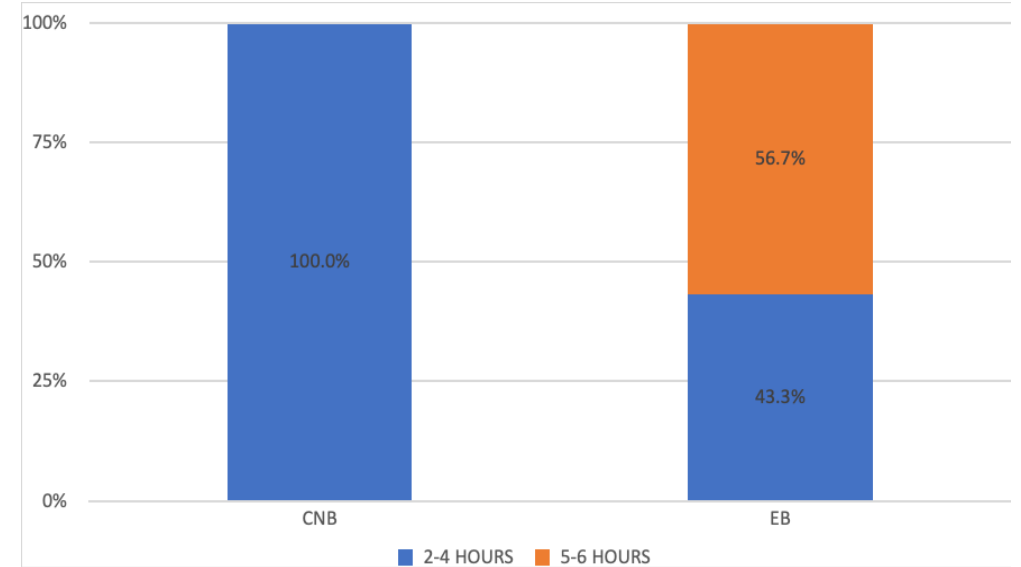


**Title:** A prospective clinical study to compare results of preoperative core needle biopsy and excision biopsy to determine accuracy of ER, PR and Her-2 neu status in invasive breast carcinoma in rural tertiary care Institute.

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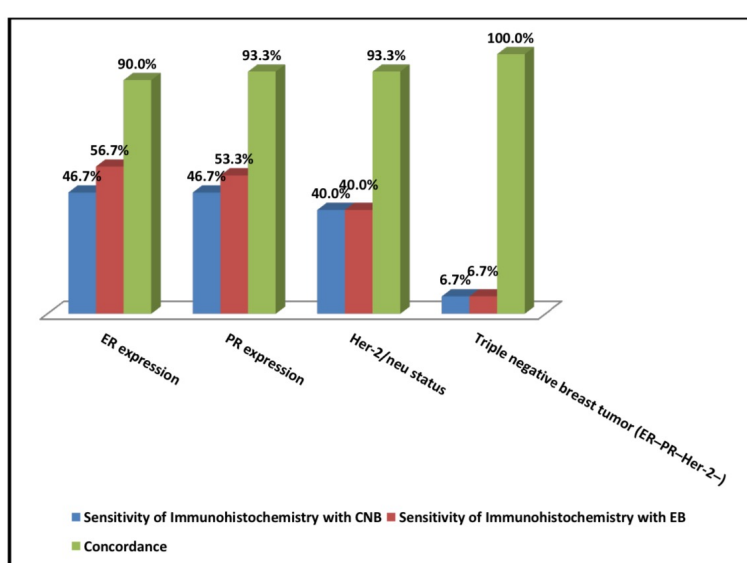
**Introduction:** Core needle biopsy is a minimally invasive, outpatient, and cost-effective diagnostic procedure. The agreement between the assessment of predictive factors ER, PR, and HER2 in core biopsies and excision specimens is still a topic of discussion. Hence, this study aims to compare the analysis of ER, PR, and HER2 neu status in the initial core needle biopsy (CNB) with the results obtained from the subsequent excision biopsy in breast carcinoma patients.



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**Discussion:** The present study revealed that tumours expressed 56.7 percent of ER positivity and 53.3 percent of PR positivity in excision biopsy, while two-fifths (40.0%) were Her-2/neu positive. However, in core needle biopsy, half (50.0%) of the tumours had expressed ER and PR positivity each, while 42.9 percent of them were Her-2/neu positive. Whereas Arnedos M et al.<sup>86</sup> (2009) showed that ER was positive in three-fourths (75%) of the Core Needle Biopsy and similar results for ER, in Excision Biopsy (76%) of the cases. For PR in the Core Needle Biopsy, two-thirds (66%) were positive compared with 67.6 percent in the surgical specimens. Regarding the concordance between preoperative Core Needle Biopsy and Excision Biopsy for ER, PR, and Her2/neu status accuracy in invasive breast carcinoma, the observed concordance rates were 90 percent, 93 percent, and 93 percent, respectively. Similar results were found by Damodaran D et al. (2020) with concordance rates of 92 percent for ER and 89 percent for PR, but slightly lower concordance of 78 percent for Her2/neu. Using kappa statistics, the concordance between Core Needle Biopsy and Excision Biopsy was almost perfect for ER ( $k=0.813$ ), PR ( $k=0.875$ ), and Her2/neu ( $k=0.872$ ), with statistically significant results ( $p < 0.001$ ). However, Damodaran D et al. (2020) reported slightly lower concordance rates between Core Needle Biopsy and Excision Biopsy, with almost perfect concordance for ER ( $k=0.82$ ), substantial concordance for PR ( $k=0.77$ ), and moderate concordance for Her2/neu ( $k=0.60$ ), all statistically significant ( $p < 0.001$ ). You K et al. (2017) found very good agreement between ER and PR expression in Core Needle Biopsy samples and the overall concordance rates were 96.7 percent for ER ( $\kappa=0.903$ ) and 94.3 percent for PR ( $\kappa=0.870$ ). Her2/neu expression also showed good agreement between Core Needle Biopsy and surgical specimens, with an overall concordance rate of 84.8 percent ( $\kappa=0.684$ ).

**Conclusion:** In this study, Core needle biopsy can confidently confirm tumour PR / Her-2 status and shows evidence supporting the accuracy of Core Needle Biopsy in determining the molecular profile of invasive breast cancer. particularly in evaluating the PR and HER2/neu.



Excision Biopsy (N=30)					
Immunohistochemistry					
Her-2	Total	ER+	ER-	PR+	PR-
<b>Positive</b>	12 [40.0]	1 [5.9]	11 [84.6]	0 (0.0)	12 (85.7)
<b>Negative</b>	18 [60.0]	16 [94.1]	2 [15.4]	16 (100.0)	2 (14.3)
<b>Total</b>	30 (100.0)	17 (56.7)	13 (43.3)	16 (53.3)	14 (46.7)
Core Needle Biopsy (N=28) *					
Her-2	Total	ER+	ER-	PR+	PR-
<b>Positive</b>	12 (42.9)	1 [7.1]	11 [78.6]	0 [0.0]	12 [42.9]
<b>Negative</b>	16 (57.1)	13 [92.9]	3 [21.4]	14 [100.0]	2 [14.3]
<b>Total</b>	28 (100.0)	14 (50.0)	14 (50.0)	14 (50.0)	14 (50.0)

**Aim:** To assess the level of agreement or disagreement in the status of ER, PR, and HER2 between the pre-operative core needle biopsy (CNB) and the subsequent excision biopsy (EB).

Sensitivity of IHC	Core Needle Biopsy Number of specimen (%)	Excision Biopsy Number of specimen (%)	Concordance (%)	
<b>ER expression</b>	14 (46.7)	17 (56.7)	90.0	
<b>PR expression</b>	14 (46.7)	16 (53.3)	93.3	
<b>Her-2/neu status</b>	12 (40.0)	12 (40.0)	93.3	
<b>Triple negative breast tumor (ER-PR-Her-2-)</b>	2 (06.7)	2 (06.7)	100.0	
<b>ER / PR</b>	<b>Indeterminate</b>	02 (6.7)	00 (0.0)	86.7
	<b>ER+PR+</b>	13 (43.3)	17 (56.7)	
	<b>ER+PR-</b>	01 (3.3)	00 (0.0)	
	<b>ER-PR+</b>	01 (3.3)	00 (0.0)	
	<b>ER-PR-</b>	13 (43.3)	13 (43.3)	

**Sensitivity of Immunohistochemistry**

**Association of Her-2 status and ER/PR expression**

IHC	Observed concordance	Adjusted concordance	Standard Error	Cohen's kappa statistics	p-value	Inference
<b>ER</b>	90%	81.3%	0.096	k = 0.813	p<0.001	Almost perfect concordance
<b>PR</b>	93%	87.5%	0.080	k = 0.875	p<0.001	Almost perfect concordance
<b>Her-2</b>	93%	87.2%	0.083	k = 0.872	p<0.001	Almost perfect concordance

Concordance/Discordance between the hormonal receptors ER/PR and Her-2 neu status accuracy in preoperative core needle biopsy in invasive breast carcinoma in comparison to excision biopsy (N=30)

References: Damodaran D, Naidu BK, Varghese JC, Rajan P, Kuruvilla R, Kuruvilla S, et al. A Prospective Study on Level of Concordance Between Core Needle Biopsy and Surgical Specimen for Assessing Oestrogen Receptor, Progesterone Receptor, and Her2/Neu Receptor Status in Carcinoma Breast and Its Implications on Treatment Decisions. Indian J Surg Oncol. 2020;11(3):446-50.

**Results:** The agreement between the Her2/Neu status accuracy in preoperative core needle biopsy and excision biopsy for invasive breast carcinoma was found to be 93 percent upon observation. After accounting for chance factors using Cohen's kappa statistics, the adjusted concordance was determined to be 87.2 percent, indicating an almost perfect level of agreement.