EMBJ.ORG FOR YOUNG DOCTORS

EUROMEDITERRANEAN BIOMEDICAL JOURNAL
2021,16 (24) 100-103
(*FORMERLY: CAPSULA EBURNEA*)

Original article

SAFETY AND EFFICACY OF US-GUIDED BREAST BIOPSIES WITH 16 G NEEDLE.

Antonio Catelli [1], Angela Santoro [2], Elena Antignani [1], Pietro Venetucci [1], Salvatore Minelli [2]

1. Advanced Biomedical Sciences Department, University Federico II of Naples, Naples, Italy
2. A.O.R.N. " Cardarelli ". Breast interventional Radiology Division, Naples, Italy

ARTICLE INFO

Article history:
Accepted 19 April 2021
Revised 28 May 2021
Published 11 July 2021

Keywords:
interventional radiology, ultrasound, breast cancer, tru-cut, breast cancer, fibroadenoma.

ABSTRACT

The purpose is to describe the safety and efficacy of biopsy of a breast mass using ultrasound guidance. The breast cancer histological findings were compared with epidemiological data. The presence of statistically significant differences was evaluated based on the size of the nodule. 1000 biopsies of the total 1500 performed from January 2018 to August 2020 were included; the repetitions for inadequate withdrawal occurred at 3.6% (36/1000). Major complications were never observed. There were two cases (0.2%) of minor bleeding. The frequency of histotypes of carcinoma detected is in agreement with recent epidemiological studies. No statistically significant differences were observed based on nodule size. In conclusion, the 16G needle sampling biopsy procedure is a safe and effective procedure for characterization of indeterminate breast mass.

1. Introduction

Large needle-assisted biopsy has become a widely used technique in the evaluation of palpable and non-palpable breast nodules since its introduction in the early 1990s[1-2]. Several published studies have shown that guided biopsy can have, if performed by experienced operators, a result similar to that of surgical excision biopsy [1-3-4]. Most guided biopsy papers have focused on stereotaxic-guided procedures [2-5]. Ultrasound guided breast biopsy with a 14 gauge needle was first described in 1993 by Parker et al and then later in several articles[6-7-8-9]. A small number of papers are available describing ultrasound-guided breast biopsy with 16 G. The purpose is to describe an experience on ultrasound-guided biopsy of palpable and non-palpable breast nodules through a semi-automatic 16 G needle, focusing on the safety and diagnostic efficacy of the interventional procedure.

2. Material and methods

Population

From January 2018 to August 2020, we examined the medical records and image storage systems available to the breast radiology of 1500 patients with indeterminate palpable and non-palpable nodular mass of the breast and undergoing subsequent biopsy interventional radiology procedure.

Collected data include: age, family history of mammary and gynecological cancers, blood count, coagulation index, anticoagulation and antiplatelet therapy, size and site of the mass, palpable or non-palpable nodule. The inclusion criteria are: mass greater than 5 mm in maximum diameter, echo-detectable mass, use of semi-automatic Tru-cut 16 G, execution of 5 standard samples, absence of drug-allergy to anesthetics. The exclusion criteria are: non-echo-detectable mass, thrombocytopenia, coagulopathy. Informed consent on the risks and benefits of the procedure was obtained from all patients prior to surgery.

Technique

The operator who performed the survey has more than 15 years of experience in interventional breast radiology.

The examination is performed on an outpatient basis. Coagulation and platelet counts were monitored for each procedure; SIR-CIRSE guidelines for bleeding risk procedures were followed[10]. The intake of clopidogrel and aspirin was suspended 5 days before the procedure. Suspended anticoagulants according to drug kinetic and drug dynamic profile. No antibiotics were administered in accordance with current protocols. The ultrasound used was a GE Logiq F6.

The patient is placed in the supine position or on the right or left side according to the target mass.

* *Corresponding author*: Antonio Catelli, catelliantonio89@gmail.com
DOI: 10.3269/1970-5492.2021.16.24
 ISSN: 2279-7165 - Available on-line at www.embj.org

Subsequently, after careful disinfection of the skin, ultrasound-guided injection of 5 cc of Lidocaine is performed through a syringe with a 22 G needle in the peri-nodular site, obtaining the detachment of the nodule from the adjacent anatomical structures. After a 3 mm skin incision, under ultrasound control, following a practically vertical path to the pectoral muscle, the mass is sampled with a 16 G Tru-cut needle through 5 samples. All the samples obtained were placed in 10% formalin neutral buffer and sent for pathological analysis. At the end of the procedure, compresses were performed manually for 10 minutes, medicated and peri-nodular ultrasound checks were performed after compression and subsequently at 90 minutes. The patient underwent a further examination 10 days after the procedure. The procedural factors evaluated are as follows: technical-diagnostic and frequency of short-term complications (after 10 days). The technical success evaluated was considered as a conclusive sample for histological diagnosis. Complications were assessed according to the CIRSE Standard for Classification of Complications [11]. We subsequently evaluated statically significant differences between nodules <or = 10mm and> 10mm. We evaluated the frequency of the obtained histological data and compared them with the existing literature.

Statistical analysis

All statistics were developed in MATLAB® (Mathematics Works, Inc., Natick, Massachusetts, USA). We also performed a comparison of procedural data of the interventions in patients who have a lesion <or = 10 mm and> 10 mm: the differences in terms of safety and efficacy were considered statistically significant if p-value <0.05, using the test Student's t or Wilcoxon Sign Rank test.

3. Results

Among the 1500 patients examined, 1000 patients were enrolled for safety and efficacy. Among the 500 excluded, 370 had performed biopsy interventional procedures under tomosynthetic guidance, 100 had performed ultrasound-guided FNAC examination, and the remaining 37 had masses <5 mm. Patients ranged in age from 18 to 89 years (mean, 48 years; median, 46 years). The lesions ranged in size from 5 to 60 mm (mean, 14 mm; median, 13 mm). No structural features were used to select ultrasound-guided biopsy instead of surgical excision. Palpable lesions were 20.3% (203/1000). Bleeding that partially obscured lesions occurred in 0.2% of biopsies. There were no bleeding that blocked the execution of the 0% procedure (1000/1000). Two cases (0.2%) of minor bleeding with self-limited bleeding from the skin breach at 90 minutes without clinical sequelae in an asymptomatic patient. The patient underwent an ultrasound examination 10 days after the procedure showing the presence of small (<4 mm) hematoma in 7% (Table 1). The diagnostic failure intended as anatomo-pathological inadequacy of the sample occurred in 0.36% (36/1000). Of these 1000 women, 79.3% had a biopsy of 1 lesion, 20.7% had biopsy of 2 separate lesions. The ultrasound-guided sampling showed carcinoma in 61.5% (651/1000). Of these, 79% were ductal carcinoma. Lobular carcinomas were 12%; the remaining histotypes had a frequency <3%. Metastases had a frequency of 0.5% (Table 1).

Fibroadenomas (28%) and adenoses (20%) were the most frequently encountered benign lesions (Table 1). The correlation of BI-RADS US 5th with histopatological examination showed: BIRADS 5 (98% cancer), BI-RADS IV (a: 7%, b: 49%, c: 93% cancer) (Table 2). There were no statistically significant differences between the results of biopsies performed on masses < or = 10 mm and> 10 mm. Subsequent surgery of the tumor masses confirmed the biopsy diagnosis in all cases.

	Frequency (%)
Complications	
Bleeding that partially obscured lesions	0.2
Minor bleending	0.2
Major bleendig	0
Hematomas detected after 10 days	7
Breast cancer	
K ductal	79
K lobular	12
K mucinous	3
K papillary	1.5
K cribiform	1
K tubular	3
Metastasis	0.5
Ductal intraepithelial cancer	
DIN I a	0.4
DIN I b	2
DIN I c	0.2
DIN II	1.2
DIN III	0.2
Lobular intraepithelial cancer	
LIN I	0.2
LIN II	0.8
LIN III	0.2
Breast lesions in follow-up	
Fibroadenoma	28
Apocrine metaplasia	19
Adenosis	20
Ordinary ductal hyperplasia	18
Radial Scar	10
Complex sclerosing	5

Table 1. Characteristics of the subject enrolled in the study.

Score US	Frequency Breast cancer
BI-RADS 5	98%
BI-RADS IV a	7%
BI-RADS IV b	49%
BI-RADS IV c	93%

Table 2. Score US of the breast cancer analysed.

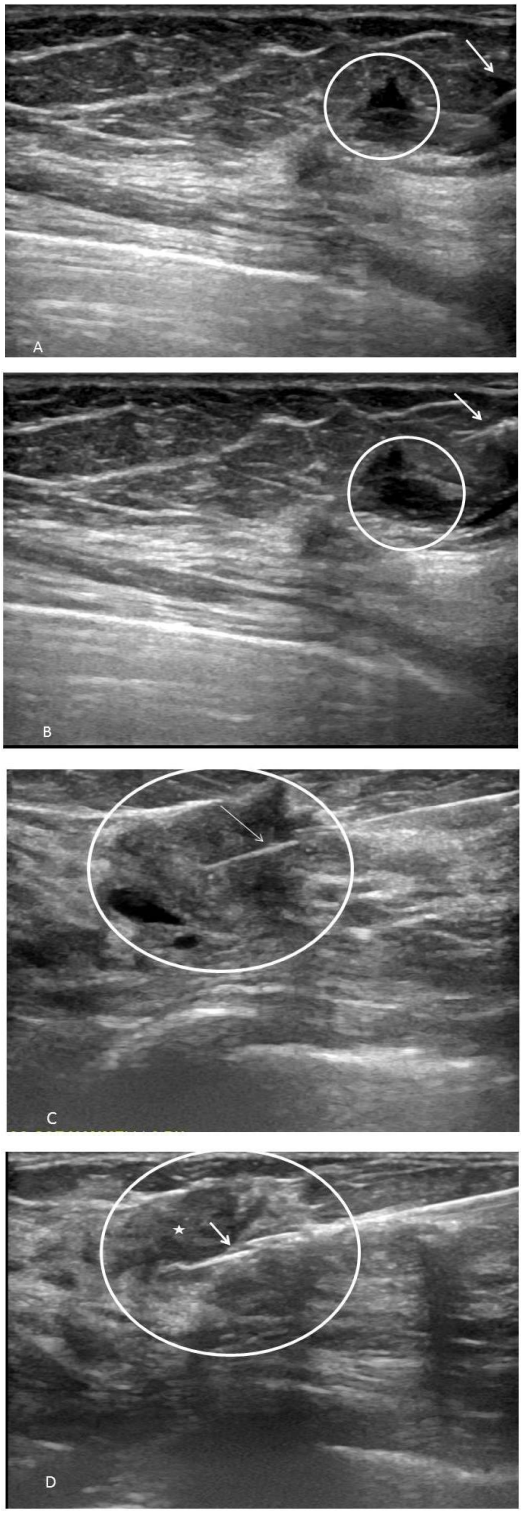

Figure 1 A – B – C - D. US-guided procedure (arrow) of anesthetic administration (circle) peri-nodular breast lesion; (C): ultrasound-guided breast biopsy procedure (circle) with semi-automatic 16 G needle drawer opening (arrow) in the lesion (asterisk); (D): ultrasound-guided breast biopsy procedure (circle) with semi-automatic 16 G needle drawer opening (arrow) in the lesion (asterisk).

4. Discussion and Conclusions

Our Recent scientific indications in the treatment of breast cancer have favored conservative surgery with particular attention to aesthetics. In the past twenty years of breast surgery, one of the most important advances has been the ability to diagnose cancer outside the operating room using percutaneous biopsy techniques under stereotaxic guidance versus excisional biopsy.

The latter often requires repetition of the surgery[12-13-14-15]. The diagnosis of cancer before surgery can allow for correct preoperative planning with a reduction in re-operations. Ultrasound-guided percutaneous biopsy is the preferred minimally invasive method for characterization of both palpable and non-palpable breast masses. An international interdisciplinary consensus in 2001, 2005 and again in 2009 agrees that biopsy under ultrasound guidance is the " gold standard " for the removal of tissue from palpable, non-palpable and microcalcification masses of the breast [12]. In the United States, percutaneous ultrasound-guided biopsy has almost replaced fine needle aspiration (FNA) as the diagnostic method of choice for breast lesions, as it provides histological diagnosis and prognostic markers[12-13-16]. In fact, as described in numerous papers available in the literature, the micro-histological biopsy is superior to the cellular aspirate derived from a fine needle in the diagnosis of the nature of the suspected lesion[17-18]. This has also been demonstrated for other parts of the body[17-18-19-20].The thick needle aspiration biopsy provides only the presence or absence of suspicions or cell malignancy while the micro-histology allows for precise diagnosis of the mass. The biopsy gun is used to remove different pieces of tissue and in some cases completely remove the lesion. It is recommended that at least 5 tissue fragments be taken from a single lesion for adequate sampling. Even the size of the tissue fragments is fundamental for the correct diagnosis, in fact, our pathologists have observed that the samples of breast tissue tend to fragment easily, and the analyzes are more complex [17-21]. This consideration is further confirmed by recent scientific studies in which small caliber needles have been used [17]. In the literature there are several papers available describing the use of 14 G needle for breast biopsies, but as far as we know there are a low number of papers describing the use of a 16 G biopsy needle. Large (16 gauge) needles, on the other hand, can deliver lumps of intact breast tissue. The 16 G diameter reduces friction with the surrounding tissue. The function is simpler and the strength of the blow is greater. In the literature, the described complications of ultrasound-guided biopsy are rare and not significant. Both hematomas and are very rare and represent less than 1 / 1,000 biopsies [6-25]. Our experience confirms that the use of 16 gauge needles do not increase morbidity and allow diagnosis in most cases. In our experience, no significant complications occurred. Small (< 4 mm) hematomas in 7% in ultrasound examination at 10 days. In the follow-up of 90 minutes, there were 0.2% bleeding. The correct characterization of the mass allows an adequate therapeutic choice in fact the histological, imaging and clinical findings must be evaluated together. If the biopsy result is benign and agrees with imaging results, continuous surveillance is acceptable. If the result is indeterminate or discordant from the image, surgical excision is indicated to exclude malignancy. In addition, surgical excision is indicated for biopsies demonstrating atypical hyperplasia (lobular or ductal), lobular carcinoma in situ, or coexisting in situ or invasive ductal carcinoma. Carcinoma in situ can be the cause of 30% of potential erroneous sampling [12-26-27].The frequency of ductal

carcinoma and lobular carcinoma detected is in agreement with recent epidemiological studies of cancer breast disease frequency in the global population. Furthermore, the results obtained from the correlation of the BI-RADS US with the pathological results are in accordance with the risk assessment and quality assurance tool developed by A.C.R. 5th. There are several limitations. First of all, there is no direct comparison with a group of biopsies performed with a 14 G needle or with a 12 G needle by the same operators; moreover, it has a series limited to a single operator. In conclusion, the ultrasound-guided micro-histological biopsy with 16 G needle is a safe and effective technique with a very low complication rate and inadequate samples for diagnosis. In conclusion, the 16G needle sampling biopsy procedure is a safe and effective procedure for characterization of indeterminate breast mass.

References

1. Smith DN , Rosenfield Darling ML, Meyer JE, Denison CM, et al.The utility of ultrasonographically guided large-core needle biopsy: results from 500 consecutive breast biopsies. J Ultrasound Med; 2001. 20(1):43-9.
2. Parker SH, Lovin JD, Jobe WE. Stereotactic breast biopsy with a biopsy gun. Radiology; 1990. 176:741–747.
3. Elvecrog EL, Lechner MC, Nelson MT. Nonpalpable breast lesions: correlation of stereotaxic large-core needle biopsy and surgical biopsy results. Radiology;1993.188:453–455.
4. Meyer JE, Christian RL, Lester SC. Evaluation of nonpalpable solid breast masses with stereotaxic large-needle core biopsy using a dedicated unit. Am J Roentgenol;1996. 167:179–182.
5. Liberman L, Dershaw DD, Glassman JR. Analysis of cancers not diagnosed at stereotactic core breast biopsy. Radiology; 1997. 203:151–157.
6. Parker SH, Jobe WE, Dennis MA US-guided automated large-core needle biopsy. Radiology; 1993. 187:507–511.
7. Francesco Campanile , Simone Maurea, Pierpaolo Mainenti, Antonio Corvino, Massimo Imbriaco. Duodenal involvement by breast cancer. Breast J. Nov-Dec 2012;18(6):615-6.
8. Rubin E, Dempsey P, Pile NS. Needle-localization biopsy of the breast: impact of a selective core needle biopsy program on yield. Radiology; 1995. 195:627–631
9. Chare MJB, Flowers CI, O'Brien CJ. Image guided core biopsy in patients with breast disease. Br J Surgery; 1996. 83:1415–1416.
10. Giurazza F, Corvino F , Contegiacomo A, et al.. Safety and effectiveness of ultrasound-guided percutaneous transhepatic biliary drainage: a multicenter experience. J Ultrasound ; 2019. 22(4):437-445.
11. Filippiadis DK, Binkert C, Pellerin O et al. Cirse quality assurance document and standards for classification of complications: the cirse classification system.Cardiovasc Intervent Radiol. 2017. 40:1141–1146
12. Klimberg VS, Rivere A. Ultrasound image-guided core biopsy of the breast. Chin Clin Oncol . 2016. 5(3):33.
13. Devaraj S, Iqbal M, Donnelly J. Axillary ultrasound in invasive breast cancer: experience of our surgeons. Breast J; 2011.17:191-5.
14. Rakha EA, Ellis IO. An overview of assessment of prognostic and predictive factors in breast cancer needle core biopsy specimens. J Clin Pathol; 2007. 60:1300-6.
15. Layeequr Rahman R, Crawford S, Hall. Surgicaloffice- based versus radiology-referral-based breast ultrasonography: a comparison of efficiency, cost, and patient satisfaction. J Am Coll Surg; 2008. 207:763-6.
16. Garg S, Mohan H, Bal A. A comparative analysis of core needle biopsy and fine-needle aspiration cytology in the evaluation of palpable and mammographically detected suspicious breast lesions. Diagn Cytopathol; 2007. 35:681-9.
17. S H Parker , W E Jobe, M A Dennis, A T Stavros, K K Johnson, W F Yakes, J E Truell, J G Price, A B Kortz, D G Clark. US-guided automated large-core breast biopsy. Radiology. 1993. 187(2):507-11.
18. S H Parker , J D Lovin, W E Jobe, J M Luethke, K D Hopper, W F Yakes, B J Burke. Stereotactic breast biopsy with a biopsy gun. Radiology; 1990. 176(3):741-7.
19. S H Parker , K D Hopper, W F Yakes, M D Gibson, J L Ownbey, T E Carter. Image-directed percutaneous biopsies with a biopsy gun. Radiology .1989.
20. Dowlatshahi K, Yaremko ML, Kluskens LF, Jokich PM. Non palpable breast lesions: findings of stereotaxic needle-core biopsy and fine-needle aspiration cytology. Radiology. 1991.
21. Löfgren M, Andersson I, Lindholm K. Stereotactic fine-needle aspiration for cytologic diagnosis of nonpalpable breast lesions. AJR Am J Roentgenol; 1990.154(6):1191-5.
22. Corben AD, Edelweiss M, Brogi E. Challenges in th interpretation of breast core biopsies. Breast J; 2010. 16 Suppl 1:S5-9.
23. Landercasper J, Linebarger JH. Contemporary breast imaging and concordance assessment: a surgical perspective. Surg Clin North Am; 2011. 91:33-58.