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A. Introduction
Bangladesh Heart Journal is the official journal of Bangladesh Cardiac Society, and accepts articles for publication from home and abroad. This is a biannual, peer-reviewed journal and aims to publish work of the highest quality from all sub-specialties of cardiology and cardiovascular surgery. The aim of the publication is to promote research in Bangladesh and serve as platform for dissemination of scientific information in cardiology.

B. Categories of Articles
The journal accepts original research, review articles, case reports, cardiovascular images and letters to the editor, for publication.

Original Research:
Original, in-depth research article that represents new and significant contributions to medical science. Each manuscript should be accompanied by a structured abstract of up to 250 words using the following headings: Objective, Methods, Results, and Conclusions. Three to 5 keywords to facilitate indexing should be provided in alphabetical order below the abstract. The text should be arranged in sections on INTRODUCTION, METHODS, RESULTS and DISCUSSION. The typical text length for such contributions is up to 3000 words (including title page, abstract, tables, figures, acknowledgments and key messages). Number of references should be limited to 50.

Review Articles:
Generally review articles are by invitation only. But unsolicited reviews will be considered for publication on merit basis. Following types of articles can be submitted under this category: Newer drugs, new technologies and review of a current concept. The manuscript should not exceed 5000 words (including tables and figures). A review article should include an abstract of up to 250 words describing the need and purpose of review, methods used for locating, selecting, extracting and synthesizing data, and main conclusions. The number of references should be limited to 50.

Case Reports:
Only case reports of exceptional quality will be published in the case report format. The text should not exceed 1500 words and is arranged as introduction, case report and discussion. Include a brief abstract of about 150 words. Number of tables/figures should be limited to 3. Include up to 10 most recent references. The patient’s written consent, or that of the legal guardian, to publication must be obtained.

Cardiovascular Images:
Only clinical photographs with or without accompanying skiagrams, pathological images, echocardiographic images, angiographic images etc. are considered for publication. Image should clearly identify the condition and have the classical characteristics of the clinical condition. Clinical photographs of condition which are very common, where diagnosis is obvious, or where diagnosis is not at all possible on images alone would not be considered. Photographs should be of high quality, usually 127 × 173 mm (5 × 7 in) but no larger than 203 × 254 mm (8 × 10 in). A short text of up to 250 words depicting the condition is needed. Figures should be placed exactly at a logical place in the manuscript. The submitted images should be of high resolution (>300 dpi). The following file types are acceptable: JPEG and TIFF. The number of authors should not exceed 3. The authors should ensure that images of similar nature have not been published earlier. Authors must obtain signed informed consent from the patient, or the legal guardian.

Letter to the Editor:
Letters commenting upon recent articles in Bangladesh Heart Journal are welcome. Such letters should be received within 16 weeks of the article’s publication. Letters should be up to 250 words; should contain no more than 1 figure/table and up to 5 most recent references. The text need not be divided into sections. The number of authors should not exceed 3.

C. Criteria for Acceptance
All manuscripts should meet the following criteria: the material is original, study methods are appropriate, data are sound, conclusions are reasonable and supported by the data, and the information is important; the topic has general cardiology interest; and that the article is written in reasonably good English. Manuscripts which do not follow the guidelines of Bangladesh Heart Journal are likely to be sent back to authors without initiating the peer-review process. All accepted manuscripts are subject to editorial modifications to suit the language and style of Bangladesh Heart Journal and suggestions may be made to the authors by the Editorial Board to improve the scientific value of the journal.

D. Editorial Process
The Bangladesh Heart Journal commits to high ethical and scientific standards. Submitted manuscripts are considered with the understanding that they have not been published previously in print or electronic format (except
in abstract or poster form) and are not under consideration by another publication or electronic medium. Statements and opinions expressed in the articles published in the Journal are those of the authors and not necessarily of the Editor. Neither the Editor nor the Publisher guarantees, warrants, or endorses any product or service advertised in the Journal. Bangladesh Heart Journal follows the guidelines on editorial independence produced by the International Committee of Medical Journal Editors (ICMJE). All manuscripts correctly submitted to the Bangladesh Heart Journal are first reviewed by the Editors. Manuscripts are evaluated according to their scientific merit, originality, validity of the material presented and readability. Some manuscripts are returned back to the authors at this stage if the paper is deemed inappropriate for publication in the Bangladesh Heart Journal, if the paper does not meet the submission requirements, or if the paper is not deemed to have a sufficiently high priority. All papers considered suitable by the Editors for progress further in the review process, undergo peer review by at least two reviewers. If there is any gross discrepancy between the comments of two reviewers, it is sent to a third reviewer. Peer reviewers’ identities are kept confidential; authors’ identities are also not disclosed to the reviewers. Accepted articles are edited, without altering the meaning, to improve clarity and understanding. Decision about provisional or final acceptance is communicated within 8 weeks.

E. Cover Letter
The cover letter should outline the importance and uniqueness of the work. It should include the signed declaration from all authors on:

1. Category of manuscript (original research, review article, case report, cardiovascular image, letter to the Editor)
2. Statement that the material has not been previously published or submitted elsewhere for publication (this restriction does not apply to abstracts published in connection with scientific meetings.)
3. Transfer of copyright to the Bangladesh Heart Journal upon the acceptance of the manuscript for publication
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The cover letter should also include the mailing address, telephone and fax numbers, and e-mail address of the corresponding author.

F. Manuscript Preparation
The manuscripts should comply with the prescribed guidelines. It should be well organized and written in simple and correct English under appropriate headings. The abbreviations and acronyms should be spelled out when they occur first time.

The Introduction should address the subject of the paper. The Methods section should describe in adequate detail the laboratory or study methods followed and state the statistical procedures employed in the research. This section should also identify the ethical guidelines followed by the investigators with regard to the population, patient samples or animal specimens used. A statement should be made, where applicable, that their study conforms to widely accepted ethical principles guiding human research (such as the Declaration of Helsinki) AND also that their study has been approved by a local ethics committee.

The Results section should be concise and include pertinent findings and necessary tables and figures. The Discussion should contain conclusions based on the major findings of the study, a review of the relevant literature, clinical application of the conclusions and future research implications. Following the Discussion, Acknowledgements of important contributors and funding agencies may be given.

a. Title page information
   • Title. Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations where possible.
   • Author names and affiliations. Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. Present the authors’ affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower case superscript letter immediately after the author’s name and in front of the appropriate address. Provide the e-mail address of each author.
   • Corresponding author. Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. Ensure that the e-mail address is given and that contact details are kept up to date by the corresponding author.

b. Abstract
A concise and factual abstract is required. The abstract should state briefly the purpose of the research, the principal results and major conclusions. An abstract is often presented separately from the article, so it must be able to stand alone. References should be avoided. Also, non-standard or uncommon abbreviations should be
avoided, but if essential they must be defined at their first mention in the abstract itself.

c. Keywords
Immediately after the abstract, provide a maximum of 5 keywords. Keywords should be the listed terms in the Medical Subject’s Headings (MeSH) of the National Library of Medicine (NLM), available at https://www.nlm.nih.gov/mesh.

d. Abbreviations
Define abbreviations that are not standard in this field in a footnote to be placed on the first page of the article. Such abbreviations that are unavoidable in the abstract must be defined at their first mention there, as well as in the footnote. Ensure consistency of abbreviations throughout the article.

e. Acknowledgements
Collate acknowledgements in a separate section at the end of the article before the references. List here those individuals who provided help during the research (e.g., providing language help, writing assistance or proof reading the article, etc.).

f. Units
Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI. Generic rather than trade names of drugs should be used.

g. Figures and graphics
• For graphics, a digital picture of 300 dpi or higher resolution in JPEG or TIFF format should be submitted.
• Figures should be numbered consecutively according to the order in which they have been first cited in the text, if there is more than 1 figure. Each figure should be cited in the text.
• Each figure/illustration should be provided with a suitable legend that includes enough information to permit its interpretation without reference to the text.
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• When symbols, arrows, numbers or letters are used to identify parts of the illustrations, each one should be explained clearly in the legend.

h. Tables
Tables should be placed next to the relevant text in the article.
• Number tables consecutively in accordance with their appearance in the text. Each table should be cited in the text in Arabic numerals.

i. References
References should follow the standards summarized in the NLM’s International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals (ICMJE recommendations), available at: http://www.icmje.org/recommendations/. The titles of journals should be abbreviated according to the style used for MEDLINE (www.ncbi.nlm.nih.gov/nlmcatalog/journals). Journals that are not indexed should be written in full.
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• The names of authors in the text should concur with the reference list.
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• In general: All authors/editors should be listed unless the number exceeds six, when you should give six followed by “et al.”
Examples of correct forms of references are given below:

**Articles in Journals** (see also *Journal article on the Internet*).

1. **Standard journal article**
   - List the first six authors followed by et al.

2. **Organization as author**

3. **Both personal authors and organization as author** (List all as they appear in the byline.)

4. **Volume with supplement**

5. **Issue with supplement**

6. **Type of article indicated as needed**

7. **Article published electronically ahead of the print version**

**Books and Other Monographs**

1. **Personal author(s)**

2. **Editor(s), compiler(s) as author**

3. **Organization(s) as author**

4. **Chapter in a book**

5. **Conference proceedings**

6. **Dissertation or thesis**

**Other Published Material**

**Newspaper article**


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Article with a Digital Object Identifier (DOI):

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3. **Homepage/Web site**

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As part of the submission process, authors are required to check off their submission’s compliance with all of the following items, and submissions may be returned to authors that do not adhere to these guidelines.

1. The submission has not been previously published elsewhere, is original and has been written by the stated authors.

2. The article is not currently being considered for publication by any other journal and will not be submitted for such review while under review by the Bangladesh Heart Journal.

3. The submission file is in Microsoft Word file format, and the figures are in JPEG or TIFF format.

4. The text is single-spaced; uses a 12-point font; employs italics, rather than underlining (except with URL addresses); and all illustrations, figures, and tables are placed within the text at the appropriate points, rather than at the end.

5. The text adheres to the stylistic and bibliographic requirements outlined in the Instruction to Authors. Make sure that the references have been written according to the ICMJE Recommendations Style.

6. Spell and grammar checks have been performed.

7. All authors have read the manuscript and agree to publish it.

**H. Submission**
Papers should be submitted to the Editor. Three copies of manuscript should be submitted duly signed by all authors with a copy of CD, to:

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Characteristics of Disease Profile of Hospitalized Patients Referred to the Department of Cardiology in a Tertiary Care Hospital

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Abstract:
Objectives: Cardiology consultation for hospitalized patients is a common and sometimes mandatory practice in every country. This is because of increased morbidity and mortality of cardiac cases that also has other co-morbidities. We conducted this study to know the pattern of disease profile and the idea of requesting doctors about the cardiac diseases from the cases they referred to the department of Cardiology.

Methods: This prospective observational study was carried out in BIRDEM General Hospital, Shahbag, Dhaka from July to December 2017. We followed every case till the final and confirmed diagnoses were made. All the relevant collected data were compiled on a master data sheet. All findings were expressed as frequency with percentage and analysis were done using SPSS for windows version 22.0.

Results: This study revealed that majority of the referred cases to the department of cardiology was routine (84.4%) and non-cardiac (57%). Non-cardiac cases were referred mainly for the fitness of general anesthesia (GA) (18.4%). But among the critical cases (14.0%), mostly were cardiac (9.1%). Among all the cardiac cases, Hypertension (8.8%) got the highest referral followed by Acute Myocardial Infarction (AMI) (3.8%) and Dilated Cardiomyopathy (DCM) (3.8%).

Conclusions: Hospitalized patients were referred to the department of Cardiology differs according to the requesting unit. The surgical units referred their cases to get the cardiac clearance for a major surgery and the medical units referred for typical cardiac emergencies like AMI.

Key words: Cardiology, Referral, Hospitalized patients

Introduction:
It is a very common practice in medical science to refer a patient to a specialist for the purpose of better as well as more specific treatment. Not only complicated or undiagnosed cases are referred but also for taking a better second opinion is considered. Even hypertension is well managed in a primary care setting; still there are many referrals to the cardiologists for uncontrolled one.¹ For hospitalized patients with multiple co-morbidities may need referral to more than one specialist care. In many hospitalized cases atypical presentations (eg in older age, women, diabetes mellitus) of a serious disease may causes aggravation of the primary disease for delayed referral.²⁻⁴ Internationally there are many recommendations of different institutions and bodies about how and when to refer a patient cardiology unit. For example, in Queensl...
before referring a patient to the cardiologist a confirm diagnosis of cardiac disease has to be made clinically as well as by relevant investigations. But it is more or less common in every recommendation about urgent referral which includes acute coronary syndrome (ACS), acute left ventricular failure (LVF), fatal arrhythmias (eg, ventricular tachycardia, complete heart block, etc).

BIRDEM General Hospital is one of the largest tertiary care hospital in the center of the capital of Bangladesh which deals mainly with diabetic patients. As the diabetes mellitus is a multi-faced chronic disease, most of our patients have multiple co-morbidities. Thus it is natural that they need a team work for proper management. We conduct a trial of cross sectional for six months to see the disease profile of patients referred to the department of cardiology from different medical, surgical and gynecological units as well as to observe the idea of non-cardiologist about cardiac diseases. This type of referrals is given from all units on daily basis for mainly excluding any serious cardiac problems that may mimic other medical problems.

Materials and Methods:
This is a prospective observational study carried out, in BIRDEM General Hospital a tertiary care hospital, from July to December 2017. Our main objective was to see which condition of the patient compelled a doctor to take suggestion from the cardiology department. We excluded patients who were below 18 years of age, known psychiatric patients, and whose diagnoses were not confirmed during hospital stay. After excluding these cases, total number of patients referred to our unit was 668. We followed every case till the final and confirmed diagnoses were made. After confirming the diagnoses we categorized the patients into following groups: Referring unit, types of referral (urgent and routine), condition of the patients (asymptomatic, symptomatic but stable, symptomatic and critical), and cardiac or non-cardiac cases. By urgent referral, the referring unit commonly indicates symptomatic and/or critical cases need prompt management. Many routine cases were asymptomatic and they were referred to us mainly for taking cardiac fitness for giving general anesthesia (GA). All the relevant collected data were compiled on a master data sheet. Data entry and analysis were done using SPSS for windows version 22.0. Frequency and percentage were calculated to find out the proportion of the findings.
Most of the total referred cases were routine (n=564, 84.4%). Among all the referral, more than half were diagnosed to have non-cardiac illness (n=382, 57%), or at least cardiac status was stable (Figure: 2 and 3).

Total number & percentage of critical patients (n=94, 14.0%) were mostly cardiac (n= 61, 9.1%). Most of them were AMI and DCM with left ventricular failure (LVF).

The top ten causes of referral were as follows: Fitness for general anesthesia (GA) (n=123, 18.4%), interpreting ECG (n=66, 9.8%), hypertension (n=59, 8.8%), routine cardiac consultation (n=44, 6.5%), stable angina (=35, 5.2%), severe left ventricular (LV) systolic dysfunction (n=28, 4.1%), AMI (n=26, 3.8%), DCM (n=26, 3.8%), chronic LVF (n= 18, 2.6%), atrial fibrillation (AF) (n=14, 2.0%).

Most critical cardiac cases were referred by Surgery unit-2 (6 cases of AMI), Endocrinology unit (6 cases of AMI), and Nephrology units (12 cases of DCM).

Discussion:
Taking cardiology consultation from a non-cardiac case is common in every hospital.8 This is because of not only for excluding any cardiac diseases but also to make sure that no serious cardiac disease of atypical presentation is missed which can be fatal for the patients.2-4, 9 We conducted this cross sectional study with the main purpose of making a disease profile of the patients.

Majority of the referred cases were routine (84.4%) and patients were asymptomatic with stable clinical condition. Among all the referrals, numbers of cardiac cases were 286 (42.8%) and non-cardiac cases were 382 (57.1%). Increased number of non-cardiac cases is likely due to avoid any case fatality because atypical presentation of cardiac cases in elderly and diabetic patients are very common world wide2,3,9, and specially, diagnosis of chest pain of various reason may need to identify first in any such cases. A large number of cases (6.5%) were referred to us without asking for any cardiac management, and these referred cases were also asymptomatic. Though we categorize these cases as “unknown” cause of referral, it is evident that taking a routine cardiology consultation of a diabetic patient in the form of “routine check-up” was the main reason. This is also the same cause of referral to the cardiology unit in abroad.8

As a universal rule, the frequency of taking cardiology consultation before going for surgery (esp under GA) is much higher than from other medical specality.8 This is why, in our study also reflects this pattern of referral. Interpreting ECG is an interesting cause of referral, because all of these patients were completely asymptomatic and their ECG findings were also normal. We think, therefore, these were also a part of routine cardiac check-up. Some non-cardiac cases drew our attention. These were End Stage Renal Disease (ESRD), sepsis, Multi Organ Dysfunction Syndrome (MODS), headache, pneumonia, hypothyroidism, stroke, bronchial asthma, etc. Because, though they were primarily non-cardiac, they could, either, affect the cardiovascular
system during the course of the disease, or might be the effect of some cardiac drugs (eg, nitrate, beta blocker). Interestingly, a good number of critical cardiac cases were initially admitted in Surgical unit and nephrology units for their atypical presentations. Six cases of AMI were admitted in Surgical unit with upper abdominal pain and vomiting, and 12 cases of DCM were admitted in Nephrology units with generalized body swelling with nausea. It is common for the diabetic patients with ACS to present with atypical symptoms. Most surprising causes of referral, though insignificant in number, were urinary tract infection (UTI) (n=2, 0.3%), peripheral neuropathy (n=2, 0.3%), acute pancreatitis (n=1, 0.1%), aphasia (n=1, 0.1%), fitness for local anesthesia (n=1, 0.1%), and pain in the eye following eye surgery (n=1, 0.1%). We could not find any cardiac disease in any of these patients during their hospital stay. This study had some limitations. First, this was an observational study. Analytical study may reveal some association that may alter the management plan. Second, the absence of demography of the patients, which, if present, may further enrich the disease profile. Third, this was a single center study and the requesting doctors were not asked about the cause of referral in obscured cases. Fourth, no associated co-morbidities were included in our study. If these were included, not only the magnitude of the problems was clarified but also the prognosis of many cases (esp the critical ones) could be predicted.

There were several strength of our study. To our knowledge, this study was one of the largest studies in our country on hospitalized patients. We did not collected the referral data according to the requesting doctors, but we also followed every cases (where needed) to reach a confirmed diagnosis to avoid the referral bias. For example, few cases were referred for suspected arrythmia. But after thorough evaluation, they were finally diagnosed to have anxiety neurosis. Moreover, referral were categorized as urgent, routine, critical, stable, cardiac, and non-cardiac to understand the magnitude of the problem, and also, the idea of the requesting doctors more clearly. We also meticulously searched the association between non-cardiac cases and possible cardiac involvement as described earlier. This study can give an idea to both the cardiologist as well as other doctors about the pattern of referral. We emphasize the importance of non-cardiology doctors for all resident doctors to identify cardiac emergencies as well as non-cardiac critical conditions mimicking cardiac disease to avoid case fatalities. This, like other hospital, will distribute the workload equally among doctors.¹⁰

References:
SYNTAX Score on Procedural Outcome among Patient Undergoing Primary Percutaneous Coronary Intervention

Md Shariful Islam¹, Md Afzalur Rahman², Abdul Wadud Chowdhury³, Mohsin Ahmed⁴, Kajal Kumar Karmakar⁵, Mohammad Ullah Firoz⁶, Mohammad Arifur Rahman⁷, Md Moshrul Haque⁸, Mohammad Sadaqul Islam Sikdar⁹, Ashrafuzzaman Tamal¹⁰, Abul khair Md. Rezawan Islam¹¹, Muhammad Ruhul Amin¹², Abeeda Tasnim Reza¹³, F. Aaysha Cader¹⁴

Abstract:
Background: Limited contemporary data exist regarding the impact of SYNTAX score on procedural outcomes undergoing primary percutaneous coronary intervention (PCI) in acute STEMI patients.

Objectives: To evaluate the significance of the SYNTAX score for predicting procedural outcome after primary PCI in patient with acute STEMI.

Methods: This perspective observational study was conducted in the department of cardiology, National Institute of Cardiovascular Diseases, Dhaka, Bangladesh from September, 2015 to September, 2016. 42 patients with acute STEMI who underwent primary PCI were considered for the study. But 2 patients were excluded from the study due to failure of primary PCI. The patients were divided into two groups: Group I (low Syntax score ≤ 22) and Group II (high Syntax score > 22). The Syntax score of all patients were calculated from an initial coronary angiogram before primary PCI. Procedural outcome was observed in between two groups.

Results: Among study patients 57.5% were in SYNTAX score ≤ 22 (Group I) and 42.5% were in SYNTAX score > 22 (Group II). Among traditional cardiovascular risk factors diabetes was significantly more prevalent in the Group II than Group I (82.4% vs 34.8%, p = 0.003). Angiographic profile revealed maximum (69.6% vs 17.6%) culprit lesion in LAD artery in Group I and maximum culprit lesion (64.7% vs 21.7%) in RCA in Group II, these were the statistically significant between Group I and Group II (P<0.05). The high SYNTAX score group had lower ejection fraction (47.8±5.1 vs. 54.4±4.3, p = 0.04), lower TIMI flow 3 rate (76.47% vs 91.3%, p = 0.03) greater rate of MACE (29.4% vs. 4.3%, p=0.041), lower procedural success rate (76.47 vs. 91.3%, p=0.046) compared to the low SYNTAX score group. ROC curve showed 77% sensitivity and 32% specificity for SYNTAX score when cut off value was 22 Performance test of SYNTAX score in the setting of Primary PCI outcome showed positive predictive value 83%.

Conclusions: SYNTAX score was an independent variable that can predict procedural outcomes of patients with acute STEMI undergoing primary PCI.

Keywords: SYNTAX score, Primary PCI, STEMI
Introduction:
Cardiovascular diseases account for more than 17 million deaths globally each year. This figure is to grow to 23.6 million by the year 2030.\(^1\) Estimates from the global burden of disease study suggests that by the year 2020 the South Asian part of the world (India, Pakistan, Bangladesh, Nepal) will have more individuals with atherosclerotic cardiovascular diseases than any other region.\(^2\)

Primary PCI reduces the risk for mortality and subsequent myocardial infarction when compared with medical therapy in patients with acute coronary syndromes. However, the invasive mechanical reperfusion strategies have their own complications. Major complications include death, MI, or stroke, and minor complications include transient ischemic attacks, vascular complications, contrast induced nephropathy, and angiographic complications.

Originally, the SYNTAX score was designed to grade the complexity of stable coronary artery disease. Higher values of this score, reflecting a more challenging coronary anatomy for the interventional cardiologist, also predict a worse prognosis after acute STEMI.\(^3\) Patients with very low predicted mortality could benefit from early discharge from the intensive care unit and from the hospital, resulting in better clinical care and optimization of health resources. In contrast, morbidity and mortality after STEMI are still high in other subgroups.\(^4\)

The aim of the study is to investigate the usefulness of SYNTAX score in predicting outcome of primary PCI in acute STEMI patients in terms of severity and complexity of CAD.

Methods:
This prospective observational study was conducted in the Department of Cardiology, National Institute of Cardiovascular Diseases, Dhaka, Bangladesh from September, 2015 to September, 2016. The study included patients with acute STEMI who undergone primary PCI during the study period. Patients with valvular heart diseases, congenital heart diseases, prior MI, PCI or CABG and severe comorbidities were excluded.

Proper medications was given in CCU. After adequate explanation Coronary angiogram (CA) was done by conventional method. Angiographic pattern and CAD severity assessment was done by visual estimation.

The SYNTAX scores of all patients were calculated by 2 independent experienced interventional cardiologists, using online version of SYNTAX calculator who were blinded to the identities. The patients were divided into 2 groups, those with low SYNTAX scores \(\leq 22\) (Group I) and those with intermediate to high SYNTAX scores \(> 22\) (Group II).\(^5\)

Data analysis was performed using SPSS version 16. Categorical variables were expressed as frequency and percentage and continuous variables as mean and standard deviation. Data was analyzed by student’s t-test, chi-square test and Fisher exact test. Multivariate logistic regression analysis was done to assess the effect of independent variable and adjustment was done for confounding variable.

Results:
Total 42 patients with acute STEMI who underwent primary PCI were enrolled in this study. The main objective of the study was to determine impact of SYNTAX score for predicting In-hospital outcome after primary PCI in patients with acute STEMI. Two patients were excluded from this study due to primary PCI failure. In our study

### Table I

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Group I (n=23)</th>
<th>Group II (n=17)</th>
<th>Total (n=40)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean age±SD</strong></td>
<td>51.40±13.20</td>
<td>46.00±13.56</td>
<td>0.397 (\text{ns})</td>
<td></td>
</tr>
<tr>
<td><strong>Smoking</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>13</td>
<td>14</td>
<td>27</td>
<td>0.085 (\text{ns})</td>
</tr>
<tr>
<td>%</td>
<td>56.5</td>
<td>82.4</td>
<td>67.5</td>
<td></td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>14</td>
<td>11</td>
<td>25</td>
<td>0.804 (\text{ns})</td>
</tr>
<tr>
<td>%</td>
<td>60.9</td>
<td>64.7</td>
<td>62.5</td>
<td></td>
</tr>
<tr>
<td><strong>DM</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>8</td>
<td>14</td>
<td>22</td>
<td>0.003 (\text{s})</td>
</tr>
<tr>
<td>%</td>
<td>34.8</td>
<td>82.4</td>
<td>75.0</td>
<td></td>
</tr>
<tr>
<td><strong>Dyslipidemia</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>11</td>
<td>13</td>
<td>24</td>
<td>0.068 (\text{ns})</td>
</tr>
<tr>
<td>%</td>
<td>47.8</td>
<td>76.5</td>
<td>60.0</td>
<td></td>
</tr>
<tr>
<td><strong>Family history of IHD</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>5</td>
<td>6</td>
<td>11</td>
<td>0.343 (\text{ns})</td>
</tr>
<tr>
<td>%</td>
<td>21.7</td>
<td>35.3</td>
<td>27.5</td>
<td></td>
</tr>
<tr>
<td><strong>Culprit vessel</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAD</td>
<td>16</td>
<td>3</td>
<td>19</td>
<td>0.014 (\text{s})</td>
</tr>
<tr>
<td>LCX</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>RCA</td>
<td>5</td>
<td>11</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td><strong>TIMI flow</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>0.14 (\text{ns})</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>0.80 (\text{ns})</td>
</tr>
<tr>
<td>3</td>
<td>21</td>
<td>13</td>
<td>34</td>
<td>0.03 (\text{s})</td>
</tr>
</tbody>
</table>

Data were analysis using t test, chi-square and Fisher exact test

Group I: SYNTAX score \(\leq 22\); Group II: SYNTAX score \(> 22\);

ns-not significant; s- significant
57.5% were in SYNTAX score ≤22 (Group I) and 42.5% were in SYNTAX score >22 (Group II).

The mean age ± SD was 51.40±13.20 years in Group I and 46.00±13.56 years in Group II (Table I). The difference was not statistically significant. There are no significant difference of traditional cardiovascular risk factors among the Group I and Group II except DM which was statistically significant different in between two group. Angiographic profile (Table I) revealed maximum (69.6% vs 17.6%) culprit lesion in LAD artery in Group I and maximum culprit lesion (64.7% vs 21.7%) in RCA in Group II, these were the statistically significant between Group I and Group II (P<0.05). Angiographic outcome showed that 91.3% patient in Group I and 76.47% in Group II achieved TIMI flow 3 and the difference was statistically significant (p=0.03). In Group I 8.7% patients and 11.76% patient in Group II achieved TIMI flow 2 and the difference was not statistically significant (p=0.8). No patient in Group I and 11.76% patient in Group II achieved TIMI flow 1 and the difference was not statistically significant (p=0.14).

Table-II
Comparison of LVEF between two group of patients after primary PCI (%) (n=40)

<table>
<thead>
<tr>
<th>LVEF (%)</th>
<th>Group I n=23</th>
<th>Group II n=17</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;30(Severe)</td>
<td>0</td>
<td>0</td>
<td>0.001*</td>
</tr>
<tr>
<td>30-39(Moderate)</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>40-49(Mild)</td>
<td>6</td>
<td>5</td>
<td>0.001*</td>
</tr>
<tr>
<td>≥50(Normal)</td>
<td>17</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Mean±SD(Range)</td>
<td>56.4±4.3</td>
<td>53.8±3.15</td>
<td></td>
</tr>
</tbody>
</table>

Data were analysis using chi-square test and Fisher exact test
Group I= SYNTAX score ≤22; Group II: SYNTAX score >22
s- significant

The above table shows that mean LVEF was 54.4±4.3 in Group I and 47.8±5.1 in Group II and the difference was statistically significant (p=0.04).

Table-III
Comparison between two group of patients according to MACE (n=40)

<table>
<thead>
<tr>
<th>Outcome(MACE)</th>
<th>Group I n=23</th>
<th>Group II n=17</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present</td>
<td>1</td>
<td>5</td>
<td>0.041*</td>
</tr>
<tr>
<td>Absent</td>
<td>22</td>
<td>12</td>
<td></td>
</tr>
</tbody>
</table>

Data were analyzed using chi-square test and Fisher exact test
Group I= SYNTAX score <22
Group II=SYNTAX score >22
s-significant

Table shows that 4.3% patients experienced adverse in-hospital outcome in group I, on the contrary 29.4% patients had such experience in group II. So the table revealed that in hospital outcome significantly more in Group I than Group II. Adverse in-hospital outcome included death, re-infarction, cardiogenic shock, acute heart failure and significant arrhythmia.
Table-IV

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Group I (n=23)</th>
<th>Group II (n=17)</th>
<th>Total</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>%</td>
<td>No</td>
<td>%</td>
</tr>
<tr>
<td>Acute heart failure</td>
<td>1</td>
<td>2.5%</td>
<td>1</td>
<td>2.5%</td>
</tr>
<tr>
<td>Cardiogenic shock</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>2.5%</td>
</tr>
<tr>
<td>Significant arrhythmia</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>2.5%</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0%</td>
<td>2</td>
<td>5.0%</td>
</tr>
</tbody>
</table>

Data were analyzed using chi-square test and Fisher exact test: Group I= SYNTAX score ≤22; Group II= SYNTAX score >22 ns- not significant.

Complications of primary PCI in Group I Vs Group II: acute heart failure 2.5% Vs 2.5%, cardiogenic shock 0% Vs 2.5%, significant arrhythmia 0% Vs 2.5% and death 0% Vs 5% and total in-hospital outcome: acute heart failure 5%, cardiogenic shock 2.5%, significant arrhythmia 2.5% and death 5%.

Table-V

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Group I n=23</th>
<th>Group II n=17</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>%</td>
<td>No</td>
</tr>
<tr>
<td>Successful</td>
<td>23</td>
<td>100</td>
<td>14</td>
</tr>
<tr>
<td>Not successful</td>
<td>0</td>
<td>0%</td>
<td>3</td>
</tr>
</tbody>
</table>

Data were analyzed using chi-square test and Fisher exact test:
Group I= SYNTAX score ≤22
Group II=SYNTAX score >22
s-significant

Table shows that primary PCI was successful in 100% patients in Group I, on the contrary 92.5% in Group II. So the table revealed that successful primary PCI was significantly more in Group I than Group II.

The area under the receiver-operator characteristic (ROC) curves for prediction of SYNTAX Score area under curve(AUC) 0.803, which gave a cut off value of d”22 with 77% sensitivity and 32% specificity for prediction of significant (p=0.006).

Discussion:
The present study has a few literatures regarding the usefulness of the SYNTAX score for predicting procedural outcome after primary percutaneous coronary intervention in patient with acute STEMI.

We found diabetes to increase the risk of MACE in patients who received primary PCI for acute STEMI. In other words, diabetes was significantly more prevalent in the Group II. Various studies have also highlighted the short term (during hospitalization and the first year after the disease) and long term effects of diabetes on the MACE. Diabetes can thus be considered as a risk factor for MACE after primary PCI.

In this study, smoking did not have any negative effects on MACE. However, a previous research reported better...
reperfusion rate after primary PCI in smokers. High arterial blood pressure is a risk factor for coronary artery disease and increases the risk of complications after acute coronary syndrome. However, we did not find significant differences in level of blood pressure between the two groups. Hyperlipidemia is a risk factor for coronary artery disease, it has no significant effects on the incidence of MACE in our study. Some studies have identified high levels of lipoprotein (a) to be associated with poor outcome in patients with acute myocardial infarction.

Angiographic profile in our study showed that left anterior descending (LAD) artery was the most common (47.5%) culprit vessel followed by right coronary artery (RCA) was 40% and left circumflex artery (LCX) was 12.5%. These were similar to the finding (LAD 51.2%, RCA 38.5% and LCX 10.2%).

The post procedural that mean L VEF was 54.4±4.3 in Group I and 47.8±5.1 in Group II which was similar to the finding of mean LVEF 44.6 ± 8.8% and 38.2±7.5%.

Systolic function of the left ventricle after AMI is one of the most important predictors of long term outcomes. In our study, patients with high SYNTAX score had lower EF. Patients with high SYNTAX score had more multivessel disease, chronic total occlusion and LAD occlusion, so the myocardium of these patients had a greater ischemic area and subsequently lower ejection fraction.

Our study showed that the patient presented with acute STEMI and having SYNTAX score >22 are associated with a higher rate of MACE. Tobbia, et al. showed that MACE was 28.2%. In the high SYNTAX score group, the presence of complex coronary anatomy was abundant and this had been associated with more no-reflow, systolic dysfunction and higher rates of re-infarction. In addition, more diabetic patients were in the high SYNTAX score group.

On the other hand failed primary PCI was 5% in our study. The overall PCI failure rate was 5.4%. They concluded that independent predictor of primary PCI failure included age >65 years, procedure time, calcification, lower preprocedural TIMI flow. Barbash, et al. showed that female gender, cardiogenic shock, previous PCI and type C lesion are independent predictors of primary PCI failure. In our study we observed that PCI failure due to high SYNTAX score, heavily calcification and type C lesion.

Though the small number of failed primary PCI in our study, we hardly concluded that failed primary PCI is associated with high SYNTAX score. Finally ROC curve revealed that cut off value 22 for SYNTAX score in our study showed 77% sensitivity and 32% specificity and positive predictive value was 83%.

Conclusion:
This study demonstrates that a high SYNTAX appeared reproducible, feasible and prognostic information with regards to procedural outcome. In our acute STEMI cohort, risk of cardiovascular event was notably increased during index hospitalization. So we proposed that the SYNTAX score can be used for risk stratification in patients undergoing primary PCI.

Limitations:
Interpretation of angiograms and assessment of the SYNTAX score was not performed by QCA. Although the result of the study supports the hypothesis, during study we face several limitations such as coronary angiogram was evaluated by visual estimation. So there was chance of interobserver and intraobserver variation to calculate the SYNTAX score. The study was carried out only in single centre, study period was short sample size was small it was a non randomized study.

Conflict of interest- None

References:


Abstract:
Background: Preoperative risk assessment before cardiac surgery to predict mortality become literally important and practicing worldwide, whereas EuroSCORE II is most updated and popular. So we examined the hypothesis that Performance of EuroSCORE II in predicting early mortality after Mitral, Aortic or mitral & aortic valve surgery patients in National Heart Foundation Hospital and Research Institute.

Objectives: To compare EuroSCORE II predicted early mortality and observed early mortality in a sample of patients of National Heart Foundation Hospital who underwent for Mitral, Aortic or Mitral & Aortic valve surgery.

Methods: An observational prospective study was done in Department of cardiac surgery, National Heart Foundation Hospital and Research Institute who underwent for Mitral, Aortic or Mitral & Aortic valve surgery in the period of July 2016 to March 2018. Sample size was 356 and all inclusion criteria full filled. Patients were divided into 3 group (low, medium & high) depending on the score. Model discrimination and calibration were assessed additive and logistic EuroSCORE and EuroSCORE II.

Results: The in hospital mortality of this series was 2.8% (10 out of 356) and the predicted mortality was 2.73% (95% CI 1.02-4.38) by the EuroSCORE II, 2.15% (95% CI 0.68-3.72) by the additive method and 2.25% (95% CI 0.74-3.86) by the logistic EuroSCORE. The model's discriminatory power also good and useful as indicated by an area under ROC curve of 0.779 in EuroSCORE II model, 0.675 in additive method and 0.696 in logistic method that means EuroSCORE II method can predict the outcome with 77% accuracy, additive method with 67% accuracy and the logistic method does that with 69% accuracy.

Conclusion: EuroSCORE II was validated and performed well on National Heart Foundation patients and could be recommended as a simple risk stratification system to estimate the probability of early mortality in patients scheduled for valve surgery in Bangladesh.

Key Words: EUROSCORE-II, Heart Valve Surgery
Introduction
Preoperative risk stratification has become a core issue for patients with valve surgery, because progress in operative and perioperative care has led to a wide extension of surgical indications, addressing by surgical intervention even patients with severe multiple comorbidities who were previously treated with medical therapy. In this scenario, perioperative death cannot be considered the only quality measure, and the overall preoperative assessment of patients should also take into account the life expectancy after the valve operation (Fabio, et al., 2016).

EuroSCORE (European System for Cardiac Operative Risk Evaluation) is a risk model which allows the calculation of the risk of death after a heart operation. EuroSCORE, first developed as an additive model (additive EuroSCORE, AES) first published in 1999. It was based on data collected from 128 centers of eight European countries (German, France, United Kingdom, Italy, Spain, Finland, Sweden and Switzerland). The model asks for 17 items of information about the patient, the state of the heart and the proposed operation, and uses logistic regression to calculate the risk of death. However this model generally overestimates mortality in low risk patients and underestimates it in high risk groups (Shanmugam, et al., 2005).

Then logistic EuroSCORE (LES) was published in 2003 (Roques, et al., 2003) to gain predictive performance in high risk group. The model has been adopted worldwide, becoming the most widely used risk index for cardiac surgery. Over the last few years, several professionals from many parts of the world have reported that the model now overpredicts risk, as a result of cardiac surgery have improved significantly. To overcome this effect an updated version of this model named EuroSCORE II - was announced at the EACTS meeting in Lisbon on Monday, 3 October 2011 and published in the European Journal of Cardiothoracic Surgery in April 2012, based on the logistic regression analysis of 23,000 patients in 150 hospitals in 43 countries over a 12 week period (May – July 2010) (Mohammad, et al., 2016).

EuroSCORE II, the updated version, has better discriminative power & calibration. The discriminative power is important to determine how the model distinguishes between alive & died patients during in-hospital period. Calibration is also important to determine the agreement between the real observed & predicted mortality. The discriminatory power and precision in risk prediction of the EuroSCORE II in mitral and aortic valve surgery has recently become increasingly important for 2 reason. First - In the most centers, valve procedures, either isolated or combined actually represent more than 30% of the total caseload, therefore, accurate risk estimation in this patient population, mainly elderly and very elderly people has become much more important. The second reason, is strictly related to the recent evolution in technical options in valve operations- minimally invasive valve surgery in patients at the high risk.

In UK, a dedicated website collected prospective risk and outcome data on 22,381 consecutive patients undergoing major cardiac surgery in 154 hospitals in 43 countries over a 12-week period (May–July 2010). Information was obtained on existing EuroSCORE risk factors and additional factors proven to influence risk from research conducted since the original model. The outcome was early mortality after valve surgery (within 30 days). A logistic risk model (EuroSCORE II) was then constructed and tested. Results shows Compared with the original 1995 EuroSCORE database (in brackets) Overall mortality was 3.9% (4.6%). When applied to the current data, the old risk models over predicted mortality (actual: 3.9%; additive predicted: 5.8%; logistic predicted: 7.57%). EuroSCORE II was well calibrated on testing in the validation data subset of 5553 patients (actual mortality: 4.18%; predicted: 3.95%). Very good discrimination was maintained with an area under the receiver operating characteristic curve of 0.8095 (Nashef, et al., 2012).

A literature search identified 37 potentially eligible studies, and 12 were selected for meta-analysis comprising 26,621 patients with 1250 events (mortality rate, 4.7%). Meta-analysis of these studies provided an average area under the curve (AUC) value of 0.730. The same results were obtained when meta-analyses were performed separately, in the seven studies reporting (8175 patients with 358 events; mortality rate, 4.4%); the ROC curve provided an average AUC value of 0.724. The five studies not reporting reliable uncertainty estimation (18,446 patients with 892 events; mortality rate, 4.8%) had an average AUC of 0.732. Studies documented a constant trend to over predict mortality by EuroSCORE, both in the additive and especially in the logistic form. In conclusion, The EuroSCORE has low discrimination ability for valve surgery, and it sensibly over predicts risk. Alternative risk scoring algorithms, EuroSCORE II should be seriously considered (Alessandro, et al., 2010).

National Heart Foundation Hospital and Research Institute (NHF&RI), Dhaka, is a high volume cardiac center in Bangladesh. At NHF&RI, previously a study was done to assess the performance of former EuroSCORE model among coronary artery bypass grafting (CABG) patients (Rahman MZ, et al.2012) although performance of EuroSCORE II has never been tested in valve surgery patients. The aim of this work in this center is to evaluate the current clinical profile of patients submitted to mitral and aortic valve surgery and
to check expected risk of death in this group of patients by applying EuroSCORE II and compare its predictive performance with additive EuroSCORE (AES) and logistic EuroSCORE (LES) in terms of calibration and discrimination, thus to see whether EuroSCORE II could validate risks on our patient at NHFH&RI.

Rationale: The European System for Cardiac Operative Risk Evaluation II (EuroSCORE II) is an updated version of the original EuroSCORE and used for prediction of early mortality in cardiac surgery patients in Europe. This risk scoring system has been found highly successful on CABG patients and previously two study were conducted at NHFH&RI. But its validity was never been tested on mitral and aortic valve surgery of our population.

At present, NHFH&RI a high volume center in Bangladesh operating various valve surgery which is about more than 30% of total surgery. The EuroSCORE II predicted value can be used in mitral and aortic valvular surgery for preoperative decision making & risk assessment, counselling of patient, fitness of patients ,management planning, postoperative outcome & follow-up and make a comparison between institutions and surgeons.

So, significant differences in the demography ,risk profiles, surgical strategy in different countries of the world made individual population study necessary to confirm the predictive value of this pan-European method in that population.

The purpose of this study is to see whether EuroSCORE II can predict early mortality after elective mitral and aortic valve surgery & optimize its usefulness in valve surgery in NHFH&RI and compare its predictive performance with additive and logistic EuroSCORE.

Materials & Methods
Study design: Prospective observational Study.
Place of study: Department of Cardiac surgery, National Heart Foundation Hospital & Research Institute, Mirpur, Dhaka.
Period of study: July 2016 to March 2018
Ethical Issue: Permission was taken from the academic and institutional ethical and review board (IRB) of National Heart Foundation Hospital and Research Institute for conducting the study.
Study population: Patients operated in the department of cardiac surgery at NHFH & RI, underwent Mitral, Aortic or mitral & aortic valve surgery under CPB irrespective of sex.
Sampling Techniques: Purposive sampling.
Selection criteria:
  a. Inclusion Criteria: Adult Patients (>18 years) who will plan for Mitral, Aortic or mitral & aortic valve surgeries at National Heart Foundation Hospital, Dhaka.
Weights (score) of additive and logistic EuroSCORE:

### Patient related factors

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Definition</th>
<th>Additive score</th>
<th>Logistic score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Continues (per 5 years of part thereof over 60 years)</td>
<td>1</td>
<td>0.0666354</td>
</tr>
<tr>
<td>Sex</td>
<td>Female</td>
<td>1</td>
<td>0.3304052</td>
</tr>
<tr>
<td>Chronic pulmonary disease</td>
<td>Long term use of bronchodilators or steroids for lung disease</td>
<td>1</td>
<td>0.4931341</td>
</tr>
<tr>
<td>Extracardiac arteriopathy</td>
<td>any one or more of the following: claudication, carotid occlusion or &gt;50% stenosis, previous or planned intervention on the abdominal aorta, limb arteries or carotids</td>
<td>2</td>
<td>0.6558917</td>
</tr>
<tr>
<td>Neurological dysfunction</td>
<td>severely affecting ambulation or day-to-day functioning</td>
<td>2</td>
<td>0.841626</td>
</tr>
<tr>
<td>Previous cardiac surgery</td>
<td>requiring opening of the pericardium</td>
<td>3</td>
<td>1.002625</td>
</tr>
<tr>
<td>Active endocarditis</td>
<td>patient still under antibiotic treatment for endocarditis at the time of surgery</td>
<td>3</td>
<td>1.101265</td>
</tr>
<tr>
<td>Critical preoperative state</td>
<td>Any one or more of the following: ventricular tachycardia or fibrillation or aborted sudden death, preoperative cardiac massage, preoperative ventilation before arrival in the anesthetic room, preoperative inotropic support, intraaortic balloon counter pulsation or preoperative acute renal failure (anuria or oliguria&lt;10 ml/hour)</td>
<td>3</td>
<td>0.9058132</td>
</tr>
<tr>
<td>Serum creatinine</td>
<td>&gt;200 micromole/l preoperatively</td>
<td>2</td>
<td>0.6521653</td>
</tr>
</tbody>
</table>

### Cardiac related factors:

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Definition</th>
<th>Additive score</th>
<th>Logistic score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unstable angina</td>
<td>resting angina requiring iv nitrates until arrival in the anesthetic room</td>
<td>2</td>
<td>0.5677075</td>
</tr>
<tr>
<td>LV dysfunction</td>
<td>moderate or LVEF30-50%</td>
<td>1</td>
<td>0.4191643</td>
</tr>
<tr>
<td></td>
<td>poor or LVEF &lt;30</td>
<td>3</td>
<td>1.094443</td>
</tr>
<tr>
<td>Recent myocardial infarct</td>
<td>(&lt;90 days)</td>
<td>2</td>
<td>0.5460218</td>
</tr>
<tr>
<td>Pulmonary hypertension</td>
<td>Systolic PA pressure&gt;60 mmHg</td>
<td>2</td>
<td>0.7676924</td>
</tr>
</tbody>
</table>

### Operation related factors:

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Definition</th>
<th>Additive score</th>
<th>Logistic score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency operation</td>
<td>Carried out on referral before the beginning of the next working day</td>
<td>2</td>
<td>0.7127953</td>
</tr>
<tr>
<td>Other than isolated CABG</td>
<td>Major cardiac procedure other than or in addition to CABG</td>
<td>2</td>
<td>0.5420364</td>
</tr>
<tr>
<td>Surgery on thoracic aorta</td>
<td>For disorder of ascending aorta</td>
<td>3</td>
<td>1.159787</td>
</tr>
<tr>
<td>Post-infarct septal rupture</td>
<td></td>
<td>4</td>
<td>10462009</td>
</tr>
</tbody>
</table>
Beta co-efficient value of factors of EuroSCORE II:

Patient related factors

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Beta co-efficient value for EuroSCORE II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.0285181</td>
</tr>
<tr>
<td>Female sex</td>
<td>0.02196434</td>
</tr>
<tr>
<td>Chronic pulmonary disease</td>
<td>0.1886564</td>
</tr>
<tr>
<td>Extracardiac arteriopathy</td>
<td>0.5360568</td>
</tr>
<tr>
<td>Neurological dysfunction disease</td>
<td>0.2407181</td>
</tr>
<tr>
<td>Previous cardiac surgery</td>
<td>1.118599</td>
</tr>
<tr>
<td>Active endocarditis</td>
<td>0.6194522</td>
</tr>
<tr>
<td>Critical preoperative state</td>
<td>1.086517</td>
</tr>
<tr>
<td>Insulin dependant diabetes mellitus</td>
<td>0.3542749</td>
</tr>
</tbody>
</table>

For age, $Xi= 1$ if patient age <60; $Xi$ increases by one point per year thereafter (age 60 or less $Xi = 1$; age 61 if $Xi=2$; age 63 if $Xi= 3$ and so on.

Cardiac related factors:

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Beta co-efficient value for EuroSCORE II</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA class II</td>
<td>0.1070545</td>
</tr>
<tr>
<td>III</td>
<td>0.2958358</td>
</tr>
<tr>
<td>IV</td>
<td>0.5597929</td>
</tr>
<tr>
<td>CCS class IV angina</td>
<td>0.2226147</td>
</tr>
<tr>
<td>Recent myocardial infarct</td>
<td>0.1528943</td>
</tr>
<tr>
<td>LV ejection fraction-Moderate</td>
<td>0.3150652</td>
</tr>
<tr>
<td>Poor</td>
<td>0.8084096</td>
</tr>
<tr>
<td>Very poor</td>
<td>0.9346919</td>
</tr>
<tr>
<td>Pulmonary artery systolic pressure</td>
<td>0.1788899</td>
</tr>
<tr>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>0.3491475</td>
</tr>
</tbody>
</table>

Operation related factors:

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Beta co-efficient value for EuroSCORE II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urgency of operation</td>
<td></td>
</tr>
<tr>
<td>Urgent</td>
<td>0.3174673</td>
</tr>
<tr>
<td>Emergency</td>
<td>0.7039121</td>
</tr>
<tr>
<td>Salvage</td>
<td>1.362947</td>
</tr>
<tr>
<td>Weight of the intervention</td>
<td></td>
</tr>
<tr>
<td>Single non CABG</td>
<td>0.0062118</td>
</tr>
<tr>
<td>2 procedure</td>
<td>0.5521478</td>
</tr>
<tr>
<td>3 procedure</td>
<td>1.362947</td>
</tr>
<tr>
<td>Surgery on thoracic aorta</td>
<td>0.6527205</td>
</tr>
</tbody>
</table>

Follow up of patient

Patients were discharged at the 7th postoperative day routinely unless any of them were complicated by any factor.

1) Those who were successfully discharged was contacted via mobile phone at the 31st postoperative day whether any mortality event occur and record accordingly.
2) Those who were complicated by any factor and had postoperative hospital stay prolong were followed till their discharge or any mortality event and record accordingly.

Surgical Techniques & Anesthesia:
All patients were received General Anesthesia according to standard anesthetic protocol. A uniform operative
technique were used. Surgical correction of all patients included in the study were done through standard median sternotomy and using cardiopulmonary bypass (CPB). A standard CPB circuit were used. After completing operative procedure, Protamine sulphate (100:1 ratio) were used to reverse the heparin effect at completion of the surgical procedure. Per-operative Aortic Cross clamp time, ECCT were recorded.

Data processing
Data were collected using a preformed data collection sheet (questionnaire). Baseline information was collected from the patient after exploration of different complains, sign and symptoms. Data acquisition were performed by using EuroSCORE II and original EuroSCORE datasheet from patients file and later compiled in online calculator present in this site http://www.euroscore.org/calc.html. Data were analyzed by computer software Statistical Packages for Social Scientist (SPSS) for windows version 20. The results were presented in tables. Continuous variables were expressed as mean ± standard deviation and discrete variables were summarized by percentages. The cohort was grouped into low, medium and high risk group according to EuroSCORE II, additive and logistic version of EuroSCORE model. The validity of the model were analyzed by its calibration (statistical precession) with Hosmer-lemeshow chi square test and discriminatory capacity (statistical capacity) with ROC curve. And association between observed and predicted mortality figure with 95% confidence interval using Pearson chi square test, p value less than <0.05 considered significant.

Results:
This was a prospective cohort study conducted in the department of cardiac surgery, from July 2016 to June 2018 among the patients admitted for valve surgery. After fulfilling the inclusion and exclusion criteria a total of 356 patients were enrolled in this study.

Distribution of the patients by age shows majority of patients were within 4th decade and was mean age 43.29 ± 12.35. In this study 49.4% patients were male and 50.6% were female.

Table I shows that out of 356 patients 31 had extra cardiac arteriopathy among them 03 mortality were seen. Fisher’s Exact test demonstrates that association between extra cardiac arteriopathy and early mortality was statistically significant. Association between diabetes on insulin and early mortality was statistically significant. Other factors demonstrates no association with early mortality and statistically not significant.

Most of the patient (281 out of 356) in this study population were in NYHA class II and shows mortality of 1.8%. Also 68 out of 356 patient were in class III and shows mortality of 7.4%. Fisher’s Exact test demonstrates that association between NYHA class and early mortality was statistically not significant. Similarly, most of the patient ( 218 out of 356) in this study group have good left ventricular ejection fraction and 3 patient died, 7 mortality seen among patients with moderate LV function. Fisher’s Exact test demonstrates that association between Left ventricular ejection fraction and early mortality was statistically not significant. Cardiac risk factors like CSS class IV angina, recent MI (Within 90 days), Pulmonary Hypertension and association between urgency of operation and early mortality was not statistically significant.

Table II shows shows association between weight of intervention and early mortality was statistically not significant.

Table III shows shows single valve surgery mortality 2.3 % ( 7 out of 296) and double valve surgery mortality 5.7 % (3

Table-I
Distribution of the patient’s risk factors by early mortality

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Early mortality (within 30 days)</th>
<th>p valuea</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes (95)</td>
<td>No (5)</td>
</tr>
<tr>
<td>Extra Cardiac arteriopathy</td>
<td>3 (9.7)b</td>
<td>28 (90.3)</td>
</tr>
<tr>
<td>Poor mobility</td>
<td>0 (.0)</td>
<td>13 (100.0)</td>
</tr>
<tr>
<td>Previous cardiac surgery</td>
<td>1 (3.7)</td>
<td>26 (96.3)</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>5 (3.1)</td>
<td>154 (96.9)</td>
</tr>
<tr>
<td>Active endocarditis</td>
<td>0 (.0)</td>
<td>16 (100.0)</td>
</tr>
<tr>
<td>Clinical preoperative state</td>
<td>1 (2.1)</td>
<td>46 (97.9)</td>
</tr>
<tr>
<td>Diabetes on insulin</td>
<td>8 (4.7)</td>
<td>162 (95.3)</td>
</tr>
</tbody>
</table>

aFisher’s Exact test was done to measure the level of significance. P value <0.05 is considered significant. bFigure within parentheses indicates in percentage.
out of 50), association between single and double valve operation and early mortality was statistically not significant.

Table IV demonstrates that in low risk group 158 patients with no mortality, in moderate risk group 121 patients with mortality 5 (4.1%) and in high risk group 77 patients with mortality 5 (6.5%).

Table V demonstrates that in low risk group 15 patients with no mortality, in moderate risk group 218 patients with mortality 4 (1.8%) and in high risk group 123 patients with mortality 6 (4.9%).

Table VI demonstrates that in low risk group 27 patients with no mortality, in moderate risk group 168 patients with mortality 3 (1.8%) and in high risk group 161 patients with mortality 7 (4.3%).

Validation of EuroSCORE II model on NHFH&RI sample

Model calibration means how precisely model can predict the outcome. Model calibration was analyzed by determining Hosmer-Lemeshow goodness of fit statistic in multiple regression analysis. The Hosmer-Lemeshow chi-square statistic (C statistic) measures the differences between expected and observed outcomes in different risk groups. A well calibrated model gives corresponding p value greater than 0.05 that means all the risk factors taken into consideration to predict mortality therefore can accurately predict operative mortality.

Here on NHFH&RI cohort applying EuroSCORE the predicted and observed mortality after Hosmer-Lemeshow test p value found >0.05 in all subgroups including overall cohort. Therefore all risk factors taken into consideration in the EuroSCORE II model can accurately predict early mortality on NHFH&RI cohort.

Table VII shows association between EuroSCORE II predicted mortality and observed early mortality was statistically not significant. Therefore all risk factors taken into consideration in the EuroSCORE II model can accurately predict early mortality on NHF cohort.

Table VIII shows association between Additive EuroSCORE predicted mortality and observed early mortality was statistically not significant. Therefore all risk factors taken into consideration in the Additive EuroSCORE model can accurately predict early mortality on NHF cohort.

Table IX shows association between Logistic EuroSCORE predicted mortality and observed early mortality was statistically not significant. Therefore all risk factors taken into consideration in the Logistic EuroSCORE model can accurately predict early mortality on National Heart Foundation cohort.

Performance of the patients by EuroSCORE II, Additive EuroSCORE and Logistic EuroSCORE in mortality prediction and comparing with early mortality:

<table>
<thead>
<tr>
<th>Weight of intervention</th>
<th>Early mortality (within 30 days)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single non CABG</td>
<td>7 (2.4)</td>
<td>281 (97.6)</td>
</tr>
<tr>
<td>2 Procedures</td>
<td>3 (4.4)</td>
<td>65 (95.6)</td>
</tr>
<tr>
<td>Total</td>
<td>10 (2.8)</td>
<td>346 (97.2)</td>
</tr>
</tbody>
</table>

*aFisher’s Exact test was done to measure the level of significance. P value <0.05 is considered significant. bFigure within parentheses indicates in percentage.*

<table>
<thead>
<tr>
<th>Weight of intervention</th>
<th>Early mortality (within 30 days)</th>
<th>p valuea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single valve (Aortic /Mitral)</td>
<td>7 (2.3)</td>
<td>296 (97.7)</td>
</tr>
<tr>
<td>Double valve</td>
<td>3 (5.7)</td>
<td>50 (94.3)</td>
</tr>
<tr>
<td>Total</td>
<td>10 (2.8)</td>
<td>346 (97.2)</td>
</tr>
</tbody>
</table>

*aFisher’s Exact test was done to measure the level of significance. P value <0.05 is considered significant. bFigure within parentheses indicates in percentage.*
**Table IV**

*Distribution of the patients EuroSCORE II by early mortality*

<table>
<thead>
<tr>
<th>EuroSCORE II</th>
<th>Early mortality (within 30 days)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Low (0-2)</td>
<td>0 (0  )</td>
<td>158 (98.8)</td>
</tr>
<tr>
<td>Moderate (2-5)</td>
<td>5 (4.1 )</td>
<td>116 (96.7)</td>
</tr>
<tr>
<td>High (&gt;5)</td>
<td>5 (6.5 )</td>
<td>72 (94.7)</td>
</tr>
<tr>
<td>Total</td>
<td>10 (2.8)</td>
<td>346 (97.2)</td>
</tr>
</tbody>
</table>

*Figure within parentheses indicates in percentage.

**Table V**

*Distribution of the patient’s additive EuroSCORE by early mortality*

<table>
<thead>
<tr>
<th>Additive EuroSCORE</th>
<th>Early mortality (within 30 days)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Low (0-2)</td>
<td>0 (.0)</td>
<td>15 (100.0)</td>
</tr>
<tr>
<td>Moderate (2-5)</td>
<td>4 (1.8)</td>
<td>214 (98.2)</td>
</tr>
<tr>
<td>High (&gt;5)</td>
<td>6 (4.9)</td>
<td>117 (95.1)</td>
</tr>
<tr>
<td>Total</td>
<td>10 (2.8)</td>
<td>346 (97.2)</td>
</tr>
</tbody>
</table>

*Figure within parentheses indicates in percentage.

**Table VI**

*Distribution of the patients logistic EuroSCORE by early mortality*

<table>
<thead>
<tr>
<th>Logistic EuroSCORE</th>
<th>Early mortality (within 30 days)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Low (0-2)</td>
<td>0 (.0)</td>
<td>27 (100.0)</td>
</tr>
<tr>
<td>Moderate (2-5)</td>
<td>3 (1.8)</td>
<td>165 (98.2)</td>
</tr>
<tr>
<td>High (&gt;5)</td>
<td>7 (4.3)</td>
<td>154 (95.7)</td>
</tr>
<tr>
<td>Total</td>
<td>10 (2.8)</td>
<td>346 (97.2)</td>
</tr>
</tbody>
</table>

*Figure within parentheses indicates in percentage.

**Table VII**

*Calibration of the EuroSCORE II model on overall patients*

<table>
<thead>
<tr>
<th>Category</th>
<th>No. of Patients</th>
<th>Early mortality</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Observed</td>
<td>Expected</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>38</td>
<td>0</td>
<td>0.625</td>
</tr>
<tr>
<td>2</td>
<td>37</td>
<td>0</td>
<td>0.632</td>
</tr>
<tr>
<td>3</td>
<td>37</td>
<td>0</td>
<td>0.654</td>
</tr>
<tr>
<td>4</td>
<td>37</td>
<td>0</td>
<td>0.691</td>
</tr>
<tr>
<td>5</td>
<td>35</td>
<td>0</td>
<td>0.704</td>
</tr>
<tr>
<td>6</td>
<td>36</td>
<td>2</td>
<td>0.781</td>
</tr>
<tr>
<td>7</td>
<td>36</td>
<td>2</td>
<td>0.901</td>
</tr>
<tr>
<td>8</td>
<td>36</td>
<td>2</td>
<td>1.109</td>
</tr>
<tr>
<td>9</td>
<td>36</td>
<td>3</td>
<td>1.474</td>
</tr>
<tr>
<td>10</td>
<td>28</td>
<td>1</td>
<td>2.430</td>
</tr>
</tbody>
</table>

*Hosmer and Lemeshow test was done to measure the level of significant, P value < 0.05 is considered significant.
Table-VIII

Calibration of the Additive EuroSCORE model on overall patients

<table>
<thead>
<tr>
<th>Category</th>
<th>No. of Patients</th>
<th>Early mortality</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Observed</td>
<td>Expected</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>15</td>
<td>0</td>
<td>0.222</td>
</tr>
<tr>
<td>2</td>
<td>96</td>
<td>0</td>
<td>1.713</td>
</tr>
<tr>
<td>3</td>
<td>65</td>
<td>1</td>
<td>1.398</td>
</tr>
<tr>
<td>4</td>
<td>57</td>
<td>3</td>
<td>1.476</td>
</tr>
<tr>
<td>5</td>
<td>49</td>
<td>3</td>
<td>1.527</td>
</tr>
<tr>
<td>6</td>
<td>29</td>
<td>2</td>
<td>1.086</td>
</tr>
<tr>
<td>7</td>
<td>45</td>
<td>1</td>
<td>2.578</td>
</tr>
</tbody>
</table>

*Hosmer and Lemeshow test was done to measure the level of significant, P value <0.05 is considered significant.

Table-IX

Calibration of the Logistic EuroSCORE model on overall patients

<table>
<thead>
<tr>
<th>Category</th>
<th>No. of Patients</th>
<th>Early mortality</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Observed</td>
<td>Expected</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>27</td>
<td>0</td>
<td>0.505</td>
</tr>
<tr>
<td>2</td>
<td>35</td>
<td>0</td>
<td>0.683</td>
</tr>
<tr>
<td>3</td>
<td>36</td>
<td>0</td>
<td>0.721</td>
</tr>
<tr>
<td>4</td>
<td>37</td>
<td>1</td>
<td>0.787</td>
</tr>
<tr>
<td>5</td>
<td>27</td>
<td>0</td>
<td>0.594</td>
</tr>
<tr>
<td>6</td>
<td>33</td>
<td>2</td>
<td>0.772</td>
</tr>
<tr>
<td>7</td>
<td>36</td>
<td>2</td>
<td>0.894</td>
</tr>
<tr>
<td>8</td>
<td>36</td>
<td>1</td>
<td>1.017</td>
</tr>
<tr>
<td>9</td>
<td>36</td>
<td>1</td>
<td>1.207</td>
</tr>
<tr>
<td>10</td>
<td>53</td>
<td>3</td>
<td>2.821</td>
</tr>
</tbody>
</table>

*Hosmer and Lemeshow test was done to measure the level of significance, P value <0.05 is considered significant.

Table X shows association between observed early mortality and predicted mortality by EuroSCORE II, Additive EuroSCORE and Logistic EuroSCORE was statistically not significant.

**Discriminatory capacity of the EuroSCORE model**

It was analyzed by calculating the area under the ROC curve. The models ability to discriminate was assessed in terms of its capacity to distinguish between patients who died during hospitalization from those who did not. Typical C values for cardiac surgery models range from 0.72 to 0.76 that means prediction of individual outcome is correct 72% to 46% of the time. A value of 0.5 indicates no discrimination and a value of 1.0 indicates perfect predictor. Areas of greater than 0.7 are generally thought to be useful. The discriminatory power of the model is Excellent if ROC exceeds 0.80, Very good if it exceeds 0.75 and good if it exceeds 0.70.

In this study, the model's discriminatory power was found good and useful, as indicated by an area under ROC curve of 0.779 in EuroSCORE II model, 0.675 in additive method and 0.696 in logistic method that means EuroSCORE II can predict the outcome with 77% accuracy, additive method does with 67% accuracy and logistic method with 69% accuracy.

The Table XI demonstrates that EuroSCORE II bears area under Receiver Operating Characteristic (ROC) curve 0.779 which means it can predict mortality with 77% accuracy, whereas AUC of ROC curve of additive EuroSCORE and logistic EuroSCORE was 0.675 and 0.696 respectively. EuroSCORE II and Logistic EuroSCORE shows p value <0.05 which indicates result statistically significant. Additive EuroSCORE shows P value >0.05 which indicates result statistically not significant.
Table-X

<table>
<thead>
<tr>
<th>EuroSCORE</th>
<th>Observed early mortality (%)</th>
<th>Predicted mortality (%)</th>
<th>95%CI</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>EuroSCORE II</td>
<td>2.8</td>
<td>2.73</td>
<td>1.02-4.38</td>
<td>0.884</td>
</tr>
<tr>
<td>Additive EuroSCORE</td>
<td>2.8</td>
<td>2.15</td>
<td>0.68-3.72</td>
<td>0.786</td>
</tr>
<tr>
<td>Logistic EuroSCORE</td>
<td>2.8</td>
<td>2.25</td>
<td>0.74-3.86</td>
<td>0.852</td>
</tr>
</tbody>
</table>

*One proportion z test was done to measure the level of significance. P value < 0.05 is considered significant.

Table-XI

<table>
<thead>
<tr>
<th>Test Result Variables</th>
<th>Area under the ROC Curve</th>
<th>p value#</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lower Bound</td>
</tr>
<tr>
<td>EuroSCORE II</td>
<td>0.779</td>
<td>0.003</td>
<td>0.690</td>
</tr>
<tr>
<td>Additive EuroSCORE</td>
<td>0.675</td>
<td>0.059</td>
<td>0.543</td>
</tr>
<tr>
<td>Logistic EuroSCORE</td>
<td>0.696</td>
<td>0.034</td>
<td>0.594</td>
</tr>
</tbody>
</table>

#Null hypothesis: true area = 0.5, P value <0.05 is considered significant.

Fig.-1: ROC curve of EutoSCORE II, Additive EuroSCORE and Logistic EuroSCORE.

Discussion:

The current clinical profile of patients submitted to heart surgery puts into question the incidence of operative or hospital deaths as reliable indicators and not sufficient to evaluate the quality of services provided by the cardiac hospital. Without individual risk adjustment, taking into considerations associated risk factors, the conclusions might be incorrect. Prognostic models which take into account patients specific characteristics and which provides risk adjusted outcomes for intervention are required and more useful to allow meaningful comparison of outcomes to be performed between institutions and surgeons.

The choices available to a surgical unit are to create a new model, recalibrate an existing model or to use a ready-made model. The former two options are impractical to most cardiac surgical units as they require comprehensive database management and accumulation of large patient number to allow creation or recalibration of a model. The use of a ready-made widely used model has the additional advantage of allowing meaningful comparison to be made regionally and internationally.

Different systems of risk stratification have been utilized over the last two decades in different countries with the objective of predicting mortality in cardiac surgery. Additionally the application of a scoring system provides information to patients and their families in respect to the risk that individual patients will be submitted.

In the recent years the EuroSCORE has become one of the most widely used prognostic scoring system. Among the different studies to stratify the risk, the Euro score
has proved to be accurate, even when applied to non-European populations. Some countries found poor calibration of this model on their population and therefore they readjusted that version of EuroSCORE on their population. EuroSCORE is easy to use at the bedside and allows an analysis very close to the results, particularly in surgeries of the valve surgeries.

National heart foundation hospital & research institute is a reference centre for this type of heart surgery and performs a large numbers of valve surgeries every year. Before using a probabilistic model in a context other than upon which it was created should be validated otherwise it may produce erroneous probabilities.

From January 2008 to December 2009 a prospective cohort study was done among 234 patients who underwent coronary artery bypass grafting in this institute to validate the former EuroSCORE model. Calibration was analysed by Hosmer-Lemeshow goodness of fit test. The area under ROC curve in additive method was found 0.74 and 0.73 in logistic method. In that study both the additive and logistic method of EuroSCORE showed good calibration and discrimination (Rahman, et al., 2012).

The EuroSCORE was recently reported to overestimates the cardiac surgery risk because of improved outcomes in cardiac surgery and marked reduction of risk adjusted mortality. To overcome this limitation, an updated version of this model named EuroSCORE II was developed. The purpose of this study was to assess the performance of the EuroSCORE II and to compare its prediction performance with that of original model.

We prospectively applied the EuroSCORE to analyse early mortality in 356 consecutive patients who underwent elective valve surgery in NHFH. In the original work (Nashef, et al., 2012) studied on 22,381 patients in 154 hospitals in 43 countries (average 145 patients per centre). Many risk factors were critically observed in this sample. The mean age of our sample was 43.29 ± 12.35 and of the EuroSCORE II was 64.6 ± 12.5 in our country there is no patient over 72 years.

In our patient majority were female 50.6% (180 out of 356) and male were 49.4% (176 out of 356). According to Nashef, et al., females have a higher mortality than males.

The mean serum creatinine of our study was 1.10 ± 0.21 t test was done to measure the level of significance P = 0.927 and it is considered not significant. Renal function was assessed by the estimated creatinine clearance using the Cockroft-Gault formula, and it is a better predictor than serum creatinine (Nashef, et al., 2012). In this study early mortality is seen in moderately impaired renal function.

This study shows the significant relation between extra cardiac arteriopathy, diabetes on insulin and early mortality. Fisher’s Exact test was done to measure the level of significance which shows p value 0.047 and 0.053 respectively. Poor mobility, chronic lung disease, previous cardiac surgery, critical preoperative state, active endocarditis shows non-significant on Fisher’s Exact test.

Among the cardiac factors, left ventricular ejection fraction (LVEF) of major portion of our patient of this study had good left ventricular ejection fraction, only 3 patient had poor ejection fraction and no mortality was seen in this group. Patients with moderate ejection fraction shows mortality of 5.2% (7 out of 135). Fisher’s Exact test was done to measure between other factors and early mortality CCS class IV angina, recent MI, and pulmonary hypertension shows p value of 0.999, 0.999 and 0.999 respectively and all of them considered non-significant.

Among the operation related factors, weight of intervention shows no significant association with early mortality. Chi-square test was done to measure the level of significance which shows p value of 0.410 (considered not significant).

In this study group distribution of early mortality in EuroSCORE II Mean ± SD (4.6± 3.19), Mann-Whitney U test to measure the level of significance showed p value of 0.003 (considered significant). Whereas distribution of additive EuroSCORE (6.00 ± 1.41) with p value 0.059 (considered not significant). Distribution of logistic EuroSCORE (8.21 ± 5.03) with p value 0.034 (considered significant).

Study population were grouped into three category, in EuroSCORE II 45% patients falls into low risk, 33.7% in moderate risk and 21.3% in high risk group. In additive EuroSCORE 4.2% patient in low risk group followed by moderate risk 61.2% and high risk 34.6%. Where in logistic EuroSCORE 7.5% patient in low risk group followed by 47.3% moderate risk and 45.2 % in high risk group.

In this study, the C statistics obtained with the Hosmer-Lemeshow test was p=0.226 in EuroSCORE II, p=0.221 in additive method and p = 0.641 in logistic method and were not significant in different risk groups of NHF sample and p value remains >0.05 in all subgroups which indicates risk factors used EuroSCORE model could predict the operative mortality satisfactorily for patients undergoing valve surgery in our centre.

The area under ROC curve was 0.8905 in the original EuroSCORE II data set (Nashef, et al., 2012) In this study, the model’s discriminatory power also good and useful, as indicated by an area under ROC curve of 0.779 in EuroSCORE II model, 0.675 in additive method and 0.696
in logistic method that means EuroSCORE II method can predict the outcome with 77% accuracy, additive method with 67% accuracy and the logistic method does that with 69% accuracy. It signifies that EuroSCORE II model has better discriminatory power than the additive and logistic version of EuroSCORE.

The overall mortality in our setting was 2.80 % (10 out of 356) and predicted mortality was 2.73% (95% confidence interval 1.02-4.38) by the EuroSCORE II, 2.15% (95% confidence interval 0.68-3.72) by the additive method and 2.25% (95% confidence interval 0.74-3.86) by the logistic EuroSCORE.

One proportion Z test was done to see the association between the predicted mortality using EuroSCORE II, additive and logistic method with the observed early mortality. The performance of the model was assessed by comparing the observed and predicted mortality figures with 95% confidence intervals. The observed early mortality in three different risk groups was compared by univariate analysis with predicted mortality by EuroSCORE II, additive and logistic method of EuroSCORE. The p value was 0.884 in EuroSCORE II, 0.786 in additive method and 0.852 in logistic method of EuroSCORE that means both EuroSCORE II predicted mortality and mortality predicted by logistic EuroSCORE is as similar to observed early mortality for valve surgery in National Heart Foundation Hospital & Research Institute.

By this present study, we validated the EuroSCORE II model for use in this centre and that it has been proven to be a reliable instrument for risk stratification. This signifies that the model’s predictions of the probability of dying are valid and appropriately risk-adjusted for patients undergoing valve surgery in National Heart Foundation Hospital & Research Institute.

Limitation: This analysis was done in a single centre of Bangladesh, and the sample represents only a fraction of patients undergoing valve surgery in Bangladesh. The focus of this study was adult patients undergoing valve surgery, the identified independent risk factors may not be applicable to other surgeries as aortic surgery, congenital heart surgery or heart transplantation.

Conclusion:
The results of this study allow us to conclude that despite substantial demographic and epidemiological differences between Bangladesh and European population EuroSCORE II was validated and performed well on NHFH&RI patients and could be recommended as a simple risk stratification system to estimate the probability of early mortality in patients scheduled for valve surgery in Bangladesh.

This study demonstrates that the EuroSCORE II is more accurate in predicting operative mortality than the additive EuroSCORE (AES) and logistic EuroSCORE (LES) in patients undergoing valve surgery patients. The model validated in the present study could be useful in providing systematic information on the outcome of valve surgeries in other centers of Bangladesh.

References:


Original Article

Evaluation of Blood Lactate Level as Predictor of Early Adverse Outcome after Cardiac Surgery under Cardiopulmonary Bypass

Azad MAK¹, Islam KS², Quasem MA³

Abstract:
Background: We examined the hypothesis that high blood lactate level in intensive care unit patient after adult cardiac surgery under cardiopulmonary bypass is associated with early adverse outcome. The objective of this study was to evaluate whether high blood lactate level after cardiac surgery is a predictor of the early outcome after adult cardiac surgery under cardiopulmonary bypass.

Methods: This prospective observational study was carried out in the department of Cardiac Surgery at National Institute of Cardiovascular Disease (NICVD), Dhaka from July, 2013 to April 2014. A total number of 100 patients who underwent cardiac operation with cardiopulmonary bypass were enrolled in this study as per inclusion and exclusion criteria. Patients were divided into two groups according to their blood lactate level 6 hours after transfer to intensive care unit. Peroperative variables and postoperative variables were observed and recorded during the hospital course of patient. Categorical variables were analyzed by Chi-square test and Fisher’s exact test and continuous variables were analyzed by ‘t’ test. Multiple Binary Logistic Regression Analysis of predictors for each of the outcome variables was done.

Results: Blood lactate levels ≥3mmol/L 6 hours after transfer to intensive care unit were present in 57(57%) patients. Multiple logistic regression analysis showed higher blood lactate level was an independent predictor for early postoperative low output syndrome (OR 9.073, 95% CI 2.819 – 29.207, p = < .0001), pulmonary complication (OR 5.734, 95% CI 1.814 – 18.122, p = .003), neurological deficits (OR 9.725, 95% CI 1.111 - 85.147, p = .040), renal dysfunction (OR 7.393, 95% CI 1.855-29.469, p = .005), arrhythmia (OR 10.512, 95% CI 1.902 – 58.108, p = .007) and wound infection (OR 7.742, 95% CI 1.418 - 42.259, p = .018).

Conclusions: High blood lactate level 6 hours after transfer to intensive care unit is an independent predictor for worse outcomes in adult patients after cardiac surgery under cardiopulmonary bypass.

Keywords: Lactate, cardiopulmonary bypass.

Introduction:
High blood lactate level is a well-recognized marker of circulatory failure, and its severity has been associated with morbidity and mortality in different clinical conditions. After cardiac surgery, hyperlactatemia (HL) is relatively common and is associated with morbidity and mortality. Elevated lactate concentrations in the immediate postoperative period reflect unmet metabolic demand and may be associated with poor outcome. Irrespective of its origin, hyperlactatemia and its persistence have been demonstrated to be an early indicator of worse outcome in cardiac surgical patients. Prolongation of lactate clearance is associated with increasing mortality and failure of a patient to normalize lactate is associated with morbidity and mortality in different clinical conditions.
with 100% mortality. The evolution of the lactate concentration after therapeutic management is able to predict the outcome more accurately.

Lactate represents a useful and clinically obtainable surrogate marker of tissue hypoxia and disease severity, independent of blood pressure. Persistently elevated lactate has been shown to be better than oxygen transport variables (oxygen delivery, oxygen consumption, and oxygen extraction ratio) as an indicator of mortality rate. Among septic shock patients, only survivors had a significant decrease in lactate concentrations over the course of the disease. In contrast, non survivors had significantly higher lactate concentrations during both the initial and final phases of shock.

Various preoperative factors or comorbidities may create the right environment for HL during CPB. Age, female gender, congestive heart failure, low left ventricular ejection fraction, hypertension, atherosclerosis, diabetes, preoperative hemoglobin value, redo or complex surgery, and emergency procedures were found to be risk factors for HL. Cardioplegic cardiac arrest and extracorporeal circulation (ECC) result in systemic inflammation, cardiac damage, myocardial stunning, hemodynamic instability, tissue edema, bleeding diathesis and finally multiorgan dysfunction. Cardioplegic arrest induces anaerobic myocardial metabolism with a net production of lactate from glycolysis. Persistent lactate release during reperfusion suggests a delayed recovery of normal aerobic metabolism and may lead to depressed myocardial function.

Lactate level 6 hours after intensive care unit (ICU) admission is an independent predictor of postoperative complications including 30-day all-cause mortality and severe morbidity after cardiac surgery in adult patients. In patients with clinical shock, associated with tachycardia, hypotension, cold and clammy skin and decreased urine output, lactate levels have been referred to as the best objective indicator of the severity of shock.

High blood lactate levels are associated with tissue hypoperfusion and may contribute to postoperative adverse outcome. Hyperlactatemia and its persistence have been demonstrated to be an early indicator of worse outcome in cardiac surgical patients. National Institute of Cardiovascular Diseases (NICVD), Dhaka, Bangladesh is a high volume center and a considerable number of cardiac surgeries are performed under cardiopulmonary bypass. Hence, it is an ideal place for investigating lactate level.

In current practice, lactate is frequently measured usually with the goal of detecting tissue hypoxia during ICU care. However, high blood lactate levels in ICU are getting more importance to predict early outcome after cardiac surgery in recent journals.

Methods:
The study was designed as prospective observational study. It was carried out in the department of Cardiac Surgery from July 2013 to April 2014, at National Institute of Cardiovascular Diseases (NICVD), Dhaka, Bangladesh.

The adult patients undergoing elective cardio-pulmonary bypass (CPB) during cardiac surgery at NICVD and fulfilled the inclusion and exclusion criteria were selected. Sampling method was Purposive and convenient. The study protocol was approved by ethical committee of NICVD.

Exclusion criteria were patients with pre-CPB high blood lactate level, emergency surgery, adult complex congenital heart defects, hepatic dysfunction, end-stage renal disease, intraoperative mortality or mortality less than 6 hours after transfer to ICU and patient’s refusal for enrollment in the study. Postoperative variables were lactate (mmol/L) after transfer in ICU (6 hours &12 hours after transfer in ICU, blood transfusion units, mechanical ventilation time, low output syndrome (LOS), duration of ICU stay, postoperative Intra-aortic balloon pump requirement, postoperative complications (within 30 days), re-operation for bleeding, neurological deficit, myocardial Infarction, pulmonary complication, arrhythmia, renal dysfunction, wound infection, mortality.

The patients were divided into two groups according to the blood lactate level 6 hours after transfer in ICU after cardiac surgery. Those patients who had less than 3 mmol/L of blood lactate level 6 hours after transfer in ICU were in group A and those patients who had e’3 mmol/L of blood lactate level were in group B.

All patients undergoing cardiac surgery were given general anesthesia with endotracheal intubation and were treated with the standard CPB technique. Five arterial blood samples were drawn: After the anesthetic induction, at the end of CPB, immediately after transfer in ICU (0 hour), and then 6 hours and 12 hours after transfer in ICU. Arterial blood samples were analyzed by blood gas analyzer, model – Siemens RAPIDlab 1265, manufactured by Beckman int. California, USA.

Standard ICU management protocols were used and the patients were subsequently shifted to Post-ICU, ward or cabin and discharged whenever appropriate according to operating consultant’s judgment.

Data were collected using a pre designed case record form. Postoperative complications after discharge was recorded during follow up after 1 month.

Results were expressed as means with standard deviation. Potential risk factors were assessed using ax2 test, Fisher’s exact test, t test. A forward multiple
logistic regression analysis was then performed to estimate independent predictive factors for complications. For all analysis a $p$-value <0.05 were considered statistically significant. Statistical analysis was performed by using statistical program for social science (SPSS 17.0).

**Results:**
A total number of 100 patients undergoing elective CPB were recruited for this study. Those patients who had < 3 mmol/L of blood lactate level were designed as control group and those patients who had ≥ 3 mmol/L of blood lactate level at 6th hour after transfer to ICU were designed as subject group.

**Preoperative demographic variables**
Table I shows the distribution of study population according to preoperative variables. Majority of patients were in < 60 years age group (91%), male sex (62%), normal BMI categories (87%), non-diabetic (75%), non-hypertensive (86%), normal lipid profile (83%) and good LVEF status (89%). Difference between two groups is not statistically significant.

<table>
<thead>
<tr>
<th>Table-I</th>
<th>Preoperative variables distribution of study population (n = 100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age# Group</td>
<td>Lactate Group (mmol/L)</td>
</tr>
<tr>
<td>Age &lt; 60 years</td>
<td>Control group (n = 43)</td>
</tr>
<tr>
<td>&gt;60 years</td>
<td>4 (9.3%)</td>
</tr>
<tr>
<td>Sex Male</td>
<td>25 (58.1%)</td>
</tr>
<tr>
<td>Female</td>
<td>18 (41.9%)</td>
</tr>
<tr>
<td>BMI Normal &amp; U.weight</td>
<td>39 (90.7%)</td>
</tr>
<tr>
<td>Obese &amp; Overweight</td>
<td>4 (9.3%)</td>
</tr>
<tr>
<td>DM Present</td>
<td>11 (25.6%)</td>
</tr>
<tr>
<td>Absent</td>
<td>32 (74.4%)</td>
</tr>
<tr>
<td>HTN Present</td>
<td>7 (16.3%)</td>
</tr>
<tr>
<td>Absent</td>
<td>36 (83.7%)</td>
</tr>
<tr>
<td>Dys-lipidemia Present</td>
<td>8 (18.6%)</td>
</tr>
<tr>
<td>Absent</td>
<td>35 (81.4%)</td>
</tr>
<tr>
<td>LVEF Good</td>
<td>38 (88.4%)</td>
</tr>
<tr>
<td>Impaired</td>
<td>5 (11.6%)</td>
</tr>
</tbody>
</table>

#Data were analyzed using Fisher's Exact test; Level of significance was 0.05.

<table>
<thead>
<tr>
<th>Table-II</th>
<th>Comparison of Operation time, CPB time, ACC time and Blood transfusion units between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peroperative Variables</td>
<td>Lactate Group (mmol/L)</td>
</tr>
<tr>
<td>Operation time#</td>
<td>Control group(n = 43) &lt;3</td>
</tr>
<tr>
<td>CPB time#</td>
<td>319.02 ± 70.479</td>
</tr>
<tr>
<td>ACC time#</td>
<td>121.65 ± 43.449</td>
</tr>
<tr>
<td>Blood transfusion unit#</td>
<td>7.28 ± 29.124</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>2.186 ± 0.4502</td>
</tr>
</tbody>
</table>

# Data were analyzed using ‘t’ test,(n = number of patients, S = significant)
Postoperative measures of adverse outcome

Table III shows the distribution of study population according to postoperative variables. Low output syndrome, prolonged mechanical ventilation time (>24h), neurological deficit, pulmonary complications, arrhythmia, renal dysfunction, wound infection are found statistically significant.

Table 04 shows the multiple binary logistic regression analysis and high lactate level was found to be an independent predictor of postoperative low output syndrome, arrhythmia, pulmonary complications, renal dysfunction, neurological deficits and wound infection. Multiple logistic regression analysis shows higher blood lactate level is an independent predictor for early postoperative low output syndrome (OR 9.073, 95% CI 2.819 – 29.207, p = < .0001), pulmonary complication (OR 5.734, 95% CI 1.814 – 18.122, p = .003), neurological deficits (OR 9.725, 95% CI 1.111 - 85.147, p = .004), renal dysfunction (OR 7.393, 95% CI 1.855-29.469, p = .005), arrhythmia (OR 10.512, 95% CI 1.902 – 58.108, p = .007) and wound infection (OR 7.742, 95% CI 1.418 - 42.259, p = .018).

### Table-III
Postoperative variables distribution of study population (n = 100)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Lactate Group (mmol/L)</th>
<th>Total</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group (n = 43)</td>
<td>Subject group (n = 57)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low output syndrome Present</td>
<td>08 (18.6%)</td>
<td>36 (63.1%)</td>
<td>44 (44%)</td>
</tr>
<tr>
<td>Absent</td>
<td>35 (81.4%)</td>
<td>21 (36.9%)</td>
<td>56 (56%)</td>
</tr>
<tr>
<td>Prolonged MVT (&gt;24h) Present</td>
<td>0 (0%)</td>
<td>6 (10.5%)</td>
<td>6 (6%)</td>
</tr>
<tr>
<td>Absent</td>
<td>43 (100%)</td>
<td>51 (89.5%)</td>
<td>94 (94%)</td>
</tr>
<tr>
<td>Prolonged ICU stay (&gt;48h) Present</td>
<td>7 (16.3%)</td>
<td>18 (31.6%)</td>
<td>25 (25%)</td>
</tr>
<tr>
<td>Absent</td>
<td>36 (87.7%)</td>
<td>39 (68.4%)</td>
<td>75 (75%)</td>
</tr>
<tr>
<td>Reoperation for bleeding Yes</td>
<td>0 (0%)</td>
<td>3 (5.3%)</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>No</td>
<td>43 (100%)</td>
<td>54 (94.7%)</td>
<td>97 (97%)</td>
</tr>
<tr>
<td>Neurological Deficit Present</td>
<td>1 (2.3%)</td>
<td>12 (21.1%)</td>
<td>13 (13%)</td>
</tr>
<tr>
<td>Absent</td>
<td>42 (97.7%)</td>
<td>45 (78.9%)</td>
<td>87 (87%)</td>
</tr>
<tr>
<td>Perioperative Mi Present</td>
<td>0 (0%)</td>
<td>5 (8.8%)</td>
<td>5 (5%)</td>
</tr>
<tr>
<td>Absent</td>
<td>43 (100%)</td>
<td>52 (91.2%)</td>
<td>95 (95%)</td>
</tr>
<tr>
<td>Pulmonary Complications Present</td>
<td>9 (20.9%)</td>
<td>31 (54.4%)</td>
<td>40 (40%)</td>
</tr>
<tr>
<td>Absent</td>
<td>34 (79.1%)</td>
<td>26 (35.6%)</td>
<td>60 (60%)</td>
</tr>
<tr>
<td>Arrhythmia Present</td>
<td>4 (9.3%)</td>
<td>19 (33.3%)</td>
<td>23 (23%)</td>
</tr>
<tr>
<td>Absent</td>
<td>39 (90.7%)</td>
<td>38 (66.7%)</td>
<td>77 (77%)</td>
</tr>
<tr>
<td>Renal dysfunction Present</td>
<td>5 (11.6%)</td>
<td>23 (40.4%)</td>
<td>28 (28%)</td>
</tr>
<tr>
<td>Absent</td>
<td>38 (88.4%)</td>
<td>34 (59.6%)</td>
<td>72 (72%)</td>
</tr>
<tr>
<td>Wound infection Present</td>
<td>7 (16.3%)</td>
<td>2 (3.5%)</td>
<td>9 (9%)</td>
</tr>
<tr>
<td>Absent</td>
<td>36 (83.7%)</td>
<td>55 (96.5%)</td>
<td>91 (97%)</td>
</tr>
<tr>
<td>Mortality Present</td>
<td>1 (2.3%)</td>
<td>6 (10.5%)</td>
<td>7 (7%)</td>
</tr>
<tr>
<td>Absent</td>
<td>42 (97.7%)</td>
<td>51 (89.5%)</td>
<td>93 (93%)</td>
</tr>
</tbody>
</table>

# Data were analyzed using Fisher’s Exact test; Level of significance was 0.05. (n = number of patients, * = significant)

### Table-IV
Multiple Binary Logistic Analyses of Predictors of Mortality and Morbidity

<table>
<thead>
<tr>
<th>Morbidity</th>
<th>Variable</th>
<th>OR</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOS</td>
<td>High Lactate</td>
<td>9.073</td>
<td>2.819 – 29.207</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>10.512</td>
<td>1.902 – 58.108</td>
<td>0.007*</td>
<td></td>
</tr>
<tr>
<td>Pulmonary Complications</td>
<td>5.734</td>
<td>1.814 – 18.122</td>
<td>0.003*</td>
<td></td>
</tr>
<tr>
<td>Renal Dysfunction</td>
<td>7.393</td>
<td>1.855 – 29.469</td>
<td>0.005*</td>
<td></td>
</tr>
<tr>
<td>Neurological Deficits</td>
<td>9.725</td>
<td>1.111 – 85.147</td>
<td>0.040*</td>
<td></td>
</tr>
<tr>
<td>Wound Infection</td>
<td>7.742</td>
<td>1.418 – 42.259</td>
<td>0.017*</td>
<td></td>
</tr>
</tbody>
</table>
Discussion:
The present study has demonstrated that a lactate level of 3 mmol/L at 6 hours after transfer to ICU are related to postoperative adverse events and is independently associated with risk of major complication after cardiac surgery. Although the causes of these high lactate levels are numerous and diverse, these results raised the possibility that targeting therapy to reduce or prevent the initial increase in this variable may prevent complications and improve postoperative outcomes.

The distribution of co morbid conditions as diabetes and hypertension among both groups were recorded. Among the study population the difference between the two groups was not statistically significant (p = .907 and p = .568 respectively). Similar non-significant result was found by Hajjar et al.15

Outcome after cardiac operation is determined by preoperative characteristics of the patients in addition to intra operative factors such as operation time, CPB time, and ACC time. The difference between the two groups is statistically significant which indicates that operation time; CPB time and ACC time are one of the important causes of hyperlactatemia. Similarly, Rao et al, Hajjar et al, Maillet et al and Ranucci et al stated that there is significant correlation between CPB time and postoperative adverse outcome.4, 6, 14, 15 Maillet et al and Demers et al also found ACC time as an important perioperative factor that had statistically significant difference between two groups. 11, 14

In the observation of postoperative outcome, the present study found blood transfusion after transfer to ICU control group and in subject group was statistically significant (p = .012). It was consistent with reports in Hajjar et al.15

Rao et al stated that the development of postoperative LOS, in the absence of an intraoperative misadventure revealed a failure of myocardial protection causing persistent anaerobic metabolism and lactate release. In this study regarding low output syndrome the difference between the two groups is statistically significant (p = < .0001).4

Maillet et alashowed in previous study that prolong mechanical ventilation and ICU stay found in hyperlactatemia group and was statistically significant and results werenot similar to our study (p = .080).14 Vincent et al, Bakker et al and Nichol et al ashowed a strong positive correlation between blood lactate levels and the risk of morbidity with neurological deficits as in our study (p = .006), but mortality was not statistically significant (p = .234).6, 10, 18

In our study, we found significant difference among outcome variables like perioperative MI (p = 0.005), arrhythmia (p = 0.001), renal dysfunction (p = 0.002) and pulmonary complications (p = 0.001). Provenchere et al found statistically significant (p = <0.0001) correlation among CPB duration, low output syndrome, vasoactive drugs, reoperation for bleeding with renal dysfunction after cardiac surgery.17 Hajjar et al, Maillet et al and Ranucci et alashowed in their studies a strong correlation between high lactate and major complications after cardiac surgery that are similar with current study. The risk estimation among the study variables are analyzed by multiple binary logistic regressions.6, 14, 15

Hajjar et alashowed that hyperlactatemia 6 hours after ICU admission is an independent risk factor for worse outcome after cardiac surgery.15 This study brought a new perspective to the role of lactate monitoring after cardiac surgery.

In our study, multiple logistic regression analysis showed that higher blood lactate level 6 hours after transfer to ICU is an independent predictor for early postoperative low output syndrome (OR 9.073, 95% CI 2.819 – 29.207, p = < .0001), pulmonary complication (OR 5.734, 95% CI 1.814 – 18.122, p = .003), neurological deficits (OR 9.725, 95% CI 1.111 - 85.147, p = .040), renal dysfunction (OR 7.393, 95% CI 1.855-29.469, p = .005), arrhythmia (OR 10.512, 95% CI 1.902 – 58.108, p = .007) and wound infection (OR 7.742, 95% CI 1.418 - 42.259, p = .018) These findings are similar to previous study. In current study, high lactate is not found as independent predictor of mortality.

Conclusion:
Peak blood lactate level of 3 mmol/L or higher at 6th hour after transfer to ICU is associated with an increased risk of perioperative morbidity and is an independent predictor of major postoperative complications after cardiac surgery under cardiopulmonary bypass.

Limitations of the Study
The study has been prospectively designed; but no real randomization has been performed. Finally, it is performed in a single center, which could restrict the generalization of our findings.

Recommendations
Randomized, controlled trials are needed to evaluate the potential benefit of normalizing lactate levels after cardiac surgery.
References:
Abstract:
Background: The leading cause of mortality in men and women worldwide is coronary artery disease (CAD). For hospitalization in our country, acute coronary syndrome (ACS) is a major reason. Dyslipidemia is found one of the most important modifiable risk factors for CAD.

Aim: The aim of the study was to determine the pattern and prevalence of dyslipidemia among patients with ACS admitted in National Institute of Cardiovascular Diseases (NICVD), Dhaka.

Subjects and methods: One thousand (1000) patients with ACS were included and classified according to clinical presentation, the findings on the admission electrocardiogram (ECG) and the results of serial cardiac troponin levels, into myocardial infarction(MI), either ST-elevation or non ST- elevation MI, and unstable angina(UA) subgroups. In the other group 500 healthy subjects were included as controls. All subjects were subjected determination lipid profile. ECG and Troponin-I were done for diagnosis and follow up of the patients.

Results: In patients with ACS, high levels of TC (>200 mg/dl) were found in 60.67%, high levels of LDL (> 130 mg/dl) were found in 58%, high levels of TG (>150 mg/dl) were found in 63.33%, however, low levels of HDL (< 40 mg/dl) were found in 66%. There was a statistically significant elevation in TC, LDL, TG serum levels in patients with ACS compared to control subjects (p<0.05) while the HDL was significantly low in ACS patient compared to control subjects (p <0.05). TC/HDL > 5 and TG/HDL> 4 were significantly higher in patients with ACS than controls. There was no significant difference between MI and UA patients regarding all lipid profile parameters. TC, LDL, TG were significantly higher in males than in females while HDL was significantly higher in females compared to males. Also TC/HDL and TG/HDL ratios were significantly higher in males compared to females. All lipid components were significantly more prevalent in males than in females except TG where there was no significant difference between males and females. Stepwise regression analysis of lipid parameters revealed that TC/HDL and TG/HDL ratios were independent risk factors for ACS.

Conclusion: Dyslipidemia is one the major risk factors which is widely prevalent in patients with ACS and is more prevalent in males than in females. We recommend paying more attention to serum lipids and other modifiable risk factors for prevention of ACS and more studies about them as risk factors of atherosclerosis and its impact on other systems is advised.

Key words: Dyslipidemia, Acute Coronary Syndrome (ACS)
Introduction:
Worldwide, coronary artery disease (CAD) is the most important cause of death in men and women. Despite of declines in developed countries, both mortality by CAD and the prevalence of risk factors of CAD is continued to increase rapidly in developing countries. The risk factors of CAD used for the categorization and setting of management targets have been established on the basis of evidence accumulated over a long time. Hypertension, Diabetes Mellitus and cigarette smoking have been reported to be risk factors of CAD and stroke through many studies respectively. The risk of CAD was about 4 and 3 times higher in male and female smokers than nonsmokers respectively. Elevated levels of total- and low density lipoprotein cholesterol (TC and LDL-C), elevated levels of triglycerides (TG) and low levels of high density lipoprotein (HDL-C) are important risk factors for CAD. LDL-C is considered as ‘bad cholesterol’ since too high level of this cholesterol is associated with an increased risk of coronary artery disease and stroke. Treating dyslipidemia has clear benefits in the primary and secondary prevention of coronary heart disease (CHD) in both sexes. This study focused on dyslipidemia as a risk factor of acute coronary syndrome (ACS). The aim of the study was to determine the prevalence and pattern of dyslipidemia in subjects with acute coronary syndrome, its relation to age, gender and other modifiable risk factors.

Subjects and Methods:
This cross sectional comparative study was carried out in the National Institute of Cardiovascular Diseases (NICVD), Dhaka during the period from September 2016 to February 2018.

The study included two groups.
Group I included 1000 patients with ACS with the age ranged from 20 to 80 years with a mean age ±SD of 59 ys±8.24. Male patients in the study were 600 (60% of patients) [mean age ±SD (58.85 ys±7.70)] while female patients were 400 (40% of patients) [mean age±SD (61.29 ys±9.37)]. ACS were classified according to clinical presentation, the findings on the admission electrocardiogram (ECG) and the results of troponin-I levels into ST-elevation ACS (STE-ACS) patients presented with acute chest pain, persistent ST-segment elevation and a rise in troponin levels [ST-elevation MI (STEMI)].

Non-ST-elevation ACS (NSTEMI) with a rise in troponin levels. NSTE-ACS is further divided into: Unstable angina (UA) normal troponin levels, Non-ST-elevation MI (NSTEMI) with a rise in troponin levels.

Group II included 500 healthy subjects of non-diabetic, non-hypertensive and nonsmokers. They were selected from attendants coming with the patients. Their ages ranged from 20 to 72 years with a mean age of 57ys±3.53 years. They were 275 (55%) males and 225 (45%) females.

Exclusion Criteria
Patients with stable angina and those receiving anti lipid drugs were excluded from the study.

Methods:
A written consent to participate in the study was taken from each subject. Thorough history of present illness and history of any other diseases were taken. History of previous attacks of acute coronary syndrome and family history of ischemic heart disease were recorded, history of smoking and previous hospital admission were taken in consideration. Clinical examinations of all participants were done. Investigations for lipid profile [total cholesterol (TC), high density lipoprotein (HDL), low density lipoprotein (LDL) and triglycerides (TG)], 12 leads ECGs were performed for diagnosis of the case. Normal and abnormal levels of lipid profile were set shown in Table I.

<table>
<thead>
<tr>
<th>Lipid Profile</th>
<th>Recommended</th>
<th>Borderline</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC</td>
<td>&lt;200 mg/dl</td>
<td>200-240 mg/dl</td>
<td>&gt;240 mg/dl</td>
</tr>
<tr>
<td>HDL</td>
<td>≥40 mg/dl</td>
<td>&lt;40 mg/dl</td>
<td></td>
</tr>
<tr>
<td>LDL</td>
<td>&lt;130 mg/dl</td>
<td>130-160 mg/dl</td>
<td>&gt;160 mg/dl</td>
</tr>
<tr>
<td>TG</td>
<td>&lt;150 mg/dl</td>
<td>150-200 mg/dl</td>
<td>&gt;200 mg/dl</td>
</tr>
</tbody>
</table>

Procedure of cholesterol estimation
5ml blood were withdrawn from each case after 4 hours of admission, then centrifuged at 3000 rpm for 10 minutes. 1 ml of serum was kept at -20°C for measurement. The patients were not getting anti lipid drugs.

Statistical Analysis
Statistical presentation and analysis of the collected data were conducted, using the mean, standard deviation, analysis of variance [ANOVA] test and chi-square test by the SPSS statistical software version 18 for windows.

Results:
Regarding risk factors, we found that 620 patients (62% of patients) were hypertensive, 520 patients (52% of patients) were diabetic and 470 patients (47% of patients) were smokers. All smokers were males.
Myocardial infarction patients included STEMI and NSTEMI. Hypertension was found in 620 patients (62% of subjects). 520 patients were diabetics (52% of patients). Smoking was a habit in 470 patients (47% of patients).

<table>
<thead>
<tr>
<th>Disease</th>
<th>Whole study</th>
<th>Gender</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N %</td>
<td>Male (n=600)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>786 78.6%</td>
<td>n=4 98(83%)</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>214 21.4%</td>
<td>n=102 (17%)</td>
</tr>
</tbody>
</table>

Table-III
Prevalence of the risk factors in relation to gender and ACS

<table>
<thead>
<tr>
<th>Hypertension</th>
<th>DM</th>
<th>Smoking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>%</td>
<td>Number</td>
</tr>
<tr>
<td>Male</td>
<td>434 72%</td>
<td>260 43.3%</td>
</tr>
<tr>
<td>Female</td>
<td>520 52%</td>
<td>296 74.0%</td>
</tr>
<tr>
<td>MI</td>
<td>186 46%</td>
<td>107 10.7%</td>
</tr>
<tr>
<td>UA</td>
<td>520 52%</td>
<td>107 10.7%</td>
</tr>
</tbody>
</table>

Table IV show high levels of TC (more than 200 mg/dl) were found in 606 patients (60.6% of patients), high levels of LDL (more than 130 mg/dl) were found in 580 patients (58% of patients), high levels of TG (more than 150 mg/dl) were found in 633 subjects (63.3% of patients). However, low levels of HDL (less than 40 mg/dl) were found in 660 patients (66% of patients).

<table>
<thead>
<tr>
<th>Type of lipid</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cholesterol [TC] (&gt;200 mg/dl)</td>
<td>606</td>
<td>60.6%</td>
</tr>
<tr>
<td>Low density lipoprotein [LDL] (&gt;130 mg/dl)</td>
<td>580</td>
<td>58%</td>
</tr>
<tr>
<td>High density lipoprotein [HDL] (&lt;40 mg/dl)</td>
<td>660</td>
<td>66%</td>
</tr>
<tr>
<td>Triglycerides [TG] (&gt;150 mg/dl)</td>
<td>633</td>
<td>63.3%</td>
</tr>
</tbody>
</table>

The table V show that there was a statistically significant elevation in TC (total cholesterol), LDL (low density lipoprotein), TG (triglyceride) serum levels in patients with ACS compared to control subjects while the HDL (high density lipoprotein) was significantly low in ACS patients compared to control subjects. TC/HDL>5 and TG/HDL>4 were significantly higher in patients with ACS than controls.

Regarding prevalence and pattern of dyslipidemia in our study,(Table 6), we found that high levels of TC (more than 200mg/dl) were found in 91 patients (60.67% of patients) [mean±SD (217.87 mg/dl±43.61)].

<table>
<thead>
<tr>
<th>Type of lipid</th>
<th>Myocardial Infarction</th>
<th>Unstable Angina</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC (mg/dl)</td>
<td>217.84±44.99</td>
<td>217.97±38.75</td>
</tr>
<tr>
<td>LDL (mg/dl)</td>
<td>139.34±39.94</td>
<td>138.91±32.82</td>
</tr>
<tr>
<td>HDL (mg/dl)</td>
<td>38.15±4.91</td>
<td>38.15±4.91</td>
</tr>
<tr>
<td>TG (mg/dl)</td>
<td>176.45±66.04</td>
<td>175.75±52.95</td>
</tr>
<tr>
<td>TC/HDL</td>
<td>5.74</td>
<td>5.71</td>
</tr>
<tr>
<td>TG/HDL</td>
<td>4.72</td>
<td>4.60</td>
</tr>
</tbody>
</table>

*p <0.05 means significant.

The table VI show high levels of TC (total cholesterol), LDL (low density lipoprotein), TG (triglyceride) serum levels in patients with ACS compared to control subjects while the HDL (high density lipoprotein) was significantly low in ACS patients compared to control subjects. TC/HDL>5 and TG/HDL>4 were significantly higher in patients with ACS than controls.

Regarding prevalence and pattern of dyslipidemia in our study,(Table 6), we found that high levels of TC (more than 200mg/dl) were found in 91 patients (60.67% of patients) [mean±SD (217.87 mg/dl±43.61)].
The prevalence of MI was higher in male gender than females (83.52 % vs 71.19 % respectively) (Table 7).

The prevalence of dyslipidemia and its pattern in patients with ACS were more significant in males than females (p<0.01)(Table 8).

### Table-VIII

<table>
<thead>
<tr>
<th>Prevalence of dyslipidemia in ACS patients in relation to gender</th>
<th>Male (n=600)</th>
<th>Female (n=400)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC (&gt;200 mg/dl)</td>
<td>160</td>
<td>131</td>
<td>0.023</td>
</tr>
<tr>
<td>LDL (&gt;130 mg/dl)</td>
<td>180</td>
<td>127</td>
<td>0.042</td>
</tr>
<tr>
<td>HDL (&lt;40 mg/dl)</td>
<td>102</td>
<td>84</td>
<td>0.011</td>
</tr>
<tr>
<td>TG (&gt;150 mg/dl)</td>
<td>182</td>
<td>76</td>
<td>0.053</td>
</tr>
</tbody>
</table>

*p <0.05 means significant.

Using stepwise regression of lipid profile parameters we found that TC/HDL and TG/HDL ratios were independent risk factors for ACS (Table 9).

### Table-IX

<table>
<thead>
<tr>
<th>Stepwise regression analysis of dyslipidemia in relation to ACS</th>
<th>B</th>
<th>Std. Error</th>
<th>β</th>
<th>Sig.</th>
<th>95% Confidence Interval for B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lower</td>
</tr>
<tr>
<td>TC</td>
<td>.000</td>
<td>.003</td>
<td>-.034</td>
<td>NS</td>
<td>-.012</td>
</tr>
<tr>
<td>LDL</td>
<td>.000</td>
<td>.003</td>
<td>.032</td>
<td>NS</td>
<td>.006</td>
</tr>
<tr>
<td>HDL</td>
<td>.003</td>
<td>.008</td>
<td>.040</td>
<td>NS</td>
<td>.012</td>
</tr>
<tr>
<td>TG</td>
<td>.000</td>
<td>.001</td>
<td>-.141</td>
<td>NS</td>
<td>.002</td>
</tr>
<tr>
<td>TC/HDL</td>
<td>2.435</td>
<td>1.231</td>
<td>0.031</td>
<td>Sig.</td>
<td>1.549</td>
</tr>
<tr>
<td>TG/HDL</td>
<td>2.201</td>
<td>0.768</td>
<td>0.41</td>
<td>Sig.</td>
<td>1.386</td>
</tr>
</tbody>
</table>

Constant: 1.133 .364 --- 0.002 --- ---

**Discussion:**

CAD is a complex and multifactorial process that manifests as stable angina, unstable angina or myocardial infarction. The atherosclerotic process underlies each of these pathologies. Indeed, clinical symptomatology in CAD is frequently triggered by a thrombus formation on an eroded or ruptured atherosclerotic, lipid-rich plaque characterized by a thin fibrous cap.

CAD is the leading cause of death in men and women. Dyslipidemia preponderated among the nine major risk factors (smoking, diabetes, hypertension, visceral obesity, psychosocial stress, sedentary life, low fruit and vegetable consumption and alcohol consumption), and alone accounted for more than 50% of population attributable risk. Regardless of declines in developed countries, both CAD mortality and the prevalence of CAD risk factors continue to rise rapidly in developing countries.

Hypertension is a clear risk factor of ather sclerotic CAD. The risk of CAD has been reported to be 2-6 times higher in diabetics than in non-diabetics. Cigarette smoking has been reported to be a risk factor of CAD and stroke through many studies. The risk of CAD was about 4 and 3 times higher in male and female smokers than nonsmokers respectively.

Dyslipidemia, manifested by elevated levels of total- and low density lipoprotein cholesterol (TC, LDL-C), low levels of high density lipoprotein cholesterol (HDL-C) and high levels of triglycerides (TG), is an important risk factor for CAD.

Our study revealed that hypertension is the most common risk factor of ACS (62.67%) followed by diabetes mellitus (52.67%). Cigarette smoking came at the last (47.33%). Our results agreed with some other studies. Saito et al. found that the prevalence of hypertension was 45.8%, diabetes mellitus was 15.8% while cigarette smoking was 16.7% which differs regarding the prevalence from our study. According to Saito et al., hypertension was the commonest risk factor of acute coronary syndrome followed by cigarette smoking, diabetes mellitus came at the last. In our study smoking, as a risk factor for ACS, came after hypertension and diabetes mellitus, probably, because all our female patients were nonsmoker.

Our study revealed that myocardial infarction (MI) was found in 787 patients (78.67% of patients) while unstable angina (UA) was found in 213 patients (21.33% of patients). In MI, 79 patients (66.95%) were hypertensive, while 63 patients (53.39%) were diabetic and 59 patients (50%) were smokers. On the other hand, in UA, 15 patients (46.88%) were hypertensive, 16 patients (50%) were diabetic and 12 patients (37.50%) were smokers. The increased prevalence of hypertension and smoking were significant in patients with MI (p<0.05) compared to those with UA while it was insignificant regarding diabetes, (table-5). Esteghamati et al. in agreement with our results, found that the prevalence of hypertension and smoking were significantly higher in patients with MI compared to those with UA (96% vs 89.2% for hypertension and 52.8% vs. 38.6% for smoking) while diabetes mellitus was significantly higher in patients with MI compared to patients with UA which was different from our results (44.6% vs 25.2%). Also our results revealed that there was no significant difference between patients with MI and UA regarding all lipid profile parameters (Table 6) which did not agree with that of Guler et al. and Esteghamati et al. who reported that Low levels of HDL were significantly low in subjects with MI compared to those with UA.

High levels of LDL (more than 130 mg/dl) were found in 87 patients (58% of patients) [mean±SD (139.25 mg/dl±38.43)]. Low levels of HDL (less than 40 mg/dl) were...
found in 99 patients (66% of patients) [mean±SD (37.88 mg/dl±4.79)]. High levels of TG (more than 150 mg/dl) were found in 95 patients (63.33% of patients) [mean±SD (174.41 mg/dl±61.42)]. Also, our results revealed that the TC/HDL ratio was more than five (TC/HDL>5) and TG/HDL ratio was more than four (TG/HDL>4). According to the American Heart Association, the goal is to keep TC/HDL ratio <5 and TG/HDL <4. A higher ratio indicates a higher risk of heart disease; a lower ratio indicates a lower risk.

Assessment of lipid profile parameters revealed that there was a statistically significant elevation in serum levels of TC, LDL, TG, TC/HDL, TG/HDL in ACS patients compared with the control subjects while regarding HDL it was significantly low in ACS patients compared to the control subjects (p < 0.05) (Table 7). Our results were in agreement with that of Kamariya et al., 23 and Yadav and Bhagwat15 who reported increased TC, TG, LDL and decreased HDL levels in patients with ACS than controls.

The prevalence of MI was higher in male gender than females (83.52 % vs 71.19 % respectively) (Table 7). This can be explained by our finding that hypertension and smoking were more prevalent in males than in females. Smokers were only males. Regarding the prevalence of diabetes, there were 45 diabetic males (49.45 %( vs 34 diabetic females (57.63%) which was statistically insignificant (Table 4) Another factor which can explain occurrence of MI in males than females was the more prevalent dyslipidemia in male than female patients (Table 7). Our results agreed with that of Leebmann et al.,24 El-Menyal et al.,25 Youssef et al.26 and Noureiddine et al.,27 who reported that MI was more prevalent in males than females.

A higher levels of TG [mean ±SD (174.41mg/dl±61.42)] were found in males compared to that in females [mean ±SD (173.41mg/dl±5, 78)], which was insignificant (p=0.172). These results were the same results of Jacob et al., [32] who reported that men had higher TG and TC levels and lower HDL-levels compared to women (P < 0.001). On the other hand, Esteghamati et al.21, found that mean levels of TG were lower in male patients [170.6±97.3 mg/dl] than in female patients [188.4±88.3 mg/dl]. That would be due to differences in genetics, bodyfat distribution, life styles and dietary habits between different countries where studies were carried out.

Conclusions:
In conclusion, this study revealed that hypertension was the most common risk factor followed by diabetes mellitus and smoking. Hypertension and smoking were more prevalent in males than in females. Regarding dyslipidemia, it was prevalent in ACS patients compared to control. Low level of HDL was the most common, followed by high TG, high TC then high level of LDL, TC/ HDL and TG/HDL ratios. Dyslipidemia was significantly related to gender. TC, LDL, TG were significantly higher in males than in females. There was no significant difference between patients with MI and those with UA regarding all lipid profile parameters, also found that HDL was significantly lower in male than females. Using backward stepwise logistic regression analysis of dyslipidemia, we found that TC/HDL and TG/HDL ratios were independent risk factors for ACS. Based on these results, we can recommend paying more attention to serum lipids for prevention of acute coronary syndrome, periodic check of fasting lipid profile and enriching the people culture about dyslipidemia, its hazards and how to avoid.

References:


Fractional Flow Reserve (FFR) guided Percutaneous Coronary Intervention (PCI) to Avoid Inappropriate Stenting in Patient with Angiographically Significant Stenotic Coronary Artery Lesion–Our Experiences at Apollo Hospitals Dhaka

AHM Waliul Islam¹, Shams Munwar ², Azfar Hossain ³, AQM Reza ², Sahabuddin Talukder ², Tamzeed Ahmed ², Kazi Atiqur Rahman⁴

Abstract:
Background: Importance of Physiological study by Fractional Flow Reserve (FFR) in the management of patient with coronary artery disease (CAD) is well established.

Objective: Angiographic-guided percutaneous coronary intervention (PCI) is a common practice in Bangladeshi interventional era. Data on Pre-PCI physiological study by Fractional Flow Reserve (FFR) in our patient is not available. Therefore, our primary aim was to perform pre-PCI FFR to assess the angiographically significant coronary stenosis and thus to avoid inappropriate stenting.

Methods: Total 22 patients (Male 20, Female 2) were enrolled in this observational non-randomized prospective cohort. Patient who had angiographically significant lesion, planned for physiological study by pre-PCI FFR. Cut off value for FFR were clinically significant only if Pd/Pa ratio <0.75 and differed stenting if > 0.76-0.80 or above.

Results: In the studied patient population, FFR done in total 27 vessels of 22 patients. Among the vessel wise FFR distribution were in LAD 67%(18), LCX 14.8%(4), RCA 14.8%(4) and Ramus Intermedius 3.7% (1). FFR was non-significant (<0.75) in 59% (13) patients and significant (>0.75) were in 41%(9) patients.

Conclusion: In this single center, very preliminary observational prospective cohort of non-randomized study, we found, that FFR is an important aid to perform PCI in patient with angiographically significant coronary lesion, and to avoid inappropriate stenting of insignificant stenosis by physiological study. Thus, to reduce cost and untoward effects of inappropriate stenting.

Key words: PCI, FFR

Introduction;
Myocardial ischemia is a predictor for clinical outcomes in patient with CAD. The presence of myocardial ischemia symptoms is an important determinant or risk factors for adverse clinical outcome.¹ Angiography is the established invasive approach for assessing coronary artery disease, but its ability to evaluate the functional significance of

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Fractional Flow Reserve (FFR) is generally known as an index to assess the physiological significance of coronary stenosis and defined as the ratio of the distal coronary pressure to the proximal pressure during maximum hyperemia using a pressure wire during maximal vasodilatations by using intracoronary or IV adenosine. It has been shown to be an effective method for guiding revascularization. FFR value of <0.75 identifies ischemia-causing coronary stenosis with an accuracy of more than 90%. FFR’s clinical effectiveness first demonstrated by FAME trial which compared angiography guided PCI with FFR guided PCI in patients with Multivessel diseases has showed favorable outcome in FFR-guided PCI.

Recent Guideline on myocardial revascularization recommend revascularization for ischemia related stenosis and medical therapy for non-ischemia stenosis. Current guideline recommendation for FFR guided PCI is class 1A for ESC and class IIA from American College of Cardiology.

In our hospital patient population, data on FFR guided PCI were not available. Therefore, we carried out this very preliminary observational cohort study to see the clinical significance of FFR guided PCI in patients with angiographically significant lesion, thus to avoid inappropriate stenting and cost to patients.

Methods and materials:
Total 22 patients (Male 20, Female 2), were enrolled in this observational non-randomized prospective cohort study of patients. Who had CAG done at our center and found to have approximately >70%-80% lesion were planned for pre-PCI FFR study. Subsequent PCI based on FFR study. Study period were November 2017 to December 2018. Patients were only selected as cases when they were still on aspirin and clopidogrel. Patient were routinely loaded with pre-procedural Ticagrelor 180mg or Clopidogrel 300mg and Aspirin 300mg with post procedural maintenance doses Ticagrelor 180mg bid Clopidogrel 150mg and Aspirin 150mg. Common exclusion criteria were ST elevated acute MI, NSTEMI, Heart Failure, referral for CABG.

Coronary angiogram:
Diagnostic CAG were performed using 5-6 French Terumo Radial catheter through radial approaches. To avoid spasm and to achieve maximal epicardial vasodilatation, intracoronary (0.1-0.3mg) nitroglycerine and mild sedation with 1 mg IV midazolam was commonly given to enrolled patient with prior written consent for the procedures in detail. All stenosis was assessed visually. Patient with approximately >70%-80% lesion were enrolled for pre-PCI FFR study.

FFR:
FFR was defined as the ratio between mean distal coronary pressure and mean aortic pressure at maximal hyperemia. Intracoronary pressure wire 0.014-inch was introduced via a 6F guiding catheter, calibrated, advanced into the coronary artery and placed >3cm distal to the assessed stenosis as described previously. FFR was assessed after the administration of 200mcg/m adenosine to achieve maximal hyperemia. FFR was calculated as the ratio of the mean distal (trans-stenotic) coronary pressure measure by the pressure wire to the aortic pressure measured by the guiding catheter at maximal hyperemia. Generally, PCI was performed in patients with FFR <0.75 and deferred in those with FFR >0.80. For FFR value between > 0.75 to < 0.80, kept on medical management.

Results:
Figure 1. shows the distribution of patient. Total 22 patients (Male 20, Female 2) were enrolled in this observational non-randomized prospective cohort. Patient who had angiographically significant lesion, planned for pre-PCI physiological study by FFR. Cut off value for FFR were clinically significant only if Pd/Pa ratio < 0.75 and deferred stenting if > 0.76. Fig 2. Shows the distribution of CAD risk factors. Fig 3. Shows the percentage distribution of coronaries in which FFR was done. Among the vessel wise FFR distribution; in LAD 67%(18), LCX 14.8%(4), RCA 14.8%(4) and Ramus Intermedius 3.7%(1). Fig 4. Shows the percentage distribution Significant FFR and non-significant FFR. Non-significant were found in 59%(13) patient and significant i.e., > 0.75 were in 41%(9) patient. <Pl add figure 1-4 here>
Fig 5. Coronary Angiogram and FFR in a patient with angiographically significant Proximal OM lesion on left panel and physiological study by FFR of 0.95, insignificant and left for medical management.

Fig 6. Coronary Angiogram and FFR in a patient with angiographically significant Proximal LAD lesion on left panel and physiological study by FFR of 0.75 borderline and kept on medical management.

Fig 7. Coronary Angiogram and FFR in a patient with angiographically significant Proximal LAD lesion on left panel and physiological study by FFR of 0.81 and kept on medical management.

Fig 8. Coronary Angiogram and FFR in a patient with angiographically significant Proximal LAD lesion on left panel and physiological study by FFR of <0.72 and stenting was done.

Fig 2: Percentage Distribution of CAD risk factors

Fig 3: Percentage distribution of studied coronary artery

Fig 4: Percentage distribution of Significant and non-significant Coronary lesion by FFR guided physiological study

Fig 5: Coronary Angiogram and FFR in a patient with angiographically significant Proximal OM lesion on left panel and physiological study by FFR of 0.95, insignificant and left for medical management.
Fig.-6: Coronary Angiogram and FFR in a patient with angiographically significant Proximal LAD lesion on left panel and physiological study by FFR of 0.75 borderline and kept on medical management

Fig.-7: Coronary Angiogram and FFR in a patient with angiographically significant Proximal LAD lesion on left panel and physiological study by FFR of 0.81 and kept on medical management

Fig.-8: Coronary Angiogram and FFR in a patient with angiographically significant Proximal LAD lesion on left panel and physiological study by FFR of <0.72
Discussion:
The presence of myocardial ischemia is a major prognostic factor in patients with symptomatic coronary artery disease and the decision to perform revascularization should be guided on the presence of myocardial ischemia. Fractional flow reserve (FFR) is a reliable physiological parameter to determine the functional significance of coronary stenosis. FFR guided PCI reported to be safe and effective in patients with various lesions subset. In addition, to coronary angiographic abnormalities, the presence and extent of inducible myocardial ischemia is an important prognostic factor in coronary artery disease. The absence of inducible myocardial ischemia is associated with excellent outcome during medical treatment. Therefore, revascularization of non-ischemic stenosis is usually not indicated. However, ischemia-inducing stenosis improves symptoms and outcomes.

The benefit of PCI as an initial treatment strategy in patients with stable CAD remains controversial. De Bruyne et al has shown that FFR guided PCI plus best available medical therapy reduces urgent revascularization. The potential results from revascularization depends on the extent and degree of myocardial ischemia.

In the Bangladeshi interventional era, PCI is a common mode of treatment to open angiographically significant coronary artery stenosis. Although, Pre-PCI FFR is deem neccesitate or mandated to assess physiological significance and thus, to the benefit of PCI by stenting. We are lacking of doing routine FFR due to poor socio-economic status in Government or public hospitals. Recently, we performed some the FFR on those patient who were convinced to have it done before PCI and thus to avoid inappropriate stenting and its hazards.

Fractional flow reserve is generally known as an index to assess the physiological significances of coronary stenosis. A fractional flow reserve value of 0.80 or less (i.e. a drop in maximal blood flow of 20% or more caused by stenosis) as measured by coronary pressure wire during catheterization, indicating the potential of a stenosis to induce myocardial ischemia with an accuracy of more than 90%.

In the current, non-randomized prospective observational study of 22 patients (male 20 and Female 2) in whom the coronary stenosis was angiographically significant, were enrolled for Pre-PCI FFR. FFR less than <0.75 were considered significant and >0.75 were non-significant. Thus, PCI were performed only on FFR<0.75 and for FFR>0.75, were kept on medical management. We found that 59%(13) patient had non-significant FFR and thus, defer PCI, while 41% (9) had significant FFR and PCI done by stenting with a Drug Eluting Stent(DES). The total number of patients are quite small in this present study. The total percentage distribution of non-significant FFR, is more among this studied group of patients, who has eye ball estimated coronary lesion about approximately >70%-80%. FFR was done to validate or justify the needs of PCI, thus to reduce ischemic symptoms. Therefore, it is very primitive to conclude the exact scenario in our Bangladeshi patient population. That’s why we recommend more patient inclusion and if possible to include multicenter in Bangladesh.

Many studies have proved that deferring PCI is safe, based on FFR in coronary intermediate stenosis and FFR guided PCI compared with CAG-guided PCI get much benefit to CAD patients.

Several author has favored FFR guided revascularization, as compared to angiography alone guided revascularization. De Bruyne et al demonstrated that patient with stable CAD, FFR guided PCI as compared with medical therapy alone improved the outcome. In the FFR versus angiography for Multivessel evaluation (FAME) trial, the rate of death, myocardial infarction and urgent repeat revascularization at 2 years with contemporary DES was less than half the rate among patients who received medical therapy alone. It is well known, that the benefits of PCI are mainly attributable to reduction of myocardial ischemia. Therefore, clinical practice guidelines currently recommended PCI only when symptoms of myocardial ischemia are identified.

These important studies increased physician’s awareness on the benefits of FFR-guided PCI and in the current guidelines on coronary revascularization of the ESC, FFR has been upgraded to a class 1A classification in Multivessel PCI.

Moreover, the FAME II trial, subsequently reported that combination of an FFR-guided treatments strategy and the best available medical therapy, improved outcomes in patients with stable coronary disease compared to best available medical therapy. De Bruyne et al demonstrated that more than 25% of patients with stable coronary artery disease who were scheduled to undergo PCI on the basis of clinical and angiographic data, had no significant stenosis with an FFR value of 0.80 or less and were thus unlikely to have had ischemia. Also demonstrated that this patient had favorable clinical outcome at 2year medical therapy alone, a finding that is similar to results in patients with at least one clinically
significant stenosis who were treated with PCI plus medical therapy.

FFR assess the significance of a coronary artery lesion during maximal vasodilation through the use of vasodilators such as adenosine. FFR value (<0.75 have high sensitivity 88% and specificity 100%, positive predictive value 100% with an overall accuracy of 93%. For detecting a reduction in coronary blood flow in patients with stable coronary artery disease. In ACS patients, FFR is limited, not reliable in STEMI patients, whom microvascular dysfunction as embolization of plaque occurs distally as well as inflammation and vasoconstriction. In NSTEMI there is less microvascular dysfunction and FFR may not be significant i.e., <0.80. This is because the clot may dissolve with the initiation of medical therapy resulting lesion to be less of a pressure gradient. Although FFR <0.75 has been shown to be significant in patient with stable coronary disease, this value may not be appropriate in patients with NSTEMI due to physiological differences.

Besides a very high sensitivity and specificity for the detection of inducible myocardial ischemia related to a coronary artery stenosis, FFR has some additional advantages and specific features that make it an easy and convenient practical index to be used in catheterization laboratory, particularly for the assessment of Multivessel disease.

Although, our present patient population number was very small and we found 59% patient angiographically significant stenotic lesions has non-significant FFR and thus defer PCI. Hence, it is very early to say, whether this number reflects the reality in our population in terms of appropriateness of stenting. Also, we need to study FFR in more patients with ACS, stable coronary diseases and Multivessel disease.

In addition, FAME study showed that the FFR-guided PCI resulted in significant cost-saving by reducing stent use, re-hospitalizations and MACE. Thus, the FFR guided treatment could have been more economical in daily practice if decision making for PCI relies more strictly on FFR value.

Baptista et al demonstrated that routine assessment of coronary lesions by FFR, safely changes patient management strategy in half of the patients with a low likelihood of events in deferred revascularization. In addition, our present study is very much consistent with Baptista et al, where we deferred PCI in more than 50% of patient based on FFR value <0.75 and waiting to observe an event in future if any.

Conclusion:
Fractional flow reserve measurements were first introduced at the Mayo clinic in 1999, now is considered as the gold standard for the detection of myocardial ischemia. The safety of functional evaluation is attributed to identification of ischemia-causing coronary stenosis, and its contribution to judicious decision making revascularization. Although, some of the patient with FFR 0.75-0.76 had PCI based on his clinical significant angina. FAME study showed that FFR guided PCI resulted in significant cost saving by reducing stent use of inappropriate stenting, avoidance hospitalization and MACE.

Our present study, supported the rationale for the use of FFR in routine practice. In this present non-randomized observational study, we were able to justify that approximately >70%-80% angiographically significant coronary stenosis by eye ball estimation, were not significant by FFR for PCI and thus, to prevent inappropriate stenting.

Limitation:
We already documented in our center, that FFR is an important tool to evaluate the clinical significance of ischemia, especially in a patient with angiographically significant stenosis. Thus, proved that not all coronary stenosis needs to be stented unless it is proved by FFR. Major limitation is the cost of FFR, if it is significant that is <0.75, then stenting of the coronary artery is mandated and it will increase the total cost of PCI. On the contrary, if not significant, then it will help patient of not to have inappropriate stenting, repeat hospitalization due to stent induced ischemia.

Future perspective
FFR is a cost effective tool to determine the hemodynamic significance of coronary lesion, and can be used to guide appropriate PCI in the cost-conscious setting. Based on our observation, we recommend to make a national data base with mandatory FFR prior to any PCI except STEMI or NSTEMI and compare the benefits of FFR with multicenter involvement.

References:


17. Davis RF, Goldberg AD, Forman, Et al. Asymptomatic cardiac ischemia pilot study two year follow up: outcomes of patients randomized to initial strategies of medical therapy versus revascularization. Circulation 1997;95:2037-2043


Abstract:
Objectives: The objective of this study was to see whether there is an association between high blood glucose levels after operation under CPB and post operative morbidity and mortality.
Methodology: This cohort study was carried out in the Department of Cardiac Surgery at National Institute of Cardiovascular Disease (NICVD), Sher-e-Bangla Nagar, Dhaka from January, 2012 to December, 2013 for a period of twenty four (24) months. A total number of 110 patients who underwent MVR operation with CPB were enrolled in this study as per inclusion and exclusion criteria. Patients were divided into two groups according to their post operative blood glucose levels, recorded within first 60 hrs after mitral valve replacement surgery under cardiopulmonary bypass. Patients having blood glucose level of less than 10.1 mmol/L (unexposed) and patients having blood lactate level of 10.1 mmol/L or more (exposed) were grouped. Post operative variables were observed and recorded during the hospital course of the patient.

Result: A total number of 110 patients were enrolled in this study. Blood glucose levels lower than or equal to 10 mmol/L after MVR were present in 55(50%) patients (Group A) Blood glucose levels higher than 10 mmol/L after MVR were present in 55(50%) patients. Postoperative morbidity was higher in this group (Group B) than in the patients who had peak blood glucose levels of less than or equal to 10 mmol/L MVR (p 0.001). Postoperative ICU stay was prolonged in patients with elevated levels of blood glucose after MVR under CPB compared with of patients with lower blood glucose levels (p 0.001). Other common morbidities are neurological complication (p 0.04), renal dysfunction (p 0.01), wound infection (p 0.04), post-operative hospital stay (p 0.004). also higher in group B patient, as well as mortality.

Conclusions: Blood glucose concentration of 10.1 mmol/L or higher after MVR under CPB is an important issues related to postoperative morbidity and mortality.

Key words: Non diabetic patient , mitral valve replacement . post operative blood glucose control.

Introduction:
Over the last decade, the incidence of diabetes mellitus has increased markedly both in developed and developing countries. Diabetes mellitus has been associated with a poor clinical outcome after cardiac surgery, including a

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higher incidence of wound infections, ischemic events, neurological and renal complications, and mortality. Nevertheless, derangement of glucose metabolism after surgery is not specific to patients with DM.

Hyperglycemia is present in up to 80% of patients after cardiac surgery, about 80% of ICU patients with hyperglycemia have no history of diabetes prior to admission. The risk of hospital complications relates to the severity of hyperglycemia, with a higher risk observed in patients without a history of diabetes compared to those with known diabetes. Improvement in glycemic control reduces hospital complications and mortality. A target glucose level between 7.8 and 10.0 mmol/l (140 and 180 mg/dl) is recommended for the majority of ICU patients.

Hyperglycemia is a marker of in-hospital morbidity and mortality. Observational studies showed that hyperglycemia predicted mortality and infections after surgery. Intravenous insulin regimens to reduce blood glucose immediately after surgery decreased the incidence of infection. Intensive insulin therapy markedly decreased sepsis and mortality among critically ill patients in a surgical ICU.

In recent years, it has also been recognized that tight glucose control markedly improves acute outcomes of hospitalized diabetic patients, including lowering the risk of infection and death. Reports have demonstrated that tight glucose control with continuous intravenous insulin in diabetic cardiac surgery patients reduces mediastinitis, mortality, costs, and length of stay. Lazar and colleagues showed there was also a reduction in postoperative atrial fibrillation and ischemia in cardiac surgery patients. There are now reports demonstrating the outcome benefits of tight glucose control in hospitalized patients, even in the absence of diabetes. For this reason, many researchers have proposed tight glucose control as an effective tool to prevent the deleterious effects of glucose unbalance.

The disturbances in blood glucose homeostasis have been attributed to insulin resistance and/or a failure of pancreatic Î²-cell function caused by the systemic inflammatory response syndrome after cardiopulmonary bypass (CPB) and its effects on systemic temperature. Hyperglycemia is associated with poor outcomes in critically ill and post surgical patients.

Acute hyperglycemia may also have its own deleterious effects that can lead to poor peri-operative outcomes. Once the renal threshold is crossed osmotic diuresis leads to dehydration, electrolyte and acid base imbalance. Hyperosmolarity leads to central nervous system dysfunction and its rapid correction can worsen cerebral oedema.

Acute hyperglycemia occurring intra-operatively abolishes ischemic preconditioning and amplifies reperfusion injury to the heart. In addition, during ischemia, glucose is the preferred substrate for the myocardium, but marked insulin resistance leads to hyperglycemia as a result of impaired cell uptake of glucose which in turn leads to increased concentrations of free fatty acids. Fatty acids are detrimental to the ischemic myocardium because of the increased oxygen consumption required to metabolize the new substrate. Hyperglycemia also leads to increased free radical release and hence increased oxidative stress, causing endothelial dysfunction, which may further affect myocardial ischemia.

Hyperglycemia has a pro-inflammatory action that is normally restrained by the anti-inflammatory effect of insulin secreted in response to that stimulus. Free fatty acids (FFAs) also induce pro-inflammatory changes. During illness, stress increases the concentration of counter-regulatory hormones (mainly glucagon, an epinephrine). Given this background, it is plausible that in the presence of high concentrations of both glucose and FFA, inflammation is more prominent. High circulating concentrations of glucose and FFAs may explain, at least in part, the oxidative and inflammatory derangements during acute illness; insulin may exert its anti-inflammatory action by ameliorating glucose and lipid parameters.

Cardiopulmonary bypass increases post-operative glycemia and insulin consumption in both diabetic and non-diabetic patients. The use of cardiopulmonary bypass during cardiac surgery diabetic patients is associated with more difficult glycemic control in early post operative period.

Material & Method:
This Prospective, Observational study was conducted in the department of cardiovascular surgery, National Institute of Cardiovascular Diseases (NICVD), Sher-e-Bangla Nagar, Dhaka from January 2012 to December 2013. The study was approved by Ethical review committee of NICVD. Informed written consent was obtained from each patient and data will be collected in approved data collection form. The participants had the right to withdraw himself or herself from the study at anytime during study. Interest of study was given highest priority and confidentiality was maintained with safe guard of the right and health of the participants.

Inclusion Criteria:
All non-diabetic adult patients undergoing mitral valve replacement surgery with the use of cardiopulmonary bypass both who are either normoglycemic or developed hyperglycemia postoperatively.

Exclusion Criteria:
Age: Below 18 yrs, above 65years, all diabetic patients, emergency cardiac surgery, patients with poor LV...
function. (LVEF<30%), patients with redo-valve surgery, patient with LA thrombus, patient with congestive cardiac failure, patients with cardiomyopathy, patient with renal failure, patients with stroke, Patients with prolonged cardiopulmonary bypass(>120 mins).

Study population: The study was carried out on non-diabetic adult patients undergoing mitral valve replacement surgery with the use of cardiopulmonary bypass developing postoperative hyperglycemia fulfilling the inclusion and exclusion criteria.

Preoperative characteristics of study patient: Each patient was assessed by history, clinical examination, and preoperative investigations (All routine investigation and was recorded in the preformed data).

Grouping of the Patients:
Group: A (n=55) Patients with good post operative blood glucose control(10 mmol/l or less).
Group: B (n=55) Patients with poor post operative blood glucose control( blood glucose >10 mmol/l).

Anesthesia, surgical technique and postoperative management
Standard anesthetic and surgical techniques was followed, heparin was given to maintain the activated clotting time at 480 seconds throughout CPB. A standard CPB circuit was used with non pulsatile flow at a rate through out bypass of 2.4 L / min / m2 and a mean arterial pressure kept 50 to 60 mm Hg. Myocardial protection was achieved with intermittent ante grade cold-blood cardioplegia. For all cases, myocardial protection was predominantly maintained by intermittent antegrade with moderate systemic hypothermia (28°C to 32°C).

For all patients mechanical bi-leaflet valve prosthesis was used. At the end of mitral valve replacement, adequate de-airation was ensured, patients were weaned from CPB, then patients was transferred to the intensive care unit and ventilated with 70% oxygen using volume-controlled ventilation. Patients were extubated after fulfilling the criteria for extubation. Proper perioperative analgesia and sedation was ensured. Patient was discharged from ICU after attainment of haemodynamic stability, weaning from all inotropic support and removal of chest drain.

Per-operatively CPB time, X-clamp time, post operatively highest post operative (venous) blood glucose value ( within first 60 hrs), mechanical ventilation time( hrs), ICU stay (hrs), neurological complications (stroke), renal failure (elevated serum creatinine two times preoperative value), post surgical infection (wound infection) and inhospital mortality were recorded and were compared between two groups. Proper management of all these complications were be done accordingly. After achieving target INR patients were discharged. Patients developing complications were kept in hospital for adequate management.

Post-operative Glucose Measurement:
Venous sample of blood will be taken to measure blood glucose. Blood glucose measurement was done by enzymatic colourimetric method with DIMENSION X-PAND, PLUS, SIEMENS analyzer.

Post-operative Glucose Management:
All MVR patients developing post operative hyperglycemia (blood glucose>10mmol/L) were started on a sliding-scale insulin infusion as well as iv bolus soon after surgery to maintain blood glucose levels less than 10mmol/L according to a standard protocol. Multiple samples were collected according to the protocol for blood glucose measurement. The highest blood glucose value was recorded within 60 hrs after surgery.

Protocol for blood glucose management: ( Bojar 5th edition P 755)

<table>
<thead>
<tr>
<th>Blood Sugar</th>
<th>Regular Insulin IV Bolus</th>
<th>Infusion Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>151-200</td>
<td>No bolus</td>
<td>2Units/h</td>
</tr>
<tr>
<td>8.3-11.11mol/l</td>
<td></td>
<td></td>
</tr>
<tr>
<td>201-240</td>
<td>4 Units</td>
<td>2 Units/h</td>
</tr>
<tr>
<td>11.12-13.33mol/l</td>
<td></td>
<td></td>
</tr>
<tr>
<td>241-280</td>
<td>6 Units</td>
<td>4 Units/h</td>
</tr>
<tr>
<td>13.34-15.55mol/l</td>
<td></td>
<td></td>
</tr>
<tr>
<td>281-320</td>
<td>10 Units</td>
<td>6 Units/h</td>
</tr>
<tr>
<td>15.56-17.77mol/l</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This infusion was continued for the first 24 hours and blood glucose measurement was done hourly. Then, patients were switched to subcutaneous soluble insulin, and blood sugar levels were monitored every 8 hours.

Data Collection: Data were collected by interview of the patients, clinical examination, laboratory investigation, hospital records peroperative and postoperative findings. Then data was put in data master sheet using SPSS.

Statistical Analysis:
After processing all available data, statistical significance was analyzed. Data were expressed as mean ±SD, frequency, percentage as applicable. Intergroup comparisons of BGC after surgery was done using 2-tailed t tests to determine the significance of difference. To show the relationship between the variables Pearson correlation analysis was performed. P-value <0.05 will be considered statistically significant. All the data entry and analysis were done by using SPSS (latest version) soft ware program.
Results:
A total number of 110 elective MVR patients were enrolled for this study and divided into two groups according to the post operative blood glucose level. Those patients who were below ≤10 mmol/L were designated as Group A and those patients who were above 10 mmol/L were designated as Group B.

Table-I
Age distribution of the study patients (n=110)

<table>
<thead>
<tr>
<th>Age in years</th>
<th>Group A (n=55)</th>
<th>Group B (n=55)</th>
<th>Total (n=110)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td>20 – 30</td>
<td>12</td>
<td>21.8</td>
<td>14</td>
<td>25.5</td>
</tr>
<tr>
<td>31 – 40</td>
<td>31</td>
<td>56.4</td>
<td>31</td>
<td>56.4</td>
</tr>
<tr>
<td>41 – 50</td>
<td>12</td>
<td>21.8</td>
<td>10</td>
<td>18.2</td>
</tr>
<tr>
<td>Mean ± SD(Range)</td>
<td>36.4±6.7(20-50)</td>
<td>35.3±6.2(22-50)</td>
<td>35.9±6.5(20-50)</td>
<td>0.34ns</td>
</tr>
</tbody>
</table>

Table-II
Distribution of study patients according to sex (n=110)

<table>
<thead>
<tr>
<th>Sex</th>
<th>Study group</th>
<th>Total</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A(n=55)</td>
<td>Group B(n=55)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>25 (45.5%)</td>
<td>26 (47.3%)</td>
<td>51 (46.4%)</td>
</tr>
<tr>
<td>Female</td>
<td>30 (54.5%)</td>
<td>29 (52.7%)</td>
<td>59 (53.6%)</td>
</tr>
<tr>
<td>Total</td>
<td>55(100.0%)</td>
<td>55(100.0%)</td>
<td>110(100.0%)</td>
</tr>
</tbody>
</table>

Table-III
Distribution of BMI and BSA status of the study patients (n=110)

<table>
<thead>
<tr>
<th>Categories</th>
<th>Study group</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A(n=55)mean±SD</td>
<td>Group B(n=55)mean±SD</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>21.4±1.7</td>
<td>21.5±1.4</td>
</tr>
<tr>
<td>BSA (m²)</td>
<td>0.7±0.1</td>
<td>0.7±0.1</td>
</tr>
</tbody>
</table>

Table-IV
Distribution of pre-operative biochemical parameters among the study patients (n=110)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Glucose Group</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A(n=55)mean±SD</td>
<td>Group B(n=55)mean±SD</td>
</tr>
<tr>
<td>HbA1C (%)</td>
<td>5.22±0.35</td>
<td>5.22±0.38</td>
</tr>
<tr>
<td>S. Creatinine (mg/dl)</td>
<td>0.78±0.08</td>
<td>0.81±0.07</td>
</tr>
<tr>
<td>RBS (mmol/L)</td>
<td>6.24±0.59</td>
<td>6.36±0.57</td>
</tr>
</tbody>
</table>

Table-V
Echocardiographic results (LVEF) among the study patients (n=110)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Study group</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A(n=55)mean±SD</td>
<td>Group B(n=55)mean±SD</td>
</tr>
<tr>
<td>LV EF %</td>
<td>52.29±5.01</td>
<td>52.36±4.46</td>
</tr>
</tbody>
</table>
Table VI

Comparison of per-operative variables between groups

<table>
<thead>
<tr>
<th>Duration</th>
<th>Study group</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A(n=55)</td>
<td>Group B(n=55)</td>
</tr>
<tr>
<td>Mean±SD</td>
<td>Mean±SD</td>
<td></td>
</tr>
<tr>
<td>CPB time (min.)</td>
<td>85.07±8.46</td>
<td>88.65±14.42</td>
</tr>
<tr>
<td>X clamp time (min.)</td>
<td>57.21±6.03</td>
<td>60.05±6.66</td>
</tr>
</tbody>
</table>

Table VII

Distribution of stress-induced hyperglycemia among the post-surgical patients (n=110).

<table>
<thead>
<tr>
<th>Stress induced hyperglycemia</th>
<th>Post operative Blood Glucose</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperglycemic &gt;7.80mmol/L (n=82)</td>
<td>Normoglycemic ≤7.80mmol/L (n=28)</td>
<td>110 (100.0)</td>
</tr>
<tr>
<td>Frequency (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>84 (76.4)</td>
<td>26 (23.6)</td>
<td></td>
</tr>
</tbody>
</table>

Table VIII

Comparison of the highest post-operative blood glucose value among the study patients (n=110)

<table>
<thead>
<tr>
<th>Highest post-operative blood glucose value</th>
<th>Study Group</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A(n=55)</td>
<td>Group B(n=55)</td>
</tr>
<tr>
<td>Mean±SDmmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.12±1.42</td>
<td>14.18±2.24</td>
<td>0.001&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Table IX

Comparison of Mechanical Ventilation Time (MVT) and Duration of ICU stay among the study population (n=110)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Study group</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A(n=55)</td>
<td>Group B(n=55)</td>
</tr>
<tr>
<td>Mean±SD</td>
<td>Mean±SD</td>
<td></td>
</tr>
<tr>
<td>Mechanical Ventilation Time (min.)</td>
<td>8.94±2.47</td>
<td>13.02±10.42</td>
</tr>
<tr>
<td>Duration of ICU stay in days</td>
<td>1.47±0.50</td>
<td>2.00±0.66</td>
</tr>
</tbody>
</table>

Table X

Comparison of post-operative complications among the study patients (n=110)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Study group</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A(n=55)</td>
<td>Group B(n=55)</td>
</tr>
<tr>
<td></td>
<td>Mean±SD</td>
<td>Mean±SD</td>
</tr>
<tr>
<td>Neurological Complications (Present)</td>
<td>3</td>
<td>11</td>
</tr>
<tr>
<td>Renal Dysfunction (Present)</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>Post operative Hospital stay in days</td>
<td>8.89±1.81</td>
<td>10.38±3.28</td>
</tr>
<tr>
<td>Post surgical infection (Present)</td>
<td>4</td>
<td>12</td>
</tr>
<tr>
<td>Mortality (Yes)</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>
Discussion:
The present study performed in NICVD, Dhaka, included a total number of 110 mitral valve replacement surgery patient under CPB and was divided into two groups according to post operative blood glucose level. Those patients whose highest blood sugar level were below or equal to 10 mmol/L were designated as group A and those patients whose highest blood sugar level were above 10 mmol/L were designated as group B. The distribution of study population is recorded according to age. All patients in group A 55 (50.0%) and group B 55 (50.0%) are within less than 60 years group. It has been found that middle aged people or young adult persons most commonly underwent mitral valve replacement surgery in this study.

The mean age of the studied patients were 35.9±6.5 years ranging from 20 to 50 years. The mean age was found 36.4±6.7 years in group A and 35.3±6.5 years in group B. There was no significant difference of age distribution between two groups (P>0.05) (tabe 1).In the study of Chowdhury et al mean age was 33.08 years. Our observation was similar to these studies.

The distribution of stress induce hyperglycemia among the study population 85 (78.54%), (table- 7). This result is consistent with other studies. Farnoosh et al, showed in one study that 80% non diabetic patients develop stress induced hyperglycemia after cardiac surgery during their ICU stay in their early post operative days.

The distribution of BMI, BSA, HbA1C, LVEF, Serum Creatinine and RBS between Blood Glucose groups were recorded (Table 3-6). Most of the patients were non smokers. The left ventricular ejection fraction was observed in group A and group B (52.29±5.01 vs 52.36±4.46) with statistically insignificant difference (p>0.05). Body mass index and body surface area were almost identically distributed in both groups insignificant difference (p>0.05).

The biochemical parameters were similar in the both groups. HbA1C was found in group A and group B (5.22±0.35 vs 5.22±0.38) with statistically insignificant difference. Serum creatinine was observed in group A and group B (0.78±0.08 vs 0.81±0.07) with statistically insignificant difference. Random blood sugar was also observed in group A and group B (6.24±0.59 vs 6.36±0.57) with statistically insignificant difference.

Mechanical ventilation time was observed significantly greater in group B than group A (8.94±2.47 vs 13.02±10.42) minute with p=0.02 ( Table-9 ). It was also observed that duration of ICU stay was observed (1.47±0.50 vs 2.00±0.66) days which was significantly higher in group B (p=0.001), (Table-9). Similar result was published by Ascione, et al., Ouattara, et al.

Neurological complication (Table-10) was observed 20% in group B and 5.5% in group A with statistically significant
difference (p=0.04). Capes and his associates showed poor prognosis for poor postoperative blood glucose controlled individuals 18.

Renal dysfunction (Table-10) was also observed 23.3% in group B and 5.5% in group A with statistically significant difference (p=0.01). Similar result was published by Ascione et al.1 They showed that in post operative poor blood glucose control patients the renal dysfunction is about 25%. Which is almost as same as our study results.

Post operative hospital stay was observed in group B and group A (10.38±3.28 vs 8.89±1.81) days with significant difference (p=0.004). Ascione and associates in 2008 observer increased hospital stay in post operative hyperglycemic population. This finding is consistent with our study.

Post operative surgical infection (Table-10) was observed significantly greater in group B than group A (21.8% vs 7.3%) with p=0.04. 3 (5.5%) Ascione, et al., 2008 also showed significant wound infection resulted in post operative poor blood glucose group. Dandona and his colleagues explained this in their study 14.

Patient's post operative death 3(3 (5.5%) in group B and 1(1.8%) in group A (table-10) which was found statistically insignificant (p=0.31). Capes et al. 18 and Ascione, et al.1 showed significant mortality in poor post operative blood glucose control group of patients.

Highest post operative blood glucose level was observed significantly higher in adverse hospital outcome patients than good hospital outcome patients (15.18±3.05 vs10.44±2.12) mmol/L with p=0.001. Similar result was published by Ascione et al.1. Dandona et al 14. So, controlling of post operative blood glucose level is an important factor to reducing adverse in hospital outcome.

Conclusion:
In conclusion, the findings of this study permit to conclude that a peak blood glucose level of 10.1 mmol/L or higher during CPB is associated with an increased risk of perioperative morbidity. Most common morbidities are infection, neurological complication and renal dysfunction. Post operative ICU stay and hospital stay is also longer in higher blood glucose group. Although mortality is higher in the high blood glucose group of patients operated under CPB during mitral valve surgery difference between higher and lower blood glucose group is not significant. Although initially we thought that a high blood glucose level could be an independent predictor of in-hospital mortality, but the study showed insignificant result. It would be worth mentionable that a higher proportion of mortality is observed in the higher post operative blood glucose group, a further study with larger sample size could be done to see the consequence.

Limitations:
There are some limitations in this study. Some are mentioned below. It was a purposive non-random sampling method. The proposed post operative blood glucose control threshold value differed from the threshold value chosen by other authors for different clinical setup.

For further study, the following recommendations are proposed: Further large scale study should be carried out. Further studies should be carried out to determine level of blood glucose control during and after CPB time and interventions based on blood glucose values to improve survival in adult non-diabetic cardiac surgical patients.

References:


Management of Diabetic Foot Ulcer in a Tertiary Level Hospital-Faridpur

Gaddafi AL1, Das DK2, G Faruque3, Z Islam4, Rahman MA5, FN Jui6, KM Walid7, A Biswas8

Abstract:
A descriptive type of cross sectional study among 210 diabetic patients with foot ulcer was carried out in Diabetic Association Medical College during the period of May 2016 to April 2017 and were categorized based on Meggitt-Wagner system to find out the complications, management, below knee amputation rate and mortality rate. The aim of this study was to practise a profile of diabetic foot ulcer (DFU), complications and its management to assess the outcome of the surgical interventions. Majority of the patients were male 112(53%), and most of them 1 16 patients (55.23%) presented within Wegner grade - 2 and grade-3 diabetic foot ulcers. The duration of diabetes more than 10 years was 116 (55%). 99 (47%) patients out of 210 patients developed diabetic neuropathy . 76 (36%) patients presented with CKD. Lack of awareness about diabetes mellitus and its lower limb complications, poor compliance to the treatment, poorly controlled blood sugar levels, delay in diagnosis, and late presentation to the tertiary care center, associated habit of smoking are all factors which lead to incidence of DFU at an earlier age than that seen in other studies. After admission of diabetic foot ulcer patients, diabetic foot ulcer is classified according to Wagner grading and treated the diabetic foot ulcer patients as the using protocol '11'.Assessment whether it was conservative or surgical. 2. Optimal blood sugar control. 3. Systemic antibiotic. 4. Moist wound environment. 5. Offloading such as total contact casting. 6. Improves peripheral arterial circulation due to lack of vascularity. 7. Surgical debridement or minor amputation or major amputation.

Keywords: Diabetic foot ulcer, Management, Meggitt-Wagner grading, Diabetes mellitus.

Introduction:
The world is facing a major epidemic of diabetes. About 194 million people worldwide or 5.1% in the age group of 20 to 79 were estimated to have diabetes in 2003 and this estimate is expected to increase to some 330 million or 6.3% of the adult population by 20251. Diabetes mellitus appears to be a global epidemic and increasingly a major non-communicable disease threatening both affluent and non-affluent society2,3. More than 170 million people

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worldwide have diabetes and this figure is projected to be more than double by the year 2030, if the current trend is allowed to continue further\(^4\). One of the major complications of DM is diabetic foot.

The World Health Organization defines, “Diabetic foot as the lower limb of a diabetic patient that has the potential risk of pathological consequences, including infection, ulceration and/or destruction of deep tissues associated with neurologic abnormalities, various degrees of peripheral vascular disease, and/or metabolic complications of diabetes”.

Diabetic foot ulcer is the most common cause for prolonged hospitalization. It occurs in 15% of patients with diabetes in their lifetime\(^5\), \(^6\), \(^7\). Risk factors for foot ulcer include male gender, duration of diabetes more than 10 years, peripheral neuropathy, foot deformity, peripheral vascular disease, smoking, history of prior ulcers or amputation, poor glycem control\(^7\), \(^8\), \(^9\), genetic and nutritional factors\(^10\), diabetic retinopathy and nephropathy\(^11\).

Among them the main factor is peripheral neuropathy. Diabetic neuropathy can cause insensitivity or a loss of ability to feel pain, heat and cold\(^12\). Diabetics suffering from neuropathy can develop minor cuts, scrapes, blisters or pressure sores that they may not be aware of due to the insensitivity. If these minor injuries are left untreated, complications may result and lead to ulceration and possibly amputation of toe and even loss of foot\(^13\). Diabetic peripheral neuropathy can also cause foot deformities such as bunions, hammer toes and charcot’s foot. These are resulting from undue bony prominences with high pressure points, leading to calllosities and ulcerations\(^10\).

The best approach in dealing with diabetic foot is prevention of ulcer through the identification of individuals at risk, patient education and follow up \(^4\).

In this study, all cases were known case of type 2 diabetes and neuropathy was the main factor for developing diabetic foot ulcer. This study shows that increasing age, long duration of diabetes, high level of HbA\(_1c\) usually more than 10%, late presentation, inadequate control of diabetes, smoking and lack of education about diabetes increased the risk of diabetic foot.

Materials and methods:
In this descriptive type of cross sectional study conducted on all diabetic foot ulcer patients in DAMCH, Faridpur from May 2016 to April 2017 were studied.

Inclusion criteria: All type-2 diabetic patients were included in this study.

Exclusion criteria: Diabetic foot patients with septic shock, diabetic ketoacidosis, hyperglycemic hyperosmolar state and electrolyte imbalance were excluded in this study.

Ankle-brachial pressure index, doppler study and retinopathy were excluded in all patients. Detailed history such as age, sex, marital status, smoking, socio-economic condition, duration of ulcer with associated other condition and standard clinical examination for neuropathy such as callus formation in the foot, claw toes, flat foot, hammer toes, charcot foot, vascular assessment were done. Possible included laboratory investigations such as Hb%, fasting blood sugar, 2 hours after breakfast, serum creatinine, HbA\(_1c\), ECG were done. Foot ulcers were treated according to Wagner classification.

Wagner grading is given bellow:
Grade - 0 - No ulceration in a high risk foot.
Grade - 1 - Superficial ulceration
Grade - 2 - Deep ulceration but no bony involvement, no abscess
Grade - 3 - Osteomyelitis or deep abscess
Grade - 4 - Localized gangrene
Grade - 5 - Extensive gangrene

Questions regarding symptoms of neuropathy and vascular disorder including numbness, abnormal hot and cold sensation, tingling sensation, burning pain, aching pain, intermittent claudication, skin discoloration of foot were asked and recorded.

Neuropathy was assessed by tuning fork and monofilament. Areas of callus, necrotic and ulcer area were avoided in testing. Sensory testing was performed at seven locations on each foot using the Semmes-Weinstein monofilament. The patient was explained what were we going to be done and why? Then monofilament was applied somewhere on the person, such as the forearm, so that the sensation of the monofilament can be experienced. The person was asked to close his or her eyes and to say “yes” every time the monofilament is felt. The monofilament was applied to the tips of the first, third, and fifth toes on the weight-bearing surface of each foot in any order. The person’s ability to detect the light pressure of the monofilament was recorded. Any sites that do not invoke a response was rechecked.

The monofilament must be placed at 90 degree to the skin surface. It should be applied and released in a controlled manner, over a period of 1-2 seconds. When applied and held, the monofilament should buckle at about 1 cm from the horizontal line. It must not “wiggle” or slide when held in place. Inability to detect one or more sites in each foot indicates sensory deficit and increased ulcer risk.
Sensory testing was also assessed by tuning fork. The tuning fork was held by gripping the flat-ridged area at the base of the thumb and forefinger. With thumb and forefinger the limbs of the tuning fork were pressed together at its tip. Then thumb and forefinger were sharply pulled away allowing the limbs resonate.

The tuning fork was placed on a bony area away from the foot, such as the elbow, so that individual can identify the sensation of the vibrating tuning fork. This process was repeated and the tuning fork was placed on the tip of the individual’s great toe and the patient was asked what he or she could feel. There was little need to test anywhere else, for the same reason outlined for 10-g monofilament use.

Peripheral vascular disease was assessed only by palpatory method because hand held doppler was not available in this institute to determine ankle brachial index.

Result:

Fig-1: Distribution of the diabetic foot ulcer patients according to sex.

Fig-1 shows that among 210 DFU patients, 112 (53%) patients were male and 98 (47%) patients female.

Fig-2: Distribution of the diabetic foot ulcer patients according to age.

Fig-2 shows that the age of the patients ranged from 40-70 years, where 122 (58%) patients were below 50 years and 88 (42%) patients were above 50 years

Table-I

<table>
<thead>
<tr>
<th>Time of attending the healthcare centre following ulceration.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset of diabetic foot ulcer</td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td>&lt; 10 days</td>
</tr>
<tr>
<td>10-20 days</td>
</tr>
<tr>
<td>&gt;20 days</td>
</tr>
</tbody>
</table>

Table-1 shows that 96 (45%) patients attended in this hospital within 10 days, 66 (31%) patients within 10-20 days and 48 (24%) patients more than of 20 days of onset of symptoms.

Fig-3: Distribution of the diabetic foot ulcer patient according to duration of diabetes

Fig-3 shows that the duration of diabetes below 10 years was 94 (45%) patients, where as above 10 years was 116 (55%) patients.

Fig-4: Distribution of the patients according to smoking habit.
Fig-4 shows that 47 (22%) patients were smokers and 163 (78%) patients were non-smokers.

Table-II
Distribution of patients according to grading of diabetic foot

<table>
<thead>
<tr>
<th>Grade</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>G - 1</td>
<td>54</td>
<td>26%</td>
</tr>
<tr>
<td>G - 2</td>
<td>58</td>
<td>28%</td>
</tr>
<tr>
<td>G - 3</td>
<td>58</td>
<td>28%</td>
</tr>
<tr>
<td>G - 4</td>
<td>18</td>
<td>8%</td>
</tr>
<tr>
<td>G - 5</td>
<td>22</td>
<td>10%</td>
</tr>
</tbody>
</table>

Table-2 shows out of the 210 cases, 54 (26%) patients were in G-1, 58 (28%) patients were in G-2, 58 (28%) patients were in G-3, 18 (8%) patients were in G-4, 22 (10%) patients were in G-5.

Table-III
Distribution of the patients according to hemoglobin & HbA1C level

<table>
<thead>
<tr>
<th>Hb%</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;10 g/dl</td>
<td>130</td>
<td>62%</td>
</tr>
<tr>
<td>&lt;10 g/dl</td>
<td>80</td>
<td>38%</td>
</tr>
<tr>
<td>HbA1C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.8-10</td>
<td>103</td>
<td>49%</td>
</tr>
<tr>
<td>&gt;10</td>
<td>107</td>
<td>51%</td>
</tr>
</tbody>
</table>

Table-3 shows 130 (62%) patients had Hb level > 10 g/dl and 80(38%) patients had < 10 g/dl. HbA1C level was 7.8-10% in 103 (49%) patients where it was >10% in 107 (51%) patients.

Table-IV
Distribution of patients according to hospital stay

<table>
<thead>
<tr>
<th>Hospital stay (days)</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10</td>
<td>97</td>
<td>46%</td>
</tr>
<tr>
<td>10-20</td>
<td>65</td>
<td>31%</td>
</tr>
<tr>
<td>&gt;20</td>
<td>48</td>
<td>23%</td>
</tr>
</tbody>
</table>

Table-4 shows that 97 (46%) patients had to stay in this hospital below 10 days, 65 (31%) patients ranged from 10-20 days, 48 (23%) patients above 20 days. Amputation rates were high in G-4, 5 compared to other Grades.

54(26%) patients of G-1 were treated by conservative (1. Optimal blood sugar control. 2. Systemic antibiotic. 3. Moist wound environment. 4. Offloading 5. Improves peripheral arterial circulation due to lack of vascularity) and discharged without any complication where as other Grade patients were treated by operation. 75(36%) patients of G-2 & G-3 ulcers were treated by surgical debridement followed by secondary closure or split thickness skin graft. 59(28%) patients of G-3 and G-4 were treated by minor amputation because it could not be preserved due to vascular insufficiency. 22(10%) patients of G-5 were treated by major amputation.

Table-V
Distribution of patients according to treatment protocols.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number and percentage of G-1</th>
<th>Number and percentage of G-2 and G-3 combined</th>
<th>Number and percentage of G-3 and G-4</th>
<th>Number and percentage of G-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conservative</td>
<td>54(26%)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Debridement followed by secondary closure split thickness skin graft</td>
<td>-</td>
<td>75(36%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Minor amputation</td>
<td>-</td>
<td>-</td>
<td>G-3 41 (19%)</td>
<td>G-4 18 (9%)</td>
</tr>
<tr>
<td>Major amputation</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>22 (10%)</td>
</tr>
<tr>
<td>Total Patients (G1-G5)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>210</td>
</tr>
</tbody>
</table>
Discussion:
In this study, majority of the patients (55%) had duration of diabetes of more than 10 years and mean duration of symptoms was 9.2 ± SD years. In our study, mean duration of diabetes was dissimilar than those of muduli et al study and Bansal et al study respectively. Slight male predominance was observed as the male female ratio was 1.14 only. On the other hand, the average age of the present study population was similar with that of 54.57 years in muduli et al study and 57.05 years in Bensal et al study respectively. Majority of the patients were non-compliant to the treatment protocol due to prolonged hospital stay, higher cost, delay in healing potential, neglected by their near and dear ones. 51% patients presented HbA1C >10% in this hospital which was similar to the other studies. In our study, Neuropathy was more prevalent to develop DFU.

Major amputation rate was high in grade 5 and minor amputation was high in grade-4 compared to grade-3. G-1 patients (26%) were treated conservatively where as other grade (G-2 & G-3) patients were treated by operation such as surgical debridement followed by secondary closure or split thickness skin graft or minor amputation. 97 (46%) patients had to stay in this hospital below 10 days, 65 (31%) ranged from 10-20 days, 48(23%) above 20 days. 96 (45%) patients were attended in this hospital within 10 days of onset of developing ulcer, 66 (31%) patients within 10-20 days and 48 (24%) patients more than 20 days of onset of developing ulcer which were late presentation due to insensitive foot, unawareness of lower limb complication.

In this study, DFU was a complication seen exclusively in diabetic patients and it developed usually in the sixth and the seventh decades of life which was compatible with other studies. It usually developed at 5- to 10-years duration of diabetes mellitus. The main predisposing factors were peripheral neuropathy and peripheral vascular disease. Other contributory risk factors include obesity, sedentary life style, poor glycemic control, and alcoholism. Smoking has got special attention with 3 times higher incidence in this study supported by others which may mimic the disease process. DFU coexist with comorbidities like CKD that was shown in our study. Other systemic complications such as septic shock, diabetic ketoacidosis, hyperglycemic hyperosmolar state and hyponatremia which could be life threatening if not recognized and treated promptly. Among the 210 patient, most of the patients presented within Wagner G-I to G-3. Debridement and split thickness skin graft were the most frequently performed surgical intervention for DFU in present and the same in other studies. Maximum patients of G-1,2 thus saved conservatively or by minimal intervention where in G-3, 4 and 5 patients need to be amputated. The disease was a financial burden to the patient as the average hospital stay was 15 days.

Conclusion:
Early presentation of diabetic foot ulcer patients can be prevented from minor or major amputation. We should emphasis to identify the high risk foot and should arrange health education programs so that the diabetic patients can know about the importance of optimizing blood glucose level, using appropriate footwear, avoiding foot trauma, performing self foot examination daily by using mirror and reporting any changes to health care profession to prevent diabetic foot ulcer. So the outcome of management is better in G-1 and G-2 than G-3, G-4 and G-5.

Reference:-


Peripheral Vascular Intervention: A Review

Mohsin Ahmed 1, Abul Hasan Muhammed Bashar 2, Abdullah Al Gaddafi 3

Abstract:
The prevalence of peripheral artery disease (PAD) continues to increase worldwide. It is important to identify patients with PAD because of the increased risk of myocardial infarction, stroke, and cardiovascular death and impaired quality of life because of a profound limitation in exercise performance. Lower extremity PAD affects approximately 10% of population, with 30% to 40% of these patients presenting with claudication symptoms. Peripheral arterial disease is common, but the diagnosis frequently is overlooked because of subtle physical findings and lack of classic symptoms. Screening based on the ankle brachial index using doppler ultrasonography may be more useful than physical examination alone. Noninvasive modalities to locate lesions include duplex scanning, computed tomography angiogram, magnetic resonance angiography and invasive modalities peripheral angiogram is the gold standard. Major risk factors for peripheral arterial disease are cigarette smoking, diabetes mellitus, older age (older than 40 years), hypertension, hyperlipidemia, and hyperhomocystinemia. Intermittent claudication may be improved by risk-factor modification, exercise, and pharmacologic therapy. Based on available evidence, a supervised exercise program is the most effective treatment. Effective drug therapies for peripheral arterial disease include aspirin (with or without dipyridamole), clopidogrel, cilostazol, and pentoxifylline. By contrast, critical limb ischemia (CLI) is considered the most severe pattern of peripheral artery disease. It is defined by the presence of chronic ischemic rest pain, ulceration or gangrene attributable to the occlusion of peripheral arterial vessels. It is associated with a high risk of major amputation, cardiovascular events and death. The management of CLI should include an exercise program, guideline-based medical therapy to lower the cardiovascular risk. Most of the cases, revascularization is indicated to save limbs; an “endovascular first” approach and lastly surgical approach, if all measures were failed. The choice of the intervention is dependent on the anatomy of the stenotic or occlusive lesion; percutaneous interventions are appropriate when the lesion is focal and short but longer lesions must be treated with surgical revascularisation to achieve acceptable long-term outcome.

Introduction:
The prevalence of peripheral artery disease (PAD) continues to increase worldwide. It is important to identify patients with PAD because of the increased risk of myocardial infarction, stroke, and cardiovascular death and impaired quality of life because of a profound limitation in exercise performance and the potential to develop critical limb ischemia1,2. Despite effective therapies to lower the cardiovascular risk and prevent progression to critical limb ischemia, patients with PAD continue to be under-recognized and undertreated. The management of PAD patients should include an exercise program, guideline-based medical therapy to lower the cardiovascular risk, when revascularization is indicated, an "endovascular first" approach and lastly surgical

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approach, if all measures were failed. The indications and strategic choices for endovascular revascularization will vary depending on the clinical severity of the PAD and the anatomic distribution of the disease. In this chapter, we discuss peripheral vascular intervention (PVI) management of patients with PAD.

Endovascular Therapy
Endovascular revascularization plays a key role in the management of patients with PAD. Patients with stable claudication have a low risk of limb loss but may be severely limited by their symptoms. If the patient is not improved after a trial of medical therapy, endovascular revascularization can be considered. Patients with CLI require more urgent revascularization because of an increased risk of tissue loss and amputation, as well as an extremely high risk of cardiovascular events. There are 2 well-established classification schemes to describe the severity of PAD. The first is a functional assessment (Fontaine or Rutherford classification [RC]) (Table 3), and the second is an anatomic lesion classification (Trans-Atlantic Inter-Society Consensus [TASC]) (Table 4). If the patient is a candidate for either endovascular or open surgery, the less invasive option (i.e., an endovascular-first strategy) is the current standard of care. The selection of a complex lesion (TASC D), for endovascular therapy will vary with the skill and experience of the interventionalist. The goal in treating a patient who has functional impairment because of claudication is durable relief of symptoms. In patients with CLI and a threatened limb or tissue loss, the goal is rapid reperfusion of the ischemic tissue to relieve the ischemia, prevent amputation, and restore ambulation.

Strategies for PVI
Revascularization is typically considered in patients with PAD who have developed any 1 of 3 distinct clinical presentations: (1) lifestyle-limiting claudication no longer responsive to conservative therapy (IC); (2) critical limb ischemia (CLI); or (3) acute limb ischemia (ALI). Although the first 2 clinical syndromes represent separate yet related stages of progressive PAD, ALI is frequently because of peripheral thromboembolism rather than occlusive PAD. The urgency and goals of treatment depend on the presenting syndrome, comorbidities, and anatomy (Tables 1 and 2).

Technological improvements in the equipment used for endovascular revascularization have increased options for complex lesions once exclusively treated by open surgery. Lower risk endovascular techniques to revascularize focal anastomotic disease after bypass grafting or focal restenosis of peripheral artery stents are an attractive and feasible treatment strategy. Surgical revascularization is often preferred for disease in the common femoral or popliteal arteries; regions that may

<table>
<thead>
<tr>
<th>Clinical Goal</th>
<th>Angiographic Goal</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermittent claudication</td>
<td>Symptom resolution without recurrence</td>
<td>Long-term vessel patency</td>
</tr>
<tr>
<td>Critical limb ischemia</td>
<td>Limb salvage</td>
<td>Restoration of in-line flow</td>
</tr>
<tr>
<td>Acute limb ischemia</td>
<td>Limb salvage</td>
<td>Restoration of in-line-flow</td>
</tr>
</tbody>
</table>

| Common Endovascular Revascularization Strategies Stratified by Anatomic Level |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| Vessel Diameter | Balloon Angioplasty | Stenting       | Provisional for simple lesions No data | Primary stenting for Complex or ostial disease Balloon-expandable (ostial/occlusions) Self-expanding (tapered Artery of near hip joint) Diffuse disease Self-expanding stents Balloon result Coronary stents |
| Aortoiliac                  | =7-10mm | Focal disease | Bare-Metal Drug-Coated | No data Primary stenting for Complex or ostial disease Balloon-expandable (ostial/occlusions) Self-expanding (tapered Artery of near hip joint) Diffuse disease Self-expanding stents Balloon result Coronary stents |
| Femoropopliteal            | =5-7mm | Focal Disease | Recently approved | Provisional for simple lesions No data Primary stenting for Complex or ostial disease Balloon-expandable (ostial/occlusions) Self-expanding (tapered Artery of near hip joint) Diffuse disease Self-expanding stents Balloon result Coronary stents |
| Infra popliteal             | =2-5mm | Focal or diffuse disease | Provisional for poor | Provisional for simple lesions No data Primary stenting for Complex or ostial disease Balloon-expandable (ostial/occlusions) Self-expanding (tapered Artery of near hip joint) Diffuse disease Self-expanding stents Balloon result Coronary stents |
Table III
Classification of severity of PAD

<table>
<thead>
<tr>
<th>Fontaine</th>
<th>Clinical Grade</th>
<th>Category</th>
<th>Rutherford</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Asymptomatic</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>IIa</td>
<td>Mild claudication</td>
<td>I</td>
<td>1</td>
</tr>
<tr>
<td>IIb</td>
<td>Moderate-severe claudication</td>
<td>I</td>
<td>2</td>
</tr>
<tr>
<td>III</td>
<td>Ischemic rest pain</td>
<td>II</td>
<td>4</td>
</tr>
<tr>
<td>IV</td>
<td>Ulceration or gangrene</td>
<td>III</td>
<td>5</td>
</tr>
</tbody>
</table>

Table IV
TASC classification

<table>
<thead>
<tr>
<th>Arterial Segment</th>
<th>TASC A</th>
<th>TASC B</th>
<th>TASC C</th>
<th>TASC D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortoliac</td>
<td>Unilateral or bilateral stenosis of CIA</td>
<td>Unilateral or bilateral single short (≤3cm) stenosis of EIA</td>
<td>Short (≤3cm) stenosis of infrarenal aorta Unilateral CIA occlusion Single of multiple stenosis totaling 3-10cm involving the EIA, not extending into the CFA Unilateral CIA occlusion not involving the origins of internal iliac or CFA</td>
<td>Bilateral CIA occlusions Bilateral EIA stenosis 3-10cm long, not extending into the CFA Unilateral EIA stenosis extending into the CFA Unilateral EIA occlusion that involves the origins of internal iliac and/or CFA</td>
</tr>
<tr>
<td>Femoral-popliteal</td>
<td>Single stenosis ≤10cm in length Single occlusion ≤10cm in length</td>
<td>Multiple lesions (stenoses or occlusion), each ≤5cm Single stenosis or Occlusion ≤5 cm, not involving the infrageniculate popliteal artery Heavily calcified occlusion ≤5 cm in length Single popliteal stenosis</td>
<td>Multiple stenoses or occlusions totaling ≤5 cm, with or without heavy calcification Recurrent stenoses or occlusions after failing treatment</td>
<td>Chronic total occlusions of CFA of SFA (&gt;20 cm, involving the popliteal artery) Chronic total occlusion of popliteal artery and proximal trifurcation vessels</td>
</tr>
<tr>
<td>Infrapopliteal</td>
<td>Single focal stenosis, ≤5 cm in length, in the target tibial artery, with occlusion or stenosis of similar or worse severity in the other tibial arteries.</td>
<td>Multiple stenosis, each ≤5 cm in length, or total length ≤10 cm, or single occlusion ≤3 cm in length, in the target tibial artery with occlusion or stenosis of similar or worse severity in the other tibial arteries.</td>
<td>Multiple stenosis in the target tibial artery and/or single occlusion with total lesion length &gt;10 cm with occlusion or stenosis of similar or worse severity in the other tibial arteries.</td>
<td>Multiple occlusions involving the target tibial artery with total lesion length &gt;10 cm, or dense lesion calcification or nonvisualization of collaterals; the other tibial arteries occluded or with dense calcification.</td>
</tr>
</tbody>
</table>

increase stent fracture because of greater compression, torsion, and stretch associated with flexion and extension of the hip and knee. However, even in these locations, single-center series suggest treatment comprised of percutaneous angioplasty with provisional stenting is associated with acceptable 12-month results particularly in high-risk surgical patients requiring limb salvage. The development of drug-coated balloons (DCBs) with adjunctive atherectomy may
address some issues associated with stent placement in these challenging arterial segments although any flow-limiting dissections, recalcitrant recoil, or residual disease would still limit such an approach.6

Aortoiliac Occlusive Disease
There has been a practice shift over the past 25 years as the treatment of aortoiliac disease transitioned from open surgery with aortobiiliacor aortobifemoral bypass to endovascular treatments for complex and diffuse disease (TASC D). This preference for less invasive therapy is evidence based and driven by shorter length of stay and lower per procedural morbidity and mortality rates, while achieving comparable patency rates (4- to 5-year primary patency of 60% to 86%, with secondary patency rates of 80% to 98%).9

In 2011, the European Society of Cardiology(ESC)3and ACC/AHA PAD guidelines 2 recommended an endovascular-first approach for aortoiliac lesions, recommending that borderline lesions be assessed with hemodynamic gradients, and supported primary stent placement in the aortoiliac arteries (Table 5).

For focal aortoiliac disease, balloon angioplasty alone provides excellent long-term patency with provisional stent placement reserved for suboptimal result.10 No randomized studies comparing iliac stenting versus angioplasty only are currently available. The Dutch Iliac Stent Trial comparing stenting with balloon angioplasty and provisional stenting resulted in comparable clinical outcomes although this may have been caused by relatively low complexity TASC (Trans-Atlantic Society Consensus) A and B disease included in the trial.11,12 Given the increased recoil seen with ostial iliac disease and risk of dissection with the more complex disease now more frequently encountered (ie, total occlusions, ulcerated or calcified lesions, and aneurysmal segments) the use of primary stenting for aortoiliac disease has increased.13

BRAVISSIMO (Belgian-Italian-Dutch Trial Investigating Abbott Vascular Iliac Stents in the Treatment of TASC A, B, C, and D Iliac Lesions) reported 100% technical success in 325 patients with aortoiliac lesions with a 24-month primary patency rate of 87.9%.14 Neither TASC category nor lesion length was predictive of restenosis. These data further support the endovascular-first strategy, regardless of TASC classification, and take into consideration the evolution of devices (i.e., re-entry catheters, crossing devices, and stents), which improve success rates for the most complex lesions.

### Table-V

**Aortoiliac Guideline-Based Recommendation for Stable Limb Ischemia**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Endovascular procedures are indicated for patients with a vocation or lifestyle limiting disability due to intermittent claudication when clinical features suggest a reasonable likelihood of symptomatic improvement with endovascular intervention and: 1) there has been and inadequate response to exercise or pharmacological therapy; and/or 2) there is a very favorable risk-benefit ratio (e.g., focal aortoiliac occlusive disease) (Class I, Level of Evidence:A)</td>
<td>When revascularization is indicated, an endovascular-first strategy is recommended in all aortoiliac TASC A-C lesions (Class I, Level of Evidence: C)</td>
</tr>
<tr>
<td>Translesional pressure gradients (with and without vasodilation) should be obtained to evaluate the significance of angiographic iliac arterial stenoses of 50% to 75% diameter before intervention (Class I, Level of Evidence: C)</td>
<td>A primary endovascular approach may be considered in aortoiliac TASE D lesions in patients with severe comorbidities, if done by an experienced team (Class IIb, Level of Evidence: C)</td>
</tr>
<tr>
<td>Stenting is effective as primary therapy for common iliac artery stenosis and occlusions (Class I, Level of Evidence: B)</td>
<td>Primary stent implantation, rather than provisional stenting, may be considered for aortoiliac lesions(Class IIb, Level of Evidence: C)</td>
</tr>
</tbody>
</table>

ACC = American College of Cardiology; AHA = American Heart Association; ESC = European Society of Cardiology; PAD = Peripheral artery disease; TASC = Trans – Atlantic Inter-Society Consensus.
Femoral-Popliteal Disease

This segment begins at the bifurcation of the common femoral artery (CFA) into the superficial femoral artery (SFA) and the deep femoral (profundafemoris) artery. The SFA is subject to flexion, elongation, compression, and torsion unlike any other lower extremity artery. This complexity leads to many challenges for endovascular technology, but despite this, an endovascular-first approach is currently the standard of therapy for the majority of lesions because of the very high procedural success rate and low risk. Some of the most lengthy and complex lesions (TASC D) are more approachable because of the re-entry and crossing devices, more experienced operators, drug-eluting stents (DES) and drug-coated balloons (DCBs) that promise improved long-term patency for patients with claudication. The ACC/AHA (2006, 2011) and ESC (2011) PAD guidelines recommend revascularization in femoral-popliteal lesions for patients with CLI or for patients with claudication who have had a suboptimal response to a trial of exercise (Table 6). An endovascular-first approach is recommended for TASC A through C lesions and is a reasonable option for TASC D lesions, depending on the experience of the operator, the patient's comorbidities, and procedure safety (Table 6).

Table VI

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Endovascular procedures are indicated for patients with a vocational or lifestyle-limited disability due to intermittent claudication when clinical features suggest a reasonable likelihood of symptomatic improvement with endovascular intervention and: 1) there has been an inadequate response to exercise or pharmacological therapy, and/or 2) there is a very favorable risk-benefit ratio (e.g., focal stenosis) (Class I, Level of Evidence: A)</td>
<td>when revascularization is indicated, an endovascular-first strategy is recommended in all femoropopliteal TASC A-C lesions (Class I, Level of Evidence: C)</td>
</tr>
<tr>
<td>Stents (and other adjunctive techniques such as lasers, cutting balloons, atherectomy devices, and thermal devices) can be useful in the femoral, popliteal, and tibial arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g., persistent translational gradient, residual diameter stenosis &gt; 50% or Flow-limiting dissection (Class IIa, Level of Evidence: C)</td>
<td>Primary stent implantation should be considered in femoropopliteal TASC B Lesions (Class Ib, Level of Evidence: A)</td>
</tr>
<tr>
<td>The Effectiveness of stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of femoral-popliteal arterial lesions is not well established (except to salvage a suboptimal result from balloon dilation) (Class IIb, Level of Evidence: A)</td>
<td>A primary endovascular approach may also be considered in TASC D lesions in patients with severe comorbidities if and when experienced interventionist is available (Class IIb, Level of Evidence: C)</td>
</tr>
<tr>
<td>Primary stent placement is not recommended in the femoral, popliteal, and tibial arteries (Class III, Level of Evidence: C)</td>
<td>Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower-extremity PAD (Class III, Level of Evidence: C)</td>
</tr>
</tbody>
</table>
Stents – Balloon expandable and Self expandable Stents

Stents are broadly classified as either Balloon expandable (BE) or Self expandable (SE) based on how deployment is effected. In brief, BE stents are mounted in a crimped state on a balloon that is inflated to deploy the stents against the vessel wall. In contrast, SE stents are manufactured an expanded state and are then crimped and constrained by a covering sheath that is retracted at the target site to allow the SE stent to expand to a predefined diameter and appose the vessel wall. In general, BE stents are made from steel that is composed of cobalt-chromium and nickel. Based on the properties of cobalt-chromium, these stents have the ability to be stronger than stainless steel stents with thinner metal struts and thus potentially can provide increased radial strength, lower crossing profile with enhanced flexibility and deliverability. Self-Expanding Stents are now mostly made of nitinol, self-expanding stents possess thermal shape memory and are more resilient to mechanical stresses by expanding on deployment at body temperature and then re-expanding after external radial compression. Because of rigidity, BE stents are typically employed in peripheral intervention for the treatment of disease in relatively static arteries, such as iliac arteries, where torsion and flexion forces are low and there is minimal risk of deformation or fracture. SE stents are used in peripheral intervention at sites that are subject to significant deformation (e.g., external iliac artery, SFA, popliteal artery and internal carotid artery).

Drug-Eluting Stents

Restenosis remains one of the major limitations associated with long segments of SFA stenting, and stimulated the development of drug-eluting stents. The first trials (Sirolimus Coated Cordis SMART Nitinol Self-Expandable Stent for the Treatment of SFA Disease [SIROCCO I and II trials]) compared sirolimus-coated versus bare-metal self-expanding stents. Initial results were promising, but later results showed no clinical advantage with this particular stent platform, which was associated with a high rate of stent fracture (31% of all patients). Two studies have tested new platforms of self-expanding drug-eluting stents (DES) eluting other ant proliferative agents. The Superficial Femoral Artery Treatment with Drug Eluting Stents (STRIDES) trial was a multicenter, nonrandomized, single-arm study assessing an everolimus-eluting self-expanding stent. Although stent fracture rates were low, the restenosis rates at 6 and 12 months were 6% and 32%, respectively. Although DES use for coronary revascularization requires a longer duration of dual antiplatelet therapy, the optimal length of treatment after peripheral DES implantation requires further investigation.

Drug coated balloons

A recent innovation, Drug coated balloons (DCBs) has potential benefits applicable to endovascular therapy. DCBs are effective in the coronary vasculature, particularly in small arteries, bifurcation disease, inStent stenosis and are used where avoiding stent implantation and its attendant risks, including thrombosis, fracture, and the need for prolonged antiplatelet therapy. The potential limitations include the lack of a mechanical scaffold to address elastic recoil or dissection and the uncertainty of delivering effective, homogenous concentrations of ant proliferative agents to calcified or tortuous arterial segments.

Infraoplitale Disease

Infrapopliteal or below-the-knee disease begins with the popliteal artery at the knee joint and continues to the tibial and personal arteries to the ankle. Revascularization is indicated in patients with CLI and, rarely, for those with claudication. The ACC/AHA (2006, 2011) and ESC (2011) PAD guidelines agree that an endovascular-first approach is reasonable in patients with CLI and infrapopliteal arterial disease (Table 7). In candidates for endovascular treatment, both guidelines support PTA as the initial approach, with the use of BMS as needed for bailout lesions (Table 7). There are several issues unique to below-the-knee interventions that warrant consideration. Occlusive infrapopliteal disease is often complex with severely calcified, diffuse high grade stenosis or total occlusions. Successive, incremental balloon inflations to treat lengthy expanses of disease risks dissection and perforation, which may be reduced by specifically designed long balloons. Poor distal runoff elevates the risk of stent thrombosis, and distal embolization complicating below-the-knee interventions is poorly tolerated. The BASIL (Bypass Versus Angioplasty in Severe Ischemia of the Leg) trial compared PTA (balloon alone) to surgery in 452 CLI patients and found no difference for amputation-free survival but a lower cost with PTA.
Infrapopliteal Balloon Angioplasty for CLI

Several clinical series have demonstrated that angioplasty alone can promote limb salvage in CLI patients with infrapopliteal disease with 12-month limb salvage rates as high as 75%. Although higher complexity tibial disease has been traditionally treated surgically, Schmidt et al. reported 95.6% limb salvage at 12 months for complicated (average length 184 mm with 64.9% occlusions) infrapopliteal disease. A recent meta-analysis showed that even with severe tibial disease and poor distal run-off, reasonable rates of limb salvage can be achieved with angioplasty alone. Infrapopliteal angioplasty with DCB is currently being investigated particularly for the potential to diminish the need for future reintervention.

Infrapopliteal Stenting for CLI.

Because of the typically small diameter vessels, coronary BMS and DES have been used for infrapopliteal stenting. Several unique issues must be considered. Because of the diffuse nature of tibial disease, extensive infrapopliteal stenting in conjunction with poor outflow may elevate the risk of stent thrombosis. The use of DES, in particular, may amplify this risk further because of issues related to delayed re-endothelialization. Suboptimal stent expansion and apposition or flow-limiting dissection because of severely calcified small-vessel disease may also be encountered. Small, single-center nonrandomized studies have shown that rates of major amputation, surgery, and TLR are lower for patients

### Table-VII

**Infrapopliteal Guideline-Based Recommendation for CLI**

<table>
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<tr>
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<tbody>
<tr>
<td>For individuals with combine inflow and outflow disease with CLI, inflow lesions should be addressed first (Class I, Level of Evidence: C)</td>
<td>For infrapopliteal lesions, angioplasty is the preferred technique, and stent implantation, and stent implantation should be considered only in the case of insufficient PTA (Class IIa, Level of Evidence: C)</td>
</tr>
<tr>
<td>For patients with limb-threatening lower – extremity ischemia and an estimated life expectancy ≥2 years in whom an autogenous vein conduit is not available, balloon angioplasty is reasonable to perform when possible as the initial procedure to improve distal blood flow (Class IIb, Level of Evidence: C)</td>
<td>When revascularization in the infrapopliteal segment is indicated, the endovascular first strategy should be considered(Class Ib, level of Evidence: C)</td>
</tr>
<tr>
<td>The Effectiveness of uncoated /uncovered stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of infrapopliteal lesions (except to salvage a suboptimal result from balloon dilation) is not well established. (Class IIb, Level of Evidence: C)</td>
<td></td>
</tr>
<tr>
<td>Primary stent placement is not recommended in the femoral, popliteal, or tibial arteries (Class III, Level of Evidence: C)</td>
<td></td>
</tr>
<tr>
<td>Surgical and endovascular intervention is not indicated in patients with severe decrements in limb perfusion (e.g., ABI&lt;0.4) in the absence of clinical symptoms of CLI ( Class III, Level of Evidence: C)</td>
<td></td>
</tr>
</tbody>
</table>

**Infrapopliteal Balloon Angioplasty for CLI**

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**Infrapopliteal Stenting for CLI.**

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with CLI treated with DES versus BMS.\textsuperscript{28,29} Ongoing and future trials will hopefully clarify the clinical efficacy and cost-effectiveness of DES for this indication. Primary balloon angioplasty with provisional stenting, using either BMS or DES based on operator discretion, for a suboptimal angiographic result or flow-limiting dissection remains a reasonable strategy for infrapopliteal revascularization for CLI at this time.

**Conclusion:**

The past few decades have witnessed remarkable innovation in technology leading to an expanding use of endovascular therapy to treat lower extremity peripheral occlusive arterial disease of increasing severity. This has resulted in a shift away from open surgical revascularization and toward percutaneous endovascular therapy as a first option. The use of DCBs increases patency and TLR outcomes in both femoropopliteal and infrapopliteal PAD. Stenting has a rising role in both bail-out and primary interventions and is particularly promising with the development of DES. The proposed advantages of atherectomy have not yet reliably translated into improved clinical outcomes, although the effectiveness of this approach will increase with technique optimization, refinement of the technology, and further study. Although the guidelines currently support PVI, particularly PTA with bail-out stenting conclusively in patients in a low TASC category who are otherwise not surgical candidates, further study of these emerging technologies in well-designed and highly powered trials are needed to determine the ideal treatment strategies for the management of patients with PAD.

**References:**


Abstract:
Objective: Carotid body tumour is a rare tumour. This is a case report of carotid body tumour of the right side involving the right hypoglossal nerve with MRI appearance and pathological features. The objective is to present a case of Hypoglossal nerve palsy due to carotid body tumour involving the right carotid artery bifurcation.

Method: A 18-year old male presented with a well-defined swelling of his right neck, increasing hoarseness, and left ward tongue deviation on protrusion present for two years CT neck and MRI were done. The tumour was identified and the patient underwent surgery. His Histopathology report commented it to be carotid body tumour.

Result: The patient showed significant improvement after surgery. His tongue deviation improved and his hoarseness of voice had been begun to improve.

Conclusion: Carotid body tumours are benign lesion mimicking other pathology. High level of suspicision, imaging and careful resection is important for avoiding complications.

Keywords: Carotid body tumour , chemodectoma, hypoglossal nerve palsy, schwannoma, deviation of tongue

Introduction:
Carotid body tumor (CBT) is a rare lesion of the neuroendocrine system. The carotid body was first anatomically described by Albrecht Von Haller in 1743. Carotid body tumors, with an incidence of less than 0.5% of all tumors, are rare neoplasms arising from the paraganglion cells of the carotid body. Carotid body tumors (CBT) are a rare entity that should be considered in evaluating every lateral neck mass. Carotid chemodectomas or carotid body tumors are rare neoplasms, generally benign, slow-growing and frequently asymptomatic. Hallett reported 153 carotid body tumours between 1935 and 1985, a span of fifty years.

The carotid body is located on the posterior aspect of the carotid bifurcation. These paired, reddish-brown, ellipsoid structures are approximately 3 × 5 × 1.5 mm, with an average weight of 12 mg. They usually present in the neck, anterior to the sternocleidomastoid muscle at the level of the hyoid bone, near the carotid bifurcation and can be pulsatile due to their juxtaposition with the carotid artery. The carotid body originates from mesoblastic and neural components. The neural components are derived from neural crest ectoderm as sympathogonia, which further differentiate into sympathoblasts or chromaffinoblasts.

Incidence:
Between 1949 and 1985 there were 84 patients. Of the 64 patients with a skull base tumor, 46 were female and 18 male. Twenty patients with carotid body tumors treated in our institution over a period of 50 years, 1941-1991. William’s review comprises 33 tumors in 30 patients treated surgically from 1956 through 1990 at two private teaching hospitals in Denver. Patetsio had...
treated thirty-four tumors in 29 patients between 1971 and 2001. There were 10 men and 19 women. In Patel's series, in the group of 41 patients twenty-four of the patients were women and 17 were men. There was an equal incidence of involvement of the right and left carotid bodies; two patients had bilateral tumors. Wang stated between 1973 and 1998. Twenty-nine patients with 36 carotid body tumors were identified. There were 16 men and 13 women. The age of patients varied from 10 to 78 years. There were 22 right-sided tumors and 14 left sided tumors. Seven patients had bilateral tumors. 3 patients had CN X deficits, and 2 patients had CN XII deficits. Kraus reported, from June 1979 through June 1987, 15 patients were treated for carotid body tumors at the Cleveland (Ohio) Clinic Foundation. Resection and ligation of the internal carotid artery were required in one case.

In 1971, Shamblin introduced a classification system based on tumors size. They classified small tumors that could be easily dissected away from the vessels as group I. Group II (7 of their cases) included paragangliomas of medium size that were intimately associated and compressed carotid vessels, but could be separated with careful subadventitial dissection. Group III consisted of (5 of their cases) tumors that were large and typically encased the carotid artery requiring partial or complete vessel resection and replacement.

Report of the Case:
A 18-year old male presented with a well-defined swelling of his right neck, increasing hoarseness, and leftward tongue deviation on protrusion present for two years. He complained of difficulty in eating and deglution for six months. He had no history of prolonged fever or night sweats. On physical examination there was a right lateral neck mass, extending from the superior aspect of the sternocleidomastoid muscle to the angle of the mandible with concomitant right tongue hemiatrophy and impairment of lingual mobility (Fig. 1). The lesion was firm to hard, non-tender and mobile horizontally but not cephalocaudally. It was not attached to the underlying tissue. There was a transmitted impulse from the tumour. Neurological examination revealed hypoglossal nerve palsy with fasciculation and wasting of right side of the tongue and deviation to the left on protrusion. The function of the cervical sympathetic chain was intact. No palpable cervical lymph nodes were present. The patient's past medical history was unremarkable. His fiberoptic laryngoscopy revealed that his rt. vocal cord was fixed.

Computed tomography (CT) scan with contrast showed a well-defined 4.9x3.5 cm mass, located between the internal carotid artery and the external carotid artery splaying the bifurcation and compressing the internal jugular vein (Fig. 1). Intravenous injection of contrast medium also demonstrated the tumour to be vascular.

Magnetic resonance imaging (MRI) scan revealed a contrast enhancing mass within the right carotid canal extending from the angle of the mandible to the carotid bifurcation (Fig. 2). Fine needle aspiration cytology (FNAC) was performed. CT guided FNAC, there was atypical tumour cell in lymphoid background. They had commented that it was suspicious of neurogenic tumour.

At the time of the operation, it was determined that the tumour was located around the bifurcation, the vagus
nerve was intact. The lesion was densely adherent to the carotid arteries and the internal jugular vein was compressed. The right hypoglossal nerve was severely adherent to the tumour. Adequate vascular control was taken around the tumour. The mass was encapsulated and could be resected en bloc since the vagus nerve was not coursing through the tumour but was passing under the tumour capsule. There was no flow through the arteries after the control was released. So, the tumour, along with the involved vessel was resected.

On gross examination, (Fig 3 & 4) the tumors were well-circumscribed and may had a pseudocapsule. The cut surface was typically solid with a smooth, rubbery texture but had displayed some areas of hemorrhage.

Histopathological Exam: (Fig 5)
Microscopic sections of the carotid tumor contained lobules of glomic tissue, comprised of multiple clustered nests of chief cells surrounded by a thin rim of sustentacular cells embedded in a collagenous reticular stromas.

Fig.-2: MRI with Contrast axial

Fig.-3: Intraoperative view:

Fig.-4: Tumour: The ecsised tumour

Fig.-5: Histopathology: H&E preparation
Patient’s postoperative course was uneventful and 1 month later the mobility of the tongue was improved. His voice was not back to normal, but hoarseness had diminished. His difficulty in deglutition had improved.

In Bernard’s series between 1973 and 1984, five patients underwent excision of a carotid body tumor without operative mortality, cranial nerve palsy, cerebrovascular accident, or recurrence\(^\text{16}\). In our patient no new deficit had occurred.

Surgical management is still the only curative treatment, but carotid body tumor resection remains a surgical challenge and is associated in more than 15% of cases with cranial nerve injuries, with a high risk of vascular complications\(^\text{19}\).

**Conclusion:**
Carotid body tumor is an infrequently diagnosed but curable lesion if resected without metastatic or residual disease.\(^\text{10}\). Early surgical treatment is recommended in almost all patients after preoperative evaluation and detection of multifocal tumors. Surgical excision of small tumors was safe and without complication, but resection of Shamblin 3 tumors can be challenging.

**References:**

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**Fig.-7: Post op**

**Discussions:**
In a series of Leonetti, all 16 patients underwent complete tumor removal. No patients suffered a stroke or major postoperative hemorrhage\(^\text{14}\). Sanghvi has advocated Radiotherapy postoperatively in cases in which tumor is left behind, especially in tumors extending to the base of the skull\(^\text{5}\).

Luna Ortiz reviewed 69 CBT cases in 66 patients. Age ranged from 18 to 94 years (mean = 50.2 years). Thirty-six (54%) patients lived at an altitude higher than 2200 m above sea level. Forty-six (70%) patients were subjected to surgery, 7 (10.6%) to radiotherapy, 1 (1.5%) to surgery followed by radiotherapy, and 13 (19.6%) did not accept any treatment at all. From the 47 surgeries, 44 (93.6%) corresponded to subadventitial resections, and the other three (6.3%) patients required vascular reconstruction. One patient (2%) was also subjected to hemithyroidectomy due to a papillary carcinoma found at the time of paraganglioma resection.\(^\text{15}\).

Kenneth described post-operative complications like vascular Injury, baroreflex failure and Cranial Nerve Injury\(^\text{16}\). Anderson’s series of the thirteen definitive cases, one patient had ligation of the carotid artery prior to excision of the tumor\(^\text{17}\). This is what was followed in our case.


OBITUARY

Professor Rakibul Islam Litu

Professor Rakibul Islam Litu’s untimely departure has done immeasurable damage to Bangladesh’s community of physicians. In a small span of time, he was able to make a mark for himself amongst the common people of the country.

Dr. Litu was born on 7th March, 1967 at Boalmari, Chuadanga. He graduated from Sir Salimullah Medical College in the year 1992, studied MD in Cardiology in the National Institute of Cardiovascular Diseases (NICVD), Bangladesh, in the year 2001. After entering into his professional life, Dr. Litu was able to establish himself in the field of interventional cardiology due to his in depth of knowledge and sheer skill. He played an important role in establishment of Bangladesh Society of Cardiac Intervention (BSCI), and the success behind BSCI is largely due to Dr. Litu’s efforts and vision.

Cardiac interventions are expensive procedures that is inaccessible to mass people of the country. Professor Rakibul Islam Litu felt a keen responsibility towards the financially incapable people. With his charisma and support from people from all walks of life, he was able to form the Patients' Welfare Foundation, which helped underprivileged people.

Tragically, Dr. Litu died on 18th February 2019 from heart attack only at the age of 52 years. He left behind his wife and 3 sons, as well as, numerous admirers.

We pass our deepest condolence to his grief-stricken family. We bid our farewell to his kind soul and hope that his vision of providing quality cardiac healthcare for downtrodden people becomes a reality.