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Review

Review of 40-year MD theses in Medical Oncology

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KEYWORDS

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Abstract *Background and objective:* It is almost 40 years since the foundation of the Medical Oncology (MO) Department. We aimed to appraise the clinical research to fulfill the Medical Doctorate (MD) degree in MO at the National Cancer Institute, Cairo University (NCI, CU).
Methods: This review included 62 MD theses containing 66 studies. They were reviewed regarding aims, type of study, clinical trial phase, design and methodology, statistical tests, results, limitations, consent and IRB approval. Theses were grouped into 3 periods: 1970–1989, 1990–1999 and 2000–2008.
Results: Almost 76% of the studies were interventional and 24% were observational. Informed consent and Institutional Review Board approval were mentioned in 18 and 2 studies, respectively. While all studies mentioned the aims, none, clearly mentioned the research question. Outcomes were mainly efficacy followed by safety. Study design was inadequately considered, especially in 70's–80's period ($p = 0.038$). Median sample size and study duration were almost stable through the three periods ($p = 0.441$, 0.354, respectively). Most of the studies used both descriptive and analytical statistical methods. In a descending order, researched cancers were lymphoma, breast, leukemia, liver, urinary bladder, lung and colorectal. The commonest stages researched were IV and III. The number of studies focused on assessing biomarkers, biomarkers plus drugs/procedures, drugs and procedures are 20, 20, 16 and 6, respectively.
Conclusion: With time, research within MD theses in MO increased quantitatively and qualitatively. Improvements were noticeable in documentation of study design.

Contents

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Introduction

Research is a careful inquiry or examination in seeking facts or principles. It comprises defining and redefining problems; formulating hypotheses or suggested solutions; collecting, organizing and evaluating data; making deductions and reaching conclusions; and carefully testing the conclusions to determine whether they fit the formulated hypotheses [1]. The goals of scientific research are description; prediction and understanding/explanation of the findings [2]. There are two categories of research: research on primary data means performing the actual scientific studies. This is intended to answer scientific questions and to gain new knowledge. In contrast, research on secondary data involves the analysis of studies that have already been performed and published. In secondary research, a distinction is made between narrative reviews, systematic reviews and meta-analysis [3].

Clinical research is the scientific investigation of the etiology, prevention, diagnosis or treatment of human disease using human subjects, human populations or materials of human origin [4]. A study was considered a clinical trial if it involved therapeutic, preventive or diagnostic intervention with assessment of its outcome on participants. This also includes studies of biomarkers or tests to assess their sensitivity and specificity regarding given endpoints [5]. On the other hand, studies where application of tests or biomarkers to participants was followed by assessing participant's fate are considered prospective "cohort studies".

Study design is a major determinant of its scientific value and informativeness. There are six essential considerations in the planning and evaluation of a medical research study design. These include the question to be answered, the study population, the type of study, the unit of analysis, the measuring technique and the calculation of sample size. Errors in study planning cannot be corrected after study conduction. Thus, consulting an experienced biostatistician very early in the planning phase of a study is crucial [2].

The National Cancer Institute (NCI), Cairo University (CU), is the largest comprehensive cancer center in the region and has been a pivotal corner in cancer research and management in Egypt. It is almost 40 years since the foundation of the Medical Oncology Department (MOD) at NCI [6]. Those years witnessed the conduct of valuable researches at different levels as a mandate to fulfill the requirements for Medical Doctorate (MD) degree with clinical trials being at the core of this research.

It is not known what the past research in MOD focused on and what the quality of this research was. The aim of this work was to review the clinical research done as a part of the requirements for the MD degree in MO at NCI, CU. This will show past trends in research and thus pointing out areas of strength and shedding lights on areas of weakness or difficulties to avoid in future research.

Methods

Search strategy

The NCI thesis registry was searched for theses done in the MOD between the years 1970 and 2010. The registered theses were 62; one of them was in German language and could not be assessed comprehensively. One thesis was delivered by the authors, as it was not in the library registry (Fig. 1).

Almost all theses (58/62; 93.5%) included only one study per thesis except four that included two studies per thesis leading to 66 studies (Fig. 1). For the sake of clarity and unless mentioned specifically, more in-depth data will be presented as studies (i.e. 66) and not as theses (i.e. 62). This is because it was felt that the theses with two studies mentioned have separate methodology, results and comments for the two components to the extent that it will be unfair to sacrifice one component.

Data abstraction

Data were collected jointly by two team members (WB and AD) and reviewed jointly by two other members (AZ and MM). To avoid inconsistencies, all the study members discussed the abstraction items and had them written in a data collection form. This form was piloted in 10 theses and the tool was subsequently modified.

The form included the following items: thesis title, candidate and supervisor information, details of the study center(s), cancer under study and its stage, study scope (prognostic, therapeutic or predictive), study aims, research question and its PICO components [7], study design, sampling method and core eligibility criteria.

For CTs, the number of arms, phase of the trial, use of control group, randomization and blinding were recorded. The form also included study outcomes (efficacy, safety, descriptive Epidemiology, cost-effectiveness, diagnostic and causation), study endpoints (primary/secondary and efficacy/safety), total study duration (divided into recruitment time where participants were identified and recruited and follow-up time where participants are no longer being treated but just followed) [8], results, the statistical methods, recommendations and limitations. The last section of the form included the ethical issues, e.g., the informed consent, assent and approval by the institutional review board (IRB).