratory criteria with hematocrit exceeding institutional thresholds, typically 65 percent or higher, or clinical symptoms of hyper viscosity including headache, dizziness, visual disturbances, or poor concentration that could be attributed to elevated hematocrit.

4.4. Sample Size Determination and Sampling Method

4.4.1. Sample Size Determination

Initial sample size calculations were performed using the single population proportion formula for cross-sectional studies, assuming an expected proportion of moderate-to-severe procedural pain of 50% based on general pediatric venipuncture literature, a 95% confidence level, and a 5% margin of error. This calculation yielded an initial target sample size of 384 participants.

To adjust for the finite nature of the target population at the study site, the finite population correction formula was applied:

$$n_{adj} = \frac{n_0}{\left(1 + \frac{n_0 - 1}{N}\right)}$$

A recent study at the same hospital documented 146 patients with polycythemia. Because only a subset of these patients undergoes therapeutic phlebotomy, N = 146 serves as a conservative upper-bound estimate of the target population size.

Applying the correction formula with $n_0 = 384$ and N = 146 yields the following adjusted sample size requirement:

$$n_{adj} = \frac{384}{\left(1 + \frac{384 - 1}{146}\right)}$$

Adjusted sample size is 106.

4.4.2. Sampling Method

A consecutive sampling approach was employed to minimize selection bias and maximize statistical efficiency. All children meeting the eligibility criteria and presenting for therapeutic phlebotomy during the predefined six-month study period were approached for enrollment. This method was selected over probability sampling given the relatively small number of eligible children undergoing the procedure during any given time period, which would have made random sampling logistically challenging.

A total of 118 children met the eligibility criteria and were enrolled in the study with complete data collection, representing all eligible participants who presented during the study period with no refusals or withdrawals.

The achieved sample of 118 participants exceeds the adjusted sample size requirement.

4.5. Inclusion and exclusion criteria

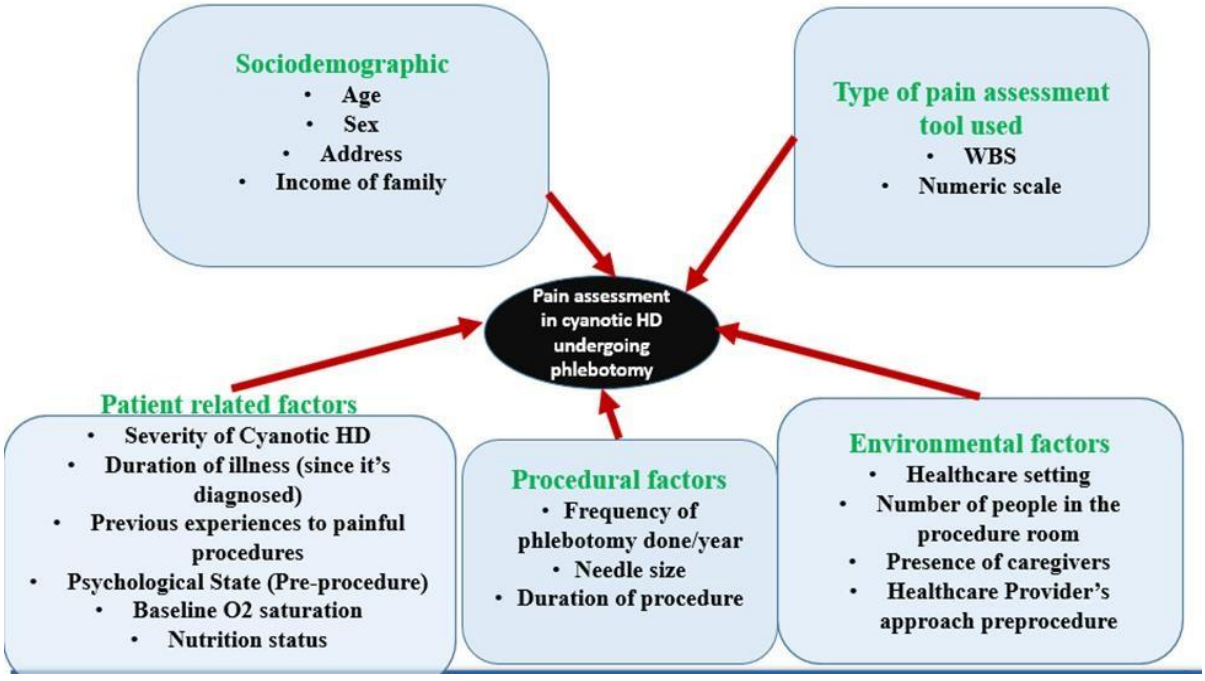
4.5.1. Inclusion criteria:

- Children aged 4 years and above.
- Echocardiography-confirmed diagnosis of cyanotic congenital heart disease.
- Undergoing phlebotomy for polycythemia
- Ability to understand and communicate pain levels using the study tools

4.5.2. Exclusion criteria

- Children with acute illness or decompensated heart failure at the time of assessment.
- Children with other chronic neurological or medical conditions that may affect pain perception.
- Children who had major surgery within the past month.
- Use of analgesics or sedative medications within 24 hours before phlebotomy.
- Non-compliance or inability to participate in the assessment process.

4.6. Conceptual Framework



4.7. Study variable

4.7.1. Dependent variable

- Phlebotomy pain severity score

4.7.2. Independent variables

- **Patient-related factors:** Age, Sex, baseline oxygen saturation, nutritional status, duration of illness, prior exposure to painful procedures, psychological state.
- **Procedural factors:** Frequency of phlebotomy, needle size, duration of procedure.
- **Environmental factors:** Presence of caregivers, number of people in the procedure room, and provider approach before the procedure.

4.8. Operational definition

Key concepts and variables were operationally defined to ensure consistency in measurement and interpretation.

- **Therapeutic phlebotomy** was defined as the removal of blood via venipuncture for the purpose of reducing hematocrit and blood viscosity in children with secondary polycythemia due to cyanotic congenital heart disease, with volume removed determined by the treating physician based on patient weight, baseline hematocrit, and clinical status [10]. This distinguished therapeutic phlebotomy from diagnostic venipuncture where smaller volumes are removed solely for laboratory testing.
- **Pain severity** was defined as the level of pain reported by the child using either the Numeric Rating Scale scored from 0 to 10 or the Wong-Baker FACES Pain Rating Scale scored from 0 to 10, with higher scores indicating greater pain intensity [20,21]. For categorical analysis, pain was classified as mild pain for scores of 2 to 3, moderate pain for scores of 4 to 5, and moderate-to-severe pain for scores of 6 or higher. The binary classification used in logistic regression analysis defined mild pain as scores of 2 to 3 and moderate-to-severe pain as scores of 4 or higher, based on established clinical interpretation guidelines indicating that scores of 4 and above represent pain requiring intervention. [20,21]
- **Validated pain assessment tool** was defined as an instrument that has been tested for

reliability and validity in pediatric populations and is applied according to recommended age group guidelines. For this study, the Wong-Baker FACES Pain Rating Scale was used for children aged 4 to 7 years, and the Numeric Rating Scale was used for children aged 8 years and older, following established recommendations for developmental appropriateness of pain assessment instruments. [20]

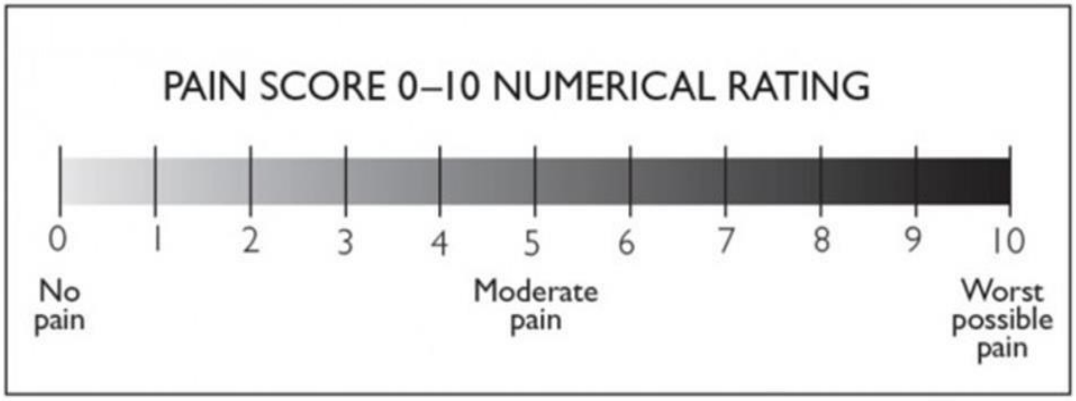
- **Pre-procedural psychological** state was defined as the child's emotional and behavioral state observed immediately before the therapeutic phlebotomy procedure, assessed by trained observers using standardized criteria. Children were categorized as calm when they appeared relaxed with normal facial expression, cooperative behavior, and minimal signs of anxiety. Children were categorized as mildly anxious when they demonstrated some signs of worry including nervous facial expression, fidgeting, or mild reluctance but remained generally cooperative and able to follow instructions. Children were categorized as very anxious or fearful when they demonstrated overt distress including crying, strong verbal protests, physical resistance, or attempts to escape the situation [18].
- **Hyperviscosity symptoms** were defined as clinical manifestations related to increased blood viscosity in children with elevated hematocrit, including headache, dizziness, visual disturbances, poor concentration, or fatigue that could be attributed to polycythemia rather than other causes [7,8]. The presence of these symptoms represented one indication for therapeutic phlebotomy even when hematocrit levels were below absolute thresholds.

4.9. Data collection tool

- A structured questionnaire was used to collect socio-demographic and clinical information.
- Pain severity was assessed using the **Wong–Baker FACES® Pain Rating Scale** and the **Numeric Rating Scale (NRS)**, which are validated and widely used in children.
- Using two scales allows data triangulation, which strengthens validity and helps identify differences in how children understand pain scores.
- The age of 4 years and above was chosen because children at this stage can reliably self-report using both numeric and face scales.

- A data extraction format was used to obtain relevant information from patients' medical records.
- To mitigate barriers, data collectors used simple scripts in the child's primary language, provided caregiver-assisted translation when needed, and conductedbrief comprehension checks to ensure accurate responses.





4.10. Data collection Method

After obtaining written informed consent from parents/guardians and assent from eligible children, trained data collectors conducted face-to-face interviews with caregivers and children. Pain scores were recorded immediately after the phlebotomy procedure, while socio-demographic and clinical data were collected through interviews and chart reviews.

4.10.1. Wong–Baker FACES® Pain Rating Scale (WBF)

- Generally used for children 4–12 years.
- For this study Applied to participants aged 4 years and above immediately after phlebotomy.

How to administer (step-by-step)

1. Show the 6 faces in order and read the standard script in simple language:
   "These faces show how much something can hurt. This face (point to 0) means no pain. This face (point to 10) means the worst pain you can imagine. Point to the face that shows how much you hurt right now."
2. Ensure the child chooses one face without coaching; accept first choice.
3. Record the corresponding number below (0, 2, 4, 6, 8, 10).

Scoring

- Faces map to even numbers: **0, 2, 4, 6, 8, 10** (interval scale).

Interpretation (use these bands consistently)

- **0** = No pain
- **2–4** = Mild pain
- **6** = Moderate pain
- **8–10** = Severe pain

4.10.2. Numeric Rating Scale (NRS)

For children typical **≥8 years** who understand numbers 0–10.

How to administer (step-by-step)

1. Say: "On a scale from **0 to 10**, where **0** means *no pain at all* and **10** means *the worst pain you can imagine*, what number is your pain **right now**?"
2. If needed, anchor examples: "0 is no pain; 5 is in-between; 10 is the worst."
3. Record the **single number** the child says (integers preferred; accept 0–10).

Scoring

- Single number from **0–10**.

Interpretation

- **0** = No pain
- **1–3** = Mild pain
- **4–6** = Moderate pain
- **7–10** = Severe pain

4.11. Data analysis:

Data were collected using KoboToolbox and exported to SPSS version 27 for analysis. Descriptive statistics (means, standard deviations, frequencies, and percentages) were used to summarize the data. Logistic regression was applied to identify factors associated with pain severity, and the results were presented as odds ratios with 95% confidence intervals. Statistical significance was set at $p < 0.05$. Results were displayed using tables, charts, and graphs.

4.12. Ethical clearance

Ethical approval was obtained from the Department of Pediatrics and Child Health, School of Medicine, Addis Ababa University. Written informed consent was obtained from parents or guardians, and assent was obtained from children aged 12 years and above. Confidentiality was maintained through anonymized data coding, and participation was voluntary. Participants were informed of their right to withdraw from the study at any time without any consequences.

5. RESULTS

5.1. Sociodemographic Characteristics

The most common cardiac diagnosis was Tetralogy of Fallot and its variants, representing 45.8% (n = 54) of the study population. Other diagnoses included tricuspid atresia and its variants (8.5%, n = 10), double-outlet right ventricle variants (3.4%, n = 4), and D-transposition of the great arteries (3.4%, n = 4). The remaining 39.0% (n = 46) consisted of a heterogeneous group of complex cyanotic congenital heart lesions.

Most participants were residents of the Oromia Region (44.1%, n = 52) or Addis Ababa (37.3%, n = 44), while 18.6% (n = 22) originated from other regions, including Southern Ethiopia and Amhara. Caregiver educational attainment varied, with 37.3% (n = 44) having completed primary education, 32.2% (n = 38) secondary education, 23.7% (n = 28) college or higher education, and 6.8% (n = 8) having no formal education.

Nutritional status was assessed using weight-for-height or BMI-for-age z-scores for wasting and height-for-age z-scores for stunting. Regarding wasting, 40.7% (n = 48) of children had normal nutritional status, 35.6% (n = 42) were moderately wasted, and 23.7% (n = 28) were severely wasted, resulting in an overall wasting prevalence of 59.3% (n = 70). For linear growth, 44.1% (n = 52) had normal height-for-age, whereas 25.4% (n = 30) were moderately stunted and 30.5% (n = 36) were severely stunted, yielding an overall stunting prevalence of 55.9% (n = 66). Concurrent wasting and stunting were identified in 42.4% (n = 50) of participants.

With respect to clinical characteristics, the mean baseline oxygen saturation was 72.7% (SD = 12.2; range: 40–94%). The mean hemoglobin concentration was 22.1 g/dL (SD = 2.1; range: 18.0–28.0 g/dL), and the mean hematocrit was 69.8% (SD = 6.6; range: 56–88%).

The psychological state of participants immediately before the procedure varied across the sample. Overall, 37.3% (n = 44) were calm, 27.1% (n = 32) were mildly anxious, and 35.6% (n = 42) were very anxious or fearful.

Table 1. Sociodemographic Characteristics (N=118)

Characteristic	n (%) or Mean ± SD
Demographics	
Age (months), mean ± SD	99.8 ± 47.2
Age (years), median (IQR)	8.0 (4.6–12.0)
Age group	
4–8 years	56 (47.5%)
8–10 years	22 (18.6%)
11–13 years	28 (23.7%)
14 years or older	12 (10.2%)
Sex	
Male	58 (49.2%)
Female	60 (50.8%)
Residence	
Oromia	52 (44.1%)
Addis Ababa	44 (37.3%)
Other regions	22 (18.6%)
Caregiver education	
No formal education	8 (6.8%)
Primary school	44 (37.3%)
Secondary school	38 (32.2%)
College or higher	28 (23.7%)
Cardiac Diagnosis	
Tetralogy of Fallot and variants	54 (45.8%)
Tricuspid atresia and variants	10 (8.5%)
Other complex cyanotic lesions	54 (45.8%)
Clinical Parameters	
Baseline O_2 saturation (%), mean ± SD	72.7 ± 12.2
Hemoglobin (g/dL), mean ± SD	22.1 ± 2.1
Hematocrit (%), mean ± SD	69.8 ± 6.6
Nutritional Status	
Wasting (W/H or BMI-for-Age z-score)	
Normal (z-score above -2)	48 (40.7%)
Moderately Wasted / MAM (z-score -2 to -3)	42 (35.6%)
Severely Wasted (z-score below -3)	28 (23.7%)
Stunting (Height-for-Age z-score)	
Normal (z-score above -2)	52 (44.1%)
Moderately Stunted (z-score -2 to -3)	30 (25.4%)
Severely Stunted (z-score below -3)	36 (30.5%)
Psychological State Pre-Procedure	
Calm	44 (37.3%)
Mildly anxious	32 (27.1%)
Very anxious/fearful	42 (35.6%)

5.2. Pain Score Distribution and Classification

Pain was assessed immediately following the therapeutic phlebotomy procedure using age-appropriate validated pain scales: the Wong-Baker Faces Pain Scale for younger children and the Numeric Rating Scale for older children capable of providing numeric ratings. Observed pain scores ranged from 2 to 6 on the combined 1–10 scale, with a mean score of 4.0 (SD = 1.0) and a median of 4 (IQR, 3–5). No child reported a pain score within the severe range (7–10).

The distribution of pain scores was as follows: 5.1% (n = 6) of children reported a score of 2, 27.1% (n = 32) a score of 3, 37.3% (n = 44) a score of 4, 23.7% (n = 28) a score of 5, and 6.8% (n = 8) a score of 6.

For analytical purposes, pain scores were dichotomized using a threshold of ≥4 to create a binary outcome variable distinguishing mild pain (scores 2–3) from moderate-to-severe pain (scores 4–6). Based on this classification, 32.2% (n = 38) of children experienced mild pain, whereas 67.8% (n = 80) experienced moderate-to-severe pain during therapeutic phlebotomy. The distribution of pain scores is presented in Table 2.

Table 2. Distribution of Pain Scores (N=118)

Pain Score	n (%)	Cumulative %
2	6 (5.1%)	5.1%
3	32 (27.1%)	32.2%
4	44 (37.3%)	69.5%
5	28 (23.7%)	93.2%
6	8 (6.8%)	100.0%
Summary Statistics		
Mean ± SD	4.00 ± 1.00	
Median (IQR)	4 (3–5)	
Range	2–6	
Binary Classification		
Mild pain (scores 2–3)	38 (32.2%)	
Moderate-to-severe pain (scores ≥4)	80 (67.8%)	

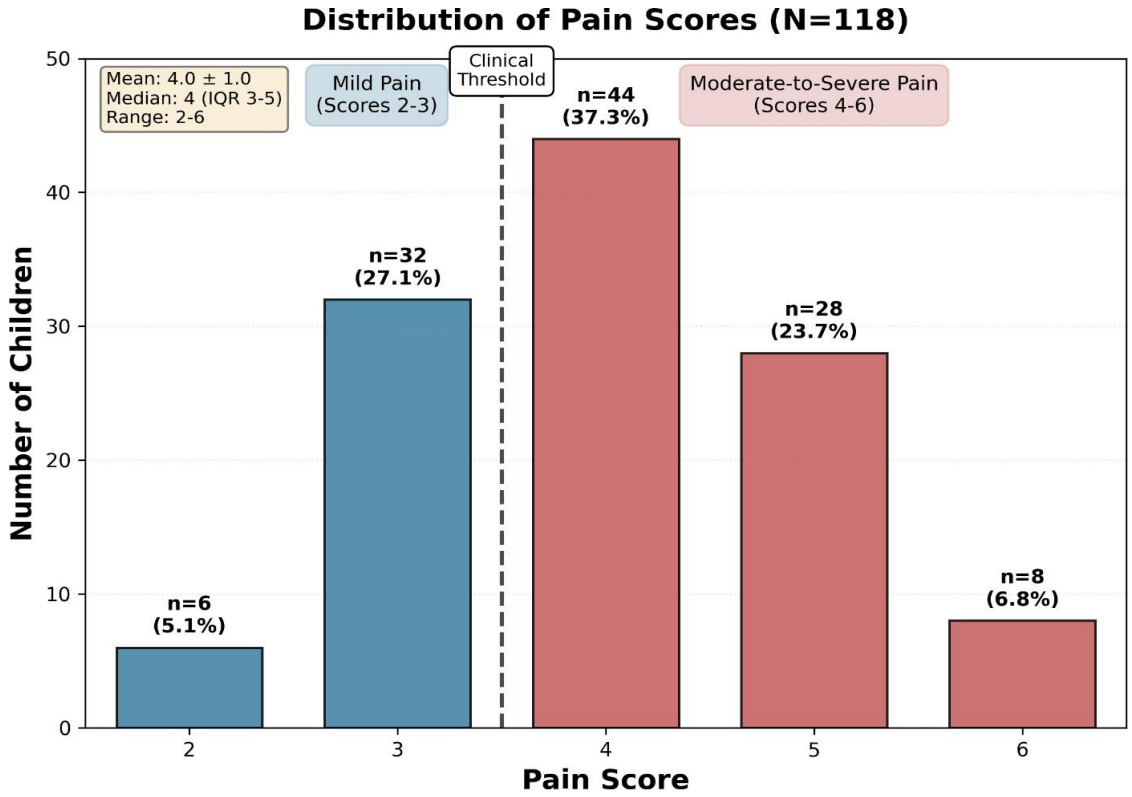


Figure 1. Distribution of self-reported pain scores among 118 children with cyanotic congenital heart disease undergoing therapeutic phlebotomy.

5.3. Procedural Characteristics

The majority of therapeutic phlebotomy procedures (81.4%, n = 96) were performed based on laboratory hematocrit cutoff criteria, whereas 18.6% (n = 22) were indicated for symptomatic hyperviscosity, including headache, dizziness, or visual disturbances. Most children (83.1%, n = 98) had not received hydration within the two hours preceding the procedure, while 15.3% (n = 18) had received hydration. Hydration status was unknown for 1.7% (n = 2) of participants.

Needle gauge selection varied across procedures: 40.7% (n = 48) were performed using 24-gauge needles, 30.5% (n = 36) using 21–22-gauge needles, and 28.8% (n = 34) using 20-gauge needles. The venipuncture site was the hand in 61.0% (n = 72) of cases and the antecubital fossa in 39.0% (n = 46). A tourniquet was applied in 91.5% (n = 108) of procedures, whereas 8.5% (n = 10) were performed without tourniquet use.

The number of venipuncture attempts required varied across procedures. Successful venipuncture was achieved on the first attempt in 52.5% (n = 62) of procedures, while 32.2% (n = 38) required two attempts and 15.3% (n = 18) required three or more attempts.

The median procedure duration, measured from initial skin puncture to completion, was 20 minutes (IQR, 15–20 minutes). The median volume of blood removed was 200 mL (IQR, 147–315 mL). All participants (100%, n = 118) received iso-volumic replacement with normal saline following blood removal. The mean number of individuals present in the procedure room, including healthcare staff, physicians, and family members, was 6.5 (SD = 1.2).

Regarding pain management approaches, provider communication prior to the procedure included explanation of procedural steps in all cases (100%, n = 118). In addition, 81.4% (n = 96) of cases included reassurance or coping strategies, while 18.6% (n = 22) involved explanation only.

Non-pharmacological support strategies during the procedure were also commonly used. Positioning or comfort holds were provided in all cases (100%, n = 118), while distraction techniques (e.g., video, phone, or toys) were used in 44.1% (n = 52) of cases, and breathing techniques (e.g., deep breathing, counting, or blowing) were used in 35.6% (n = 42) of cases.

Only 1.7% (n = 2) of children had received analgesic medication within the 24 hours preceding phlebotomy; in both cases, the medication was low-dose aspirin prescribed for cardiac indications rather than procedural pain prophylaxis. No adverse events related to the phlebotomy procedure were reported among the 118 participants (100%).

5.4. Association Between Psychological State and Pain Severity

The relationship between pre-procedural psychological state and pain severity showed a clear association. Table 3 presents the cross-tabulation of psychological state and the binary pain outcome.

Among the 44 children who were calm, 77.3% (n = 34) experienced mild pain and 22.7% (n = 10) experienced moderate-to-severe pain. In the mildly anxious group (n = 32), 12.5% (n = 4)

experienced mild pain, while 87.5% (n = 28) experienced moderate-to-severe pain. All children who were very anxious or fearful (100%, n = 42) experienced moderate-to-severe pain, with no cases of mild pain observed in this group.

A chi-square test showed a statistically significant association between psychological state and pain severity ($p < 0.001$). The distribution of pain outcomes across psychological states is illustrated in Figure 2.

Table 3. Cross-Tabulation of Psychological State and Pain Severity (N=118)

Psychological State	Mild Pain (Scores 2–3)	Moderate-to-Severe Pain (Scores ≥4)	Total
Calm	34 (77.3%)	10 (22.7%)	44 (100%)
Mildly anxious	4 (12.5%)	28 (87.5%)	32 (100%)
Very anxious/fearful	0 (0%)	42 (100%)	42 (100%)
Total	**38 (32.2%)**	**80 (67.8%)**	**118 (100%)**

Note: Chi-square test, $p < 0.001$. Complete separation observed in the very anxious/fearful category, where all children experienced moderate-to-severe pain

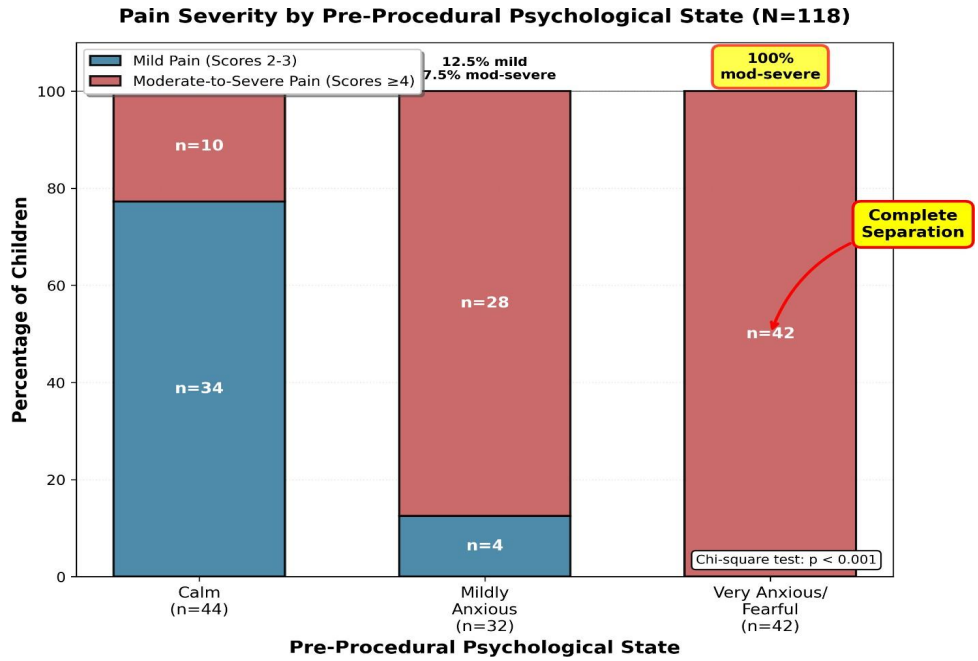


Figure 2. Distribution of pain severity by pre-procedural psychological state among children undergoing therapeutic phlebotomy (n = 118)

5.5. Bivariate Associations with Pain Severity

Bivariate analysis identified several patient-related and procedural variables significantly associated with moderate-to-severe pain.

Age showed a strong inverse association with pain severity ($p < 0.001$). Children with moderate-to-severe pain had a lower median age of 60 months (IQR, 49–108) compared to 144 months (IQR, 120–165) among those with mild pain.

The number of venipuncture attempts was also significantly associated with pain outcomes ($p < 0.001$). Children with mild pain had a median of 1 attempt (IQR, 1–1), whereas those with moderate-to-severe pain had a median of 2 attempts (IQR, 1–2).

The indication for the procedure was significantly associated with pain severity ($p = 0.011$). Among children undergoing phlebotomy for symptomatic hyperviscosity, 90.9% ($n = 20$) experienced moderate-to-severe pain, compared to 62.5% ($n = 60$) among those treated based on laboratory cutoff criteria.

Sex showed a statistically significant association with pain severity ($p = 0.049$), with moderate-to-severe pain reported in 76.7% ($n = 46$) of female participants compared with 58.6% ($n = 34$) of male participants.

Use of distraction techniques was significantly associated with pain severity ($p < 0.001$). Distraction was more frequently observed among children experiencing moderate-to-severe pain.

Procedure duration was associated with pain severity ($p < 0.001$). The median duration was 20 minutes (IQR, 20–30) among children with mild pain and 20 minutes (IQR, 15–20) among those with moderate-to-severe pain.

Blood volume removed was also associated with pain severity ($p < 0.001$). The median volume was 300 mL (IQR, 239–400) in the mild pain group and 176 mL (IQR, 139–230) in the moderate-to-severe pain group.

Based on a screening threshold of $p < 0.25$, 21 variables were selected for multivariable analysis, including residence, needle gauge, venipuncture site, tourniquet use, breathing support techniques, time since last phlebotomy, prior phlebotomy frequency, baseline oxygen saturation, hemoglobin level, and hematocrit.

5.6. Multivariate Analysis: Binary Logistic Regression

5.6.1. Variable Selection and Model Specification

A binary logistic regression model was constructed to identify independent predictors of moderate-to-severe pain during therapeutic phlebotomy. Candidate variables were selected based on bivariate screening ($p < 0.25$), clinical relevance, and sample size considerations to reduce the risk of model overfitting. Prior to model fitting, multicollinearity among candidate predictors was assessed and found not to be problematic. The final model included age, sex, pre-procedural psychological state, number of venipuncture attempts, needle gauge, use of distraction support, clinical indication for phlebotomy, and hematocrit level.

5.6.2. Model Fit and Discrimination

As shown in Table 4, the final binary logistic regression model demonstrated strong explanatory performance, with a Cox and Snell R^2 of 0.614 and a Nagelkerke pseudo-R^2 of 0.859. The model had a -2 Log Likelihood value of 35.890, indicating good overall model fit.

Model calibration was assessed using the Hosmer–Lemeshow goodness-of-fit test. The test was not statistically significant ($\chi^2 = 10.918$, $df = 8$, $p = 0.206$), indicating no evidence of poor model fit and suggesting that the predicted probabilities were consistent with the observed outcomes.

The classification results presented in Table 5 demonstrated excellent discriminatory performance. Overall, the model correctly classified 93.2% of cases. Using moderate-to-severe

pain as the outcome of interest, the model achieved a sensitivity of 95.0% and a specificity of 89.5%.

Table 4. Binary Logistic Regression Model Fit Statistics

Statistic	Value
-2 Log Likelihood	35.890
Cox & Snell R^2	0.614
Nagelkerke R^2	0.859
Hosmer-Lemeshow Test	
Chi-square	10.918
df	8
p-value	0.206

Note: Model terminated at iteration 20 due to complete separation in the very anxious psychological state category. Hosmer-Lemeshow test $p > 0.05$ indicates adequate model fit.

Table 5. Classification Table for Binary Logistic Regression Model

	Predicted Mild Pain	Predicted Moderate-to-Severe Pain	Percentage Correct
Observed Mild Pain	34	4	89.5%
Observed Moderate-to-Severe Pain	4	76	95.0%
Overall			**93.2%**

Note: Classification cutoff value = 0.50. Sensitivity = 95.0%, Specificity = 89.5%.

5.6.3. Regression Coefficients and Adjusted Odds Ratios

5.6.4. Regression Coefficients and Adjusted Odds Ratios

The results of the multivariable logistic regression analysis are presented in Table 6. After adjustment for potential confounders, only two variables remained significantly associated with moderate pain during therapeutic phlebotomy.

Pre-procedural psychological state was an independent predictor of pain severity. Compared with children who were calm before the procedure (reference category), those who were mildly anxious had significantly different odds of experiencing moderate pain (adjusted OR = 0.037, 95% CI: 0.004–0.379, p = 0.005). The direction and magnitude of this association should be interpreted in the context of the model coding and reference category specified in the regression

analysis.

The number of venipuncture attempts was also independently associated with pain severity. Children requiring additional venipuncture attempts had substantially higher odds of experiencing moderate pain (adjusted OR = 454.17, 95% CI: 5.32–38,797.73, p = 0.007). The extremely wide confidence interval suggests imprecision in the estimated effect size, likely due to sparse data and the small number of observations in some categories.

The remaining predictors included in the model age, sex, needle gauge, use of distraction techniques, clinical indication for phlebotomy, and hematocrit level were not significantly associated with pain severity after adjustment for other covariates (all p > 0.05). Although these variables did not reach statistical significance, the estimated effects generally followed clinically plausible directions and may warrant further investigation in larger studies.

Complete regression coefficients, adjusted odds ratios, standard errors, and 95% confidence intervals are presented in Table 6.

Table 6. Binary Logistic Regression Predicting Moderate-to-Severe Pain (N=118

Predictor	Category	Adjusted OR	95% CI	p-value
Age (months)				
	4-8 years	1		
	Above 8 years	0.970	0.935–1.007	0.112
Sex	Male	1		
	Female	9.028	0.387–210.57	0.171
Psychological state:	Mildly anxious	**0.037**	**0.004–0.379**	**0.005**
	Very anxious†	—	—	0.995
Number of attempts		**454.17**	**5.32–38,797.73**	**0.007**
Needle gauge	Small (24G)			
	Medium (21–22G)	28.82	0.578–1435.81	0.092
	Large (20G)	1.688	0.083–34.25	0.733
Distraction support used		0.105	0.001–9.87	0.331
Indication for phlebotomy	Symptomatic	4.285	0.000066–279,053	0.797

	Hematocrit (%)	0.964	0.754–1.233	0.769
Constant		—	—	0.996

Reference categories: Psychological state = Calm; Needle gauge = Small (24G); Sex = Male; Distraction = Not used; Indication = Laboratory cutoff

†Complete separation: All 42 very anxious children experienced moderate-to-severe pain. Coefficient and OR cannot be meaningfully estimated.

Note: Model fit statistics - Nagelkerke $R^2 = 0.859$; Hosmer-Lemeshow $\chi^2 = 10.92$, $p = 0.206$; Overall classification accuracy = 93.2%

5.6.5. Interpretation of Model Results

The multivariable binary logistic regression model demonstrated excellent overall discrimination and goodness-of-fit, yielding a Nagelkerke R^2 of 0.859 and classification accuracy of 93.2%

Regarding individual predictors, pre-procedural psychological state exhibited a significant association with pain severity. Complete separation was observed within the "very anxious" cohort, with all 42 patients in this group experiencing moderate-to-severe pain. Conversely, the "mildly anxious" subgroup demonstrated significantly lower odds of moderate-to-severe pain compared to the "calm" reference group (adjusted OR, 0.037; 95% CI, 0.004–0.379; p = 0.005).

The number of venipuncture attempts was also significantly associated with increased odds of moderate-to-severe pain (adjusted OR, 454.17; 95% CI, 5.32–38,797.73; p = 0.007).

The remaining covariates including age groups (>8 years relative to the 4–8 years reference), sex, needle gauge, distraction support use, clinical indication for phlebotomy, and hematocrit percentage did not reach statistical significance in the adjusted model (all $p > 0.05$).

6. DISCUSSION

This cross-sectional study examined procedural pain during therapeutic phlebotomy among 118 children with cyanotic congenital heart disease at a tertiary cardiac center in Ethiopia. Two-thirds of participants experienced moderate-to-severe pain, with pre-procedural psychological distress emerging as the overwhelming determinant of pain outcomes. All 42 very anxious children experienced moderate-to-severe pain with no exceptions, creating complete statistical separation that prevented finite parameter estimation in logistic regression. Younger children reported substantially higher pain levels than older children, and procedural factors including multiple venipuncture attempts were associated with increased pain. These findings expose systematic gaps in procedural pain management for a vulnerable population dependent on palliative phlebotomy while awaiting access to corrective cardiac surgery.

6.1. The Dominant Role of Pre-Procedural Anxiety

The finding that all 42 highly anxious children experienced moderate-to-severe pain, while the majority of calm children experienced only mild pain, establishes pre-procedural psychological state as a critical determinant of pediatric procedural pain. This relationship reflects established neurobiological pathways where anxiety acts to amplify pain perception through both direct effects on central pain processing and indirect mechanisms, such as increased muscle tension and heightened anticipatory distress.

These findings align with literature documenting the association between pre-procedural anxiety and elevated pain intensity in pediatric populations. The underlying mechanism operates through descending pain modulatory circuits; anxiety activates threat detection systems within the central nervous system, reducing endogenous pain inhibition and increasing perceived pain intensity for identical nociceptive stimuli. Furthermore, heightened anxiety reduces cooperation during the procedure, which increases the likelihood of movement, multiple venipuncture attempts, and prolonged interventions all of which independently contribute to increased procedural pain [18].

The high prevalence of pre-procedural anxiety observed in this cohort likely reflects the clinical reality of children with cyanotic congenital heart disease, who undergo repeated medical procedures from infancy. This history can lead to conditioned fear responses and anticipatory

distress prior to therapeutic phlebotomy. The data suggest that standard reassurance during the procedure may not fully mitigate this distress, highlighting the need for structured, pre-procedural psychological preparation and evidence-based anxiety-reduction protocols.

The context of general under-recognition and undertreatment of pediatric pain in similar settings helps explain why children present with high baseline anxiety levels, having potentially experienced inadequately managed pain during previous procedures, which creates anticipatory distress [13, 22].

6.2. Age and Developmental Trajectories in Procedural Pain

The inverse relationship between age and pain severity observed in this study, with younger children experiencing median pain scores corresponding to five years of age compared to twelve years for those with mild pain, aligns with established developmental patterns in pain perception and coping. This age gradient reflects multiple converging developmental factors including cognitive limitations in understanding procedural necessity and temporal sequencing in younger children, less developed repertoires of cognitive coping strategies such as distraction and reappraisal, greater reliance on caregiver presence and reassurance which may be variably effective, and heightened general anxiety about medical settings based on limited experience differentiating routine from threatening procedures.

Research on pediatric venipuncture consistently demonstrates that younger children report higher pain scores and exhibit greater behavioral distress during needle procedures compared to older children and adolescents [16]. A study examining the Wong-Baker Faces Pain Scale versus skin conductance fluctuations during venipuncture in children found that both self-report and physiological measures showed age-related decreases in pain responses, with the steepest decline occurring between ages four and eight years, precisely the age range most represented in our sample [16]. The developmental mechanisms underlying this age effect include maturation of prefrontal cortical systems supporting executive control over emotional responses, expansion of cognitive schemas about medical procedures as protective rather than purely threatening, acquisition of distraction and attention-diversion skills, and development of meta-cognitive awareness allowing children to recognize that pain is temporary and tolerable.

The concentration of cyanotic heart disease diagnoses in early childhood in Ethiopia, driven by severely limited access to corrective cardiac surgery, creates a population disproportionately composed of young children requiring repeated therapeutic phlebotomy [6]. The mean age of 99.8 months in our sample, with nearly half the participants under eight years of age, reflects this access-related age distribution and helps explain the high overall prevalence of moderate-to-severe pain. In healthcare systems with greater surgical capacity, therapeutic phlebotomy for polycythemia would occur predominantly in adolescents and adults awaiting surgery or deemed ineligible for surgical correction, potentially resulting in substantially lower average pain scores due to developmental advantages in pain modulation and coping.

6.3. Multiple Venipuncture Attempts and Technical Proficiency

The strong link between the number of attempts and pain severity (OR = 454) highlights technical skill as a crucial, modifiable factor. Over half of the children required at least two attempts, and 15% (13 patients) required three or more. This points to potential gaps in training, challenges with vessel visibility in polycythemia patients, or underutilization of techniques to improve first-attempt success. First-attempt success rates vary widely based on practitioner experience, age, and vessel accessibility [15, 24]. In preschool aged children, pain intensity is often severe across diverse healthcare settings [24]. Factors like young age, poor vessel visibility, and prior failed attempts make access difficult, with success rates dropping to 30% to 40% in children with difficult venous access [25].

Hand venipuncture was used in 61% of procedures. While the association with pain was not statistically significant after adjustment, hand sites were often preferred for younger children possibly to preserve antecubital veins for future access or due to small vessel size. Because hand punctures are generally more painful and technically difficult, protocols should balance vessel preservation with pain minimization.

The trend toward increased pain with larger needle gauges was not statistically significant. While larger needles cause more tissue trauma, selecting the appropriate gauge for polycythemia patients requires balancing pain with clinical needs. Larger needles facilitate faster blood flow, which helps manage increased blood viscosity and may shorten the overall procedure duration.

6.4. Non-Pharmacologic Support Strategies and Implementation Gaps

Although distraction techniques were utilized in 44% of procedures, their apparent link to higher pain levels in initial analyses did not persist in the final multivariate model. This reflects confounding by indication, as the techniques were applied selectively to children who were already more distressed, rather than being used universally as a standard protocol.

Despite this, substantial evidence from controlled trials supports distraction as an effective pain-reduction strategy for pediatric venipuncture when implemented systematically rather than selectively [18, 19]. The mechanisms underlying distraction effectiveness involve competition for limited attentional resources, where engaging the child's attention reduces the cognitive capacity to process pain signals [19].

The gap between this evidence and the inconsistent use of distraction points to implementation barriers, such as time pressures, resource limitations, or institutional culture. Breathing techniques were used in 36% of procedures, though this did not persist in multivariate modeling after adjusting for confounders. The relatively low uptake of breathing techniques, despite being no-cost interventions, may reflect limited provider training or misconceptions about young children's ability to follow breathing exercises, even though research shows that children as young as four years can benefit when given appropriate developmental framing [18].

Although positioning and comfort holds were used universally in the sample, two-thirds of the children still experienced moderate-to-severe pain. This indicates that current support strategies are insufficient on their own. These findings highlight the need for a more intensive, multimodal approach combining evidence-based strategies, such as systematic distraction protocols implemented universally, pre-procedural psychological preparation, appropriate use of topical anesthetics, and caregiver coaching to prevent inadvertently increasing child distress [13, 19].

6.5. Strengths and Limitations

This study has several important strengths. To our knowledge, it represents the first systematic assessment of procedural pain during therapeutic phlebotomy in children with cyanotic congenital heart disease, addressing a significant gap in the literature.

The use of validated, age-appropriate pain assessment tools and immediate post-procedure assessment minimized recall bias and provided reliable pain measurement. The comprehensive collection of patients, procedural, and environmental factors allowed multidimensional analysis of pain determinants. The consecutive sampling approach over a defined period minimized selection bias and produced a representative sample from Ethiopia's largest tertiary cardiac center.

Our findings should be interpreted in light of the following limitations. The small sample size of 118 participants, although adequate for descriptive analysis, provided limited power for stable estimation in multivariate logistic regression. This was compounded by the complete separation of outcome categories where all highly anxious children experienced moderate-to-severe pain which led to convergence failures in our multivariate model and rendered individual parameter estimates unstable.

Additionally, the study relied exclusively on quantitative data without a qualitative component, which limits the insight into the subjective experiences, fears, and preferences of the children and their caregivers regarding pain management strategies.

7. CONCLUSION AND RECOMMENDATIONS

This study reveals that two-thirds of children with cyanotic congenital heart disease experienced moderate-to-severe pain during therapeutic phlebotomy at a major Ethiopian cardiac center, with pre-procedural anxiety emerging as the strongest determinant of pain outcomes. All very anxious children in the sample experienced moderate-to-severe pain regardless of other factors, while younger age, being female, requiring multiple venipuncture attempts, and symptomatic hyperviscosity significantly increased overall pain severity. These findings expose critical gaps in procedural pain management for a highly vulnerable pediatric population that depends on repeated therapeutic phlebotomies while awaiting corrective cardiac surgery.

To address these challenges, clinical care protocols at the cardiac center must be updated to introduce routine pain assessments as a core quality indicator for children undergoing phlebotomy for polycythemia. Care teams should design and implement pre-procedural psychological preparation and anxiety reduction techniques, such as age-appropriate explanations and breathing exercises, well before needle insertion to mitigate psychological distress. Furthermore, it is essential to improve first-attempt phlebotomy success rates through targeted clinical skills training focusing on optimal site selection and venous visualization—supported by a multidisciplinary approach that makes procedural comfort a standard element of routine cardiac care.

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