Cost-Effectiveness of Fine Needle Biopsy of the Breast

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Although fine needle aspiration (FNA) biopsy of the breast has been shown to be a safe and accurate technique, many surgeons question whether it is reliable enough to replace excisional biopsy. If FNA biopsy is followed by excisional biopsy for confirmation, it would seem that the cost of diagnostic work-up would be increased. In this study, however, the authors show that the major economic benefit of FNA biopsy is not that it replaces excisional biopsy, but that it allows the surgeon to triage which patients should have a 1-stage inpatient procedure with frozen section and which patients should have an excisional biopsy as an outpatient under local anesthesia. Over the past 2 years, the average cost at the East Carolina University School of Medicine of excisional outpatient biopsy (negative) was $702 ± 348; inpatient biopsy (negative) was $1410 ± 262; inpatient 1-stage procedure (positive) was $4135 ± 361; and outpatient biopsy (positive) followed by inpatient procedure was $4822 ± 586. The authors' last 100 FNA biopsies were read as 23 positive, three suspicious, 65 negative, and nine insufficient. There were no false-positives and four false-negatives, for a sensitivity of 87%, specificity of 100%, and accuracy of 96%. Using the above figures, it is possible to calculate the cost per case if all 100 cases had been biopsied by the 1-stage inpatient technique ($2227), by the 2-stage outpatient method ($1938), or guided by the FNA biopsy where positive and suspicious readings are followed by an inpatient 1-stage procedure and negative and insufficient readings followed by an outpatient 2-stage procedure ($1759). Since the FNA biopsy costs $75, it resulted in a savings per case of $393 over routine inpatient biopsy and $104 per case over routine outpatient biopsy. Computer analysis revealed that the FNA biopsy would still be economically favorable if the sensitivity of the test fell as low as 37%, the specificity as low as 80%, or if the percentage of cases of cancer in the population biopsied fell as low as 13%. Since FNA biopsy is cost effective even when followed by an excisional or frozen section biopsy for confirmation, it would be safe and reasonable to expand its use to smaller hospitals where the personnel may be initially less experienced with the technique.

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OVER THE PAST FEW YEARS, there has been a trend towards performing breast biopsies on an outpatient basis under local anesthesia rather than using the traditional 1-stage inpatient approach.[1,2] This allows a patient with breast cancer to know the diagnosis and decide on the type of definitive treatment before receiving a general anesthetic. In addition, when used routinely on all patients, outpatient biopsy is considerably more cost effective than inpatient biopsy because the majority of biopsies are benign.[3–5] For the minority of women who turn out to have a carcinoma, however, there are some disadvantages to excisional outpatient biopsy, namely, the discomfort and *increased cost* of two operative procedures rather than one, the slightly increased risk of wound infection following the second operative procedure,[6] the possibility that estrogen receptor analysis may not be performed on a lesion that is clinically not suspicious for malignancy, and the possibility that the excisional biopsy may compromise future options for conservative local control.[7]

Fine needle aspiration (FNA) biopsy recently has received enthusiasm, and several reports have established it as an accurate and reliable technique.[8–18] There is no consensus, however, as to where this procedure fits into a clinical decision tree in the work-up of a breast mass. Specifically, if the FNA diagnosis is negative, some surgeons will follow a mass conservatively,[8,11,16] although the majority will proceed with excision of the mass.[12,14,15,17] Conversely, if the FNA diagnosis is cancer, some surgeons will proceed with definitive treatment,[10,13,14,17,18] whereas others will require at least a frozen section confirmation

of the malignancy.[11,15] Purely from the standpoint of cost effectiveness, it has been argued that if FNA biopsy is usually followed by excisional biopsy for confirmation, the procedure may actually increase the cost of work-up for a breast mass.[19]

Over the past 2 years, we have performed a cost analysis of breast biopsies at our institution. In this paper, we describe an algorithm for work-up of a breast mass where the major role of FNA biopsy is to decide whether the definitive biopsy is performed on an outpatient basis under local anesthesia or is performed on an inpatient basis using the traditional 1-stage approach. This approach avoids any liability from a false-positive or false-negative needle aspiration biopsy and still results in a marked cost savings when compared with either the routine 1-stage or 2-stage approach.

Methods

FNA Biopsy

The technique for FNA biopsy has been previously described.[17,20,21] A 22-gauge, 1.5-inch needle, attached to a disposable 20 ml syringe fitted into a commercially available syringe holder was used. Because of the thinness of the needle, there was no need for prior local anesthesia. The aspirated material was expressed onto slides and compressed with another slide, similar to a bone marrow aspirate preparation. The majority of the smears were immediately wet-fixed in 95% alcohol and stained by the Papanicolaou technique. One or more air-dried smears were stained with a modified Wright stain (Diff-Quik stain, Harleco, Gibbstown, NJ). This staining process can be performed within 20 seconds and therefore lends itself to a "quick read" interpretation of the material. A final report can be rendered within a few minutes to up to 2 hours while the patient waits in the clinic or office.

Costs

Charts were reviewed over the past 2 years at our institution to determine the average cost of a 1-stage *versus* 2-stage approach for both positive and negative lesions. A 2-stage approach was defined as any case where the initial excisional biopsy was performed on an outpatient basis, and then, if positive, a second definitive procedure was performed on an inpatient basis at a later time. A 1-stage approach was defined as any case where the initial excisional biopsy was performed on an inpatient, and, if positive on frozen section, a definitive procedure was performed at the same time. Some of these patients had previous FNA biopsies and some did not, but the classification depended on the first excisional biopsy. If a FNA biopsy was performed, the cost was not included in the cost analysis but will be discussed later in the result section. The costs analyzed included all hospital, operating room, recovery room, laboratory, radiology, pathology, and anesthesia charges, but did not include the surgeon's professional fee.

The results of our last 100 FNA biopsies were reviewed and compared with the result found on excisional biopsy to determine the accuracy. Results were reported as malignant, suspicious for malignancy, benign (often with a specific diagnosis), or insufficient. For the purpose of calculating the accuracy, we did not feel that it was fair to exclude the suspicious and insufficient diagnoses; thus, a suspicious diagnosis was considered positive and an insufficient one was considered negative. Sensitivity was defined as $TP/(TP + FN) \times 100$, specificity as $TN/(TN + FP) \times 100$, and accuracy as $(TN + TP)/(TN + FN + TP + FP) \times 100$. (TN = true-negative, FN = false-negative, TP = true-positive, and FP = false-positive).

No attempt was made to study the actual cost separately for the group of patients who had FNA biopsy, but, using the average cost for each approach determined above, we could calculate what the cost would be for the 100 patients under a 1-stage approach, a 2-stage approach, or a selective approach based on the results of the needle biopsy. In actual practice, the approach in most of these patients was based on the FNA biopsy, and therefore the actual savings was similar to the calculated savings. Since the results with FNA biopsy may be different at other institutions, an Apple personal computer (Apple Computer Inc., Cupertino, CA) was used to study the effect of varying several parameters, as described in the text.

Results

Cost of Breast Biopsy

Various approaches to breast biopsy have been used at our institution, depending on the preference of the surgeon and the patient. Over the past 2 years, the average cost of each of these approaches (not including the cost of FNA biopsy, if performed) was as follows: outpatient excisional biopsy (negative for cancer) \$702 ± \$348; inpatient excisional biopsy (negative for cancer) \$1410 ± \$262; inpatient 1-stage procedure (positive for cancer) \$4135 ± \$361; and outpatient excisional biopsy (positive for cancer) followed by inpatient definitive procedure \$4822 ± \$586. The cost of outpatient excisional biopsy averaged \$702 but ranged from about \$300 to over \$1200, depending on: (1) whether it was performed in the outpatient clinic, in a free-standing surgical center, or in the hospital operating room; and (2) whether it was performed under local anesthesia, local anesthesia with general anesthesia standby, or, in a few cases, general anesthesia. The cost of inpatient biopsy (\$1410) was more consistent but varied

TABLE 1. *Results of Fine Needle Aspiration Biopsy*

FNA Result		Excisional Biopsy Diagnosis	
		Negative	Positive
Positive	23	0	23
Suspicious	3	0	3
Negative	65	63	2
Insufficient	9	7	2

somewhat depending on whether the patient spent one night or two nights in the hospital. Almost all of the inpatient biopsies were done under general anesthesia. For patients without cancer, clearly the outpatient biopsy was the least expensive.

When the biopsy was positive for cancer, in most cases the definitive procedure performed was a modified mastectomy, although a smaller percentage of cases underwent a tylectomy and axillary dissection. The average cost of a 2-stage approach for patients with cancer ($4822) was nearly equivalent to the cost of an outpatient biopsy for patients without cancer ($702) plus a 1-stage procedure for patients with cancer ($4135). Theoretically, one would expect some savings since a frozen section was unnecessary, resulting in a shortened operating time for the second procedure, but in practice this savings was modest ($15). For patients with cancer, the 2-stage approach was clearly much more expensive than the 1-stage approach using frozen section biopsy.

Results of FNA

The results of our last 100 FNA biopsies are shown in Table 1. Only those cases in which a subsequent excisional biopsy was performed are included in the table. During the same time period, there were a small number of cases where clinically the lesion was not very suspicious for cancer, and, after a negative FNA biopsy was done, no excisional biopsy was performed. So far none of these cases have developed cancer, but the follow-up is short. Of the 100 cases where the results could be compared with excisional biopsy, there were no false-positives and four false-negatives. The sensitivity of the procedure was 87%, the specificity was 100%, and the accuracy was 96%.

TABLE 2. *Cost of Different Approaches to Breast Biopsy*

FNA	True	N	All Outpatient* ($)	All Inpatient* ($)	Guided by FNA† ($)
Positive	+	23	110,906	95,105	96,830
	−	0	0	0	0
Suspicious	+	3	14,466	12,405	12,630
	−	3	0	0	0
Negative	+	2	9644	8270	9794
	−	63	44,226	88,830	48,951
Insufficient	+	2	9644	8270	9794
	−	7	4914	9870	5439
Total			193,800	222,750	183,438
Cost per case			1938	2227	1834
Savings of FNA			104	393	

* Average cost for the category involved multiplied by the number of cases in that category, *i.e.*, 23 × 4822 = 110,906.

† Cost from appropriate column on the left plus the cost of FNA biopsy ($75 multiplied by number of cases), *i.e.*, 95,105 + 1725 = 96,830.

Cost of Different Approaches to Breast Biopsy

Using the average cost for each approach as determined above, we calculated the cost for the 100 patients who underwent FNA biopsy for a 1-stage approach, a 2-stage approach, or a selective triage approach based on the results of the FNA biopsy. In the selective approach, positive and suspicious readings on the FNA are followed by an inpatient 1-stage biopsy, and negative and insufficient readings by an outpatient 2-stage biopsy. The results are shown in Table 2. As expected, for patients with cancer, the 1-stage approach was most cost effective, whereas, for patients without cancer, the 2-stage approach was most cost effective. Since the FNA was quite successful in predicting the true outcome, it allowed the most efficient approach in the majority of patients. Of course, the false-negative readings and insufficient readings added slightly to the cost, which could have been obtained if the FNA were perfect. However for the entire population of 100 patients, the FNA allowed savings of $39,300 over the routine 1-stage approach and $10,400 over the routine 2-stage approach. In actual practice, most of these 100 patients were managed in this manner; thus, the actual savings were probably similar to these calculated savings.

Computer Modeling

The cost savings we demonstrated in the previous section obviously depended on the specific results with the FNA in our 100 patients. To study how applicable these results might be to other medical centers, we used a personal computer to analyze the effect of varying certain parameters. Table 3 shows the effect of decreasing the sensitivity of the test while keeping the specificity at 100%. Each line in the table represents the cost savings calculated exactly as they were in Table 2 but with a stepwise decrease in the number of true-positives and a corresponding increase in the false-negatives. For any sensitivity greater than 37%, the FNA biopsy saved more than the $75 that the test cost. Table 4 shows the effect of decreasing the specificity of the FNA biopsy while maintaining the sensitivity at 87%. For any specificity greater than 80%, the test saved more that the $75 that it cost.

The cost savings was also dependent on the percentage of breast carcinoma in the population biopsied. A higher

TABLE 3. *Effect of FNA Sensitivity on per Patient Savings*

TP	Sensitivity	Specificity	Savings over All Outpatient*	Savings over All Inpatient*
26	86.6667	100	178.62	468.12
25	83.3333	100	171.75	461.25
24	80	100	164.88	454.38
23	76.6667	100	158.01	447.51
22	73.3333	100	151.14	440.64
21	70	100	144.27	433.77
20	66.6667	100	137.40	426.90
19	63.3333	100	130.53	420.03
18	60	100	123.66	413.16
17	56.6667	100	116.79	406.29
16	53.3333	100	109.92	399.42
15	50	100	103.05	392.55
14	46.6667	100	96.1801	385.68
13	43.3333	100	89.3101	378.81
12	40	100	82.4399	371.94
11	36.6667	100	75.5699	365.07
10	33.3333	100	68.70	358.20
9	30	100	61.83	351.33
8	26.6667	100	54.96	344.46
7	23.3333	100	48.09	337.59
6	20	100	41.22	330.72
5	16.6667	100	34.35	323.85
4	13.3333	100	27.48	316.98
3	10	100	20.61	310.11
2	6.66667	100	13.74	303.24
1	3.33333	100	6.87	296.37

* Cost of FNA biopsy ($75) not yet subtracted from savings.

TABLE 4. *Effect of FNA Specificity on per Patient Savings*

FP	Sensitivity	Specificity	Savings over All Outpatient*	Savings over All Inpatient*
0	86.6667	100	178.62	468.12
1	86.6667	98.5714	171.54	461.04
2	86.6667	97.1429	164.46	453.96
3	86.6667	95.7143	157.38	446.88
4	86.6667	94.2857	150.30	439.80
5	86.6667	92.8571	143.22	432.72
6	86.6667	91.4286	136.14	425.64
7	86.6667	90	129.06	418.56
8	86.6667	88.5714	121.98	411.48
9	86.6667	87.1429	114.90	404.40
10	86.6667	85.7143	107.82	397.32
11	86.6667	84.2857	100.74	390.24
12	86.6667	82.8571	93.66	383.16
13	86.6667	81.4286	86.58	376.08
14	86.6667	80	79.50	369.
15	86.6667	78.5714	72.42	361.92
16	86.6667	77.1429	65.34	354.84
17	86.6667	75.7143	58.26	347.76
18	86.6667	74.2857	51.18	340.68
19	86.6667	72.8571	44.10	333.60
20	86.6667	71.4286	37.02	326.52

* Cost of FNA biopsy ($75) not yet subtracted from savings.

percentage of cancer would make inpatient biopsy relatively more cost effective, and a lower percentage of cancer would make outpatient biopsy more cost effective. Table 5 shows the effect of lowering the percentage of cancer in the biopsy population while maintaining the sensitivity and specificity of the FNA biopsy at the level we obtained. As long as the biopsy population contained greater than 13% cancer, the FNA saved more than the $75 cost of the test.

The savings obtained with FNA biopsy also depended on the average cost of each approach used at our institution. If outpatient excisional biopsy were less costly, the savings obtained with FNA would be diminished. Table 6 shows the effect of reducing the cost of outpatient excisional biopsy. If the cost of outpatient biopsy were less than $302, the savings obtained with FNA would be less than the $75 cost of the test, and the *economic* advantage of FNA would be lost.

Discussion

There have been several recent reports describing FNA biopsy of the breast.[8–17] The statistical results of some of these studies are shown in Table 7. The sensitivity and specificity in each have been recalculated, assuming that "suspicious" or "atypical" is positive and "unsatisfactory" is negative. Thus, the figures may be somewhat different from those of the authors if they made calculations excluding those categories. Our results with FNA biopsy are

TABLE 5. *Effect of % Cancer on per Patient Savings*

% Cancer	Sensitivity	Specificity	Savings over All Outpatient*	Savings over All Inpatient*
30	86.6667	100	178.62	468.12
29	86.2069	100	171.75	475.2
28	85.7143	100	164.88	482.28
27	85.1852	100	158.01	489.36
26	84.6154	100	151.14	496.44
25	84	100	144.27	503.52
24	83.3333	100	137.4	510.6
23	82.6087	100	130.53	517.68
22	86.3636	100	130.53	531.63
21	85.7143	100	123.66	538.71
20	85	100	116.79	545.79
19	84.2105	100	109.92	552.87
18	83.3333	100	103.05	559.95
17	82.3529	100	96.1801	567.03
16	81.25	100	89.3099	574.11
15	86.6667	100	89.3101	588.06
14	85.7143	100	82.4401	595.14
13	84.6154	100	75.5699	602.22
12	83.3333	100	68.7001	609.3
11	81.8182	100	61.83	616.38
10	80	100	54.96	623.46
9	77.7778	100	48.0901	630.54
8	75	100	41.22	637.62
7	85.7143	100	41.22	651.57
6	83.3333	100	34.35	658.65
5	80	100	27.48	665.73

* Cost of FNA biopsy ($75) not yet subtracted from savings.

TABLE 6. *Effect of Outpatient Cost on per Patient Savings*

Outpatient Cost	Savings over All Outpatient*	Savings over All Inpatient*
702	178.62	468.12
652	165.62	505.12
602	152.62	542.12
552	139.62	579.12
502	126.62	616.12
452	113.62	653.12
402	100.62	690.12
352	87.62	727.12
302	74.62	764.12
252	61.62	801.12
202	48.62	838.12
152	35.62	875.12
102	22.62	912.12
52	9.62	949.12
2	−3.38	986.12

* Cost of FNA biopsy ($75) not yet subtracted from savings.

similar to these other recent reports. Although the accuracy varies somewhat among the various series, all of them are in the range where the FNA would be economically favorable.

Various authors differ in how they use the FNA results. Many authors[10,13,14,17,18] have emphasized that they feel perfectly safe performing a mastectomy based on a positive FNA result. However, others disagree and require a frozen section confirmation before definitive therapy.[11,15] We have performed mastectomy without frozen section confirmation when a clinically malignant lesion shows unequivocal cytologic evidence of carcinoma. However, in general, we prefer to perform a frozen section confirmation prior to definitive treatment for two reasons: (1) It provides added security that the diagnosis is correct. Although we have not had a false-positive result, there have been a few reported[11,16,17], and in today's legal climate a single malpractice award because of a false-positive result could outweigh all the cost savings of FNA in the entire country. (2) There is some evidence that the hormone receptor analysis is more accurate on a biopsy specimen than on a devascularized mastectomy specimen.[22–24] Although we have no major quarrel with those who base definitive treatment on the FNA result, we feel that, if a surgeon does decide to get a frozen section confirmation, this in no way makes the FNA less valuable, and it does not make it a redundant, costly procedure. On the contrary, our results show clearly that even if a frozen section is performed, the addition of FNA biopsy makes the work-up more cost effective.

TABLE 7. *Accuracy of FNA from Several Recent Series*

Author	Year	Ref.	Sensitivity	Specificity	Accuracy
Rimsten	1975	8	84%	99%	95%
Kline	1979	9	89%	98%	97%
Gardecki	1980	10	87%	95%	90%
Strawbridge	1981	11	70%	96%	87%
Bell	1983	12	73%	98%	92%
Abele	1983	13	95%	97%	96%
Wanebo	1984	14	90%	95%	92%
Norton	1984	15	84%	83%	84%
Ulanow	1984	16	85%	87%	86%
Frable	1984	17	89%	97%	94%
Lannin	1985		87%	100%	96%

If an FNA biopsy is negative for malignancy, some surgeons will follow a mass conservatively,[8,11,16] whereas most recommend excisional biopsy.[12,14,15,17] Here again our study shows that even when an excisional biopsy is eventually performed, a preceding FNA biopsy is not only helpful but cost effective. A negative FNA diagnosis indicates that there is very little chance that the lesion is malignant, and therefore outpatient biopsy under local anesthesia is the procedure of choice. In practice, we decide *before* doing the FNA whether the lesion is suspicious enough to warrant excisional biopsy; if so, we proceed to excisional biopsy even if the FNA is negative. On the other hand, if the lesion is not sufficiently worrisome to warrant excisional biopsy, we may occasionally still perform FNA biopsy just to reassure the patient, the surgeon, or the referring physician that the lesion is insignificant. Although these biopsies are almost always benign, we have had one clinically unsuspected cancer diagnosed in this manner.

The algorithm we recommend for work-up of a breast mass is diagrammed in Figure 1. For most breast masses, we feel that this represents the safest, most cost effective approach. However, there are some exceptions. For example, a woman less than 25 years of age with a clinically obvious fibroadenoma falls into a group where the chance of malignancy is extremely remote. If it is decided to remove the fibroadenoma, there is no reason to do an FNA biopsy, since it would be easiest and most cost effective to simply remove the lesion under local anesthesia on an outpatient basis.

Frable has previously done a cost analysis of FNA biopsy of the breast and concluded that it is cost effective.[17] We agree with his conclusions but differ somewhat in the details of the analysis. In his study, the major saving in patients with malignancy was due to lack of need for a frozen section, and the cost of FNA was not subtracted from these savings. In patients without malignancy, the major saving was in patients who were found to have cysts and thus did not require biopsy. This is certainly a very valid savings, but we feel that aspiration of a cyst is, or should be, standard treatment everywhere even if FNA cytology is not performed. We have recalculated the cost analysis data from Frable's series of FNA biopsies, using our decision tree type of analysis, and have found even a greater savings than he reported.

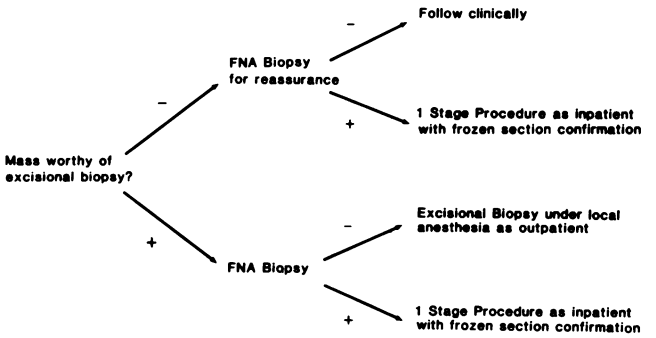

FIG. 1. Decision tree for work-up of a breast mass.

Cost savings is not the only, or even the major, reason to use FNA biopsy of the breast. The technique is simple, safe, accurate, and usually allows the diagnosis to be given at the first office visit. When malignancy is diagnosed, it greatly facilitates discussion of treatment alternatives with the patient before any operative procedure is performed. If the patient is a candidate for tylectomy, axillary dissection, and radiation therapy, the incisions can then be planned in the most expeditious and cosmetic manner. Our major conclusion from this study is simply that FNA biopsy does not need to replace excisional or frozen section biopsy to be cost effective. Perhaps the main reason that FNA biopsy of the breast has not become more widely utilized is the concern over whether it is accurate enough to replace excisional biopsy. Abele, for example, has recommended a graduated, three-phase program to safely implement FNA biopsy in centers where it has not been used.[13] If, instead, surgeons simply plan to confirm the FNA result with excisional or frozen section biopsy, there is no liability from a false result, and the tremendous benefits of FNA biopsy could be more quickly utilized in a larger number of medical centers.

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DISCUSSION

DR. J. SHELTON HORSLEY (Richmond, Virginia): I have enjoyed this paper by Dr. Pories. I think it is a real contribution to show that this technique is, in fact, cost effective.

We have had a great deal of interest at the Medical College of Virginia where Jack Frable, who is the Chairman of our Division of Surgical Pathology, has been one of the great proponents of this technique. We have done this in some 1300 patients with breast lumps. We have had approximately 400 positive findings of cancer.

I had the opportunity to review the manuscript, and the authors talked about several patients who had a negative biopsy, and in fact, they were willing to follow on that basis without excising the lesion. We have worried about that particular type of lesion, and I would like to show you our algorithm for handling this problem.

(Slide) Any mass worthy of an excisional biopsy in our institution usually undergoes a fine needle biopsy. If we think it is a cyst, we aspirate it ourselves. If it is a cyst and disappears, we do have the fluid examined cytologically. If that is negative, which invariably it is, we recommend a periodic follow-up. If it is a cyst, but there is a residual mass, we go