



Trucut biopsy of breast lesions: The first step toward international standards in developing countries

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Abstract The new concept in breast cancer diagnosis and treatment is based on a less invasive, more accurate and effective strategy, with a multidisciplinary approach in a specialised breast unit. When indicated, conservative surgery has replaced mastectomy with sentinel-node biopsy substituting routine axillary dissection. But the key factor in respect of these new standards is to confirm the cancer before going to the operating room. Trucut biopsy is performed instead of incisional or excisional biopsy and frozen section. The technique is reliable, simple, and reproducible, and not at all expensive; it can be adapted even for low-income developing countries. *Materials and methods:* Between March 2006 and June 2010, 764 patients under clinical suspicion of cancer and/or with BIRADS (Breast Imaging Reporting and Data System) III–V in imaging in one university and one private hospital in Tehran, Iran underwent trucut biopsy (60% palpable and 40% non-palpable lesions). Cancer was found in 30.8% of the cases. In benign pathology, in concordance with clinical and imaging suspicion, surgery was omitted with short-term follow-up. For palpable symptomatic benign lesions surgery was performed to relieve the patient's symptoms. When the pathology report was not in concordance with clinical/imaging suspicion (1.8%), and in the presence of moderate and severe hyperplasia with or without atypia, in lobular and papillary lesions (4.9%) open biopsy was done to rule out cancer (10 added cancers, 1.3%; total cancers 32.1%). Cancer surgery was done as a single procedure in 89.8% of cases. *Conclusion:* Trucut biopsy for breast lesion assessment is the first step toward a new concept in breast cancer care. It is simple, reduces the number of surgeries (no surgery for non-symptomatic benign lesions and one surgery for cancer), and avoids diagnostic errors with full respect for the patient's rights. We insist on its routine use to extend international guidelines while decreasing the total cost of this common disease in all low-resource countries.

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1. Introduction

First introduced by Ellis and Martin in 1930 in New York for the cytological evaluation of solid lesions,¹ fine-needle aspiration (FNA) was rapidly disseminated in Europe and then in the United States of America (USA) as part of a triple assessment of palpable breast lesions. Breast cytomorphology has been added to the educational curriculum of pathology and cytopathology fellowships.^{2–9} In 1996 the National Cancer Institute published a guideline for breast FNA interpretation.^{10,11}

Sample insufficiency is seen in 2–36% of FNA cases (mean 19%).^{10,12–15} Other disadvantages of FNA include false negatives, false positives, inability to differentiate intraepithelial or intralobular lesions, and hyperplasia from invasive cancers. The main limiting factors to the widespread use of FNA are the need for an expert breast cytopathologist and a severe shortage of such specialists even in well-developed countries.^{10–14}

Though rare, false positivity is an important issue for FNA, leading erroneously to surgery for cancer. FNA is not a reliable technique for atypical ductal and lobular hyperplasia, hypocellular cancer, papillary benign and malignant lesions, fibroepithelial tumours and mucinous cancers.^{11,14}

For small non-palpable lesions detected in screening programs, trucut biopsy has replaced FNA because. Sample insufficiency is rare for trucut biopsy even for these lesions.^{12–18} Compared to open surgery, trucut biopsy is much less invasive. The volume of tissue removed, breast deformity, and the effect on mammography are much reduced. For non-palpable lesions surgery is omitted when the pathology is benign. For malignant lesions cancer surgery can be done in a single session.^{18,15,19}

Although breast cancer assessment by either FNA or trucut biopsy has been considered a standard of care for more than one decade,²⁰ it is still not a routine procedure in many developing countries, including Iran. The absence of a national screening program and a low level of breast cancer awareness are common features of developing countries. At presentation cancers are symptomatic, mostly in stage II–III.^{21–24} The actual trend for palpable lesions is either excisional or incisional biopsy, with or without intraoperative assessment by frozen section, all frankly against the standard assessment of breast lesions.²⁰ For non-palpable lesions that are small – less than 1 cm in the majority of cases – frozen section is prohibited.²⁰ With preoperative confirmation of cancer the number of surgeries is significantly decreased.²⁵ Combined with the elimination of unnecessary surgery just to rule out cancer, the total cost of breast cancer diagnosis and treatment is decreased.

The main difference in the quality of breast cancer care between developing and developed countries is a limited health budget, which is a barrier for early

detection. So it seems that in developing countries respecting health economy must be more important than in developed ones.^{15,26}

The new concept in breast cancer care is based on a multidisciplinary team working in a specialised breast unit. The aim is to minimise invasion to the patient while increasing the accuracy and quality of care. Despite cost-effectiveness and all the other advantages of this new concept, it is still not respected in many developing countries, including Iran.^{26–29}

In this study we present our team's work to introduce trucut biopsy as an essential step in triple assessment in Iranian patients. We think that, despite all limitations, this is the key point to overcome all barriers to international guidelines.

2. Materials and methods

Between March 2006 and June 2010, in one university and one private hospital in Tehran, Iran, 34,760 patients are visited in the breast clinic. In 22,304 patients mammography was done and 764 patients aged 19–84 years underwent trucut biopsy due to clinical suspicion and/or BIRADS (Breast Imaging Reporting and Data System) III–V classification of imaging. All palpable lesions (60%) and non-palpable lesions well seen by sonography have undergone sonoguided biopsy. Stereotactic biopsy was performed for the others.

In benign pathological results in concordance with both clinical and imaging suspicions, surgery was omitted. Short-term follow-up was done to overcome the low false-negative rate. Surgery was performed only for symptomatic lesions to relieve the patients' symptoms (Figs. 1–3).

When the pathological result was not in concordance with clinical/imaging suspicions, open biopsy was done as the diagnostic procedure to rule out cancer (14 patients or 1.8% of cases). Except for one all these cases were non-palpable. Open surgery was done for moderate

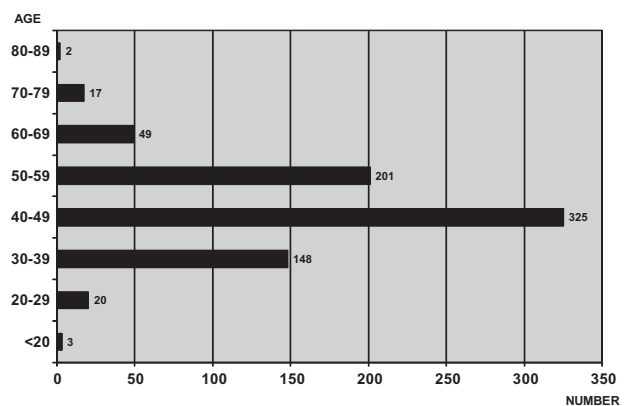


Fig. 1. Age distribution of trucut biopsy.

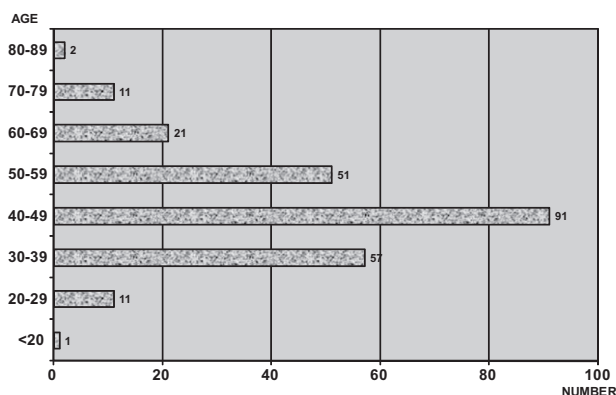


Fig. 2. Age distribution of cancer patients.

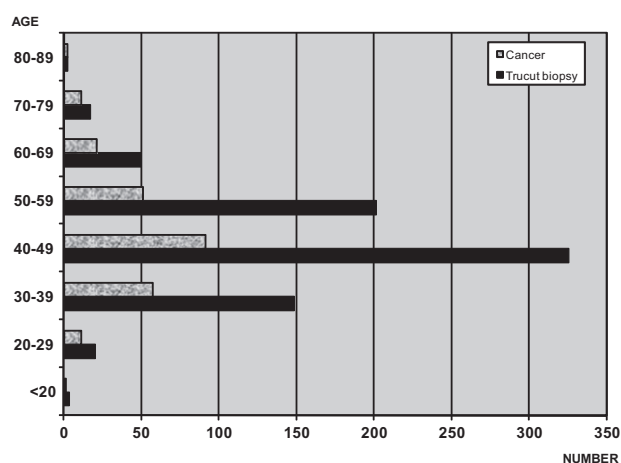


Fig. 3. Percentage of cancer in trucut biopsy samples.

and severe hyperplasia with or without atypia, lobular and papillary lesions Table 1.

The pathology report was ready in 48–72 h (in 96% of cases). In the case of cancer and in equivocal lesions mandating excisional biopsy, the result was rapidly given to the surgeon who could then inform the patient.

Cancer surgery was done as a single procedure in 89.8% of cases, with sentinel-node biopsy when indicated (breast-conservative surgery, mastectomy with or without immediate reconstruction). In locally advanced non-operable and inflammatory breast cancer neoadjuvant chemotherapy was given. Re-operation was done in 19 cases (8.1%). A third surgery was done for three patients (2.1%).

3. Findings

Cancer was found in 30.8% of the cases (34% of palpable and 26% of non-palpable lesions). Trucut biopsy was done for six cystic lesions (two with a solid component and four with a thick irregular cyst wall). Cancer was noted in three cases.

In 4.9% of cases the pathological results showed moderate or severe hyperplasia with or without atypia, lobular or papillary lesions. In 1.8% of the cases pathological results were not in concordance with clinical/imaging suspicions. Except for one, all these cases were non-palpable. In these 6.7% cases open biopsy was done to avoid diagnostic error (10 added cancers, 1.3%; total cancers 32.1%).

4. Discussion

The most important difference between this study and other Iranian studies is the percentage of detected non-palpable breast lesions (40%) thanks to the specialised breast unit with an active breast clinic designed according to the guidelines of the European Society of Breast Cancer Specialists (EUSOMA).^{20,26,27} Once they have visited in our unit for any reason, all eligible women are encouraged to follow screening guidelines.

We have chosen trucut biopsy because it is less operator-dependent, well reproducible, and can be used in all parts of the country.

The breast surgeon was the coordinator of our team. She describes the surgeon's role to as *to treat cancer*

Table 1
Pathology report mandating excisional biopsy.

	Number	Intraepithelial ductal neoplasia	IDC	Intraepithelial lobular neoplasia	ILC	Palpable	Non-palpable
Disconcordance	14	1	5	0	0	1	13
Moderate DH	4	0	0	0	0	0	4
Severe DH	8	0	1	0	0	0	8
ADH	11	1	1	0	0	0	11
Lobular hyperplasia	2	0	0	0	0	0	2
ALH	5	0	0	0	1	0	5
Papillary lesions	3	0	0	0	0	0	3
Radial scar	3	0	0	0	0	0	3
Sclerosing adenosis	2	0	0	0	0	0	2
Total	52	2	7	0	1	1	51

IDC, invasive ductal carcinoma; ILC, invasive lobular carcinoma; DH, ductal hyperplasia; ADH, atypical ductal hyperplasia; ALH, atypical lobular hyperplasia.

and to relieve symptom in symptomatic benign lesions. Needle biopsy of all suspicious palpable and non-palpable lesions is done by our interventional breast radiologist to empower her for biopsy of more difficult small non-palpable lesions. Actually in our country there is no fellowship program either for breast imaging or for breast interventional radiology. In this situation we strongly suggest that in all teams trucut biopsy be given to radiologists that would be beneficial both for the patient and the success rate of the whole team. Only when trucut biopsy was not conclusive the surgeon performed excisional simple or guide-wire biopsy as a *diagnostic* procedure. The surgeon also played the critical role for diagnostic and therapeutic planning and in the final decision for further steps (follow-up alone or surgery).^{14,26,30}

Trucut biopsy has some limitation that could result in diagnostic error. To overcome these errors multidisciplinary teamwork with close collaboration between the surgeon, radiologist and pathologist is essential.^{14,20,27,31}

There was no problem for biopsy, localisation, or surgery of non-palpable lesions. In five non-palpable lesions, described as BIRADS III by the radiologist, the surgeon insisted on trucut biopsy right after the first mammography in four, and on follow-up mammography in the fifth. One had ductal intraepithelial neoplasia and all the others had invasive ductal carcinoma (IDC).

Tissue distortion and epithelial dislodgement may interfere with differentiation of a reactive process from invasive cancer, and occasionally an intraepithelial lesion can be misdiagnosed as invasive cancer.^{32,33} In moderate to severe hyperplasia with or without atypia, lobular lesions, sclerosing lesions such as radial scar, and papillary lesions, it is mandatory to do excisional biopsy to rule out cancer (found in 13–83% of such cases). From 38 cases (4.9%) with such findings five (13%) had cancer after open biopsy (Table 1).

Masood has reported 13–50% cancer in the case of papilloma diagnosed by trucut biopsy.¹⁴ No cancer was found in three cases (0%) of papilloma after excisional biopsy. Of 12 intraepithelial lesions in our series, three (25%) had invasive ductal carcinoma on excisional biopsy. The rate is 24% in different studies (20% invasive ductal and up to 24.3% invasive lobular cancer).^{14,19,31,34–38}

The false-positive rate is less than 1%. Severe epithelial hyperplasia, atypical hyperplasia, and lobular intraepithelial lesions may be wrongly diagnosed as intraepithelial ductal neoplasia.^{14,10,15}

In one patient with recurrence after primary conservative surgery and radiation, trucut biopsy showed invasive cancer. Guide-wire biopsy showed ductal intraepithelial neoplasia.

When the pathology report was not in concordance with clinical and imaging suspicions (14 patients or 1.8% of cases), open biopsy showed cancer in 6 patients

Table 2

Percentage of detected cancers in patients with trucut biopsy.

Age	Total number of trucut biopsies	Number of detected cancers (IDC, ILC, DCIS)	Percentage of cancer (%)
<20	3	1	33
20–29	20	11	55
30–39	148	57	38.51
40–49	325	91	28
50–59	201	51	25.37
60–69	49	21	42.85
70–79	17	11	64.70
80–89	2	2	100
Total	764	245	32.06

IDC, invasive ductal carcinoma; ILC, invasive lobular carcinoma; DCIS, ductal carcinoma in situ.

(42.8%; six cancers in a total of 764 trucut biopsies: 0.78%). False-negative or missed cases are much less than the preferred (10%) and minimum (15%) suggested thresholds given by EUSOMA²⁰ and of 1–2% in the Parker review article.¹⁵ Apart from one case, all false negatives were non-palpable. So the false-negative rate for non-palpable lesions in our series is 2.9%.

Pain (14%) and ecchymosis (2%) were the most common side-effects in our series; both subsided spontaneously. Haematoma was noted in four patients (0.5%) with superimposed infection in half of them (0.26%) (one pregnant woman in her 34th week and one lactating patient). The first has responded to medical therapy but the second (lactating) woman has progressed to superficial abscess needing hospital admission and drainage (Table 2).

Because there is no national screening program, the majority of cases (60%) were palpable. This may explain the lower rate of false positives and false negatives in our study.

Cancer was found in 30.8% of the cases. In 4.9% of cases the pathology showed a lesion mandating open biopsy to rule out cancer. Thus the ratio of benign to malignant and suspicious lesions is less than 2:1 (3:1 for stereotactic biopsy and 1:1 for sonoguided biopsy). This low ratio may indicate correct policy in patient selection for follow-up alone or biopsy in favour of health economy.²⁰

Trucut biopsy is done within 48 h after the first surgical consultation. Such a facility is not available for all patients or all surgeons. In Tehran as the capital there are few centres that do trucut biopsy, and the waiting list is relatively long. Absence of a fellowship program for breast surgery in Iran is the main factor showing the dominance of old concepts in the management of breast disease.

For palpable breast lesions the patient is sent to the operating room for excisional biopsy with or without frozen section. In many cases no imaging or FNA is requested as preoperative assessment, so surgery is done

for almost all palpable lesions. The patient goes into the operating room with the stress of having cancer. Unnecessary frozen section is used for almost all these lesions to detect cancers that are only a minority of the cases. As is shown in different studies in Iran, as well as in ours, up to 65% of cancer patients are less than 50 years of age [Fig. 2](#). In this age group the percentage of benign lesions is much higher than in older patients [Fig. 3](#), [Table 2](#). So hospitalisation, surgery, frozen section, postoperative care, and absence from work are all expenses that are erroneously paid to detect only a small number of cancers. Trucut biopsy can do the same thing with a significant decrease in total expenses, the stress of the patient, and absence from work. To respect the patient's choice for the type of cancer surgery the surgeon has to discuss the options with all patients prior to surgery. Otherwise the surgeon would decide the type of surgery after the result of a frozen section. This approach would increase patient stress. Trucut biopsy confirms the diagnosis before the patient goes to the operating room, so enough time is given to the patient and the family to think, to research, and to get more information about the disease. They can choose the surgeon and the whole treating team and hospital according to their preference, budget and assurance cover. The chosen team may be different from the team who did the diagnosis. They have the opportunity for active participation in their treatment plan. Of our cancer patients, 5% have changed their surgeon to do cancer surgery elsewhere. When cancer is confirmed intraoperatively there is no way to do sentinel-node biopsy. Otherwise one would have to inject radio-isotope and/or blue dye with lymphoscintigraphy for all the patients going to the operating room to do sentinel-node biopsy in the case of cancer. This is completely contrary to the health economy and patients' rights.

Another problem is the false-positive rate of frozen sections. Though rare, it happens. It is a catastrophe when cancer surgery is done for a benign lesion falsely diagnosed as cancer by frozen section. The situation is even worse when the cancer surgery involves mastectomy and axillary dissection. Trucut biopsy omits the need for intraoperative pathological evaluation (frozen section).²⁰ So we can avoid the potential false-positive rate of frozen sections and its consequences to protect the patient, the surgeon and the whole medical team from medical error.³⁹

When only excisional biopsy is done and cancer surgery is based on permanent pathology results, there is the need for additional surgery for cancer. It means additional expense for hospitalisation and absence from work. In many cases primary surgery has disrupted lymphatics. It is not possible to do sentinel-node biopsy, and the patient is condemned to axillary dissection and its side-effects. By this approach the number of surgeries is much higher.^{14,25,39} Using trucut biopsy for suspicious

lesions, surgery is done only for 38.7% of our cases (32% cancer surgery and 6.7% to rule out cancer). So the number of surgeries is decreased to one third. In 89.8% of our cases cancer surgery is done in a single session. Second (8.1%) or third (2.1%) surgeries are needed when trucut biopsy is benign or shows an intraepithelial lesion but open biopsy shows cancer, there is marginal involvement, or when axillary lymph node dissection must be done for positive sentinel-node biopsy.

For non-palpable lesions the situation is worse. The experience of general surgeons with these lesions is very low in Iran. These lesions are mismanaged in three ways: (1) in the absence of a qualified breast surgeon and breast radiologist these lesions are not diagnosed at all; so in the case of cancer they are missed just because the surgeon does not find any abnormality on palpation; (2) sometimes the surgeon does surgery without localisation with a very low chance of finding and removing the suspected lesion, or (3) the surgeon may ask for guidewire localisation of all non-palpable lesions to remove them by surgery.

One of the most important issues in this regard is the patient's rights. When trucut biopsy can correctly give the diagnosis where is the logic in going through open surgery? When it is possible to avoid axillary dissection, how can unnecessary axillary dissection be justified?

Again it must be emphasized that the use of trucut biopsy is meaningful only in a team working together. It is the combination of an experienced breast surgeon, an interventional radiologist, and an expert breast pathologist in a specialised breast unit that makes it possible to introduce trucut biopsy as a substitute for open surgery for the diagnosis of breast lesions. A specialised breast unit eliminates city trips and improves diagnosis and treatment of heavy loads of referred patients. This heavy load increases the experience of specialists, forcing them to follow international guidelines.

The result is a significant increase in accuracy and quality of care, and a significant decrease in patient invasion and diagnostic error and total costs in favour of patients' rights, doctors' rights and the health economy.^{20,26–29} The European parliament obligates all its members to follow this standard, and considers breast cancer treated outside of these units as malpractice.^{20,26,27}

The importance of this new approach to health economy in Iran becomes more evident when we see that, according to the Iranian cancer registry, in 2006 cancer incidence in females is 98 per 100,000. With a total population of 68,856,536, breast cancer is the most common cancer in females with an incidence of 24 per 100,000, or 24.48% of all female cancers, that means 8400 new cases per year.³⁹

Due to severe limitations on health budgets and many more unsolved primary health problems in developing countries, initially it seems that there is still a very long way to go to reach the new standards.¹⁵ Inversely, the

greater the budget limitation the more it is essential to shift from old concepts towards this new approach. This shift necessarily occurs through teamwork in specialised breast units.

Although early detection of breast cancer by a national screening program is costly, and not actually possible for many developing countries, correct and rapid evaluation of breast lesions to diagnose and to treat breast cancer is a *duty* for all health systems regardless of their budget.^{26–29}

With this study we show the advantages of trucut biopsy as the first step in the assessment of suspicious breast lesions in Iran. But we emphasize that substitution of surgery by trucut biopsy for *diagnosis* is the fruit of multidisciplinary teamwork in a specialised breast unit to overcome all possible errors. In fact, only in this situation is it possible to shift from the old concept toward the new one according to international standards.

5. Conclusion

This study shows that in Iran as a developing country trucut biopsy can routinely be used as a part of triple assessment for suspicious breast lesions. Its direct benefit is the avoidance of unnecessary surgery, frozen section, and axillary dissection. Cancer surgery is done as a single session in the majority of cases. It is well planned, with active participation by patients. Because this approach decreases significantly the price of diagnosis and treatment of breast cancer while fully respecting the patients' rights, there is no logic not to use it. Multidisciplinary team work is essential to introduce trucut biopsy as a substitute for the current surgical approach to treat breast lesions in developing countries.

Conflict of interest statement

None of the authors has anything to disclose.

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