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Research Paper

Retrospective And Prospective Evaluation of Sloan Kettering Nomogram for Assessment of Axillary Lymph Node Involvement in Carcinoma Breast At Avbrh, Wardha

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ABSTRACT: *Bevilacqua et al have developed a nomogram to help estimate the risk of lymph node (LN) metastasis. The nomogram developed in the Memorial Sloan Kettering Cancer Center (MSKCC) is based on nine factors, which were found to be predictive: age, tumor size, tumor type, tumor location, lymphovascular invasion, mulifocality, histologic grade, estrogen receptor and progesterone receptor status. The area under the receiver–operator characteristic curve (AUC) was 0.771 in the validation data. This study evaluated the risk factors for LN metastasis and validated the value of the MSKCC nomogram for the prediction of LN metastasis*
Aim: *To evaluate the axillary lymph node metastasis by MSKCC Nomogram at AVBRH.*
Objectives.1)To study the clinical staging of carcinoma breast .2) To evaluate the accuracy of MSKCC nomogram for axillary lymph nodes after axillary dissection (as standard form of treatment in MRM).
Materials And Methods:- *All the patients with carcinoma breast with clinically N0 and N1 nodal status attending in the AVBRH of JNMC will be included in the study. Study was conducted retrospectively and prospectively for the evaluation of the MSKCC Nomogram.*
Type Of Study: *observational study.Sample size:-100 cases 50 retrospective cases and 50 prospective Cases.*
Result :- *In our present study as per the auc which is 0.771 validates mskcc nomogram at our setup with the point to be noted that the intermediate risk group needs to be looked for the size of tumour and lymphovascular invasion by a trucut biopsy method preoperatively to finally decide the fate of axillary lymph node dissection .*
Conclusion:- *The MSKCC nomogram is a very useful tool in predicting the axillary LNodal metastasis in breast carcinoma patients who are in a N0 or N1 axillary lymph nodal state and might avoid an unnecessary axillary lymph nodal dissection at our setup decreasing the varied morbidity caused by it.*
Keywords: *Breast,Lymph node,,MSKCC,Metastasis,Nomogram*

I. INTRODUCTION

The contemporary approach for detecting axillary metastases in clinically node-negative (N0) patients with early-stage breast cancer is intraoperative lymphatic mapping and sentinel lymph node biopsy (SLNB), a minimally invasive and a highly accurate staging procedure[(1-4)]The early and late postoperative morbidity of SLNB(Sentinel Lymph Node Biopsy) is significantly lower than that of axillary dissection, but lymphedema occurs in 5% of patients. The postoperative complications and relative medical burden of SLNB(Sentinel Lymph Node Biopsy) could not be neglected. Bevilacqua et al[(5)] have developed a nomogram to help estimate the risk of lymph node (LN) metastasis to axilla. The nomogram developed in the Memorial Sloan Kettering Cancer Center (MSKCC) is based on nine factors, which were found to be predictive: age, tumor size, tumor type, tumor location, lymphovascular invasion, mulifocality, histologic grade, estrogen receptor (ER) and progesterone receptor (PR) status. The area under the receiver operator characteristic curve(ROC) was obtained. This study evaluated the risk factors for Lymph Nodal metastasis and evaluated the value of the MSKCC nomogram for the prediction of Lymph Nodal metastasis to axilla.

The presence and extent of axillary lymph node involvement remains the most powerful predictor of recurrence and survival. It has been shown that the presence of regional metastases within the axillary basin decreases a patient's 5-year survival by approximately 28-40%.[(6),(7)] Furthermore, data derived from National

Surgical Adjuvant Bowel and Breast Project Protocol B-04 has shown that the likelihood of treatment failure increases as the number of metastatic axillary lymph nodes increases.([8] The removal of axillary lymph nodes also improves loco-regional control, which may translate into improved overall survival for the patient.[9],[10],[11],[12] However, lymph node metastases are found in only 40% of patients who undergo axillary lymph node dissection (ALND).[13],[14] The remaining patients derive no therapeutic benefit from the procedure, whereas all patients are exposed to the complications from ALND, including lymphedema, pain, stiffness, and shoulder weakness.[15],[16] Additional complications include seroma formation and vascular and brachial plexus injuries.[17]

The Memorial Sloan Kettering Cancer Center (MSKCC) nomogram model was developed to predict the Lymph Nodal metastasis in axilla .[18]

The MSKCC nomogram is a free network auxiliary approach that allows the calculation of Lymph Nodal metastatic risk by combining different histopathological prognostic factors. The predictive model was developed to provide both clinicians and patients with valuable references that help decide on the worthiness of Sentinel Lymph Node Biopsy. We have performed an evaluation of the MSKCC nomogram for the prediction of Lymph Nodal metastasis in axilla in an Indian breast cancer population. In our analysis, the MSKCC nomogram is a useful tool that could predict the probability of Lymph Nodal metastasis, but should be improved to be valid and definitive. Probably, patients who benefit the most from the nomogram would be those with a very low or high risk of Lymph Nodal metastasis. The intermediate risk group still required further evaluation to accurately predict the lymph nodal metastasis.

Thus , this nomogram can be a good prediction tool at our setup to evaluate the Lymph Nodal metastasis to axilla on the basis of probability percentage calculated by the nomogram to decide the fate of axillary lymph node dissection.

Our study evaluated the accuracy of the MSKCC model for predicting non-SLN metastasis by drawing an ROC curve and calculating the AUC. The AUC was 0.771, which indicates the MSKCC nomogram could provide a reliable prediction method.

II. AIMS AND OBJECTIVE

1)To evaluate the axillary lymph node metastasis by Memorial Sloan Kettering Cancer Centre Nomogram at AVBRH.
2) To study the demographic feature of the patients of breast carcinoma presenting at AVBRH.
3) To evaluate the accuracy of MSKCC nomogram for axillary lymph nodes after axillary dissection (as standard form of treatment in MRM)

III. MATERIALS AND METHODS

All the patients with carcinoma breast with clinically N0 and N1 nodal status attending in the AVBRH of Jawaharlal Nehru Medical College will be included in the study. Study will be conducted retrospectively and prospectively for the evaluation of the Memorial Sloan Kettering Cancer Center Nomogram.
Parameters of MSKCC
Current age
Breast tumor size
Special type Y/N
Tumor is confined to upper inner quadrant?
Lymphatic or vascular structure involvement(lymphovascular invasion)
Multifocality Y/N
Tumor type and grade
Estrogen – receptor status
Progesterone – receptor status
Predictive score on MSKCC

Age of the patient will be taken as per the records on her IPD number Size of the breast tumour will be taken by measuring it clinically in both horizontal and vertical dimension by the measuring tape and confirming it by ultrasonography of the breast.size of the tumour to be put on nomogram variable will be the greatest dimension of the tumour measurable . Type of tumour will be obtained by the histopathological report of the specimen which is given after modified radical mastectomy and axillary lymph node dissection. Lymphovascular invasion is also judged on the basis of hisstopahological report.
Presence of secondary tumours which are located 5 cm away from the primary tumour site will be considered as multifocal tumour which will be detected clinically.

Tumour type and grading of the tumour will be assessed on the histopathological report. Estrogen receptor status and Progesterone receptor status will be done on the slides and blocks prepared the MRM specimen at Jawaharlal Nehru Medical College , pathology department. However , preoperatively all the variables of the MSKCC nomogram can be assessed by a core biopsy. For assessment of the nomogram accuracy, calibration plot for observed probability against the predicted probability will be calculated. On the basis of the calibration plot, the MSKCC nomogram will estimate the risk of the probability of Lymph Nodal metastasis to axilla. To determine the discrimination of the nomograms, the area under the ROC curve will be plotted.

Type of study :

Retrospective and Prospective observational study of cancer breast according to Sloan Kettering nomogram for involvement of lymph node as per variables decided.

Sample size : 100 cases

50 retrospective cases

50 prospective cases

Inclusion criteria:

All the patients who are newly diagnosed cases of cancer breast with clinically lymph node N0 and N1 involvement who have not taken any modalities of treatment.

For patients are taken retrospectively - Those who has been investigated for all parameters of mskcc

Exclusion criteria:

1. Patients who are receiving neo-adjuvant chemotherapy or are recurrence case of post MRM
2. Post chemotherapy patient for carcinoma breast
3. Patients with clinically N2 and N3 positive lymph node in axilla
4. Patients with any previous surgery on the breast

IV. RESULTS

Table 1: Distribution of patients according to their age(years)

Age Group(yrs)	No of patients	Percentage(%)
21-30 yrs	5	5
31-40 yrs	26	26
41-50 yrs	32	32
51-60 yrs	21	21
61-70 yrs	15	15
71-80 yrs	1	1
Total	100	100
Mean ± SD	48.62±11.37(24-75 yrs)	

Table 1 shows distribution of patients according to their age in years .
In which mostly patient is of age 41-50 yrs and the mean is 48.62±11.37

Table 2: Distribution of patients according to tumor confined to UIQ.

Tumor confined to UIQ	No of patients	Percentage(%)
Yes	13	13
No	87	87
Total	100	100

Table 2 shows distribution of patient according to tumour confined to upper inner quadrant in which only 13 patients out of 100 are confined to UIQ and rest 87 patients were not confined to UIQ.

Table 3: Distribution of patients according to special type of tumor

Special type of tumor	No of patients	Percentage(%)
Yes	7	7
No	93	93

Total	100	100

Table 3 shows distribution of patients according to special type of tumour
In which 93 patient out of 100 were of invasive ductal carcinoma of no special type and 7 patients were of special type tumour

Table 4: Distribution of patients according to Multifocality

Multifocality	No of patients	Percentage(%)
Yes	1	1
No	99	99
Total	100	100

Table 4 shows distribution of patients according to mutifocality in which only 1 patient had multifocal tumour while rest of the tumours were not having multifocality.

Table 5: Distribution of patients according to size of tumour

Size of tumor(cm)	No of patients	Percentage(%)
<=2 cm	6	6
>2cm <=5cm	63	63
>5 cm	31	31
Total	100	100
Mean ± SD	4.89±2.08(0.50-12 cm)	

Table 5 shows distribution of patients according to the size of tumour in which most of the patients i.e 63 patients were included in the range of >2cm and <=5cm group , 6 patients were in <=2 cm group and rest 31 patients were included in >5cm size gROUP

Table 6: Distribution of patients according to Estrogen Receptor Status

ER Status	No of patients	Percentage(%)
Positive	46	46
Negative	54	54
Total	100	100

Table 6 shows Distribution of patients according to Estrogen Receptor Status in which 46 patients had positive ER status and rest i.e 54 were negative for ER status

Table 7: Distribution of patients according to Progesteron Receptor Status

PR Status	No of patients	Percentage(%)
Positive	28	28
Negative	72	72
Total	100	100

Table 7 shows Distribution of patients according to Progesteron Receptor Status in which 28 patients were positive for progesterone receptor status and 72 patients were negative for progesterone receptor status

Table 8: Distribution of patients according to Grade of Tumor

Grade of Tumor	No of patients	Percentage(%)
Grade I	33	33
Grade II	39	39
Grade III	28	28
Total	100	100

Table 8 shows distribution of patients according to grade of tumour in which 39 patients were in grade ii tumour group, 33 patients were in grade I tumour group and rest 28 patients were in grade iii tumour group.

Table 9: Distribution of patients according to T- Staging(clinically)

T- Staging	No of patients	Percentage(%)
T1	6	6
T2	58	58

T3	18	18
T4	18	18
Total	100	100

Table 9 shows distribution of patients according to T staging(clinically) in which 58 patients were in t2 tumour group , 6 patients had t1 stage , t3 had 18 tumour group and rest 18 patients were in t4 stage.

Table 10: Distribution of patients according to N- Staging

N- Staging	No of patients	Percentage(%)
No	55	55
N1	45	45
Total	100	100

Table 10 shows Distribution of patients according to N- Staging in which 55 patients were in N0 lymph nodal status whereas 45 patients were in N1 lymph nodal stage.

Table 11: Distribution of patients according to percentage as per MSKCC

% as per MSKCC	No of patients	Percentage(%)
≤ 16%	2	2
17-66%	42	42
≥67%	56	56
Total	100	100
Mean ± SD	68.15±22.23(14-99%)	

Table 11 shows distribution of patients according to percentage as per Mskcc in which maximum number of patients were in the group of >= 67% i.e 56 patients whereas 42 patients were in the group of 17-66% probability group and 2 patients were in the group of <= 16% probability score group as per the calculation done by computerised model on mskcc website. Mean is 68.15±22.23

Table 12: Number of lymph node positive patients in the range of 17-66% as per MSKCC

Lymph node	No of patients	Percentage(%)
Negative	19	45.23
Positive	23	54.76
Total	42	100

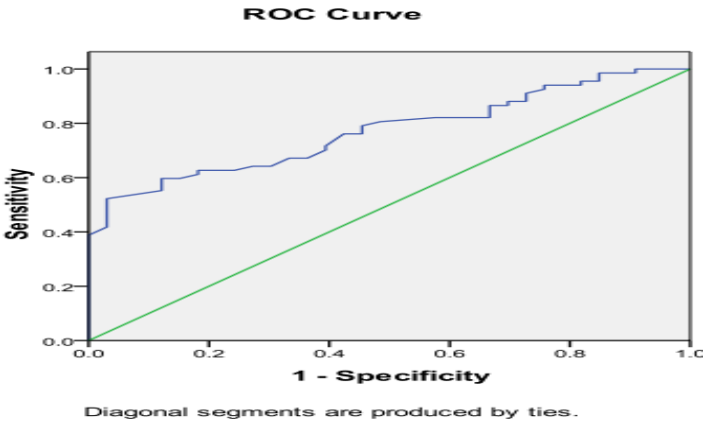
Table 12 shows number of lymph node positive patients in the range of 17-66% probability group patients which were 23 out of 42 patients i.e 54.76%

Table 13: Multiple Regression Analysis

	Unstandardized Coefficients		Standardized Coefficients	t	p-value
	B	Std. Error	Beta		
% as per MSKCC(17-66%)	0.639	0.924			
No of lymph node positive	0.052	0.087	0.049	0.599	0.551,NS
Grade of Tumour	0.055	0.054	0.086	1.016	0.312,NS
Lymphovascular Invasion	-0.274	0.086	-0.275	3.192	0.002,S
ER	-0.080	0.104	-0.080	0.764	0.447,NS
PR	-0.172	0.109	-0.156	1.581	0.117,NS
Tumor Size	0.135	0.020	0.567	6.841	0.0001,S
Tumor confined to UIQ	0.169	0.111	0.115	1.529	0.130,NS
Special Type	0.111	0.143	0.057	0.776	0.440,NS
Multifocality	0.293	0.378	0.059	0.774	0.441,NS
Age(yrs)	-0.004	0.003	-0.095	1.278	0.204,NS

By using multiple regression analysis only lymphovascular invasion (p=0.002) and tumor size(p=0.0001) is significantly associated with 17-66% as per MSKCC and other are not correlated with 17-66% as per MSKCC.

Table 14: ROC analysis of MSKCC with number of positive lymph node metastasis



Area Under the Curve				
Area	Std. Error[a]	p-value	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
0.771	0.046	0.0001,S	0.681	0.860

- Sensitivity =98.5%
- Specificity=90.9%

Statistical analysis was done by using descriptive and inferential statistics using ROC analysis and software used in the analysis were SPSS 22.0 version and GraphPad Prism 6.0 version and $p<0.05$ is considered as level of significance

V. Discussion

The present study was conducted in the Department of General Surgery , Acharya Vinoba Bhave Rural Hospital , Jawaharlal Nehru Medical College , Sawangi(Meghe) , Wardha to evaluate the axillary lymph node metastasis by Memorial Sloan Kettering Cancer Centre Nomogram. In our present study a total of 100 female patients were enrolled fulfilling the inclusion criteria in which 50 participants were taken retrospectively from April 2013 to April 2015 and the rest 50 were taken prospectively from May 2015 till September 2017 with a maximum number of patients in the age group of 41-50 years, i.e. in the 4th decade of life, the youngest patient in our study was 24 years old while the eldest was 75 years with the mean age of 48.62±11.37. The number of patients in the group of 41-50 year age group in our study was 32. In studies conducted by José Luiz B. Bevilacqua et al (19) in 2007 in New York had maximum number of patients in the age group of 41-50 year. Also, studies conducted by Peng-Fei Qiu et al(20) and Xiang Bi et al(21) in 2012 and 2015 respectively in china also had maximum number of their patients in the 4th decade of life. A study conducted by Angela Katz et Al(22) in 2007 at Boston also had similar reports which were comparable to our study. While in the tumor size group of >5cm , 31 patients were taken out of which 18 patients were in the T-3 stage, while 13 patients were in T-4 stage of tumor, making the total number of participants in T-4 stage to be 18. In the study conducted by A. S. Gur et al(23) in the year 2009 done on Taturk teaching and research hospital Izmir, Turkey it revealed that 53 % of their patients selected in the study were present in a group between >2-<=5 cm.

Whereas, a study done by Ramazan et al(24) at Turkey in 2015 and study done by Si Qui et al(25) at china in 2015 also revealed 57.1% and 69.3% of patients respectively in this group which are comparable to our study group.Patients in our study were divided into N0 and N1 Lymph nodal status, which was judged clinically which were distributed as 55 participants having N0 lymph nodal status and 45 participants having N1 lymph nodal status. This criteria determined our selection of patients who are to be included in our present study.

All those patients falling in the N0 and N1 lymph nodal status clinically were only taken in our study and rest patients falling in the N2 and N3 lymph nodal status were not taken for the study due to more chances of having positive Lymph Nodal metastasis in those groups. In our study , clinical staging status and their distribution among the population was also studied which showed that 6 patients were in stage I of the disease , while 62 patients were in the stage II of the disease and rest 32 patients were in the stage III of the disease.

13 patients had their tumor present in the Upper Inner Quadrant of the breast and rest 87 patients had a breast lump in other quadrants or in more than one quadrant which were not included in this category, only

those lumps which were entirely located in the UIQ were included. A lump present in the upper inner quadrant has less probability of metastasis to axillary lymph node.

As in our present study, 13% of the participants had their tumor located in Upper Inner Quadrant, which is quite similar to the studies conducted by Si-Qi Qiu et al(26) in 2015 in China in which 15.8% patients had their tumors located in upper inner quadrant. While studies conducted by Peng Fei Qui et al(27) in 2012 at china and Ramazan Yıldız et al[6] in 2015 at turkey yielded 21.2% and 11.4% tumor located in upper inner quadrant respectively which were comparable to our study. In our study group of 100 Patients only 1 patient was having multifocality with the presence of a secondary tumor 5 cm away from the primary which was assessed clinically. While the rest of the patients were having no multifocality. A study conducted by Peng Fei Qiu et al(28) in 2012 in China had 0.03% patient having multifocality which was comparable to our study. Whereas, studies conducted by Yao Lung Kuo et al(29) in 2013 in Taiwan reported 35.4% patients to be having multifocality, while studies conducted by Crystal J. Hessman et al[8] in 2011 in Portland and a study by Ramazan Yıldız et al (30)in 2015 in Turkey had 11.4% and 20% patients having multifocality respectively which were not comparable to our present study.

In our present study as compared to other studies, it was seen that only 46% of the patients has ER status positive as compared to the study done by Yao-Lung Kuo et al[10] in 2013 which had 77.7% patients having ER status positive, while those of Crystal J. Hessman et al[11] and peng fi qui et al(31) had 84.6 and 56.4% patients positive for ER receptor status respectively, hence only Peng Fi Qui et al[13] had comparable findings with our present study. Studies conducted by Peng Fei Qui et al(32) in 2012 in China had 56.4% patients, positive for PR status while studies conducted by Si Qi Qui et al(33) in 2015 in China had 59% patients in the PR status positive group. Thus, these studies are not comparable to our present study which had 28% of patients positive for PR receptor status while 72% patients were negative for PR status.

MSKCC(Memorial Sloan Kettering Cancer Center) nomogram Evaluation Memorial Sloan Kettering cancer center nomogram was developed on a basis of 9 variables which decided the probability of Lymph Nodal metastasis on the percentage calculated by the computerized model on MSKCC website (http://nomograms.mskcc.org/Breast/BreastSLNodeMetastasisPage.aspx) by putting the data of 9 variables which were decided by the nomogram. These variables are current age, breast tumor size, a special type of tumor, tumor confined to upper inner quadrant, lymphovascular invasion, multifocality, tumor type and grade, Estrogen Receptor status and Progesterone Receptor status.

Percentage of MSKCC were divided in three categories r5 new references [34] :-
1)Low Risk Group (<=16%)
2)Intermediate Risk Group(17-70%)
3)High Risk Group(>=71%)

These 3 categories were divided on the percentage into low , intermediate and high risk group respectively for Lymph Nodal metastasis in axilla with <=16% probability group being least prone for Lymph Nodal metastasis and >=71% probability group being highly susceptible for Lymph Nodal metastasis , While the group between 17 to 70% had intermediate risk of Lymph Nodal metastasis and required further evaluation, which was calculated by the multiple regression analysis chart which indicated that lymphovascular invasion (p=0.002s) and tumor size (p=0.0001s) is significantly associated with 17-70% probability group as per MSKCC and other are not correlated with this group as per MSKCC significantly.Thus a patient who has score of <=16% probability , had least chances of Lymph Nodal metastasis as in our study which had 2 patients in this category with negative Lymph Nodal meatstasis in axilla.

Those patients who were in the score range of >= 71% had maximum chances of Lymph Nodal metastasis as in our study 51 patients were in this group and out of that 42 patients had positive LN metastasis i.e. 82.3% patients while only 9 patients had negative Lymph Nodal metastasis i.e. only 17.64 % of patients which clearly indicated high chances of LN metastasis in this group.

In the intermediate risk group which falls in the category of 17-70% , patients in our study were 47 out of which 25 patients had positive Lymph Node metastasis to axilla i.e 53.19% patients which is much less than >=71% group patients but more than the group which had <= 16% probability for Lymph Node metastasis while number of patients who were negative for Lymph Node metastasis were 22 i.e 46.81% patients had negative Lymph Nodal status clearly indicating that this group of patients had almost 50 % chance of Lymph Nodal metastasis and thus was further evaluated by multiple regression analysis table by keeping all the variables of MSKCC nomogram and it indicated that size of the tumour and Lymohovascular invasion were the most important variables to decide the Lymph Nodal metastasis as compared to the other variables. Out of 25 patients who had positive Lymph Nodal status 23 participants had tumour size between >2->=5cm size , thus in T-2

Stage of tumour but out of these 2 patients were in T-4 stage of the disease.10 patients out of 25 were having lymphovascular invasion. Number of patients who were having positive ER status were 11 and patients with positive PR status were 5. Grade I tumour were present in 8 patients whereas grade II tumour were in 13 and grade III tumour were in 4 patients.Thus a patient presenting in this group of scoring as per MSKCC should be evaluated for lymphovascular invasion and size of the tumour to decide whether the patient require axillary Lymph Node dissection or not. Preoperatively all the variables of the MSKCC nomogram can be assessed by doing a core needle biopsy which can be used to get all the data necessary for the variables .

VI. CONCLUSION

The MSKCC nomogram is a very useful tool in predicting the axillary LNodal metastasis in breast carcinoma patients who are in a N0 or N1 axillary lymph nodal state and might avoid an unnecessary axillary lymph nodal dissection at our setup decreasing the varied morbidity caused by it.

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