Oftalmologia



PICOT: Imprescriptible items in a clinical research question

PICOT: Itens imprescindíveis em uma pesquisa clínica

Rodrigo Pessoa Cavalcanti Lira^{1,2}, Eduardo Melani Rocha³

- 1. Departamento de Oftalmologia, Universidade Federal de Pernambuco, Recife, PE, Brazil.
- 2. Departamento de Oftalmologia, Universidade Estadual de Campinas, Campinas, SP, Brazil.
- 3. Departamento de Oftalmologia, Otorinolaringologioa e Cirurgia de Cabeça e Pescoço, Faculdade de Medicina, Universidade de São Paulo, Ribeirão Preto. SP. Brazil.

Important ingredients in scientific research can be found in the acronym PICOT (Population, Intervention, Control, Outcome, and Time), which lists 5 fundamental topics, particularly in clinical trials.

In a clinical trial, a poorly devised research question can affect the choice of study design, potentially lead to futility, and thus impede the chance of determining anything of clinical significance, which affects the potential for publication and possibly raise criticism regarding the waste of time and investment as well as questions regarding ethical issues⁽¹⁾.

A checklist for a research question in a clinical trial must contain, at a minimum, the following: population (P) – to cite the eligibility criteria for participants and report the settings and locations in addition to where the data were collected; intervention (I) and control (C) – to explain the interventions for each group with sufficient details to allow for replication, including how and when the interventions were administered; and outcome (O) and time (T) – to completely define pre-specified primary and secondary outcome measures, including how and when they were assessed⁽²⁾.

A hypothetical example of a research question would be: Does the addition of intravitreous steroids (I) reduce retinal thickness (O1) and/or improve visual acuity (O2) at 12 months (T) in eyes receiving continued intravitreous anti-vascular endothelial growth factor (VEGF) therapy (C) for diabetic macular edema (P)?

Likewise, the hypothetical findings would be: In this phase 3, randomized, clinical trial including 200 eyes with diabetic macular edema (P), the addition of intravitreous steroids to continued anti-VEGF therapy (I) reduces retinal thickness (O1) at 12 months (T), but does not improve visual acuity (O2) more than continued therapy alone (C).

Although PICOT resumes the key points of clinical trials (and most other research designs), other important items supporting a well-conducted study include sample size, randomization, blinding, statistical methods, limitations, harms, ethical issues, and funding.

A helpful tool for authors is the Enhancing the QUAlity and Transparency Of health Research website at https://www.equator-network.org/. From this site, a detailed checklist for different study designs may be downloaded, for example, CONSORT (clinical trials), STROBE (observational studies), PRISMA (systematic reviews), and ARRIVE (animal pre-clinical studies).

PICOT is a model that outlines clinical research questions and acts as a framework to ask the researcher specific questions about different aspects of the investigation. It is a relevant part of evidence-based research and a guide for high-quality clinical projects.

REFERENCES

- Farrugia P, Petrisor BA, Farrokhyar F, Bhandari M. Practical tips for surgical research: Research questions, hypotheses and objectives. Can J Surg. 2010;53(4):278-81.
- Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG; CONSORT. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. Int J Surg. 2012;10(1):28-55.

Submitted for publication: September 12, 2018 Accepted for publication: September 27, 2018

Funding: No specific financial support was available for this study.

Disclosure of potential conflicts of interest: None of the authors have any potential conflicts of interest to disclose.

Corresponding author: Rodrigo Pessoa Cavalcanti Lira

Rua Irma Maria David, 200/1302 - Recife, PE - 52061-070 - Brazil E-mail: rodrigocplira@hotmail.com