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Systematized protocol for interventional pathology reports. Pathology report paradigm for pathologist-performed Ultrasound Guided Fine Needle Aspiration (USFNA) and Ultrasound Guided Core Needle Biopsy (USCNB)

Protocolo sistematizado para informes de patología intervencionista. Informe de anatomía patológica para punción-aspiración con aguja fina con ecografía (EcoPAAF) y biopsia con aguja gruesa con ecografía (EcoBAG)

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In a growing number of specialties (urology, ICU, gynecology, dermatology, etc.), ultrasound is being employed to enhance diagnostic or therapeutic procedures. Although, in experienced hands, palpation-guided fine needle aspiration (FNA) is a very reliable diagnostic tool,¹ the diagnostic yield achieved with imaging techniques such as ultrasound is noticeably superior.¹

The improvement in imaging techniques has enabled the identification of smaller masses and now both palpable and non-palpable masses can be biopsied with a fine or core needle using ultrasound guidance, which is also helpful for sampling specific areas of palpable masses. Although tra-

ditionally this procedure has been the responsibility of the radiology departments, the field of FNA is being expanded to USFNA performed by pathologists and thus defining a new role: the interventional pathologist.² Although ultrasound has become a part of many medical specialties, it should only be performed by professionals who have gained expertise through training and practice.³

When both the pathologist and the radiologist are perfectly coordinated and agreed that the aim is not merely to place the needle in the lesion, but to make a correct diagnosis, USFNA is a very efficient technique. When biopsies are performed in conjunction with radiologists, the radiologist interprets the image and guides the needle; the pathologist evaluates the quality of the material and decides whether a new USFNA pass or a core needle biopsy (CNB) is necessary, based on the rapid on-site evaluation (ROSE). However, it is

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often impossible to coordinate the agendas of both radiology and pathology departments, sometimes making this option non-viable.

Thus, the radiologist (or endoscopist, endocrinologist, etc.) usually carries out the USFNA procedure unaccompanied by the pathologist who therefore cannot participate with real time diagnostic decision making. However, with adequate training, the actual puncturing of a superficial lesion is the easier part of the procedure,¹ whereas obtaining well-fixed, well-prepared, uniform samples with adequate material requires much more expertise and is the true added value of this technique; thus the pathologist plays a key role in USFNA and Ultrasound Guided Core Needle Biopsy (USCNB).

The efficacy and the quality of the USFNA performed by pathologist have been reported⁴⁻⁷ and the interventional pathologist is now a reality in Spain.^{2,3} Despite difficulties and obstacles in its development, interventional pathology is undoubtedly a new branch of the specialty, which we believe will prove beneficial to the patient.

The ability to understand the significance of ultrasound echogenic patterns and accurately place a needle into a specific area of a lesion using ultrasound guidance requires a different set of skills than diagnostic interpretation of ultrasound studies. Interventional pathologists are not radiologists and do not pretend to replace them and their diagnostic interpretation skills. Interventional pathologists need only a basic knowledge of ultrasound that can be acquired in short courses. They will be capable of recognizing superficial and/or palpable lesions on which USFNA can be performed, either with a fine needle or a core needle, and know which area of the mass is most likely to yield diagnostic material.

It is always useful to have a systematized protocol for reporting the procedure. Thus, after completing the corresponding training in the course of the College of American Pathologists (CAP) AP3 USFNA course and subsequently accumulating self-taught skills acquired with hands-on practice, we suggest a reporting protocol³ for pathologists who are joining this new branch of pathology and who are beginning to perform interventional pathology procedures.

The report of the findings should be as complete as possible and include ultrasound data that may be relevant in the evaluation of the sample obtained. Therefore, based on the CAP protocol,⁸ we propose the following report^{3,8}:

- 1) Patient demographics (Note A)
- 2) Procedural data (Note B)
 - Use of anesthetics
 - Type needle used (fine or core) and needle gauge
 - Use of ultrasound guidance (*)
 - Sampling method
 - Puncture site or location
 - Number of FNA passes
 - Number of slides (**)
 - Needle approach (***)
- 3) Physical findings and non-diagnostic ultrasound examination (Note C)
 - Location of the lesion
 - Size of the lesion (*)
 - Shape (**)

- Ultrasound findings (***)
 - Margins of the lesion (****)
 - Calcifications (+)
 - Vascularization (++)
 - Ultrasound images documenting the needle in the target lesion (+++)
- 4) Microscopic findings (Note D)
 - 5) Adequacy statement (Note E)
 - 6) Comments and recommendations (Note F)
 - 7) Final diagnosis (Note G)
 - 8) Informed consent (Note H)

Explanatory notes

A. Patient demographics:

This must include the complete identification of the patient (at least two identifiers: name and date of birth i.e.), the date on which the procedure was performed, the referring physician, the name of the pathologist who performs the procedure and any relevant present and past medical history.

These data must be present on a mandatory basis.

B. Procedural data:

Document the procedure details. It is important to state if local anesthesia has been used, including the type of local anesthesia and the amount applied. For example, 1.5 cc of local anesthetic (Mepivacaine with epinephrine). The type of needle used in the procedure must also be included (for example, BD[®] Microlance 23 G 1" – Nr.16 (Blue) or BARD[®] MISSION[®] Disposable Core Biopsy Instrument 20 G × 10 cm).

(*) If ultrasound guidance was not used during the procedure, the reason for this should be specified (for example, a very superficial lesion).

(**) The number of slides used can be included in the report, but is not mandatory.

(***) Here the type of needle approach used can be mentioned (longitudinal approach or long axis, transverse approach or short axis). Also the use or not of aspiration can be included here (FNA performed only with a needle).

C. Physical findings and non-diagnostic ultrasound examination:

This section should include a brief description of the findings obtained from the physical examination (size, shape, location, description of the margins, etc.). The ultrasound findings should be described, clarifying that it is a non-diagnostic ultrasound scan.

The type of lesion (solid, cystic, solid-cystic complex, spongiform), the echogenicity of the lesion (anechoic, hypoechoic, isoechoic, hyperechoic) and the internal sonographic pattern (homogeneous, heterogeneous) should be recorded.⁹

Any artifacts present in the image (posterior reinforcement, rear shadow, reverb artifact, etc.) can also be included.

The presence or not of any findings suggestive of malignancy should be included, considering that there may be

a significant overlap of characteristics⁹ and taking into account that the observed findings only constitute an initial diagnostic guide. A diagnosis of benignity or malignancy should not be issued based only on the ultrasound criteria, a correlation of the images must be made with the analytical findings and the present and past medical history of the patient.³

It is important to be prudent in the description, highlighting only the characteristics of the lesion, without issuing an ultrasound image diagnosis.

(*) Size measured by ultrasound. We recommend correlating with previous imaging studies to assess change in the size of the lesion, if possible. The CAP considers a significant increase in size >20% increase in volume.^{9,8}

(**) Length-width ratio of the lesion: Anteroposterior (AP)/transverse (T) ratio. When the AP/T ratio is greater than 1 in the transverse vision, it is suspicious of neoplasia/malignancy.^{3,8,9}

(***) Describe the echographic findings of the lesion: solid, cystic or solid-cystic, echogenicity (hyper or hypoechogenic), the internal sonographic pattern (homogeneous or heterogeneous) and the artifacts present.

(****) The edges of the lesion should be described: smooth, smooth with peripheral halo, irregular, poorly defined.

(+) Describe the presence or absence of calcifications and the pattern (ring, eggshell, macrocalcifications or microcalcifications).

(++) Describe the color Doppler and/or Power Doppler findings, that is, the vascularization (avascular, peripheral vascularization, intranodular or peripheral and intranodular).

(+++)³ It is advisable to include images of the lesion if possible. When this is not possible, due to lack of availability of a printer, a digital copy should be recorded for each patient.

D. Microscopic findings:

The microscopic findings should be recorded in the usual way, explaining the cytological characteristics of the lesion.

E. Adequacy statement:

Document whether or not the USFNA is adequate for diagnosis in the ROSE ("Rapid On Site Evaluation") of the specimen. If the specimen is not adequate, clearly document why an adequate sample was not obtained.

F. Comments and recommendations:

A clear note with comments and/or recommendations should be included. For example, if the final diagnosis is consistent or not with clinical diagnosis or presentation. Also in some cases, when it is not possible to issue a definitive diagnosis, differential diagnoses can be stated, preferably supported with the recommended bibliography (e.g. recent articles).

Complex cases may require additional documentation such as the name of a secondary reviewer and their interpretation (for example, "the case has been discussed in departmental session").

G. Final diagnosis:

The final diagnosis should be clearly stated and indicate the following information: location of the lesion and the method used to obtain the sample (for example, right axillary lymph node USFNA or right thigh palpable nodule USCNB).

It is important always to remember to maintain contact with the referring physician as the best diagnoses are comprehensive and go hand in hand with the patient's clinical data and past and present medical history.

If it is necessary to perform a follow up of the lesion, excisional biopsy or surgical resection, it can be included in a note but always with the label "if clinically indicated" or "if clinically it is considered appropriate".

H. Informed consent:

Follow your institution's guidelines regarding informed consent. If there are no guidelines, follow local regulations or consider developing a guideline for your FNA and CNB practice.

Informed consent can be documented using a separate signed consent form or incorporated directly into the report.

Conclusion

Ultrasound is a common diagnostic tool in the daily practice of various medical and surgical specialties, apart from radiology, such as pulmonology, anesthesiology, critical care, cardiology, gynecology, etc. For over ten years, interventional pathologists in many countries have perfected and optimized USFNA procedures, incorporating the use of ultrasound into their daily practice.^{1,5-7} With appropriate training, pathologists have methodically systematized their experience, reporting their results in scientific publications. Undoubtedly, they have achieved a high diagnostic performance, comparable, or often superior, to that of other interventional specialties.

However in Spain, to our knowledge, interventionism in pathology is restricted to two pioneering departments, in the Hospital Universitario del Henares (Madrid) and in the Hospital Universitario Central de Asturias (Oviedo); where, for almost 4 years, USFNA and USCNB performed by pathologists are routine practice.

If we wish to maintain and expand the interventionist role of the pathologist, the implementation of pathologist-performed USFNA and USCNB should be considered a natural evolution of the specialty within the possibilities and specific characteristics of each healthcare center. Thus it should be recognized as necessary training by the Spanish Society of Pathology (SEAP) and the Spanish Society of Cytology (SEC). Consequently, the systematization of the reporting of interventional procedures in order to evaluate and improve our professional development is needed, guided by a protocol based on the recommendations of such a prestigious institution as the American College of Pathologists.

This systematized report can be adapted to the needs of each pathology department. We hope that it will prove to be a useful and indispensable tool for interventional pathologists in their daily practice.

Conflict of interests

There is no conflict of interest to declare.

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