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Adequacy of histopathology request forms and specimens sent to two histopathology centers in Khartoum, Sudan

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Abstract

Background Every branch of surgery relies in some way on histology to obtain a conclusive diagnosis. Since precise and comprehensive information on the request form is crucial to the correct analysis and interpretation of test results, it is anticipated that all patient data and information for any requested test be provided. One of the most significant duties of the peri-operative team is the care and handling of intraoperative surgical specimens. Poor labeling and handling of surgical specimens can lead to unfavorable consequences such as misdiagnosis, incorrect or delayed therapy, and even the need for repeat surgery. The study's objective is to highlight the primary mistakes that occur in the pre analytical stage of histopathology request forms and specimens at two Khartoum-based histopathological institutions.

Methods A prospective descriptive laboratory based cross-sectional study was carried out on 528 request forms and specimens sent to two histopathology centers between the period of May to August 2019 having gotten Ethical clearance from SMSB.

Results A total of 528 laboratory request forms and specimens, Age was written in 75.6% (n 399), while the gender only was written only in 46.2% (n 244). No clinical history in 48.3% (n 255). The differential diagnosis found only in 29.5% (n156) of request forms. Regarding specimen 15.7% (83) were inadequate relative to the size of the container and only 5.3% (28) were not labeled with any information. 17.4% (92) were not sent in formalin but in normal saline. Marking of the specimen was not needed in 60% (317) and among the rest cases; 34.2% was not marked.

Conclusion The study shows that laboratory request forms were not properly and thoroughly completed. Most of the specimens sent for histology had inadequate fixative and unsuitable containers, or they were mislabeled and not properly tagged. This for sure will have a detrimental effect on the quality of care.

Keywords Quality control, Histopathology, Request forms, Specimen

Introduction

Medical laboratory results are believed to be the basis for 60–70% of all choices made regarding a patient's diagnosis, course of therapy, admission to the hospital, and discharge. In a hospital context, laboratory tests for patients are ordered based on forms filled out by the attending physician or a junior physician. The accuracy of the information provided on these forms is critical to achieving a final diagnosis (Uchejeso 2019).

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Histopathology is in some way necessary for almost every branch of medicine and surgery to obtain a conclusive diagnosis. Tissues are frequently excised to diagnose and so treat a specific condition, and surgical specimens must be handled with extreme caution (Access 2018; Ali et al. 2018). During surgical procedures, a variety of specimen types are obtained, such as endoscopic biopsies and larger samples that may encompass whole or partial organs. Starting from the moment the specimens are excised from the patient during surgery to their arrival in the laboratory, a series of essential histopathological procedures must be adhered to for the collection and transportation of these specimens for analysis (Shirey and Perrego 2015). Among the paramount responsibilities of the perioperative team lies the meticulous care and handling of intraoperative surgical specimens. Poor labeling and handling of surgical specimens can have detrimental effects, including misdiagnosis, delayed or incorrect treatment, and even the need for another surgery (Ali et al. 2018; Steelman et al. 2016). Laboratory work comprises pre-analytical, analytical, and post-analytical phases, with each phase playing a vital role in determining the final histopathology results. Moreover, surgeons play an important role in the pre-analytical phase by ensuring the sterility of the field, managing specimens, and appropriately transporting, labeling, and preserving them. Clinical data is indispensable in histopathology for both diagnosis and reporting of specimens. The patient's well-being may be compromised if histopathology results are delayed due to incomplete request information (Ali et al. 2018; Steelman et al. 2016; Atanda and Raphael 2013). To the best of our knowledge, there has been no documenting quality assessment in histopathology from Sudan. This study aims to identify the primary mistakes in the pre-analytical stage of histopathology request forms and specimens in two Khartoum-based histopathological institutions.

Nucleic acid-based diagnostic technologies are rapidly replacing or enhancing more traditional diagnostic techniques in clinical laboratories. They are also utilized to predict outcomes for a range of disorders and choose the most effective course of therapy. These are very specific tests that need very small amounts of sample DNA or RNA to be performed and it is mainly the responsibility of pathologists. Like other diagnostic procedures, the results can be repeated, but they might also have certain limits because of pre- and analytical conditions. Pre-analytical errors include between 60 and 70% of all laboratory errors that occur in labs and outside of them as well, according to some study. There is significant variance in the handling of specimens before they are processed, despite the existence of useful recommendations

for standardizing specimen processing in molecular laboratories (Sotoudeh 2021).

These days, pathology departments' archives provide useful tissues for applying molecular biology methods to identify new indicators linked to response to therapy and patient progress. Both more contemporary techniques and more conventional ones, such as immunohistochemistry (IHC), require standardization of the preanalytical stages.

Molecular diagnostics is a recognized field today. In the upcoming years, they will make up a rapidly increasing percentage of the operations of pathology laboratories. The preanalytical phase methods will need to be implemented, supervised, and standardized, which will require an increasing number of laboratories to alter their operations in order to comply with the new rules (Susman et al. 2018).

Rationale and significance of study

Insufficient handling and preservation of specimens results in a substandard level of practice in this vital field of medicine. The global cancer burden is expected to increase to 28.4 million cases in 2040, which is a 47% rise from 2020. This increase is primarily due to demographic changes and may be further exacerbated by increasing risk factors associated with globalization and a growing economy. As a result, the need to reduce detection errors is growing along with the disease's increasing incidence. Pre-analytical phase in specimen management involves a number of steps, such as information sharing via forms, labeling and specimen description, all of which increase the possibility of mistakes if not carried out correctly. Pre-analytical errors can result in an incorrect diagnosis, delayed treatment plan or even the need for unnecessary follow-up care (Awadelkarim et al. 2010). Given that the accurate and comprehensive analysis and interpretation of test results hinge significantly on the precision and thoroughness of the information recorded on the request form, it is anticipated that all patient details will be included on these forms for any requested test.

On laboratory request forms, it is essential to routinely verify various fields including the patient's name, age, sex, hospital number or name, the clinic's name, specimen type, specimen collection time and date, investigation requirement, clinical details encompassing past and drug history, the consultant in charge of the patient's care, the referring physician's name, contact information, and other important information (Oyelekan et al. 2018). Inadequate specimen handling can have disastrous consequences for physicians and patients and so impacting both patient safety and turnaround time (TAT). TAT is the amount of time that begins as soon as the specimen

enters the laboratory and ends when the test result or the report is ready. Turnaround time (TAT) is one of numerous important parameters that affect the quality of histopathology results. A fast and precise diagnosis can assist the treating physicians in developing a definitive and effective strategy, and vice versa (Ali et al. 2018).

Continuous medical education programs should emphasize the importance of properly completing these forms, emphasizing the significance of each parameter requested on the forms (Oyelekan et al. 2018; Oyedeji et al. 2015). Naturally, regular assessments of the quality of request forms and the suitability of containers would significantly improve patient outcomes, management, and safety, while also reducing costs (D'Angelo and Mejabi 2016).

Since the implementation of safety checklists in numerous hospitals and healthcare facilities to ensure physicians adhere to clinical procedures and promote consistent practices, errors have diminished, and the specimen management process has shown improvement. The surgical safety checklist's efficacy was also evaluated in the systematic review, and it was discovered to be highly supportive when utilized to avoid mistakes (Kurtin and Stucky 2009).

When patients' medical history is not fully disclosed, it can hinder the diagnostic process, causes delays in case reporting, and ultimately delay of diagnosis. However, mistakes in specimen identification and labeling may result in a false diagnosis that prompts expensive and insignificant follow-up tests such as histochemical and immunohistochemistry, repeat the procedure, or re-operate on the patient, which may cause emotional distress or physical harm, placing a burden on resources or even can result in avoidable death. Researches have shown that up to 70% of medical diagnoses are influenced by the outcomes of laboratory tests (Oyedeji et al. 2015; Burton and Stephenson 2001).

Request forms serve as the main professional means of communication between pathologists and treating physicians. The problem lies in the fact that physicians often underestimate the importance of accurately completing these forms, which can result in incorrect or misdiagnosed conditions or delays in receiving the necessary treatment (Oyedeji et al. 2015).

Some surgeons presume that the analytical aspect holds sole importance in the diagnosis and quality assessment processes in histopathology; nevertheless, both the pre- and post-analytical phases are equally crucial. Many studies have shown that laboratory errors primarily occur during the per-analytical phase, undoubtedly affecting patient outcomes (Rao et al. 2016). Pre-analytical processing typically entails properly filling out laboratory request forms with

all relevant personal information and past and current clinical history, identifying specimen containers appropriately, and anatomically marking the specimen (Oyelekan et al. 2018).

According to a study by Sirota RL, the majority (68.2%) of laboratory errors happen during the pre-analytical phase, and one of the prevalent pre-analytical errors involves insufficient data on request forms. Clinical failures such as incorrect clinical procedures, improper ordering, inaccurate, incomplete, or misleading clinical information, as well as errors in specimen transportation and delivery including incorrect fixative, improper container labeling, and inadequate preservation, constitute the majority of pre-analytical errors (Sirota 2005).

Studies concentrating on pre-analytic errors in surgical pathology are very rare. One million surgical pathology specimens were analyzed from 417 institutions done by the College of American Pathologists, it was determined that 6% of cases had identification deficiencies (Nakhleh and Zarbo 1996; Roque et al. 2015), makes it difficult to provide clear and accurate reports, and cause a delay in communication with the referring physician and patients whose diseases may be life-threatening (Oyelekan et al. 2018). Other significant mistakes that laboratory personnel cannot control are the processing of samples, transportation to the lab, and specimen collecting and identification (Oyedeji et al. 2015).

The following Standards of Practice apply with regard to the proper handling and preservation of surgical specimens in the peri-operative setting:

To begin with, if more than one sample is being sent, each specimen should be provided in a different container that clearly indicates the biopsy sites. Each container should also be labeled individually with information that corresponds to the request form, which must be filled out completely, accurately, and appropriately with the following details:

- a Patient complete name, personal information, medical record number, and date of birth.
- b Complete clinical history of the patient, including any relevant prior tests, FNAC, or potentially helpful biopsies, as well as any radiological findings, if any, and without abbreviations.
- c Findings from the surgical procedure, a description of the specimen's anatomy, and the differential diagnosis should all be provided without the use of any abbreviations.
- d The time and date the specimen was collected.
- e Name of the referring physician, hospital unit, and phone number (Abbasi et al. 2023).

Other important points to be considered

Unfixed specimens must be brought right away to the lab. The specimen needs to be placed in a wide-mouthed, leak-proof, sealable container of the right size that is submerged in the right kind and volume of fixative (ideally 10% formalin). The container needs to have enough empty space inside of it to prevent the specimen's shape and anatomy from being altered. Precise labeling and identification of the specimen container in the request form, together with matching patient data. Orientation sutures should be used as necessary, and the request form should clearly identify the margins they represent (Abbasi et al. 2023).

Method

This cross-sectional study is observational, prospective, descriptive, and laboratory-based. carried out at two Histopathology centers in Sudan: The National Central Lab STAC, a central government lab in Khartoum that provides diagnostic services for 7,800 patients annually, and the Private Center (Prof. Ali Abdelsatir's lab), a private facility also in Khartoum that provides services for 15,000 patients annually. during the months of May through August in the year 2019.

Written request forms and tissue specimens provided for histopathological investigation in accordance with the inclusion criteria are used in this study.

Inclusion criteria

Any sample obtained from a patient following a major or small surgical treatment is regarded as a surgical specimen, including tissue samples obtained through surgical incisions or with a Tru-cut needle. The sample type used was non-probability, which was determined using (epi-info). 528 queries met the inclusion criteria.

The researcher used a checklist created in accordance with the standard checklist from the College of American Pathologists (CAP) to collect data regarding the following variables: Patient's personal data (e.g., age, gender, etc.); Clinical history or differential diagnosis; Operation findings; and direct observation. A total of 528 specimens were collected from request forms and containers with specimens that have been sent to pathologists. location of the biopsy, The specimen's description, the referring clinician's name, and their phone number.

Version 23.0 of the SPSS computer program (published in 2015 by SPSS Inc., USA) was used to analyze the data.

Results

A total of 528 laboratory request forms and specimens from May to August 2019 included in this study were assessed, in request forms; patient' names were the most

Table 1 Presence of personal data in request forms

Personal data	Number	Percentage
Patient name		
Written	528	100%
Age		
Written	399	75.6%
Not written	129	24.4%
Gender		
Written	244	46.2%
Not written	284	53.8%
Occupation		
Written	18	3.4%
Not written	510	96.6%
Patient contact number		
Written	20	3.8%
Not written	508	96.2%

complete information 100% as showed in Table 1. Age was written in 75.6% (n 399), while the gender only was written only in 46.2% (n 244). Out of 528 specimens, occupation was not mentioned in 510 (96.6) cases and education was missing in 526 (99.6) request forms.

No clinical history in 48.3% (n 255) cases, while the deficient history was found in 145 request form (27.5%). As showed in Fig. 1, regarding the differential diagnosis found only in 29.5% (n156) of request forms.

The radiological findings found in 17% of cases including all those that have been sent from orthopedic department, intra-operative findings have been written only in 11.6% (n 61), site of lesion and anatomical site of biopsy was mentioned in 91.3% (n 482) and 60.2% (n 318) respectively, moreover 89.2% of request forms describe the type of biopsy whether incisional or excisional mentioned in 68%. Previous histopathological reports were found in 6.4% and the type of investigation requested (e.g. histopathology or immunohistochemistry or others) was missed in 11.4% of request forms. Date of biopsy was missed in 29.2% (n 154). The name of the consultant/specialist in-charge was found only in 32.8%, the name of the registrar or the junior doctor who wrote the request forms present in 32.8% while in 28.9% (n153) of request forms the name is either unclear, not written at all or just a signature. The doctor contact's number were present in 6.8% (n 36) of requests.

There was a diversity of different types of containers used for sending the specimen; these include: intravenous drip bottles, plastic or glass jar, jam bottles, syringes and serum tubes, injection bottles. With regard to containers which were used for specimen; 15.7%.

(83) were inadequate relative to the size of the specimen and 5.3% (28) were not labeled with any information.

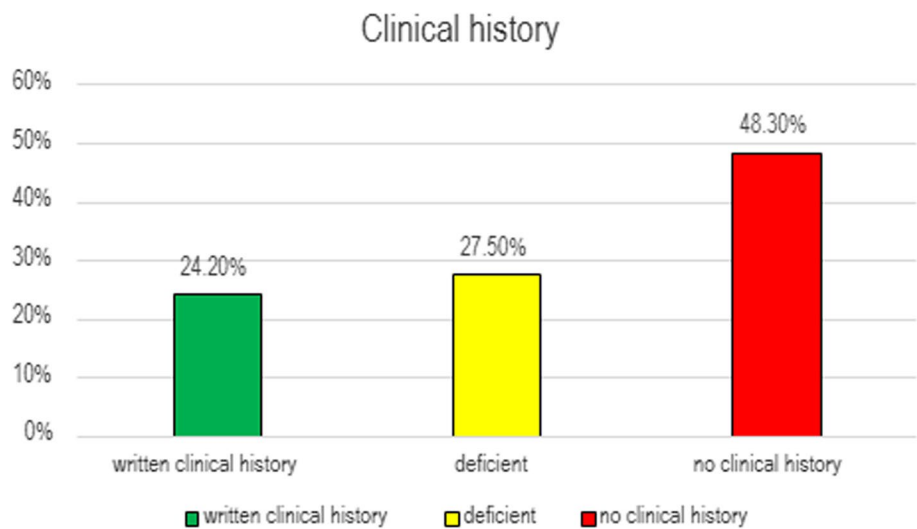


Fig. 1 Presence of clinical history in request forms

Table 2 Completion rate of parameters related to the container

Size of container	Number	Percent
Unfit	83	15.7%
Fit	445	84.3%
Identification label	Number	Percent
Unclear/ not written	28	5.3%
Written clear	500	94.7%
Fixation	Number	Percent
Using normal saline	92	17.4%
Using Formalin	436	82.6%
Surgical Marking on specimen	Number	Percent
Not applicable	317	60%
No	181	34.2%
Yes	30	5.6%

17.4% (92) were not sent in formalin but in normal saline and about 10% were not immersed in the fixative formalin completely. Marking of the specimen was not needed in 60% (317) and among the rest cases; 34.2% was not marked as shown in Table 2.

Discussion

A histopathological service must be used appropriately in order to be competent. This includes implementing clinical management principles, adopting a personalized approach based on the clinical context of each case, and categorizing specimens as diagnostic, prognostic, or therapeutic. It is important to consider the cost-effectiveness of investigations and treatment, as well as the value for money of novel technologies, if a histopathological service is to be competent, it must be used appropriately. Inadequate information provided by service users regarding the patient and themselves

will lead to deficiencies and defects in the service. The accuracy of test finding’s interpretation, which is crucial for managing patients, is primarily dependent on the information provided on the request form. Nonetheless, a number of studies have revealed errors in laboratory request forms filled out globally (Plebani 2009; Piva et al. 2009).

Patient’s name had 100% completion rate which is similar to the findings by Burton et al. (Kurtin and Stucky 2009) who reported a 100% completion for patient’s names.

Laboratory request forms that lack a patient’s name should be returned to the doctors so they can handle the situation appropriately. This could lead to a lag in the investigation, which would affect these people’s prompt medical attention.

The patient’s age was provided in 75.6% of the request forms, in the present study; this is higher than the finding of 9% by Klanl et al. (Singh and Khatiwada 2015) but lower than the report of 98.1% by Jegede et al. (Nakhleh 2003). This may alter interpretations of results since differential diagnosis are variable with age. In the present study, gender information was completed in 46.2% of the request forms. This observation is lower than the findings reported by Olayemi et al., who reported completion rates of 67.3% (Olayemi and Asiamah-Broni 2011), The incomplete gender information poses a significant impediment to accurate interpretation, as gender variances may lead to differences in the prevalence of certain diseases.

The clinical details were completely written only in 24.2% of cases; this is lower than the report from other studies (Singh and Khatiwada 2015). In contrast to this, the request forms that had deficient information were

27.5%. In similar study, Nakleh et al., found that inadequate clinical details was only 40% (Nakhleh 2003).

The provision of complete clinical information is important for accurate and correct interpretation of laboratory results and would help to suggest further investigations if needed for proper management of the patient.

Investigation requested e.g. histopathology or cytology or immunohistochemistry was specified in 88.6% of cases. This information was found to be the most commonly written, most likely due to the high likelihood that the pathologist may reject the specimen if the specific investigation is not included.

Only 10% of requests received information about the specimen's nature, including whether it was hard, cystic, or another type.; The rate is extremely lower than 99.7% obtained by Jegede et al., (Plebani 2009).

The date of specimen collection was provided in 70.8% of cases it was higher than 36.5% reported by Adegoke et al. (Roque et al. 2015). This may not be relevant to the examination or reporting but becomes necessary when turn-around time is being considered or complaints about delays in reporting arise.

The name of the consultant-in-charge and the name of the referring doctor was provided in 38.3% and 32.8% of the requests, respectively, lower than reports from other studies (Olayemi and Asiamah-Broni 2011; Singh and Khatiwada 2015).

Contact number of referring doctor were provided in 6.8% of the requests, phone numbers will facilitate communicating with the clinicians to discuss errors in requests and relay urgent results that require immediate action. Specimen identification is the fore essential step in the pre-analytical phase. Wrong labeling of specimens has resulted in groundless procedures (Nakhleh and Nakhleh 2006). 94.7% of containers were labeled satisfactory enough to cause no mess.

Fixation is the key step that not only affects histological sections but also antigen retrieval for immunohistochemistry (Werner et al. 2000). Poor fixations would result in poor morphology due to autolytic changes and hence limiting proper histopathological interpretation and diagnosis. Sending the specimen in an inappropriate fixative (especially in tropical country like Sudan) can have an adverse effect on specimens, as the tissue undergoes faster autolysis.

due to high atmospheric temperature. In this study, we found that the most commonly misused material as fixative was normal saline instead of 10% buffered formalin (17.4%). This is the case in some hospitals in Sudan where there is no formalin available. Once the pathologists have received the specimen in its entirety along with the full fees, they can transfer it from saline to formalin. However, a prior arrangement between the surgeon and pathologist should be established, ensuring that the

co-patient can afford the cost of the requested investigations. Consequently, normal saline will be replaced with formalin once the co-patient arrives at the center to prevent autolysis and specimen damage.

Considering that 15.7% of containers were unsuitable, it's worth noting that some of them were narrow-mouthed drug containers. This required pathologists and their assistants to break the glass or plastic bottles to extract the specimen, consequently putting the staff at risk of injury not mentioning that the spilled small pieces of glass will get embedded within the specimen. Other containers have been placed in intravenous drips that are inadequately sealed, resulting in half of the formalin being lost in transit. Implementing standardized containers for each specimen type, as some private hospitals do, would mitigate the issue of unsuitable containers. It is imperative that all hospitals have access to and provide these standardized containers.

Furthermore, numerous specimens do not necessitate marking due to their clear anatomical relationships, such as the thyroid, gall bladder, breast with contact nipple-areola skin, or simply being an organ biopsy. However, employing a suture to mark the specimen, for instance, facilitates pathologists in providing an accurate diagnosis, thus aiding the treating physician in determining the appropriate course of action. This practice proves particularly beneficial for ensuring clarity regarding safety margins around a neoplasm.

The preanalytical phase was formerly neglected but with the development of molecular diagnostics and targeted treatment, it is now receiving increasing attention. A key player in the procedures required to perform molecular testing is the pathologist.

Although there are helpful guidelines for standardizing specimen processing in molecular laboratories, there is a lot of variation in how specimens are handled prior to being sent to these labs. False positive or false negative test results could emerge from this crucial stage. By following solid protocols throughout sample processing, these diagnostic tests will become more accurate and reliable. Nucleic acid integrity, stability, and the impact of certain interfering substances during sample transportation are the main sample handling concerns.

Many physicians ask for molecular testing in order to make a diagnosis, determine a course of treatment, or establish a patient's prognosis classification. In order to stop autolysis and the breakdown of molecular components in tissue, fixation is an essential step in long-term tissue preservation. Pre-analytic variables should therefore be taken into account to prevent accidental result misinterpretation. Fresh, non-fixed tissues should be kept well hydrated to prevent nucleic acid destruction. To

prevent drying out, wrap the tissues in gauze soaked in regular saline.

Pathology departments often use fixed tissue specimens kept in paraffin blocks as valuable sources of nucleic acids for molecular testing.

Considering the age of the sample is vital for obtaining an accurate nucleic acid test due to potential hypoxic tissue damage and altered mRNA expression levels caused by prolonged anesthesia and ischemic procedures like arterial ligation, resulting in inaccurate quantitation of mRNAs. Choosing the specific factors in how patient samples are obtained, handled, processed, stored, and transported that are responsible for most quality issues and changes in molecules would ensure that research data is consistent and reliable (Sotoudeh 2021).

Conclusion

This study reveals inadequacies and incompleteness in the completion of laboratory request forms. A large portion of specimens submitted for histology lacked proper labeling and surgical markings, or were housed in inadequate containers with insufficient fixative. These shortcomings will have adverse effects on the standard of care, interpretation of results, and ultimately, patient management.

While staff training is crucial and undoubtedly enhances performance, it alone is insufficient. Regular audits of employees' work, implementation of an effective monitoring and evaluation system, holding individuals accountable for their tasks, and, most importantly, adopting a policy that fosters open discussion, sharing, and learning from errors, rather than placing blame or shame, will collectively contribute to the organization's success.

Acknowledgements

The authors would like to express their sincere gratitude to all individuals and organizations who contributed to the completion of this research project. First and foremost, we extend our appreciation to all the staff working at the ALI ABDELSATIR center, starting with Professor Ali for giving us the permission to begin data collection and for his guidance, expertise, and unwavering support.

Special thanks are due to Dr Sawsan who generously volunteered her time and provided invaluable insights that greatly enriched the study.

We would also like to acknowledge the staff members of STAC center for their support.

Finally, we express our heartfelt appreciation to our families and loved ones for their patience, encouragement, and understanding during the course of this research endeavor.

Authors' contributions

Eman Elhassan: Conceptualization, Methodology, original draft writing, visualization. Mohanad Khalifa: Conceptualization, methodology, formal analysis, visualization, review writing. Faisal Ibrahim: Review and supervision. Sawsan Mohammed: supervision.

Funding

The authors received no financial support for the preparation of this study.

Data availability

The data are available at the archives of both histopathology centers, Khartoum, Sudan.

Declarations

Ethics approval and consent to participate

Ethical clearance obtained from ethical committee of Sudan Medical Specialization Board. Clear written consent was received from the centers, and information was collected anonymously to protect data confidentiality. The Sudan Medical Specialization Board's ethics committee provided ethical clearance.

Consent for publication

Informed consent was obtained from the centers by clear written permission, no consent from information"s were collected anonymously.

Competing interests

The authors of this paper have no invested interests in products described or used in this paper. The authors have no conflict of interests.

Received: 4 March 2024 Accepted: 2 November 2024

Published online: 26 November 2024

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