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## RESEARCH ARTICLE

# NEW RISK STRATIFICATION (NERS) SCORE II – TO PREDICT CLINICAL OUTCOME AFTER REVASCULARISATION (PCI/CABG) OF UNPROTECTED LEFT MAIN CORONARY ARTERY DISEASE

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**ABSTRACT**

**Background:** Conventional NERS (New Risk Stratification) Score (Fajadet and Chieffo, 2012) are proven to be superior to SYNTAX score in predicting MACE, but involved complex calculation. This is duly addressed by a simplified version, by the NERS Score II. (Kalbfleisch and Hort, 1977) We performed a prospective pilot study to assess efficacy of NERS II to predict clinical outcome in form of MACE and also symptom relief / quality of life, in patients with UPLMCAD (Unprotected left main coronary artery disease) undergoing either PCI or CABG.

**Methods:** Forty-one patients with UPLMCAD undergoing coronary revascularisation (20 PCI + 21 CABG) were included in the study between 1st January, 2013 to 31st Dec 2014 in Amrita institute of Medical sciences and followed up after 1 year of procedure. All the individuals were assessed for MACE, functional class, echo, SAQ score, TMT positivity, and Duke score. All these variables were correlated with pre-procedure NERS II.

**Results:** 9 out of 41 patients had MACE (deaths 5, ACS 3, TVR 1). ROC curves for NERS II showed cut-off value as 16.55 to stratify patients as low and high risk, with a sensitivity of 87.5% and specificity of 81.2%. Although the incidence of MACCE did not vary significantly between 2 NERS II groups. Other parameters of clinical profile like TMT positivity, functional class, Duke and SAQ score were found to have significant between-group difference. Odds-ratio for TMT were positive (OR = 21, 95% CI 1.9412 to 27.21), odds-ratio for functional class (OR = 7.7, 95% CI 1.39 to 42.63), odds-ratio for duke score (OR = 15, 95% CI 2.02 to 11.07).

**Conclusion:** NERS II score is an effective tool to predict clinical outcome in the form of symptom relief in UPLMCAD patients undergoing revascularization. However with respect to MACE event, there was a definite poorer outcome with high NERS II score. No statistical significance was seen between the group differences. This was probably due to lesser number of MACE events. Also a single cut-off score of 16.55 can be used to risk stratify UPLMCAD patients as LOW RISK NERS II (< 16.55), and HIGH RISK NERS II ( >/= 16.55) with statistically significant different outcomes (Sensitivity 87.5%, specificity 81.8%).



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## INTRODUCTION

Unprotected left main coronary artery (ULMCA) disease occurs in approximately 4% of individuals who undergo angiography. Patients with LMCA disease are at high hazard for cardiovascular events because occlusion of this vessel compromises flow to at least 75% of the left ventricle and 100% in cases of the left dominant type. Severe LMCA disease reduces flow to a considerable segment of the myocardium, placing the patient at high risk for life-threatening events such as left ventricular dysfunction and arrhythmias (Fajadet and Chieffo, 2012; Kalbfleisch and Hort, 1977).

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Individuals with unprotected LMCA illness treated medically have a three-year mortality rate of 50%. Although coronary artery bypass graft (CABG) surgery has been considered as the 'gold standard' for unprotected LMCA revascularization, percutaneous coronary intervention (PCI) has currently emerged as a possible option mode of revascularization in carefully selected patients (Levine *et al.,* 2011). Risk scores are useful in determining the early and late outcomes after PCI and CABG for ULM disease, and discriminating between these two modalities for the individual patient. Predictive models, such as the SYNTAX score, may also help discussions of risk and benefit during the consent process for ULM revascularization (David *et al.,* 2011). SYNTAX score is most popular tool to predict clinical outcomes and guide revascularisation strategy. But its main drawbacks were lack of

consideration of clinical features and complexity of calculation (Sianos *et al.,* 2005; Capodanno *et al.,* 2009; Palmerini *et al.,*). The first drawback was duly addressed in conventional NERS Score (Chen *et al.,* 2010), which was proven to be superior to SYNTAX score in predicting MACE. Score calculation still remains a complex. This was duly addressed by NERS Score II (Chen *et al.,* 2013) which was a simplified version. NERS score II has a total of 16 variables (7 clinical, 5 left main trunk (LMT) lesion, and 4 downstream lesion). A multicenter, prospective, registry based Pilot study by Chen *et al*. in China (Chen *et al.,* 2013), evaluated patients undergoing PCI for UPLMCAD, with primary end-point of MACE at 1 yr of index procedure, and showed NERS score II, to have similar efficacy to the conventional NERS score, and more predictive of MACE than the SYNTAX score in UPLMCAD patients undergoing angioplasty. The main limitation of the above study is the patients undergoing CABG were not followed. Also that only MACCE events were studied and not the clinical profile including quality of life. We carried out a pilot study in this population to assess efficacy of NERS score II to predict clinical outcome in the form of MACE and also clinical profile of patient after revascularization by both PCI and CABG patients.

## MATERIALS AND METHODS

### Study design

Prospective Longitudinal Observational Study was conducted in Amrita Institute of medical sciences, Kerala, India. The study was approved by the institutional ethical committee during the period of January 2013 to December 2014, 51 patients with unprotected left main coronary artery disease who underwent revascularisation (PCI/CABG) were enrolled in the study. The data were entered into a clinical database after obtaining informed, written consent. Men and women aged 18 years or older, with coronary artery disease involving left main coronary artery in absence of a patent bypass and undergoing coronary revascularization (PCI/CABG) for the above indication were included in the study. Patients who were lost to follow-up, refusing to give consent for the study, and patients in congestive heart failure at time of index procedure were excluded.

### Important definitions related to inclusion and exclusion criteria are as follows

UNPROTECTED LEFT MAIN CORONARY ARTERY DISEASE is defined as all types of left main lesions in absence of bypass graft, or left main lesion with Non functional CABG grafts (e.g: LIMA occlusion makes left main unprotected). Total of 51 patient's (including PCI + CABG) who were satisfying the inclusion criteria were initially registered for the study. Ten patients were lost during the follow up. Therefore total number of patients were 41 (21 CABG group, 20 PCI group)

### Study protocol

A total of 41 Patients with UPLMCAD undergoing coronary revascularization (20 PCI + 21 CABG) were studied. Their NERS score II were calculated on the basis of clinical and angiographic profile. Revascularization strategy were jointly formulated by cardiologist + cardiac surgeons. All interventional / surgical procedures were according to current standard guidelines. Decisions regarding procedural, peri procedural medications were at operators discretion. Angiographic success in PCI: residual stenosis < 10% with TIMI flow grade 3 distally. These patients were called to cardiology OPD for a follow up after a period of 1 yr, during which detailed history regarding any MACE events were taken. All the cardiac related clinical event from procedure till review date were recorded. All deaths considered cardiac unless non-cardiac established clinically or at autopsy. ISR defined as > 50% diameter stenosis at follow-up. TVR – repeat PCI/CABG involving the index vessel. MI diagnosed according to third universal definition.

### TESTS

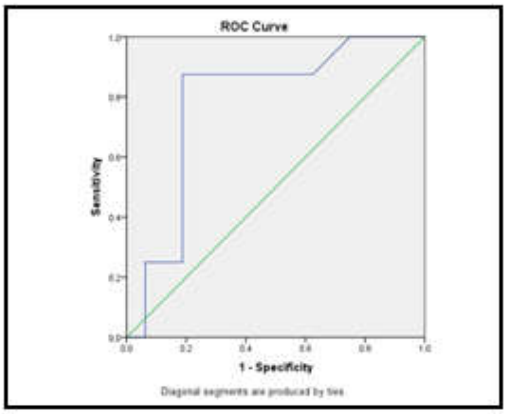
In cases of event free follow-up, till the date of review, patient were subjected to Functional Class Assessment according to NYHA guidelines (The Criteria Committee of the New York Heart Association, 1994) 2D Echo scan were done to look for LVEF, new RWMA. Treadmill test (TMT) was done based on bruce protocol (Robert *et al.,* 1949) (If no contraindication). And from the TMT, Duke's Treadmill Score given by the equation (Mark *et al.,* 1991): DTS = Exercise time – (5 x Max ST) – (4 x Angina index) is calculated. The patients were made to answer Seattle Angina Questionnaire (SAQ) (Spertus *et al.,* 1995) – which is leading health-related quality-of-life measure for patients with coronary artery disease. The answers patient give to the SAQ's questions are used to calculate scores in five scales: Anginal Stability, Anginal Frequency, Physical Limitation, Treatment Satisfaction, and Quality of Life. Finally all these parameters (MACCE, SAQ score, Duke score, echo profile) were individually correlated to baseline NERS score.

| | Definition(s) | Score |
|---|---|---|
| Clinical (n = 7) | | |
| Age, ≥75 yrs | Plus 1 score per 5-year increment | 1.34 |
| LVEF, ≤40% | Plus 1 score per 10% reduction | 2.03 |
| AMI, <12 h | AMI within 12 h | 3.65 |
| Cardiogenic shock | By AHA/ACC criteria | 4.17 |
| Diabetes | Diagnostic diabetes | 1.47 |
| eGFR, ≤60 ml/min | Plus 1.5 score per 10 ml/min reduction | 1.82 |
| Peripheral artery disease, DS >70% | DS >70% | 1.74 |
| LMT lesions (n = 5) | | |
| Ostial LM or body shaft | Lesion at ostium or at the body of LM | 1.18 |
| Distal bifurcation*/trifurcation† | Bifurcation/trifurcation lesions | 12.90 |
| Distal nonbifurcation | Medina 1,1,0; 0,0,1 | 8.67 |
| LMT-CTO | CTO ≥3 month in LM | 13.73 |
| Severe LM calcification | Needing rota (balloon failed to work) | 6.13 |
| Downstream lesions (n = 4) | | |
| RCA‡/LCX§ non-CTO lesion | TIMI flow grade ≥2 | 1.27 |
| LAD, non-CTO lesions | TIMI flow grade ≥2 | 5.21 |
| CTO in either LCX§ or RCA‡ | TIMI flow grade 0-1, ≥3 months | 3.27 |
| CTO in LAD | TIMI flow grade 0-1, ≥3 months | 5.49 |

**Figure 1. NERS II score variables**

### Statistical Method

Continuous variables were expressed as mean +/- SD. Intergroup comparison were analyzed with independent sample test (parametric data) and Mann whitney test (non parametric data).




Area Under the Curve

Test Result Variable(s): NERS II

| Area | Std. Error[a] | Asymptotic Sig.[b] | Asymptotic 95% Confidence Interval | |
|---|---|---|---|---|
| | | | Lower Bound | Upper Bound |
| .781 | .102 | .027 | .581 | .981 |

Coordinates of the Curve

Test Result Variable(s): NERS II

| Positive If Greater Than or Equal To[a] | Sensitivity | 1 - Specificity |
|---|---|---|
| .1800 | 1.000 | 1.000 |
| 3.8300 | 1.000 | .938 |
| 7.0700 | 1.000 | .875 |
| 8.8000 | 1.000 | .813 |
| 10.0400 | 1.000 | .750 |
| 11.6950 | .875 | .625 |
| 13.5650 | .875 | .563 |
| 14.2800 | .875 | .500 |
| 14.9150 | .875 | .438 |
| 15.2400 | .875 | .375 |
| 15.3400 | .875 | .313 |
| 15.9200 | .875 | .250 |
| 16.5550 | .875 | .188 |
| 16.7950 | .500 | .188 |
| 17.8100 | .375 | .188 |
| 18.8250 | .250 | .188 |
| 19.6350 | .250 | .125 |
| 22.4200 | .250 | .063 |
| 24.6350 | .125 | .063 |
| 26.4950 | .000 | .063 |
| 29.2900 | .000 | .000 |

**Figure 2. ROC curve – to estimate cut-off score for Risk stratification (High Vs Low risk)**

**Table 1. Risk stratification of all study patients**

| | LOW NERS II GROUP (NERS II SCORE < 16.55) N = 16 | HIGH NERS II GROUP ( NERS II SCORE >/= 16.55) N = 25 | TOTAL |
|---|---|---|---|
| PCI | 10 (62 %) | 10 (40 %) | 20 |
| CABG | 6 (38 %) | 15 (60 %) | 21 |
| TOTAL | 16 | 25 | 41 |

**Table 2. Clinical outcome variables**

| | | VARIABLES | CABG GROUP (n = 18) | PCI GROUP (n = 18) |
|---|---|---|---|---|
| 1 | FUNCTIONAL CLASS | A | 11 (61 %) | 12 (66 %) |
| | | B | 7 (39 %) | 6 (34 %) |
| 2 | ECHO | IMPROVEMENT | 3 (17 %) | 5 (28 %) |
| | | STATUS QUO | 15 (83 %) | 11 (61 %) |
| | | WORSENING (NEW RWMA / REDUCED EF) | 0 (0%) | 2 (11 %) |
| 3 | SAQ | | 79.8 | 81 |
| 4 | TMT (n = 12 + 11 = 23) | NOT POSITIVE | 6 (50 %) | 10 (91 %) |
| | | POSITIVE | 6 (50 %) | 1 (9 %) |
| | DUKE SCORE (n = 12 + 11 = 23) | >/ = 5 | 3 (25 %) | 2 (18.2 %) |
| | | < 5 | 9 (75 %) | 9 (81.8 %) |

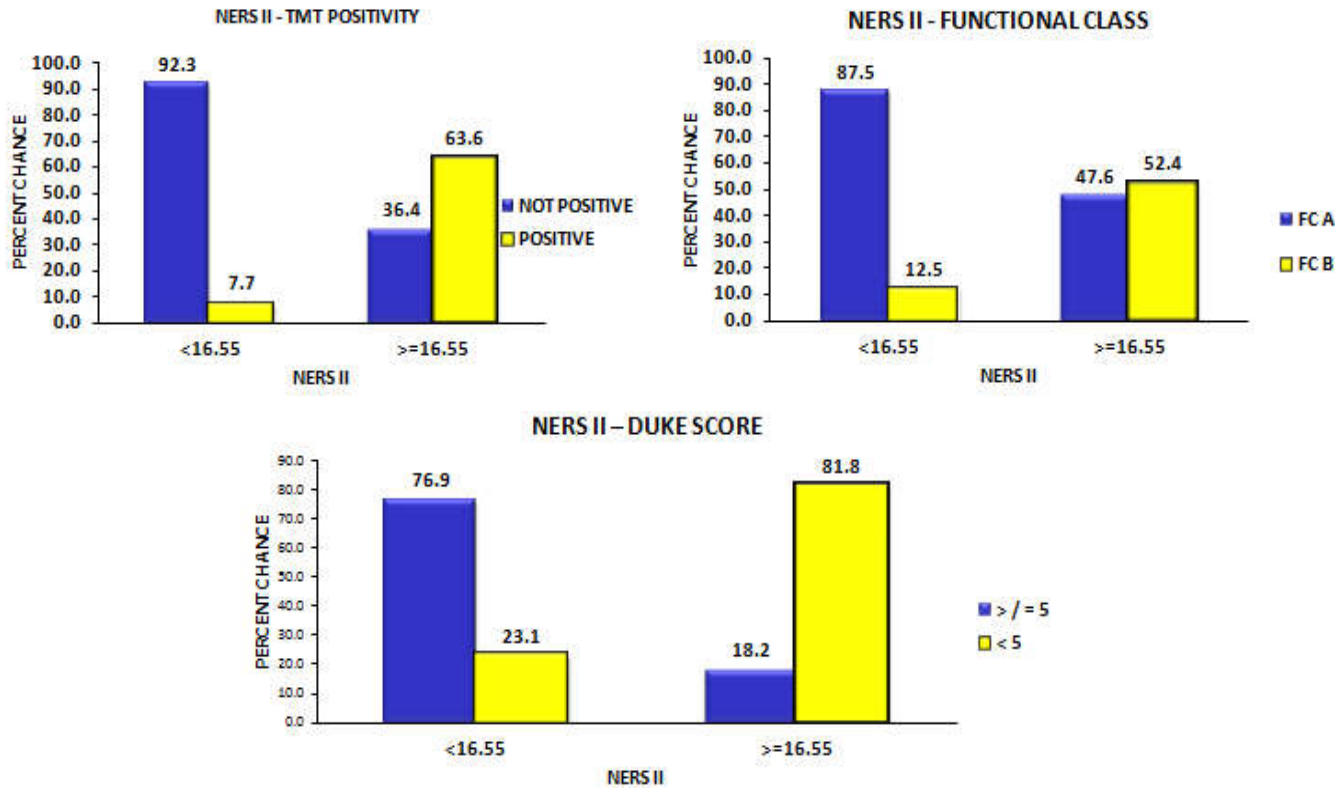
**Table 3. Correlation of clinical outcome variables with Pre-Procedure NERS II score**

| CLINICAL PARAMETERS | CATEGORY | CARDIAC EVENTS | NO CARDIAC EVENTS | TOTAL | P – VALUE |
|---|---|---|---|---|---|
| MACCE | LOW NERS II (< 16.55) | 2 (12.5%) | 14 (87.5%) | 16 | 0.441 |
| | HIGH NERS II (>/= 16.55) | 7 (28.0%) | 18 (72%) | 25 | |
| | **TOTAL** | **9** | **32** | **41** | |

5 patients died, So 36 were assessed for Functional class . 24 patients underwent TMT.

| CLINICAL PARAMETERS | CATEGORY | LOW NERS II HIGH (TOTAL = 16 PATIENTS) | (TOTAL = 20 PATIENTS) | TOTAL | P – VALUE |
|---|---|---|---|---|---|
| FUNCTIONAL CLASS | FC A | 14 (87.5%) | 9 (45.0%) | 23 | 0.017 |
| | FC B | 2 (12.5%) | 11 (55.0%) | 13 | |
| | | 16 | 20 | 36 | |
| **CLINICAL PARAMETERS** | **CATEGORY** | **LOW NERS II HIGH (TOTAL = 13 PATIENTS)** | **(TOTAL = 11 PATIENTS)** | **TOTAL** | **P – VALUE** |
| TMT | NOT POSITIVE | 12 (92.3%) | 4 (36.9%) | **16** | 0.008 |
| | POSITIVE | 1 (7.7%) | 7 (63.6%) | **8** | |
| | | 13 | 11 | **24** | |
| DUKE | < 5 | 3 (23%) | 9 (82%) | **12** | 0.006 |
| | > / = 5 | 10 (77%) | 2 (18%) | **12** | |
| | | 13 | 11 | **24** | |

The mean SAQ score of low risk group was 86.25 +/- 4.61, significantly higher than that of high risk group (75.35 +/- 8.73), with a p-value of < 0.01. Individual group analysis of CABG patients showed similar association for TMT positivity , functional class while in case of PCI patients only quality of life parameters like functional class , SAQ score had significant difference on comparing low risk and high risk NERS II groups.




**Graph 1. Correlation of clinical outcome variables with Pre-Procedure NERS II score**

Categorical variables presented as counts and percentages and compared using Fischer's exact test. Receiver operating Curves (ROC) will be generated to find a suitable cut-off value for stratifying patients into low risk and high risk with best combination of sensitivity and specificity. P-value <0.05 was considered significant for testing. All analyses were performed with SPSS version 20 software.

**Table 4. Correlation of SAQ score with Pre-Procedure NERS II score**

| GROUP | NERS II | SAQ SCORE | | P - VALUE |
|---|---|---|---|---|
| | | MEAN | SD | |
| CABG | <16.55 | 88.00 | 1.79 | 0.008 |
| | >16.55 | 75.75 | 7.75 | |
| PCI | <16.55 | 85.20 | 5.51 | 0.038 |
| | >16.55 | 74.75 | 10.58 | |

To assess role of NERS II in guiding between PCI Vs CABG, their outcome were compared against each other in high risk and low risk patients, but there was no statistically significant difference in outcome between the two modalities of treatment.

## RESULTS

Totally 41 patients (21 CABG, 20 PCI) were studied .Of these 9 had MACCE (deaths 5, ACS 3, TVR 1). Outcome variable assessment showed that 61% of CABG patients, and 66% of PCI patients were either asymptomatic or in FCI. Echo parameters showed that all of the CABG patients and almost 88% PCI patients had either improvement or remained the same. Almost 50% of CABG patients, while only 10% of PCI patients had positive TMT positive.

## DISCUSSION

The previous conventional NERS score (Chen *et al.,* 2010) highlighted the important role of utilizing clinical, anatomic, and procedural variables in driving outcome prediction for UPLMCA patients after implantation of a coronary stent, a finding similar to that of ACUITY (Acute Catheterization and Urgent Intervention Triage strategy) trial (Palmerini *et al.,* 1997). However, the complexity of the conventional NERS score and the SYNTAX score limited their extensive use in everyday practice. This limitation of conventional NERS score were overcome by NERS II score. The NERS score II contains only 16 variables and allows the realization of "real-time" scoring. Such conveniental scoring is easily performed bedside and would be meaningful to drive the prediction of clinical outcomes. Most importantly, the predictive value of the conventional NERS score were maintained and further enhanced by the simplified NERS score II. With the use of this simplified scoring system, a calculator or smart phone software app could be developed for the NERS score II system. Majority of patients undergoing CABG had TVD with a significantly higher SYNTAX score, while most PCI patients had DVD. 25% of PCI patients were taken for procedure in an acute setting, within 12 hours of presentation. With almost 20% of PCI patients being in shock state prior to procedure, whereas CABG remained an elective procedure for all the 21 patients with patients being hemodynamically stable pre-procedure. These 41 patients were followed up after end of 1 year. During this 1 yr period, 9 patients had major adverse cardiac events (5 death, 3 NSTE – ACS, 1 TVR). 5 patients had died, so the remaining 36 patients (41 – 5 death) were assessed for Functional Class, Echo, SAQ score. Among these 36 patients, only 24 could undergo TMT (12 patients could not do TMT due to reasons like severe arthritis of knee, elderly frail patients with restricted lifestyle) and from this TMT, the Duke score were calculated. All these outcome parameters were correlated with pre-procedure NERS II score. Initially, combined group analyses of all 41 patients (PCI + CABG) were done. ROC curves for NERS II were generated, from which a cut-off score of 16.55 was detected, on the basis of which all 41 patients were stratified into LOW RISK NERS II group (16 patients) and HIGH RISK NERS II group (25 patients). At the end of the study, the 6 outcome variables (Functional class, Echo, SAQ score, TMT positivity, Duke score, MACCE) were individually correlated with the risk groups. Here Significant Between-group difference (High NERS II Vs Low NERS II) were seen with respect to TMT positivity, Duke score, Functional Class, SAQ score. This implies that a UPLMCAD patient with high NERS II score (> 16.55) had significantly higher chance of having poor clinical outcome (i.e. a poorer functional class, lower SAQ score, TMT positive, with a lower Duke score.) than a low NERS II score patient.

Patient with High NERS II score had a 63.6 % chance of having a TMT positive at the end of 1 year (sensitivity = 87.5%, specificity = 75%, PPV = 63.6%, NPV = 92%, Accuracy = 79%), and has a 82% chance of Duke score < 5 (indicating moderate / high risk). (sensitivity = 75%, specificity = 83% , PPV = 81.8% , NPV = 76.9%, accuracy = 79%). This patient will also have a 60 % chance of being in Functional class B (sensitivity = 84.6%, specificity = 63.6%, PPV = 57.8%, NPV = 87.5%, Accuracy = 71%). However with respect to MACE events, echo parameters; Allthough there was a definite difference in clinical outcome, with high NERS II score having poorer results. But, there was no significant between – group difference. This was probably due to lesser number of events, which was secondary to small sample size of population. A larger sample study, with more outcome events, can probably increase the power and significance of this score in predicting MACE events. A multicentre, prospective, registry based study by Chen *et al*. in China had assessed efficacy of NERS II score only with respect to MACE, and only in patients undergoing PCI. From the ROC curve generated for that population, a value of 19 were taken as cut-off to stratify patients into Low risk NERS and High risk NERS groups. It was shown that a NERS score II >/= 19 demonstrated enhanced MACE sensitivity and specificity of 84.0% and 76.0% (MACE as the state variable), respectively, which were similar to the NERS score but significantly higher compared with the SYNTAX score. A NERS score II >/= 19 was the only independent predictor of cumulative MACE (hazard ratio: 3.27; 95% confidence interval [CI]: 1.86 to 5.23; p _ 0.001) and stent thrombosis (odds ratio: 22.15; 95% CI: 12.47 to 57.92; p _ 0.001) at follow-up. Here in CABG group, significant between-group difference (LOW NERS Vs HIGH NERS) was seen with respect to TMT positivity, functional class, and SAQ score. And in PCI group analysis, significant between-group difference was seen with respect to functional class and SAQ score.

Overall, it can be inferred that, irrespective of the mode of treatment, NERS II score is a reliable indicator of subjective clinical outcome parameters, which are indicative of Quality of life (e.g. SAQ score, functional class). When it comes to objective parameter like MACE, TMT positivity, with Duke score, echo parameters, larger sample study with more number of outcomes, will be key to determine the significance of NERS II score in predicting outcome. Another clinically relevant question is whether NERS II score can be used as a guiding tool to decide between PCI and CABG, for any patient with UPLMCAD. For this, all 41 patients will initially be divided into LOW NERS (16 patients) and HIGH NERS group (25 patients). In order to test this hypothesis, we need to demonstrate that within each of these groups (LOW and HIGH) there is statistically significant difference in outcome between PCI and CABG patients. Among the HIGH NERS group (25 patients), patients undergoing CABG (15 patients) were compared to those undergoing PCI (10 patients). Similarly among LOW NERS group (16 patients), patients undergoing CABG (6 patients) were compared to those undergoing PCI (10 patients). This comparison was done with respect to all 6 clinical outcome variables. Statistical analysis, showed that there was no significant difference in outcome between CABG and PCI patients in both low and high risk patients indicating that NERS II score cannot be used as a tool to make a decision between PCI and CABG. Only with respect to TMT positivity in High NERS II patients, p value was slightly nearing significance. However it has to be noted that this was a non-randomized study, wherein the choice of PCI or CABG for a particular patient was purely based on operator discretion, which could be based on clinical, biochemical, and angiographic parameters. Analysis showed that there was statistically significant difference between PCI and CABG patients with respect to baseline clinical and angiographic variables, which would directly affect outcome.

**Limitation**

Since this was a single centre study, done within a limited time period, and also because the disease (UPLMCAD) has a lesser incidence compared to other coronary artery disease. Total number of patients available for recruitment was limited and sample size is small. Because of the limited sample population, there was uneven distribution among baseline clinical variables, which could not be adjusted for. E.g: a) Almost 50% of PCI patients, but only 5 % of CABG patients were females. b) There were no bifurcation lesions in study population, while 90% of study patients had distal non-bifurcation lesions. All these factors will definitely make the study biased.

**Sample population was non randomized**

To assess role of NERS II score to decide between PCI/CABG, Comparison of the two modalities of treatment (PCI/CABG) would be more fruitful if the study population was randomised. The study patients were those who after a Coronary angiogram were assigned to a particular mode of treatment (PCI Vs CABG) purely on operator discretion, which obviously was based on clinical and angiographic profile. Hence the 2 groups were significantly different w.r.t baseline variables which in turn would affect the clinical outcome.

**Conclusion**

In cases of revascularization (P C I / C A B G) of Unprotected Left Main coronary Artery disease (UPLMCAD), NERS II score is an effective tool to predict clinical outcome in the form of symptom relief. However with respect to MACE events, although there was a definite poorer outcome with high NERS II score. There was no statistically significant between – group differences. This was probably due to lesser number of events, which was secondary to small sample size of population. A larger sample study, with more outcome events, can probably increase the power and significance of this score in predicting MACE events. Using the cut-off NERS II score, we can risk stratify UPLMCAD patients as LOW RISK NERS II (< 16.55), and HIGH RISK NERS II (>/= 16.55) with sensitivity of 87.5% and a specificity of 81.8%. These two groups were shown to have statistically significant difference with respect to clinical outcome. With respect to role of NERS II score in acting as a guiding tool to decide between PCI Vs CABG. This study did not show any statistically significant difference in outcome between PCI and CABG in either low or high NERS II score patients. Results could be largely affected by the non-randomised nature. However this being a pilot study, helps by highlighting a definite relevance of NERS II, with respect to revascularisation of UPLMCAD (PCI & CABG).

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