Statistical Process Control Tools In Bio-Medical Sciences – Can These Be Applied?

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Abstract

Objectives: To enumerate and assign risk score for the causes of low birth weight; construct a cause and effect diagram for low birth weight; rank order the causes of low birth weight using a pareto chart; show the cumulative effect of all the causes of low birth weight on a pareto chart; know the extent of agreement between the expert prioritization and prioritization from the study

Methods: We conducted a hospital based cross sectional study of a total of 103 low birth weight babies born in three different maternity homes of Bangalore Mahanagara Palike and their respective mothers were interviewed and examined using a semi structured partially open ended schedule. To enumerate, prioritize and assign risk scores for the risk factors of low birth weight we conducted a brain storming exercise of experts

RESULTS: THE PRIORITIZATION OF RISK FACTORS DONE BY THE EXPERTS AND THAT OBTAINED FROM THE STUDY WAS ANALYZED FOR AGREEMENT USING SPEARMAN’S RANK CORRELATION TEST. THE PRIORITIZATION OF RISK FACTORS AMONG A TOTAL OF 57 RISK FACTORS PRIORITIZED BY THE EXPERTS. THERE WAS 47.5% AGREEMENT (SPEARMAN’S RANK CORRELATION Ρ = 0.473, P<.0001) BETWEEN THE STUDY PRIORITIZATION AND THE EXPERT PRIORITIZATION. ALL VITAL-FEW RISK FACTORS IDENTIFIED IN THE STUDY ARE MODIFIABLE EXCEPT THE SEX OF THE BABY. SOCIO DEMOGRAPHIC RISKS, MEDICAL RISKS PREDATING PREGNANCY AND MEDICAL RISKS IN CURRENT PREGNANCY CONTRIBUTED MOST (71.92%) TO THE TOTAL EFFECT. CONCLUSIONS: THE CAUSE AND EFFECT (C&E) DIAGRAM AND THE PARETO CHART PROVIDE A PICTORIAL REPRESENTATION OF BOTH THE FACTORS INVOLVED IN CAUSING LOW BIRTH WEIGHT AND THE “VITAL-FEW” RISK FACTORS WHICH NEED TO BE ADDRESSED ON PRIORITY TO PREVENT LOW BIRTH WEIGHT. PARETO CHART AND C&E DIAGRAM SEEM TO BE PROMISING TOOLS, WHICH CAN BE USED EFFECTIVELY TO PLAN AND EVALUATE INTERVENTIONS. THE C&E DIAGRAM AND PARETO CHART CAN BE TAILOR MADE FOR EACH LEVEL OF HEALTH CARE DELIVERY SYSTEM AND RISK FACTORS APPROPRIATE FOR THE PARTICULAR SETUP CAN BE COUNTED BASED ON THE VITAL FEW RISK FACTORS THAT EMERGE IN EACH SETTING.

INTRODUCTION

The prevalence of low birth weight is around 33% in India, the causes of which are multifactorial and knowledge about the risk factors that are modifiable is therefore essential. There have been many studies, which give the importance of risk factors in causing low birth weight individually, but there are only a few studies, which show the cumulative effect of risk factors in causing low birth weight. The present study was conducted to highlight such cumulative effect of risk factors in causing low birth weight.

Statistical process control tools, popularly called SPC tools are known for their simplicity and ease of application in manufacturing processes in industrial production. The present study involves two such SPC tools, the Cause and Effect Diagram (C&E Diagram) and Pareto analysis. These tools are used to identify and quantify the factors contributing to the effect investigated. The application of these statistical tools in the biological and medical sciences could prove of great value in providing an insight to risk factors contributing most in causing a condition.

The cause and effect diagram is a visual tool to organize possible causes for a given effect. It is also called Fish-Bone
diagram because of its characteristic appearance. The Pareto chart is a frequency distribution of attribute data arranged by category. The Pareto chart is based on the Pareto principle, a simple way of rank ordering the causes by their contribution. Pareto principle is also known as the 80-20 rule which states that roughly 80% of the effects come from 20% of the causes. These 20% of the causes are called “vital-few” causes and the remaining 80% of the causes are called “Trivial-many” causes. The vital-few causes are the most important causes that need to be addressed on priority. The Pareto chart identifies these most important causes that need to be addressed on priority. Moreover, it is a simple statistical tool, which uses elementary knowledge of mathematics making it easy to use, at the same time providing information on the critical or vital few factors that should be addressed first.

The present study made use of these simple but effective tools, used extensively in manufacturing processes to bring out the vital-few risk factors associated with low birth weight and show the cumulative effect of these factors in causing low birth weight.

METHODOLOGY

STUDY DESIGN:

TYPE OF STUDY
Hospital based cross sectional study.

Sampling: Purposive sampling was used since the study objective was to test the applicability of new statistical tools, C&E diagram and Pareto chart.

PLACE OF STUDY
Three maternity homes of Bangalore Mahanagara Palike - South zone - Banashankari referral hospital, Yediyur maternity home and Jayanagar maternity home were selected as Banashankari and its referring hospitals were the urban field practice area of the Department of Community Medicine, KIMS, Bangalore.

STUDY PERIOD
August 2002 to July 2004

SOURCE OF DATA
The present study required a list of risk groups and risk factors causing low birth weight to build a C&E diagram. A brain storming session of experts was brought together to build the C&E diagram and Pareto chart.

BRAIN STORMING OF EXPERTS
The present study on low birth weight required experts in the field of Obstetrics, Pediatrics and Community Medicine. Two experts were chosen from each department. A structured brain storming session was conducted.

Prior to the brainstorming session, a structured brainstorming session of post graduates in the respective departments was also undertaken to determine the risk factors and assign a risk score to the causes. The list of the factors and their respective risk scores were provided to the experts one week prior to the session. The experts were also asked to prioritize the causes from the most important to the least important based on their experience. To draw consensus over prioritization a process of nominal group technique was used. The causes prioritized by experts were then correlated with the prioritization which evolved out of the study.

SUBJECTS
A total number of 103 postnatal mothers who satisfied the inclusion criteria and provided informed consent for the interview and examination were included into the study. The ethical committee of Kempegowda Institute of Medical Sciences, Bangalore reviewed and approved the protocol for this study.

INCLUSION CRITERIA
All mothers who delivered low birth weight babies i.e. babies less than 2500gm irrespective of their gestational age

Mothers who are residents in the corporation city limits of Bangalore Mahanagara Palike (local self government).

The investigator ensuring adequate privacy and good rapport interviewed eligible mothers using a pre-tested semi structured partially open-ended schedule, which included all the causes enlisted and prioritized by the experts during the brain storming session. All the causes were given a risk score of 0, 1, 5 and 10 for NO RISK, MILD RISK, MODERATE RISK AND SEVERE RISK respectively based on the draft prepared by the postgraduates, literature review and subsequent approval by the experts involved in the brainstorming session.

RESULTS
The experts identified 58 risk factors and divided these into six different risk groups as shown in figure 1

15/57(26.31%) risk factors constituted the vital few risk
factors and contributed to 76.24% of the total cumulative effect (table 1 and fig.2). These are ranked from one to fifteen (Fig 2). The remaining 43/57 (73.69%) risk factors contributed only 23.76% of the effect. These constitute the trivial remaining risk factors.

Among the six risk groups categorized, the first 4 risk groups, namely socio demographic risks, medical risks predating pregnancy, medical risks in current pregnancy and environmental and behavioral risks constituted 82.46% of the total cumulative effect (table 2 and fig.3). The other two risk groups namely obstetrical risks in current pregnancy and fetal factors contributed only to 17.54% of the effect.

The vital few risk factors or the risk factors having the greatest cumulative effect in causing low birth weight, identified in this study are all modifiable except sex of the baby. Socio demographic risks, medical risks predating pregnancy and medical risks in current pregnancy contributed to 71.92% of the total effect towards low birth weight (table 2). Table 3 shows the contribution of risk factors and the severity of their risks in causing low birth weight. There are 10 risk factors, 5 each from socio demographic risks and medical risks predating pregnancy and thus have a higher rank order among the risk groups contributing most towards low birth weight. The severity of the risk also is high among the risk factors from these two risk groups.

Table 4 shows the agreement between the prioritization of experts in the brainstorming session with that of the study (both individual and collective). The collective agreement was 47.3% which was statistically highly significant (Spearman’s rank correlation $\rho = 0.473, p<0.0001$) and individually there was agreement between three experts viz., CM1, OBG1, and OBG2 and the study prioritization to the extent of 75.7%, 44.2% and 31.2% respectively, which was also statistically highly significant ($p<0.001$) using Spearman’s rank correlation test. There was disagreement between one expert viz., PED2 to the extent of 39.6%, which was also statistically significant ($p<0.0001$).
DISCUSSION

The vital few risk factors identified in this study, indicate the socio demographic status of the population attending these hospitals, which are Bangalore city corporation hospitals, which caters to the urban poor. These risk factors have been
found to have a significant association with Low birth weight in other studies, primarily in developing countries. All the vital few risk factors identified in this study are modifiable except the sex of the baby (Table 3). Improvement of socio-economic status of the community, improvement of female literacy, ensuring adequate weight gain during pregnancy, consumption of adequate amount of iron and folic acid supplements, delaying the first childbirth will improve the problem of low birth weight. Thus, a collective approach towards the problem of low birth weight will ensure permanent results.

The Cause and Effect diagram and the Pareto chart gives a pictorial representation of both the factors involved in causing low birth weight and the factors which have to be tackled first to prevent low birth weight. The Pareto chart has the advantage of both weighing the risk factors and the frequency of occurrence of such risk factors, so that the intervention measures can be directed towards the “vital few” risk factors, which are both frequent and contributing most in severity rather than focusing on the trivial risk factors associated with low birth weight. These quality control tools not only give comprehensive knowledge on the vital few risk factors but also a logical way to ensure better intersectoral co-ordination towards combating a particular health problem. Vital few risk factors have to be the focus of intervention so that resources can be channeled towards addressing these factors to obtain maximum benefit and permanent improvement of the problem of low birth weight.

The Pareto chart uses simple statistical applications such as mean, cumulative total and percentages, which can be understood easily. With statistically significant collective agreement (table 4; Spearman’s rank correlation $\rho = 0.473$, $p<0.0001$) between the experts and the study results, we can say that brainstorming could be an effective tool in bringing out all the possible causes for a particular effect in a short period of time. However, it should be noted that only the experts from tertiary care hospitals were involved. Experts from the tertiary care hospitals tend to provide higher ranking for those causes which they routinely encounter (obstetrical risks) since these are commonly occurring in tertiary care hospitals while the study hospitals might not encounter such causes very often. This could be the reason for the statistically significant disagreement between study prioritization and prioritization by individual experts. This also may be the reason why the obstetric risks in current pregnancy and fetal factors are ranked as the group with trivial risk (table 2 and 3). Employing brainstorming technique to evolve the causes and prioritizing saves time and resources. It also has an inherent disadvantage. The factors that emerge out of the brainstorming exercise are the factors that will be evaluated in the study. Other factors, which may be associated and vital, will not be evaluated even though they may be essential in understanding the risks involved leading to low birth weight babies. It is therefore essential that an appropriate cross-section of experts is enlisted to determine the appropriate risk factors.

The vital few risk factors from this study can in no way be claimed to be universal. It depends on the type of patients attending the health center and the experts in the brainstorming session. The C&E diagram and Pareto chart can be tailor made for each level of health care delivery system and appropriate interventions can be designed based on the vital few risk factors that emerge. Thus, Pareto chart and C&E diagram seem to be promising tools, which can be used effectively to plan and evaluate interventions. Now that the statistical tools have led to an acceptable result, a representative population based study on risk factors of low birth weight is required to validate the findings of this study.

Most studies conducted in public health look at the quantum of risk contributed by individual risk factors in causing the effect using relative risks or odds ratios. These might require using multivariate analytical methods like regression techniques which are not easily understood by those who do not have formal training in epidemiology and/or statistics. Many practitioners and primary health center medical officers in India have done undergraduate studies in Medicine and may not be comfortable in doing such analysis. Using C&E diagram and Pareto chart requires elementary knowledge in mathematics and can be used by a large number of such professionals. In addition, once the risk factors or causes are known, the cumulative effect of such risk factors particularly when the disease causation is multifactorial, these statistical process control tools become very useful. Similar studies can be conducted using the C&E diagram and Pareto chart to evaluate factors causing other diseases where the causes are multifactorial in nature e.g. coronary artery disease, accidents, malignancy, naso-bronchial allergy, which are the important diseases in public health.

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