Pediatrics ultrasound-guided tissue sampling in a resource-limited setting: Initial experience from Tikur Anbessa Specialized Hospital (TASH), Addis Ababa, Ethiopia: A Retrospective cross-sectional study from July 2022-June 2024

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I, the undersigned Radiology Resident, declared that I have submitted my original work on a title: "*Pediatrics ultrasound-guided tissue sampling in a resource-limited setting: Initial experience from Tikur Anbessa Specialized Hospital (TASH), Addis Ababa, Ethiopia: A Retrospective cross-sectional study from July 2022-June 2024*" for examination.

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APPROVAL BY BOARD OF EXAMINATION

This thesis by AMANUEL ABOYE is accepted in its present form by the board of examiners as a requirement for the certificate of radiology.

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Statement of the author

By my signature below, I declare and affirm that this thesis is my own work. I have followed all ethical principles of scholarship in the preparation, data collection, data analysis and completion of this thesis. All scholarly matter that is included in the thesis has been given recognition through citation. I affirm that I have cited and referenced all sources used in this document. Every effort has been made to avoid plagiarism in the preparation of this thesis. I solemnly declare that this thesis has not been submitted to any other institution anywhere for the award of any academic degree, diploma or certificate.

MAY 2025
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Abstract

Background:

Ultrasound guided tissue biopsy is a minimally invasive, increasingly preferred tool for evaluation of pediatric pathologies due to its decreased complications and ease of accessibility in resource limited settings. However, the diagnostic yield and safety of these procedures in Ethiopian pediatric patients are not well known.

Methods:

We conducted a retrospective cross-sectional study to review the records of pediatric patients who underwent ultrasound guided tissue sampling from July 2022 to June 2024 at TASH. We collected data on demographic characteristics, type of procedure, diagnostic yield, and complications.

Results:

A total of 102 ultrasound guided tissue samples were performed, CNB accounted for 69.6%. The overall diagnostic yield was 93.1%. CNB had significantly higher diagnostic yield when compared to FNAC; the odds of obtaining a diagnostic yield were 10 times better for CNB($p<0.003$). One bleeding complication (0.97%) requiring blood transfusion was recorded. Our results are consistent with other international studies and a previous Ethiopian study which reported diagnostic yield of 92.7% for image guided procedures in a different demographic.

Conclusion:

USG guided tissue sampling is safe and highly effective diagnostic tool for the pediatric population at Tikur Anbessa Specialized Hospital (TASH) with high diagnostic yield and minimal complications. Our results support the wider adoption and standardization of ultrasound guided procedures in similar resource limited settings in Ethiopia

Keywords:

Ultrasound-guided biopsy, pediatric, diagnostic yield, core needle biopsy, fine-needle aspiration, Ethiopia, Tikur Anbessa Specialized Hospital

Acronyms

CT-Computed Tomography

MRN- Medical Registration Number

TASH-Tikur Anbessa Specialized Hospital

US-Ultrasound

SIR – Society of interventional radiology

CNB – Core Needle Biopsy

FNA – Fine needle Aspiration

Contents

1. Introduction

1.1 Background

Image-guided procedures are minimally invasive techniques performed by skilled professionals, typically interventional radiologists, who use real-time imaging modalities such as mammography, ultrasound (US), computed tomography (CT), or magnetic resonance imaging (MRI) to access target tissues for diagnostic and therapeutic purposes [1]. Image-guided interventions can be traced back to the early 20th century during World War I, when fluoroscopy was used by battlefield surgeons to detect and extract shrapnel from injured soldiers. The earliest documented tumor biopsy under image guidance was performed by John Baldy at Memorial Hospital in New York in 1939, using fluoroscopy [2]. However, the widespread clinical adoption of CT- and US-guided tissue sampling did not occur until the mid-1970s and 1980s. With the advent of cross-sectional imaging and high-resolution ultrasound, image-guided procedures have evolved considerably, enhancing the accuracy of tissue sampling and reducing complication rates [3]. Despite the inherent risks of percutaneous interventions, they are increasingly preferred over open surgical biopsies due to their lower cost, reduced complication rates, and improved cosmetic outcomes [4–7]. In 2017, a revised classification system for adverse events related to image-guided procedures was introduced, shifting from the traditional "minor vs. major" dichotomy to a five-tier system: mild, moderate, severe, life-threatening/disabling, and fatal complications (Table 1). This system is considered more reproducible and aligns with other surgical complication frameworks such as the Clavien–Dindo classification [8].

Accuracy of image guided procedure is the ability of the procedure to obtain representative sample of target tissue for diagnostic analysis which can be affected by tissue location, biopsy techniques, type of needle, number of biopsy passes, operator experience and use of advanced pathological techniques [9, 10]. On this study we will try to assess our experience of image guided procedures success rate and procedure related adverse events in Tikur Anbessa Specialized Hospital

Society of interventional radiology AE classification
AE severity assessment
Mild: No or minimal therapy
Moderate: Overnight admission, prolonged outpatient care, blood administration
Severe: ICU transfer, Admission >24hr , procedure requiring general anesthesia
Life threatening or disabling cardiopulmonary arrest, shock, organ failure, paralysis
Patient death

Table 1 [3]. The newly revised AE classification by society of interventional radiology
AE= Adverse Event

1.2 Statement of the problem

In an ideal scenario, a highly accurate image guided tissue sampling is needed to provide excellent patient care in terms of reducing the cost of repeated biopsies as well as the cost and complication of open or surgical tissue sampling.

The lack of standard image guided biopsy procedure guidelines with regarding to pre procedural patient risk assessment and procedure planning can lead to reduced diagnostic yield, harmful consequences and complications which increased morbidity resulting in increased hospital stay [11].

If TASH (Tikur Anbessa Specialized Hospital) continues to do open surgical biopsy not only there will be increased cost, time and procedure related complication but also the OR (operating room) will be occupied resulting in reduction in efficiency and increased OR waiting time for deserving patients.

Therefore, an accurate image guided tissue sampling will reduce the need to resort to open surgical biopsy. We propose to research accuracy, efficiency and safety of image guided tissue sampling.

1.3 Justification of study

Currently the field of diagnostic medicine is facing towards less invasive highly efficient procedures with high accuracy like image guided procedures. According to one study the diagnostic accuracy of image guided soft tissue is comparable with open surgical biopsy in terms of adequate tissue sample for primary diagnosis and biological characterization in addition to reduced complication rates [12].

According to our knowledge there are no studies done on importance of image guided tissue sampling with regards to accuracy and complication as well as cost compared to open surgical biopsy in pediatric patient here in TASH as well as in our country. By analyzing our data we will demonstrate our experience in the practice and impact of image guided tissue sampling in terms of diagnostic yield and complications here in TASH.

This study is of paramount importance in context of modern diagnostic medicine especially in oncology by addressing existing gap in knowledge and allowing future research to be done on techniques to improve the diagnostic yield and reduce complication rates of image guided procedures.

2. Literature review

Pediatric interventional radiology is a relatively younger field in world where it became part of medical care in the past 40yrs. Today, where an interventional procedure is being advancing at international level, our country and hospital, due to lack of trained physicians, is just in the early stages of application of pediatrics interventional procedures [13].

The standard image guided procedure room measures 650 ft2 allowing for sterile environment containing all the equipment's used for image guidance with uninterruptable power supply as well as safety equipment's. There should also be high resolution image displaying monitors , room for life support and anesthesia [14,15]. According to WHO the physicians who fill the requirement is expected to perform minimum of 200 procedures or 70 procedures for neuro radiology under supervision. Other than physicians trained medical radiographers, nurses and anesthesiologist especially in pediatrics form crucial part of team [16,17].

Patient preparation starts with planning the procedure ahead of time including review of medical history of patient and images so that the physician choose the type of imaging modality for the procedure. Followed by patient preparation at the time of procedure like assessment of bleeding risk according to the type of procedure done which is categorized as low risk , intermediate risk and high risk as well as any history of anticoagulating medication intake after which we have to proceed by the IR (Interventional radiation) bleeding risk guidelines. The final step includes taking written informed consent of the primary guardian of the patient[18]. The use of pre procedural checklist as a guideline in interventional radiology varies from institution to institution due to lack of evidence on its impact on adverse outcome of patients undergoing image guided procedures [19].

Anesthesia plays a major role in interventional radiology especially in pediatrics interventional radiology which helps the patient in reducing pain and anxiety also helps to facilitate procedure in a relaxed environment. The type of anesthetic drugs used in image guided procedures includes midazolam, ketamine, and dexmedetomidine which are sedatives as well as local anesthetic agents like lidocaine with or without epinephrine allowing less invasive monitoring. In contrast there is increased complication using general anesthesia and requires more intensive monitoring compared to sedatives used in image guided procedures [20].

In a study conducted in the Netherlands, 365 pediatric patients underwent image-guided procedures, and the diagnostic yield was 95.4%. The study also found that sample size or number had no effect on this[21] However, according to earlier research on image-guided treatments for bone and soft tissue lesions, the volume, length of the specimen, the imaging modality used, and the needle gauge for the procedure all had an impact on the diagnostic yield [22]. In a study conducted in Italy, 93.9% of 213 patients underwent image-guided procedures; the only factor that was linked to accuracy was whether the lesion was benign or malignant (OR 4.04, CI 95% as well as p=0.022). Benign lesions typically have lower yields than malignant ones [23]. While a research done in France with 396 patients who has undergone image guided procedure found out that the diagnostic yield being 89.9% and accuracy of 90.9% with 95% CI and factors affecting diagnostic accuracy includes highly advanced sample assessment techniques like immunohistochemistry (95.7% with immunohistochemistry and 82.3% without immunohistochemistry with P value <0.0001) and number of biopsy passes or sample taken (mean number of samples 3.96 for diagnostic and 3.62 for non-diagnostic p value of 0.044)[9]. Some study also show experience of physician taking the procedures can affect diagnostic yield [24].

The diagnostic yield of image guided procedures can also be affected by imaging modalities used, according to research done in South Africa found out the diagnostic yield reaches about 98.5% out of 65 samples. In addition, lesion taken from restricting cites of the mass lesion on MRI yield adequate sample and representation compared to other imaging modalities [25].

Complications regarding image guided procedures are classified as generic or organ specific. The SIR has a standard quality improvement threshold for each complication above which identification of the cause and actions recommended. In the previous classification of complications i.e. minor and major complications, the SIR recommends quality improvement threshold of >2% for the major complications requiring hospital admission [23, 26].

Hassan et al assessed the occurrence of major complication which was 40% out of 21 patient (p=0.027) in open procedure compared to 0% in image guided procedures [27]. In the study done in Italy out of 213 patients who has undergone image guided procedures minor complication rate was reported in only 1.4% without major complication [23].

In our country the first study in Addis Ababa University, Tikur Anbessa Hospital, was done including a total of 117 patient who has undergone image guided procedure out of which only 8 were children under 10 years of age. Findings showed 92.3% diagnostic yield. The reported complications include significantly higher pain compared to other studies representing 88% but other complications like bleeding, infection, hemoptysis all of which are <2 percent [7].

3. Objective

3.1 General Objective

- To understand and assess the accuracy and complication of image-guided tissue sampling among pediatric patients who underwent ultrasound-guided tissue sampling at Tikur Anbessa Specialized Hospital (TASH) between July 2022- June 2024 G.C.

3.2 Specific Objective

- To assess the diagnostic yield of ultrasound guided tissue sampling among pediatric patients who underwent the procedures in Tikur Anbessa Specialized Hospital between July 2022-june 2024 G.C.
- To assess the complication associated with ultrasound-guided tissue sampling among pediatric patients who underwent the procedures in Tikur Anbessa Specialized Hospital between 2022-2024 G.C.
- To assess factors affecting diagnostic yield for ultrasound guided procedures
- To report our 2-year experience.
- To understand the impact of pediatric image-guided procedures on healthcare provision.
- To direct the attention of involved stakeholders toward improving and supporting image-guided procedures in the pediatric population.

4. Materials and methods

4.1 Study setting and period

This study will be conducted from July 2022 to June 2024 G.C. in TASH. Tikur anbessa specialized hospital is Ethiopia's largest tertiary hospital with 700 beds. It serves 500,000 patients annually, among which children account 48% [28].It is located in Arada sub-city, Addis Ababa.

4.2 Study design

A secondary data-based retrospective study will be conducted. Pediatric patients up to the age of 14 years who underwent image-guided tissue sampling procedures at the pediatrics department of TASH will be included in the study.

4.3 Study subjects

All pediatric populations who underwent image-guided procedures at TASH from July 2022 G.C to June 2024 G.C and fulfil inclusion criteria will be included in the study.

4.4 Inclusion and exclusion criteria

Inclusion criteria: Patients within the pediatric age group registered with full information including sex, age, diagnosis, and underwent the procedure will be considered eligible.

Exclusion criteria: Patients who are not in the pediatric age group (upto 14-year-old), and registered with insufficient information about one or more of the variables will be excluded.

4.6 Study variables

- Socio-demographic factors (Sex, Age)
- Site or location of biopsy taken
- Qualification of the personnel conducting the procedure
- Diagnostic Yield of ultrasound guided procedure
- Final diagnosis
- Complications associated with ultrasound guided procedure

4.7 Sampling technique and sample size determination

Convenience sampling method were used to include all pediatric patients who underwent image-guided tissue sampling procedures at the TASH radiology department between 2022-2024 G.C and fulfil the inclusion criteria.

4.8 Data collection methods and tools

Data will be collected from the pediatrics department registry excel sheet as well as TASH online medical records (IWKET ICARE) and entered into Microsoft Excel. The data-collecting tool have several categories, such as MRN, age, sex, date of procedure, location of procedure taken , diagnosis, whether the procedure was done or not, types of procedures, site of the procedure, qualification of the personnel conducting the procedure, and incident or complication

4.9 Data management and analysis

After the data is cleared off repletion and checked for completeness and accuracy, it will be compiled and entered in to SPSS version 26. Results will be shown in tables, charts and graphs depending their appropriateness.

4.10 Ethical Considerations

This study will be conducted after getting ethical clearance from the department's research committee. Permission will be asked from Addis Ababa University, College of Health Science, Pediatrics and Child Health Department. Then we can access the patient registry to obtain the data. These measures will protect the privacy and confidentiality of the patients.

4.11 Consent

Not applicable.

4.12 Conflicts of Interest

There are no conflicts of interest to declare.

4.13 Dissemination of findings

The findings of the study will be presented to the Department of Radiology at TASH and will be submitted to be published in an international scientific journal.

5. Result

Among a total of 102 patients included in this study 46 (45.1%) were females and 56 (54.9%) were males. The study subjects age range from 1 to 13yr with median age of 6yrs and mean age of 6.4yr. Out of 102 ultrasound guided procedures 71 (69.6%) are CNB, followed by FNAC 31 (30.4%) (Table 3).All of the ultrasoud guided procedures are done by senior or fellow pediatric radiologis under supervision.

Table 1. Types of ultrasound guided procedure done

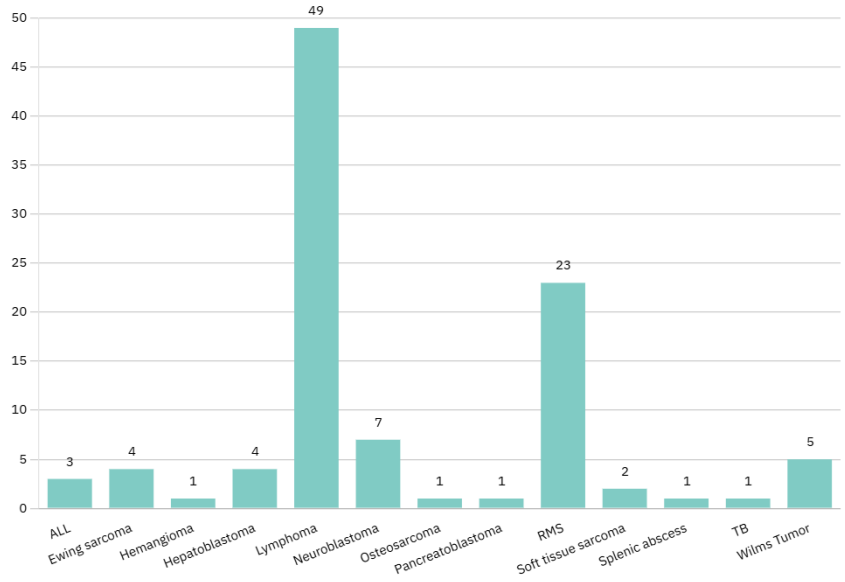
Type of procedure				
Type_of_procedure	Frequency	Percent	Cumulative Frequency	Cumulative Percent
CNB	71	69.60	71	69.6
FNAC	31	31.40	102	100.00

Majority of the procedures were intraabdominal 83 (81.37%) and other sites like head and neck, chest/mediastinum and soft tissue extremity collectively contribute to the remaining 18.63%. From the intraabdominal procedures majority were intraperitoneal lesion 65 (63.7%) including liver 6 (5.88%) , intraabdominal mesentery/abdominal wall 58 (56.8%); while retroperitoneal is 18 (17.64%) including Renal 7 (6.86%) and extrarenal retroperitoneal lesions 11 (10.78%) (Table 2). Lymphoma is the diagnosis for the majority of intraabdominal procedures accounting for 49 patients (48%) followed by Rhabdomyosarcoma representing 22 patients (21.57%) (Figure 1).

Specific Site of procedure				
Site	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Chest	5	4.76	5	4.76
Head and Neck	3	2.94	8	7.70
Intraabdominal mesentery & Abdominal wall	58	56.86	66	64.56
Liver	6	5.88	72	70.44
Mediastinal	1	0.98	73	71.42
Renal	7	6.86	80	78.28
Retroperitoneal (excluding renal lesions)	11	10.78	91	89.06
Soft tissue/Extremity	11	10.78	102	100

Table 2. Sites of ultrasound guided procedures

Figure 1. Final Diagnosis/Pathology result of the patient who has undergone ultrasound guided procedures



X axis ; Final Diagnosis, Y axis ; number of patients

Abbreviation : ALL – Acute lymphoblastic leukemia; RMS – Rhabdomyosarcoma; TB - Tuberculosis

Out of the total ultrasound-guided procedures, 95 samples (93.1%) yielded pathological results, while the remaining 7 samples (6.9%) did not, showing findings such as hemorrhage, necrosis, or cellular debris (Figure 2). Among these 7 cases without a pathological diagnosis, repeat fine needle aspiration (FNA) was performed in 2 patients, both of which confirmed lymphoma. Two other patients underwent excisional biopsy, which also confirmed lymphoma. One patient was diagnosed with acute lymphoblastic leukemia (ALL) following bone marrow aspiration. Another patient was diagnosed with pulmonary tuberculosis after a repeat GeneXpert test and chest biopsy, following an initially inconclusive GeneXpert result. In one case where FNA was performed on the liver, a repeat FNA also yielded inconclusive results

In this study the only associated factor affecting diagnostic yield is type of procedure where CNB procedures shows more yield compared to FNAC but demography of patient, anatomic site or final diagnosis are not associated with diagnostic yield. The significant associated between the type of procedure and diagnostic yield proven by Fischer exact test (since most of the cells contain value less than 5) with p value of 0.003 ($p<0.05$). Compared to FNAC , the odds of CNB obtaining a positive sample is 10.5 times with p value of 0.003 (Table 4).

One patient (0.98%) out of 102 procedures develop bleeding from site of procedure requiring blood transfusion which is controlled with hemostasis and platelet administration.

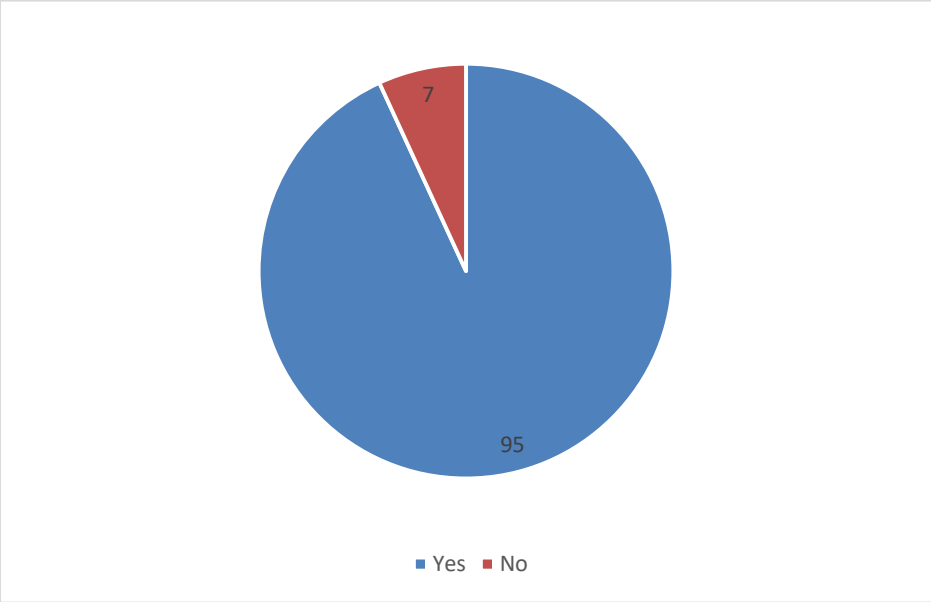


Figure 2. Pathology sample yield (Diagnostic yield) of the ultrasound guided procedures

Table 4. Association of type of procedure with diagnostic yield

Table of Pathology_sample_yield by Type_of_procedure			
Pathology_sample_yield(Pathology sample yield)	Type_of_procedure(Type of procedure)		
	CNB	FNAC	Total
No	1 0.98 14.29 1.41	6 5.88 85.71 19.35	7 6.86
Yes	70 68.63 73.68 98.59	25 24.51 26.32 80.65	95 93.14
Total	71 69.61	31 30.39	102 100.00

Fisher's Exact Test	
Cell (1,1) Frequency (F)	1
Left-sided Pr <= F	0.0030
Right-sided Pr >= F	0.9999
Table Probability (P)	0.0028
Two-sided Pr <= P	0.0030

6. Discussion

This study was conducted to evaluate safety and diagnostic yield of ultrasound guided procedures in pediatrics patient at our hospital from 2022 to 2024. Over this period, we performed total of 102 ultrasound guided procedures, majority being a CNB, accounting for 69.6% (71/102). The overall diagnostic success rate is 93.1%, and the only factor considerably influencing this outcome was the type of procedure performed. Specifically, the likelihood of achieving a diagnostic result was ten times higher with CNB than with fine-needle aspiration cytology (FNAC) ($p < 0.003$). There is only one case (0.97%) of complication which is bleeding from sample site requiring a blood transfusion. All procedures at our institution were carried out by a pediatric radiologist and a fellow under direct supervision.

The higher diagnostic yield observed with CNB compared to FNAC can be due to adequate tissue samples allowing for comprehensive histopathological analysis. This enables additional test like immunohistochemistry improving diagnostic accuracy particularly for non-epithelial malignant neoplasm [29].

The findings from this study are consistent with different literatures, which demonstrate image guided procedures particularly CNB are highly effective in obtaining diagnostic tissue samples in pediatric population. For example, a study from the Netherlands involving 365 pediatric patients reported a diagnostic yield of 95.4% from image-guided procedures not affected by the lesion size or sample number [21]. Similarly, French study have reported diagnostic yields of 89.9% and described the importance of factors such as use of advanced pathological techniques, and number of biopsies passes in achieving high diagnostic accuracy [9].

While a study done in Italy in 2020 reported out of 213 patients with image guided procedures reported diagnostic yield of 93.9% and diagnostic accuracy of 96.86% (CI of 95%) and the accuracy was only affected by nature of lesion whether its benign or malignancy (OR of 4.04, CI 95% and p = 0.022), benignancy being the one related with reduced diagnostic yield but did not find any association with needle gauge or number of biopsy passes[23]. Even though our result did not reveal significant association of final diagnosis with diagnostic yield our study population was overwhelmingly composed of malignant lesions. As a result, we were unable to assess the impact of lesion nature (benign vs. malignant) on diagnostic yield within our cohort. Similar to our study the Italian study showed the diagnostic yield is not affected by anatomic site or depth of tissue.

Our results are also consistent with findings from research done here in Tikur Anbessa Hospital which reported a diagnostic yield of 92.7% for image-guided procedures, even though it was performed in a different demographic group. This similarity shows the reliability and reproducibility of image-guided techniques across diverse patient populations [7].

There is only 1 moderate complication according to SIR adverse event classification [3] among 102 ultrasound guided procedures representing 0.98% which is acceptable according to SIR guidelines and result is concordant with other studies [21,22,23,25]. These findings are observed in our study is consistent with global and local data, supporting ultrasound guided procedures as a safe and effective modality for pediatric tissue sampling.

The successful implementation and high diagnostic yield of ultrasound-guided tissue biopsies in our pediatric population can be partly attributed to institutional capacity-building efforts. In 2008, an outreach program was initiated through a partnership between Addis Ababa University's Department of Radiology and the Children's Hospital of Philadelphia launching pediatric radiology fellowship program in 2015 [28]. These initiatives have contributed significantly to the development of pediatric image-guided procedures at our hospital, including the establishment of ultrasound-guided tissue biopsy as a routine practice. This context is important for interpreting our results and suggests that similar outcomes may be achievable in other resource-limited settings through targeted training and international collaboration.

Despite these strengths, our study has some limitations. As a retrospective, single-center study, and reliance on existing medical records limited the completeness of data regarding potential confounding factors such as needle gauge, number of biopsy passes, operator experience, lesion size, and use of advanced pathological techniques. The relatively small sample size and being single-center study may also restrict the external validity of our results. Another limitation is predominance of malignant lesion in our sample which limited our inability to assess impact of lesion nature on diagnostic yield. Future prospective and multicenter studies including all the confounding variables would be valuable to further validate and expand upon our findings.

In summary, ultrasound-guided tissue sampling particularly CNB demonstrates high diagnostic yield and safety in pediatric patients at TASH, consistent with different studies done in our country and international level. Future prospective and multicenter studies with standardized protocols are recommended to validate these findings and further explore the impact of procedural factors on diagnostic outcomes.

7. Recommendation

1. To improve diagnostic accuracy and ensure patient safety, it is recommended to prioritize the adoption and expansion of ultrasound-guided tissue sampling, especially core needle biopsy (CNB), at Tikur Anbessa Specialized Hospital (TASH) and similar institutions. Due to high diagnostic yield and very rare complications, this procedure should be the first choice in tissue diagnosis.

2. We recommend the implementation of a standardized data documentation system. The summary should consist of the patient demographics, procedural details (number of passes, needle gauge, operator experience), imaging details, histopathology results, and all complications.

3. Invest in ongoing training and capacity building for radiologists and supporting staff. A continuous education is important for maintaining high quality, safety, and optimizing outcomes importantly in settings with limited resources where the operator's experience has a much more pronounced impact on results.

4. Encourage further research and assist data sharing among institutions. Assessing the Cost-effectiveness, patients' satisfaction, and long-term outcomes of image-guided biopsies versus open surgery will streamline practice. Sharing experiences across hospitals can serve to strengthen the evidence base in Ethiopia and similar settings.

5. Advocate for policy support by engaging hospital leadership and policymakers. It is important for funding and resources needed for image-guided procedures to be emphasized and obtained for the effective implementation and sustainability.

6. Allocate resources for the procurement and maintenance of high-quality ultrasound equipment and biopsy tools. In order to maintain and expand these diagnostic services, it is vital to ensure a sterile and well-equipped procedure environment.

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