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RESEARCH ARTICLE

TRIPLE TEST SCORE AS AN EVALUATING FACTOR FOR PALPABLE BREAST LUMP.

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Abstract

Background: Breast lump is a very sensitive issue and cause of great worry and anxiety to the patient, so a reliable, preferably non-invasive and prompt diagnosis is required. Breast lump should be managed effectively and confidently with a proper protocol plan, ensuring early and best possible treatment for every patient. Triple test assessment was a major breakthrough in this direction, which streamlined the management of palpable breast lump. When all the components of triple test assessment which are Clinical Examination, FNAC, Mammography point to one possibility (are concordant) then the diagnosis is almost certain and management can be confidently planned in such a situation. But if there is discordance among the components of triple test, then what should be the next step in the management plan is the question to be answered. This is where triple test score shows us the path.

Objective of the Study:

· To perform Triple Test Score in patients with breast lump.
· To perform Histopathological Examination (HPE) of the breast lump resected.
· To evaluate the efficacy of TTS in comparison with HPE.
· To develop a standard protocol for management of breast lump especially when discordant results are obtained from triple assessment.

Materials and Methods: Study was conducted on 200 patients presenting with breast lump to the department of General Surgery at Tertiary Care Teaching Hospital, during the period from January 2012 to Dec 2016.

It was a prospective study. Women presenting for evaluation of palpable breast lump underwent assessment by clinical examination, mammography and FNAC and got the Triple Test Scoring done.

All patients who underwent a complete TTS at our institution were entered into the study.

All patients were subjected to necessary surgery, post TTS and followed up with Histopathology of the specimen.

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A structured proforma was used to collect relevant information from each patient selected.

Results: In our study the mean age of the patients was found to be 46.12 ± 1 1.48 years, most of the patients were in the age group of 35-45 years (60%). Positive family history was found in 17%. Patients on an average took 6 months to seek medical help after recognition of the breast lump. Most common location of breast lump was upper outer quadrant. 38 cases were malignant and 148 were benign 14 were intermediate group commonest lump was fibroadenoma, Histopathology was 100% specific in both the groups of study conclusions were made based on clinical radiological and pathological assessment.

Conclusion: The study clearly demonstrates the superiority of TTS over other components of triple assessment or all of them put together. A ITS of </=4 is consistent with a benign lesion; a TTS of >/=6 indicates malignancy. Only in patients in whom TTS score is 5, biopsy is recommended to obtain a definitive diagnosis. Thus a standard protocol can be developed, for the management of breast lump even with discordant results obtained via triple test assessment, which can be followed universally, thus empowering surgeon to go ahead in managing breast lump effectively and confidently.

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Introduction:-

"He will manage to cure best who has foreseen what is to happen from the present state & matters"

Hippocrates:-

The frequency of breast diseases, their recognition and the attempts at primeval cures by various cultures and societies historically antedate the therapy of diseases of other solid organs. Diseases of breast, with their uncertain causes and confusion of treatments, have intrigued physicians and medical historians throughout the ages. Despite centuries of theoretical meanderings and scientific enquiry, cancer of the breast remains one of the most dreaded of human ills. Although primarily thought of as a disease of women, it may occasionally afflict men with results just as lethal. The breast as a paired organ further increases its exposure to disease. As appendage of the skin it usually reveals its disorders to touch or sight.

A breast mass can be a difficulty at times. It may be difficult for the patient because of the anxiety associated with her underlying fear of a breast malignancy and it may be difficult for the physician to feel confident that what he or she is palpating is truly a mass rather than a variation of normal breast parenchyma. Breast symptoms and signs are common problems in clinical practice. Majority of breast symptoms or lesions will prove to bc of a benign etiology. Physical, psychological and financial costs of investigating benign breast disease, primarily to exclude malignancy are substantial. Much concern is given to malignant lesions of the breast because breast cancer is the most common malignancy in women; however, benign lesions of the breast are far more frequent than malignant.

Because the majority of benign lesions are not associated with an increased risk for subsequent breast cancer, unnecessary surgical procedures should be avoided. It is important for pathologists, radiologists, and oncologists to recognize benign lesions, both to distinguish them from in-situ and invasive breast cancer and to assess patient's risk of developing breast cancer, so that the most appropriate treatment modality for each case can be established.

The first step in evaluation of breast lump is the clinical assessment. Although many a times clinician can confidently make the diagnosis of benign or malignant lesion, the possibility of mistake is always there even in experienced hand. This is where triple assessment has played a significant role in breast lump management.

The triple assessment for breast diseases involves,

1. Clinical assessment
2. Imaging modality — Mammography
3. Fine needle aspiration cytology

Clinical diagnosis of breast cancer is of higher sensitivity than specificity and has high diagnostic error. Mammography and FNAC respectively have lower sensitivity than specificity but have high positive predictive values.

When combined in the triple assessment, a definitive diagnosis can be made when the diagnoses concur, suggesting that the triple assessment has a high sensitivity, specificity, positive predictive value and negative predictive value with minimal error and excellent Kappa statistic. The output of the triple assessment is reproducible, making it a valid and reliable diagnostic approach to diagnosis of breast cancer.
With increasing prominence and greater visibility in country specific health profiles around the world, breast cancer and its prevention, detection and treatment will continue to emerge as a major priority and challenge, for the health system in the near future.

Need For The Study:-
Breast lump is the clinical presentation of numerous breast diseases ranging from innocent benign cysts to malignant lesions. Distinction of benign from malignant is of paramount importance for patient care and proper management. Breast cancer is the most common site specific cancer in women and is the leading cause of death from cancer for women of age 40 to 44 year [1]. It accounts for 33% of all female cancers and is responsible for 20% of the cancer related deaths in women[2].

Presently a wide range of diagnostic modalities are available for the evaluation of breast lump. Conventional open biopsy, considered to be the gold standard for confirming diagnosis, has significant morbidity, is costly and time consuming. All of these cause significant trauma to the patient and are not patient friendly.

Mis-diagnosed breast cancer accounts for the greatest number of malpractice claims for errors in diagnosis. Litigation often involves younger women whose physical examination and mammography may be misleading[2]. Two techniques that are currently available with excellent patient tolerability are mammography and fine needle aspiration cytology. However if employed alone the reliability of mammography and FNAC is only around 82% and 78% respectively[3].

There are numerous reports that if the results of clinical assessment, mammography and FNAC are all combined, the accuracy of diagnosis reaches 100%[4]. Furthermore these techniques provide information on tumor size, number, extent and grade pre-operatively[5].
There is a direct need for evolving a method for establishing the diagnosis pre-operatively, which is cost effective, least invasive and least disturbing to the patient, with accuracy comparable to open biopsy. An efficient evaluation and prompt diagnosis is necessary to maximize cancer detection and minimize unnecessary testing and procedures. A thorough Clinical Breast Examination (CBE), Imaging (Mammography), and Tissue sampling (FNAC) are needed for definitive diagnosis[2].

The triple test assessment is the combination of results from CBE, imaging, and tissue sampling. When the three assessments produce concordant results (point to the same possibility), the triple test diagnostic accuracy approaches 100 percent[6-8]. But, in discordant results, there is no clear cut protocol to follow and it is in such situations that triple test scoring will be the next step forward. Discordant results are seen in 40% patients, who are subjected for open biopsy for the confirmation of diagnosis[9].

The Triple Test Score (TTS) was developed to help clinicians interpret discordant triple test results.[6-10] A three-point scale is used to score each component of the triple test (1 = benign, 2 = suspicious, 3 = malignant). A TTS of </=4 is consistent with a lesion; a TTS of indicates malignancy. Only in patients in whom TTS score is 5, biopsy is recommended to obtain a definitive diagnosis. Thus a standard protocol can be developed, for the management of discordant results in triple test assessment, which can be followed universally.

The scope of improvement in arriving at correct and confident diagnosis of the breast lump is still enormous when we keep cent percent perfect diagnosis as our goal. This study is an attempt to travel part of that journey towards the goal.

Materials and Methods:-

Source Of Data:-

Study conducted on 200 patients presenting with breast lump to the department of surgery in Tertiary Craae Teaching Hospital during the period from January 2012 to December 2016.
Inclusion Criteria: Patient aged >/= 35 years, presenting with palpable breast lump.
Exclusion Criteria: Obvious malignant lesions (fungation, ulceration).

Method of collection of data:-

It being prospective study, women presenting for evaluation of palpable breast lump to the department of surgery at Tertiary Care Teaching Hospital underwent assessment by clinical examination, mammography and FNAC and Triple Test Scoring was done.

All patients who underwent a complete TTS(Triple Test Scoring) at our institution were entered into the study.
All patients were subjected to necessary surgery, post TTS and followed up with histopathology of the specimen.

A structured proforma was used to collect relevant information from each patient selected. Each component of the triple assessment was compared with the gold standard histopathology, so also TTS was compared with histopathology and findings were analyzed.

All of patient details and relevant information was entered into the proforma.

Analysis:-

All the three components of triple test i.e., physical examination, mammography and FNAC findings were categorized as benign, suspicious and malignant. The Triple test (TT) was considered concordant if all the elements indicated a malignant condition or all indicated a benign condition, otherwise TT was considered non-concordant.
Sensitivity is defined as percentage of cases in which biopsy proven cancer was correctly diagnosed by the test.

Specificity is defined as percentage of cases in which biopsy proven benign lesion was correctly diagnosed by the test.

The values were determined by the following formula:
Sensitivity = TP / TP+FN ; Specificity = TN / TN+FP
TP - true positive,
TN - true negative,
FP - false positive
FN - false negative

Further, triple test score (TTS) was given; physical examination, mammogram and FNA were each assigned a score of 1, 2 or 3 for benign, suspicious or malignant results; TTS is the sum of these scores. TTS has a minimum score of 3 (concordant benign) and a maximum score of 9 (concordant malignant).

Results:-

A total of 200 patients who satisfied the inclusion criteria were enrolled into the study, all the patients were subjected to clinical examination followed by mammography and FNAC, individual scores were given and the triple test score was calculated. All the patients were subjected to the appropriate surgery and the specimen sent for histopathology.

In our study the mean age of the patients was found to be 46.12 ± 1 1.48 years, most of the patients were in the age group of 35-45 years (60%). Positive family history was found in 17%. Patients on an average took 6 months to seek medical help after recognition of the breast lump.

Figure 1:- Age-wise distribution of patient

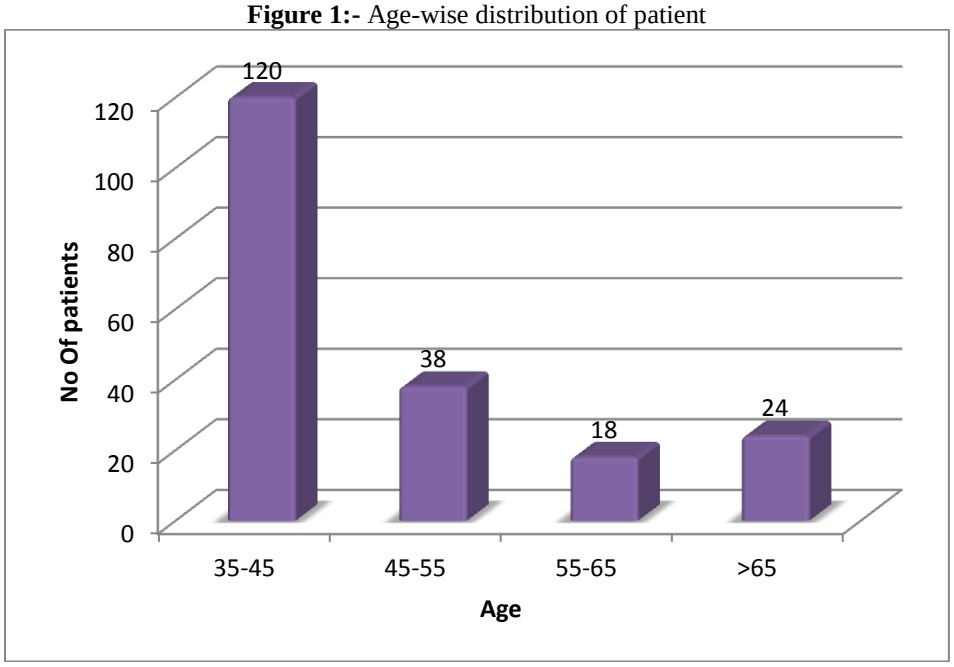
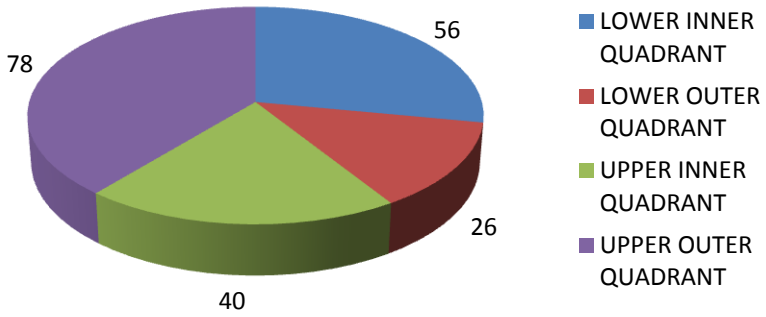


Figure 2:- Location of breast lump



Most common location of breast lump was upper outer quadrant (Figure).
Among the 200 cases which had histopathologic correlation 156 were benign disease and 44 malignant.

Table 1:- Comparision Of Clinical Assessment With Histopathology

CLINICAL ASSESSMENT	HISTOPATHOLOGY		Total
	Benign	Malignant	
Benign	146	2	148
(%)	91.1%	4.5%	53.0%
Suspicious	10	4	14
(%)	8.9%	9.1%	9.0%
Malignant	0	38	38
(%)	0.0%	86.4%	38.0%
Total	156	44	200
(%)	100%	100%	100%

Specificity: 100 %
Positive Predictive value: 100 %
Negative Predictive Value: 96.23 %
Accuracy: 97.80%
The scoring for clinical examination revealed a score of 1, 2 and 3 in 53%, 9% and 38% respectively. The clinical diagnosis of benign and malignant was comparable with HPE.

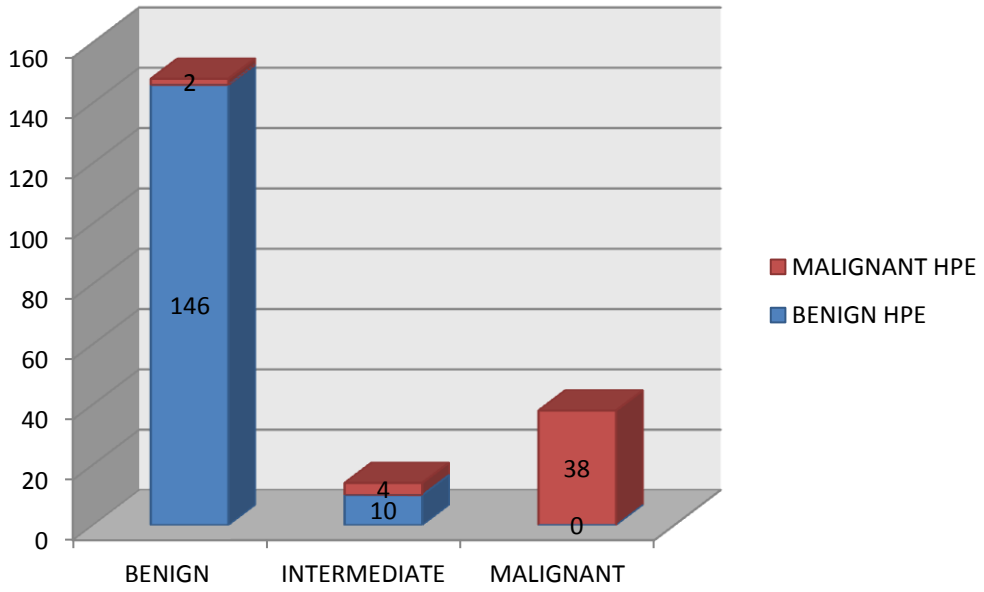


Figure 3:- Comparison of clinical assessment with histopathology

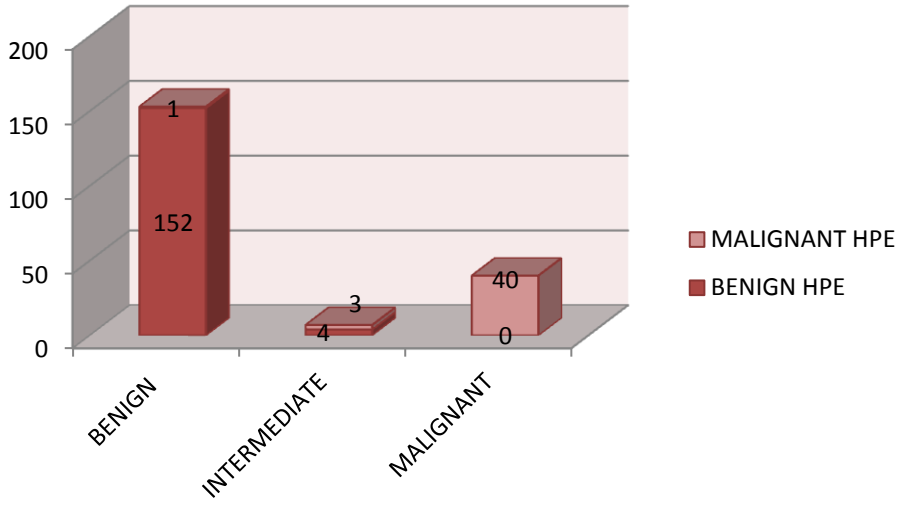
Out of 14 cases with suspicious interpretation in clinical diagnosis: 10 were diagnosed to be benign and 4 were diagnosed as malignant. 4 cases which were diagnosed clinically as benign turned out to be malignant on HPE.

Table 2:- Comparision Of Fnac With Histopathology

FNAC SCORE	HISTOPATHOLOGY		Total
	Benign	Malignant	
Benign	152	1	153
(%)	96.4%	2.3%	55.0%
Suspicious	4	3	7
(%)	3.6%	6.8%	5.0%
Malignant	0	40	40
(%)	0.0%	90.9%	40.0%
Total	156	44	200
(%)	100%	100%	100%

The scoring for FNAC revealed a score of 1, 2 and 3 in 55%, 5% and 40% respectively. The clinical diagnosis of benign and malignant was comparable with HPE.
Sensitivity: 97.56 %
Specificity: 100 %
Positive Predictive value: 100 %
Negative Predictive Value: 98.18 %
Accuracy: 98.94%

Figure 4:- Comparison of FNAC with histopathology.



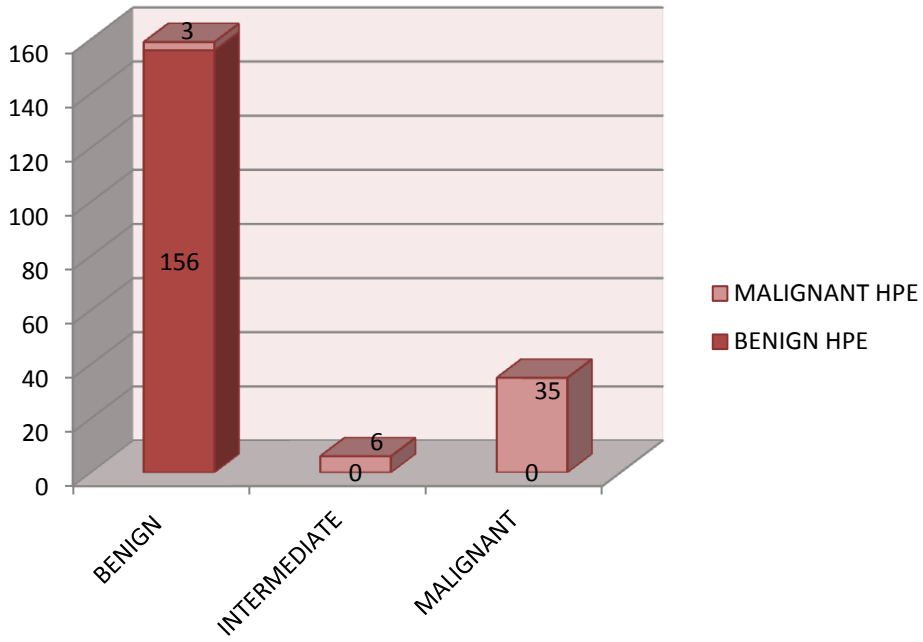
Out of 7 cases with suspicious interpretation in FNAC: 4 were diagnosed to be benign and 3 were diagnosed as malignant. One case which was diagnosed as benign turned out to be malignant on HPE.

Table 3:- Comparision Of Mammography With Histopathology

MAMMOGRAPHY	HISTOPATHOLOGY		Total
	Benign	Malignant	
Benign	156	3	159
(%)	100%	6.8%	59.0%
Suspicious	0	6	6
(%)	0.0%	13.6%	6.0%
Malignant	0	35	35
(%)	0.0%	79.5%	35.0%
Total	156	44	200
(%)	100%	100%	100%

The scoring for mammography revealed a score of 1, 2 and 3 in 59%, 6% and respectively. The mammography diagnosis of benign and malignant was comparable with HPE.
Sensitivity: 92.11 %
Specificity: 100 %
positive Predictive value: 100 %
Negative Predictive Value: 94.92 %
Accuracy: 96.80%

Figure 5:- Comparison of Mammography with histopathology



Out of 6 cases with suspicious interpretation in mammography all were diagnosed as malignant. Three cases which were diagnosed as benign turned out to be malignant on HPE.

Table 4:- Comparision Of Triple Test Score With Histopathology

TRIPLE TEST SCORE	HISTOPATHOLOGY		Total
	Benign	Malignant	
Benign	155	0	155
(%)	100%	0.0%	52.0%
Suspicious	1	0	1
(%)	1.8%	0.0%	4.0%
Malignant	0	44	44
(%)	0.0%	100.0%	44.0%
Total	156	44	200
(%)	100%	100.0%	100%

All the cases diagnosed as malignant with TTS were proved malignant by HPE, all cases diagnosed as benign were proved benign on HPE, one case with TTS of 5 required a further test in form of biopsy for confirmation, it turned out to be benign,
Sensitivity: 100 %
Specificity: 100 %
Positive Predictive value: 100%
Negative Predictive Value: 100 %
Accuracy: 100 %

Figure 6:- Comparison of TTS with histopathology

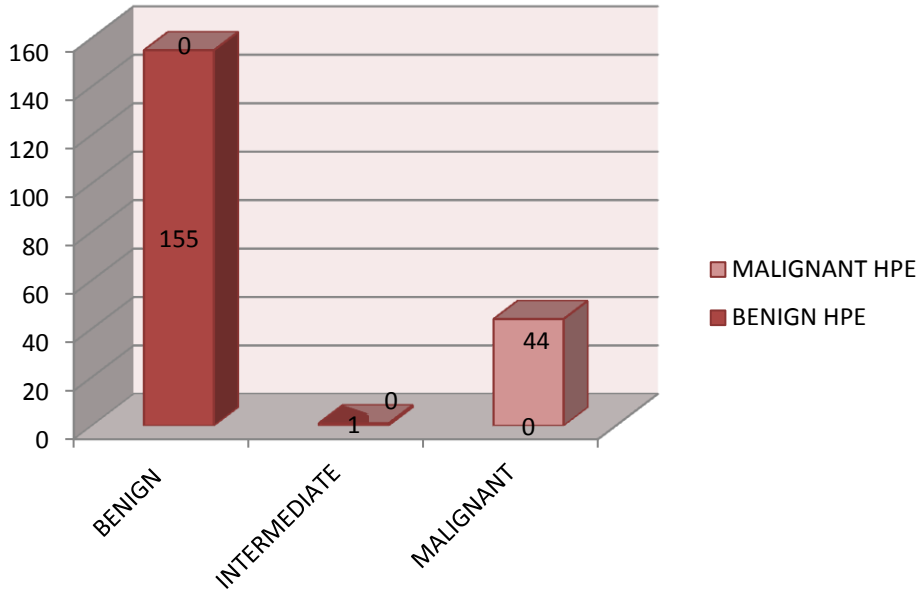
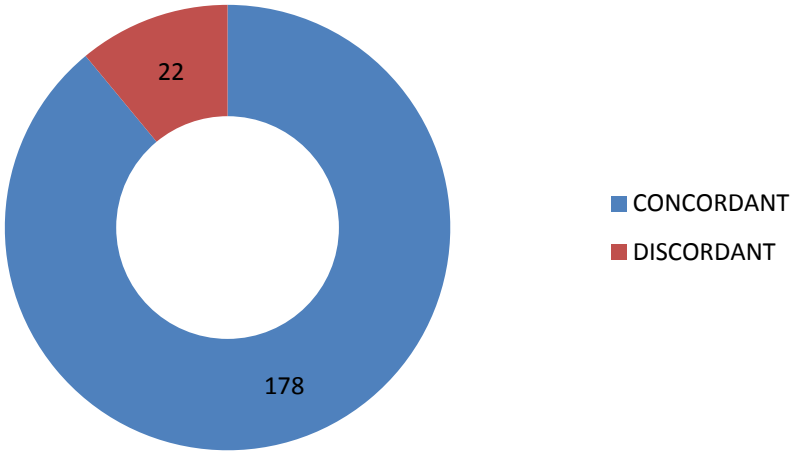


Table 5:- concordant v/s discordant results in triple assessment.

CONCORDANT	DISCORDANT
178	22

Figure 7:- Depicting the ratio between concordant and discordant results



Among the 22 discordant results, score of 7,6 and 5 were seen in 14,6 and 2 patients respectively.

Table 6:- Results Derived From Various Modalities Used In Breast Lump Analysis

Diagnosis	Clinical	FNAC	Mammography	Triple test	HPE
Benign	148	153	159	155	156
Intermediate	14	7	6	1	0
Malignant	38	40	35	44	44
Total	200	200	200	200	200

Table 7: Comparision Of All The Components Used In Breast Lump Analysis

Investigation	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)	Accuracy (%)
Clinical examination	95	100	100	96.23	97.80
FNAC	97.56	100	100	98.18	98.94
Mammography	92.11	100	100	94.92	96.80
TTS	100	100	100	100	100

Table 8: Kappa Agreement Between Biopsy And Other Diagnostic Modalities

Diagnostic Modality	Kappa value	P value
Clinical Examination	0.795	<0.01
FNAC	0.884	<0.01
Mammography	0.758	<0.01
Triple test	0.903	<0.01

Discussion:-

Prospective analysis of TTS on 200 patients and confirming the results with histopathological finding showed to be highly sensitive and specific. In the present study 100 patients with age ranging from 35 years to 90 years with a mean age of 46.12 +/- 11.48 years who presented with complaint of breast lump were evaluated. The mean age here was considerably less than that seen in the western population (57 years) [9] and comparable to study done at Nepal (48 years).60% of the patients belonged to age group between 35-45yrs. Benign diseases were more common than malignant . Fibroadenoma being the most common benign lesion and Infiltrating ductal carcinoma being the most common malignant lesion. Most of the patients aged above 55 years with breast lump were diagnosed with a malignant lesion reinforcing the fact that age is an important risk factor in carcinoma breast. The lesion was found to be present commonly in upper outer quadrant (39%). Women on an average sought medical help with a delay of 6 months after realizing the presence of breast lump, thus delaying the treatment which in cases of malignancy carry bad prognosis, thus emphasizing the need of better education of the mass at large.

In our study, clinical diagnosis (physical examination) showed a sensitivity of 95%, a specificity of 100% and positive predictive value of 100%, negative predictive value of 96.23 with an overall accuracy of 97.80% . Other studies showed that clinical examination could diagnose accurately only 70% of cases of carcinoma. Egan recorded an accuracy of 65% detection by physical examination [11]. Our study showed an accuracy of 97.80% by clinical examination. This relatively high accuracy in detecting malignancy by clinical examination is due to the fact that our patients rarely present early in the course of the disease. Breast lump in our patients on an average was about 4x3 cm on presentation. Out of 9 cases with suspicious interpretation, in clinical 5 were diagnosed to be benign and 4 were diagnosed malignant. Two cases which were diagnosed clinically as benign turned out to be malignant on HPE .

In examining the triple test elements individually, we noted that FNAC is typically more accurate thon physical examination or mammography . This agrees with the study of Morris et.al. and Vetto et. Al [12-18]. In our study, the sensitivity of FNAC was 97.56%, the positive predictive value was 100%, specificity was 100%, and the negative predictive value was 98.18% with no false positives, but 1 false negative . These results arc in accordance with those of Morris et.al. Vetto et. Al [12-18]. reported a sensitivity of 96% for FNAC, with a specificity of 100%, and a positive predictive value of 100%. Rubin and Joy concluded that FNAC is the first reliable diagnostic step in detection of breast carcinoma. They reported a positive predictive value of 100%, a specificity of 100%, a sensitivity of 87%, and a negative predictive value of 89%.

The widespread use of mammography has helped in better management of breast lump. In our study, the accuracy of mammography was 96.80%, the sensitivity 92.11%, the specificity 100%. The positive predictive value was found to be 100%. There were 3 false positives and 6 cases were inconclusive . In a Dutch study of breast cancer screening, Romback found that if mammography alone has been used the sensitivity of breast cancer diagnosis would have been 95%. Rodes et.al. reported that mammography was the sole detection modality in 56% of cases. When combined with Physical examination, an additional 30% were detected, while physical examination alone detected 14% of cases.

In our study, the best results was got by TTS, it showed sensitivity of 100%, the positive predictive value was 100%, specificity was 100%, and the negative predictive value was 100% almost in perfect alignment with that of histopathology. In one case where the TTS was 5 an additional test in the form of biopsy was required.

In our study, when all three components showed malignancy, the sensitivity and specificity were 100%. Kaufman et al described a sensitivity of 100% and a specificity of 57% for the triple test and a negative predictive value of 100% in concordant cases. Clinical examination remains indispensable for detection of different breast lesions. Mammography remains the method of choice in radiology of the breast. FNAC has proved to be a very effective diagnostic aid. It is an easy technique, safe and very acceptable to patients. TTS outweighs all of these components and also helps us proceed further even in difficult scenarios of discordant results with triple assessment, thus reducing the fall back on the option of open biopsy which carries with it a number of disadvantages.

The use of the triple test score (with highest kappa ageement-0.903) has proved itself to be a reliable tool for the accurate diagnosis of palpable breast lump. Triple test score when implemented streamlines the management of breast lump, more so when triple assessment can't come to a definitive diagnosis and thus biopsy which usually is resorted to in such a scenario can be avoided, saving the patient from anxiety, repeated operative procedure, financial burden, undue delay in treatment and also providing the surgeon a platform to base his further management.

Summary:-

This prospective study was done to evaluate the efficacy of triple test score in management of palpable breast lump and to develop a standard protocol for management of breast lump especially when discordant results arc obtained from triple assessment.

A total of 200 women with complain of breast lump presenting to the department of surgery at Tertiary Care Teaching Hospital, underwent assessment by physical examination, followed by mammography and FNAC. Triple Test Scoring was done for each component and the total score calculated. Patients were subjected to appropriate surgery and the specimen sent for histopathology. Each component was analyzed and compared with histopathology, the parameters sensitivity, specificity, positive predictive value, negative predictive value, accuracy were calculated and it was found that triple test score was best in predicting the nature of the breast lesion compared with any of the individual components of triple assessment or all of them put together.

The real value of triple test scoring was better appreciated when there was discordant results among the components of triple assessment. As no proper guidelines exist in managing such cases, it was here that triple test score can provide us something concrete on which we can base our definitive management effectively and confidently. Being a non-invasive, cost effective method it gives us the result without any undue delay and helps to manage patient in a better than managing such cases as per individual surgeon's choice.

Triple test score when implemented streamlines the management of breast lump, more so when triple assessment can't come to a definitive diagnosis and thus biopsy which usually is resorted to in such a scenario can be avoided, saving the patient from anxiety, double operative procedure, financial burden, undue delay in treatment and also providing the surgeon a platform to base his further management.

Conclusion:-

Triple test score can be safely used as an accurate and least invasive diagnostic test and based on its interpretation, definitive treatment can be initiated which would reduce the need for unnecessary biopsies. The strength of TTS seems to lie in its ability to reliably predict benign lumps and thus avoid major surgeries. Given the increased incidence of malignant lumps in elderly females and the tendency to hide asymptomatic lumps, we need more awareness programs targeting this age group.

When patient presents to us with breast lump, it has been the usual practice to do a thorough clinical assessment, reaching a provisional diagnosis, which is then confirmed by using FNAC. With triple assessment gaining popularity mammography too was included into the scheme of breast lump evaluation for more apt diagnosis thus leading to better management of the patient.

When all the components of triple assessment are concordant, that is agree on common grounds the diagnosis is easily reached and patient is managed accordingly. When the components are discordant, that is differ in their interpretation of the breast lump, what would be the next step forward is the area which needs more light to be shed upon. It is precisely in this area where triple test score can be the answer to this dilemma. TTS being non-invasive and economical, with certain diagnosis in most of the cases (except in score of 5) can be relied upon as an effective test for further management of the patient.

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