

EPIDEMIOLOGICAL METHODS IN DIABETES MELLITUS

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Epidemiological studies are of importance to provide data on the prevalence and incidence of the disease and to provide information on its natural history and the disease determinants. Above all these studies help in formulation of appropriate strategies for primary prevention of the disease.

Study Types

Epidemiological studies are of three types, based on a) routine data, b) registries and c) population surveys. Routine data is available from hospital or clinic based studies which has several bias including referral bias. Although incomplete, it provides rough estimates of the disease prevalence.

Registries are used for local, national or international data collection for epidemiological monitoring and research. Data from all participating centres are pooled and analysed using appropriate statistical methodologies. Registries are usually feasible for diagnosed cases only and not for diseases like Type 2 diabetes where a large percentage may remain undetected. Population based studies are the most useful approach where samples representative of the population are tested.

Methods in Epidemiology

Epidemiological studies could be cross-sectional, in which the disease prevalence is studied at a specific time period. Longitudinal studied at a specific time period. Longitudinal studies are prospective in natural and are usually done in selected cohorts to yield data on incidence or outcome at follow-up or with intervention measures. A cohort is group of people sharing the same experience and is exposed to the suspected determinant.

Case-control studies are used to evaluate the outcome measures in a cohort by comparing it with a matched group of non-susceptible control group, usually in 1:1 proportion. Such studies are helpful in intervention studies.

Sampling Strategies

1. Simple Random Sampling procedure involves testing a randomly selected number of subjects from the total population. Every eligible member has an equal chance of being tested.

This is difficult and not practical in studies involving large populations and therefore is seldom used. This procedure, however, becomes necessary when the community is heterogeneous with respect to the risk being assessed.

2. Selected Community Sampling is done if specific community related studies are planned. For e.g.- urban, rural or special ethnic groups, Geographically defined urban or rural groups, have to be carefully selected.
3. Random Cluster Sampling is the commonest procedure used in large epidemiological, surveys wherein geographically defined clusters of population in villages, towns or blocks of houses are initially identified and enumerated. This procedure should be used only when the community is homogenous.
4. Multi-stage Sampling : The Community is divided into subgroups based on ethnicity, occupation, socio economic levels, age group or sex and within each group random samples are selected for recruitment. This procedure allows appropriate sample size to be selected from each strata being tested.

The choice of sampling method is largely determined by practical considerations. The investigator has to have a basic knowledge of the study population which is usually obtained from the census or medical registries, if available.

Sample Size

Sample size determination is imperative to decide the appropriate sample size to be screened in order to have sufficient 'power' for the study. The power of a study is a measure of its potential to detect the real difference. Sample sizes can be easily calculated using simple statistical packages, based upon an estimation of disease frequency and required precision.

Epidemiology of the Type 2 diabetes

Population based surveys with screening for glucose intolerance are required as large proportion of the individuals with diabetes remain undetected. Type 2

diabetes being a common disorder especially in the urban areas, population samples are feasible. Within a cross-sectional study, matched groups of normal and abnormal subjects can be compared for study of specific parameters. For example. If a study of cardiovascular risk factors is planned matched cohorts of diabetic and non-diabetic can be tested and the results compared.

While analysing the result, special attention must be paid to causes of bias, especially the response bias. The proportion of non-responders from the list of selected persons has to be determined. A comparison of the demographic data of the responders and non-responders has to be made to correct for any particular bias in the responders. Where possible, the reasons for non-responders should be obtained from a sub sample of them by personal interviews. Final results have to be age-adjusted to the distribution in the population being tested. This could be done using simple calculations and the census data can be used as the reference value.

The methodology of the field study is summarised below. At each level, care has to be taken to obtain accurate and precise data.

- Aims and Objectives of the study have to be well-defined.
- The target population has to be chosen, appropriate sampling method and sample size determined.
- The study protocol has to be carefully prepared and written and all the members of the study team should be familiar with the same. It should include the ethical clearance from local committees and informed consent from the study subjects. The study population should be initially enumerated and informed about the purpose of the study. If necessary, local assistance from volunteers or organisations should be sought for.

- The survey team has to be selected and trained for conducting demographic, anthropometric, clinical and biochemical data collection.
- Measurement procedures have to be standardized. They should be accurate and precise and quality control measures in evaluation of each parameter should be strictly adhered to.
- The diagnostic criteria have to be standardized as per the WHO criteria. Blood tests have to be done strictly as per the recommendations of the WHO and proper Quality assurance measures should be employed.
- A detailed, yet simple questionnaire has to be prepared.
- Appropriate blood samples should be carefully collected, and proper measures of storage and transportation should be employed.
- It is ideal to prepare a flow chart of the survey procedure.
- Data entry and analysis should be correct and promptly done. Appropriate statistical methods should be selected for the data analysis.

For type I diabetes, which seldom goes undetected due to its acute onset and severity of symptoms, population based registers can provide reliable data. Such international registries are used in developed nations. E.g. the Eurodiab collaborative study, DIAMOND/WHO project Data from multiple sources are fed in the centralized registry. For validation, a double-source method or the "Capture-Recapture Method" is used. Continuous, regular registration data provides incidence data.

References

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2. Non-communicable Disease Risk Factor Surveys-A Field Guide –WHO/NCD/DIA/98/WHO, Geneva, 1998