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A Study on Appraisal of Post Operative Complications Among Abdominal Surgeries Using Clavien –Dindo Classification

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Abstract--- *Background: Clavien and Dindo initially gave a classification for postoperative complications which was revised and was made valid at a later date. The Clavien-Dindo classification version is modified from the initial classification of complications which was published in 1992. The basis of selecting this topic was firstly to re-evaluate the applicability of this classification in defining and grading the post-operative complications after abdominal surgeries and Secondly to re-introduce the concept of recording the post operative complications, in a standarized manner.Objectives:* To classify *postoperative* complications among abdominal surgeries using clavein-dindo classification. To correlate pre-operative risk factors & co-morbid factors with complications, classified as per clavien-dindo classification. To correlate abdominal surgeries with complications, classified as per clavien-dindo classification. *Methodology: Routine investigation will be done in all cases along with specific investigations if any, depending upon the provisional diagnosis and their requirement. The complexity of surgery will be assessed according to a modified classification for complexity of surgeries. Post-operative complications and management will be recorded, and then postsurgical complication will be classified based on clavien-dindo classification and assessed. Among the above cases those developing complications will be randomly selected to make total participant size of 100. Results: In this Study we expect to derive that the patient's with high preoperative HbA1c levels i.e >6.0 percent is having a higher risk to develop postoperative complications. We also expect that patient's with preoperative BMI of ≥ 30kg/m2 and BMI ≥ 35kg/m2 have increased postoperative morbidity. We also expect that* **Clavein-**Dindo classification is an easy tool to evaluate the post operative complications after Abdominal surgeries *in an Indian setting. Conclusion: After the completion of this study we expect to conclude that measurement of HbA1c preoperatively can identify patients at high risk of post-operative complications. We also hope to conclude that obesity can lead to adverse post operative complications especially respiratory and wound complications and that* Clavein-Dindo classification can be used as a standard classification to evaluate such post operative complications after Abdominal surgeries *in an Indian setting.*

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I INTRODUCTION:

Post operative negative outcomes like complications, sequelae, and failures have been defined and classified before[1]. Clavien and Dindo initially gave a classification for postoperative complications [2] which was revised and validated later [3]. The Clavien-Dindo classification version is modified from the initial classification of complications which was published in 1992 [1]. The Clavien-Dindo classification was developed and made valid using a cohort of general elective surgical patients [2]. The Clavien-Dindo classification of surgical complications can also be useful in patients who undergo emergency surgery [4]. Despite the International recognition and validation of this classification, its acceptability and applicability in an Indian setup remains minimal due to lack of awareness and insufficient evidences of the benefits of its use. The basis of selecting this topic was firstly to re-evaluate the applicability of this classification in defining and grading the post-operative complications after abdominal surgeries and Secondly to re-introduce the concept of recording the post operative complications, in a standarized manner. Abdominal surgeries are the most commonly encountered surgeries in an Indian setting, thus makes the study more facile, accountable and equitable.

II OBJECTIVES:

To classify postoperative complications among abdominal surgeries using clavein-dindo classification. To correlate pre-operative risk factors & co-morbid factors with complications, classified as per clavien-dindo classification. To correlate abdominal surgeries with complications, classified as per clavien-dindo classification.

III METHODS:

Routine investigation will be done in all cases along with specific investigations if any, depending upon the provisional diagnosis and their requirement. The complexity of surgery will be assessed according to a modified classification for complexity of surgeries [5]. Post-operative complications and management will be recorded, and then postsurgical complication will be classified based on clavien-dindo classification and assessed.

Study design:

Prospective cross- sectional study.

Setting: Present study will be conducted in Acharya Vinoba Bhave Rural Hospital (AVBRH), a tertiary care teaching hospital situated in rural area of Wardha district, in central India attached to Jawaharlal Nehru Medical college Sawangi Meghe Wardha and Datta Meghe Institute of Medical Sciences (deemed university) Wardha over a period of 2years. Among the above cases those developing complications will be randomly selected to make total participant size of 100. For those discharged prior to 30 days of post-operative period, telephonic interview will be conducted and evaluated. All the patients will be reviewed at the end of 30 days.

Participants: In the present study all abdomen cases admitted to surgical ward for abdominal surgery will be evaluated through history, risk factors, co-morbid conditions and thorough clinical examination on the basis of

inclusion criteria and exclusion criteria. Inclusion Criterias are: All patients who will be admitted in general surgical department of age more than 16 years, requiring abdominal surgeries. Patients who are willing to participate in the study . Exclusion criterias are, patients who have history of previously operated abdominal surgery and pregnancy with surgical problems, complications developed 30 days after surgery and Gynaecological surgeries which require opening of abdomen.

Variables: In this study the variables are HbA1c, Hypertension, Smoking.

Study size:

Formula: $N = \frac{X2.N.p(1-p)}{D^2.(n-1)+x.p(1-p)} = \frac{(3.84x\ 3.84)x\ 100x0.5\ x(0.5)}{0.05x0.05(99).(99)+(3.84x3.84)x0.5.(0.5)}$

Thus N = 93.5 = 94

X2=(table value)@d.f for desired confidence level of 0.5=3.84

N=population size.

P=population proportion(assumed to be)0.5

D= degree of accuracy(expressed as a proportion.)

Sample size=100.

Statistical methods: Data entry and analysis will be done by using STATA statistical software. $p<0.05$ will be consider as level of significance. Number, percentage, descriptive statistics will be applied. Test of significance will be calculated. Results will be presented in the form of tables and graphs. Multiple logistic regression will be used to associate in between the outcome and HbA1c levels.

IV EXPECTED OUTCOMES/RESULTS:

In this Study we expect to conclude that there is a strong co-relationship of high preoperative HbA1c levels , hypertension and smoking with post-operative complications after abdominal surgeries included in the study. We also expect to conclude that Clavein-Dindo classification can be used as a standard classification to evaluate the post operative complications after abdominal surgeries in an Indian setting.

Descriptive data: This study will include 50 males and 50 females of age more than 16 years undergoing various Abdominal Surgeries included in the study. Complications occurring in patients having HbA1c levels of > 6.0 percent will be compared to those with HbA1c levels < 6.0 [6] and a final hypothesis will be made considering the effect and advantage of evaluating preoperative HbA1c levels. BMI will be calculated in each patient included in the study and complications occurring will be analyzed to arrive at the desired conclusion.

V DISCUSSION:

Complications are unexpected events not intrinsic to the procedure. It defines any deviation from normal post operative course and their management. [1]Classification of these complications helps identifying the most common complications occurring in a particular health care set up. Once identified appropriate measures can be undertaken to prevent the occurrence of these complications which leads to better quality health care services and good post operative

outcomes. MHO (Metabolically Healthy Obesity) is concept that is emerging and which hypothesise an individual to be obese by phenotype but does not have metabolic abnormalities [7,13]. Thus it becomes important to diffentitate it from morbid obesity. In studies conducted by other authors it is stated that when patients having normal BMI when compared to obese patients were 2.6 times higher risk to develop surgical site infections and 3.5 times higher risk to develop wound dehiscence[8,9]. It was also found that obese patients have increased risk of minor post operative respiratory complications and there was no association with respiratory failure, Acute respiratory distress syndrome or pneumonia[8,10]. Raised HbA1c levels suggest a state of chronic hyperglycemia , thus it is a valuable tool for detecting high risk patients who donot have a positive history of Diabetes mellitus. Also this test is easy to be performed in large populations. A large Cohort Study on 10232 patients analyzed and concluded that HbA1c is an independent risk factor for cardiovascular diseases[6,11]. Thus in this study we expect to conclude that use of Clavein Dindo Classification for identifying post operative complications should be promoted in various health care set ups as it is an easy tool which can be used in rural set ups too. We also expect that patient's with preoperative BMI of $\geq 30 kg/m^2$ and BMI $\geq 35 kg/m^2$ have increased postoperative morbidity[6,12]. Also we would like to highlight the importance of identifying preoperative comorbidities to get a better post operative outcome. A number of studies done on different aspects of this issue were accessed and reviewed [14-70].

VI LIMITATIONS:

The sample size in this study is inadequate to give conclusions for community implications. Also the data of overall complications after abdominal surgeries is not available as specific complications are recorded separately in our settings and does not include minor complications like fever , phlebitis , paralytic ileus etc.

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