"A STUDY OF PALPABLE BREAST LUMPS WITH EMPHASIS ON EARLY DETECTION OF MALIGNANCY USING A MODIFIED TRIPLE TEST"

ABSTRACT

INTRODUCTION

Breast lumps are one of the common problems encountered in women. These lumps are frequently seen in younger to middle aged women and often they go undetected for various reasons. These lumps have different etiologic causes and can be either benign of malignant. Early recognition of malignancy plays a vital role for improving survival. The need of the hour is a system to detect malignancy earlier and minimize the time needed for the detection of malignant lumps.

OBJECTIVE

This study is done to determine the clinical characteristics of palpable breast lumps and with the objective of detecting malignancy earlier in patients presenting with palpable breast lumps using a modified triple test.

MATERIALS AND METHODS

This is a Prospective observational study done in the department of General Surgery, Coimbatore Medical College Hospital, Coimbatore from July 2016 to June 2017. 103 patients were included in this study after application of inclusion and exclusion criteria.
INCLUSION CRITERIA

1. Female patients with age of > 20 years with palpable Breast lump
2. Patient willing for lump excision

EXCLUSION CRITERIA

1. Patients who are below 20 years.
2. Male patients
3. Female patients with advanced disease which makes the diagnosis obvious
4. Patients not willing for lump excision

Each patient underwent a modified triple test comprising of a detailed Clinical examination, Ultrasonography of breast and Fine Needle aspiration. All the patients finally underwent surgery for their condition and the results of the modified triple test as analyzed individually and collectively and were compared to histopathological diagnosis.

DISCUSSION

Our study was an observational study and 103 patients were subjected to the study. In our study breast lumps were commonly seen in the age group of 31 to 40 years (45.6%) and least commonly seen after the age of 60 years, this is similar to
the distribution seen in other studies. Younger aged women have more education standards and awareness that lead them to present earlier in the course of disease.

About 59.2% of all the patients had symptoms for 4 to 9 months which was similar to that seen in few studies but some studies reported shorter duration of symptoms of mean of 3 months (Afsar A Bhatti et al 2010).

Pain over the lump was an important symptom and 60% of patients with painless lumps had malignancy on histopathological examination (30 out of 50) in contrast to 15% of the patients with painful breast lumps (8 out 53). Similar findings were also seen in a study conducted by Kaire innos et al (BMC public health 2013) and the usual mode of presentation of malignancy was a painless palpable lump.

Of the clinical examination findings nipple discharge was also found to be an important finding. Of the patients with nipple discharge 77% (17 out of 22) were found to have malignancy on final histopathological diagnosis, so nipple discharge might serve as an important clue to the diagnosis of malignancy, but many studies have shown that nipple discharge is usually benign and 10 to 15% of the patients with nipple discharge tend to have malignancy. (Van Zee K J et al Cancer 1998), probably study with a larger sample size would iron out the skewed results seen in our study.
In our study the upper outer quadrant was commonly involved with tumor (45.6%) this was also consistent with the findings with a study done by Khemka et al., Hussain et al., and Khoda et al (JMS 2015). It has been demonstrated that the upper outer quadrant of the breast has more amount of epithelial tissue compared to other quadrants leading to more incidence of tumors.

Axillary lymph node involvement was seen in 20.4 % (21 out of 103) of patients presenting with breast lumps and out of the patients who had axillary nodes 90%(19 out of 21) had biopsy proven malignancy, so axillary node involvement is a strong predictor that the tumor is malignant, this has also been recorded by Voss M et al (J Surg Oncol. 1999). It has been concluded in the study that patients with stage 3 breast cancer have a higher incidence of axillary metastasis and well differentiated tumors tend to metastasize slowly. So axillary involvement may be a pointer towards advanced or fast growing malignancy and should prompt immediate attention.

When the clinical examination findings were examined as a whole clinical examination had sensitivity of 86.34 % and specificity of 91% for the detection of malignancy. Positive predictive value of Clinical examination was 85% and Negative predictive value was 92.19%.

On analysis of various studies, it has been shown that sensitivity of the Clinical breast examination ranges from 21% to as high as 100% and the
specificity ranges from 50% to 97.8%. In the present study, the high sensitivity could be because only patients with confirmed palpable lumps were included for the study. Our results are in concordance with many studies.

**ULTRASONOGRAPHY OF BREAST**

The triple test used mammography as one of its components and mammogram had a sensitivity of 87% for malignancy detection. Crystal et al (2003), Susan k et al (2005), Corsetti et al (2006) and Sahiner et al (2007) had supported the use of USG in young patients with dense breast tissues and ultrasound was found to have a sensitivity of 89% in detecting symptomatic and palpable breast abnormalities.

Though relatively a fresh modality ultrasound has gained widespread popularity due to easy availability of the equipment, it is less expensive and is non invasive and can provide accurate information in tumors more than 2mm. Both USG and mammography have their inherent advantages and disadvantages that have been discussed in literature. But in the current scenario USG has gained the acceptance among the medical fraternity and is included in the screening for malignant lesions of breast as a part of the modified triple test and its results are adequately validated by many studies.

In our study 33 out of 103 patients had ultrasound findings suggestive of malignancy; out of them all had biopsy proven malignancy. Ultrasound had a
sensitivity of 86.84% and specificity of 100% for the detection of malignancy, Positive predictive value for detection of malignancy was 100%, Negative predictive value to rule out malignancy was 92.86%.

These findings when compared to available literature shows good correlation and in a study done by Khoda et al, USG sensitivity was 91.6%, specificity was 100%, positive predictive value was 100%, negative predictive value was 97.3%, Similarly in a study done by Pande et al sensitivity, specificity, positive predictive value and negative predictive value for ultrasonography were 95%, 94.1%, 95.5%, and 93.7%, respectively. Another study by Jan et al also yielded similar results.

A sensitivity of 86.84 % means 13.16 malignant lesions would be missed out of 100 malignant lesions, so the diagnosis of a benign lump always does not mean that it is benign and it would need a combination of tests to confirm it, but nonetheless USG of the breast is a valuable and easy tool for the detection of malignancy.

**FINE NEEDLE ASPIRATION CYTOLOGY**

In our study Fine Needle aspiration classified, 60 patients out of 103 (58.2%) as having benign breast disease, whereas 35 patients (34%) were diagnosed to have malignant disease. 8 (7.8%) patients had inconclusive reports. All patients with FNAC report suggestive of malignancy were biopsy proven to
have carcinoma. But 1 out of 60 patients (1.6%) who were reported to have benign
disease had malignant disease. Sensitivity and specificity of Fine Needle
Aspiration Cytology to detect malignancy were 92.10% and 100% respectively.
Positive predictive value was 100% and Negative predictive value was 95.58%.

**FNAC RESULTS IN VARIOUS STUDIES**

<table>
<thead>
<tr>
<th>Study</th>
<th>Sensitivity %</th>
<th>Specificity%</th>
<th>Positive predictive value%</th>
<th>Negative predictive value %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our study</td>
<td>92.10</td>
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</tr>
<tr>
<td>Sankaya &amp; Dongre</td>
<td>88.37</td>
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<td>Choi et al</td>
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<td>100</td>
<td>95.08</td>
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<tr>
<td>Kim et al</td>
<td>94.59</td>
<td>87.91</td>
<td>79.54</td>
<td>97.03</td>
</tr>
<tr>
<td>Park and Ham</td>
<td>76.90</td>
<td>91.60</td>
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It is shown that the results of our study are comparable to various studies and the values closely resemble the results seen by Mohamed et al. So the results indicate that FNAC as an independent variable has adequate diagnostic power and this is further enhanced by combination with other 2 tests.
THE MODIFIED TRIPLE TEST ANALYSIS

Using modified triple test 37 patients (36%) had features suggestive of malignant disease and 66 patients (64%) were suspected to have benign breast disease. All of the 37 patients suspected to have malignancy on Modified Triple Test were biopsy proven to have malignant breast disease, whereas 1 out of 66 (1.5%) patients assigned to have benign disease on Modified Triple Test turned out to be malignant. The sensitivity of modified triple test for the detection of malignancy was 97.36% and the specificity for the detection of malignancy was 100%. The positive predictive value of the Modified triple test was 100% and the negative predictive value was 98.4%.

Comparison of Studies Using Modified Triple Test

<table>
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<th>Study</th>
<th>Sensitivity %</th>
<th>Specificity%</th>
<th>Positive predictive value%</th>
<th>Negative predictive value %</th>
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<td>Baykara et al</td>
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<td>Khoda et all</td>
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<tr>
<td>Jan et al</td>
<td>100</td>
<td>99.3</td>
<td>93.3</td>
<td>100</td>
</tr>
<tr>
<td>Vaithyanathan et al</td>
<td>100</td>
<td>82</td>
<td>76.9</td>
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This comparison shows that our results were comparable to the results seen in many studies and it has shown that the modified triple test can be used as a valuable clinical test for the detection of malignant lumps and it helps us to plan the surgical treatment earlier, accurately and helps us save time needed for a definitive diagnosis.

CONCLUSION

Breast cancer is the foremost cause of cancer related death in young females; hence early detection of breast cancer carries much importance.

The modified triple test in our study was an accurate predictor of malignancy, all of the patients who were suspected to have malignancy by Modified triple test had malignancy on histological analysis and specificity was 100%, that proved it as a best initial test for diagnosis of malignancy preoperatively.

The results of the modified test in our study are as accurate as histological diagnosis.

Of the three components of the modified triple test FNAC and Ultrasound of breast had 100% specificity for the diagnosis of malignant lumps.
The modified triple test can be done in an outpatient clinic and the patients are not exposed to ionizing radiation. So it is a suitable diagnostic modality for breast lumps in young women of childbearing age. It has been shown that Ultrasound is as accurate as mammography in detection and differentiation of palpable breast lumps and it can also aid in guiding the site for FNAC and biopsy.

Of the three components of the modified triple test FNAC was the most accurate modality.

Three components of the modified triple test complemented each other and when done with experienced clinicians and Radiologists can reduce the time lag for the detection of malignancy and help us to institute early definitive treatment.

**KEYWORDS:**

Palpable Breast lump

Modified triple test

Clinical examination

Ultrasonogram of breast

Fine Needle Aspiration Cytology

Benign breast disease

Malignant breast disease