

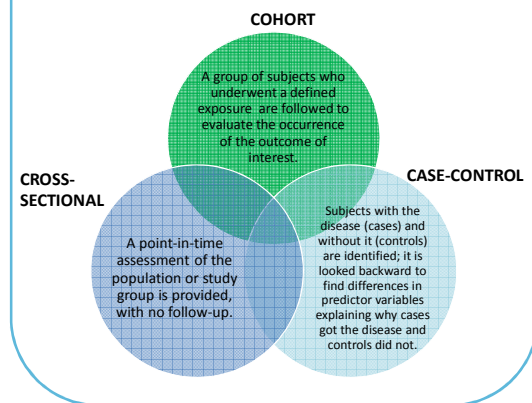
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BACKGROUND

A large part of medical research is observational. In order to reinforce widespread adoption of evidence from observational studies (Obs), a consensus regarding accepted principles for evaluation of their **relevance** and **credibility** was developed over the years by International Society of Pharmacoeconomics and Outcome Research (ISPOR)¹.

Different Obs designs exist. The most frequently adopted are reported in **Figure 1**.

Figure 1. Observational Studies Designs



OBJECTIVE

To investigate publication trends of Observational Studies (Obs) in published research over the last 38 years (1980-2018) and to compare them with Randomized Clinical Trials (RCTs).

METHODS

- Advanced research on publications in PubMed-indexed journals between 1980 and 2018 was performed searching for:
 - “Observational study” (for Obs),
 - “Real world data” (for Obs),
 - “Real world evidence” (for Obs),
 - “Registry” (for Obs),
 - “Big Data” (for Obs),
 - “Randomized Clinical Trials” (for RCTs).
- Studies involving Humans were filtered.
- The ratio between total number of articles related to RCTs and to Obs (obtained as described previously) was calculated.

Overall 241677 Obs were published from 1980 to 2018 (265 in 1980 and 18193 in 2018).

The 5-year rate of publications had a 2-fold increase from 1980-1985 to 2010-2015 (**Figure 2**).

The same analysis was performed for RCTs over the same period of time (**Figure 3**). While Obs publication trend kept growing with a 2-fold increase over the years, RCTs publication trend increase changed from a 2-fold increase (1980-1997) to a 1.5-fold increase starting from 1998.

KEY RESULTS

- Overall 241677 Obs were published from 1980 to 2018, with a peak during 2010-2015 (n=92652).
- While Obs publication trend kept growing with a 2-fold increase over the years, RCTs trend changed from a 2-fold increase (1980-1997) to a 1.5-fold increase starting from 1998.
- The ratio of RCTs/Obs decreased in a continuous manner from 1995 (ratio=7.4) till 2018 (ratio=1.3).
- Cohort studies made up 75% of all publications in the early eighties (1980-1985) and decreased to 54% in 2010-2015, while cross-sectional studies increased from 4% (1980-1985) to 12% (2010-2015).

CONCLUSIONS

An increasing trend of published Obs covering real world data was observed since 1980 as compared to the increase of RCTs. This is probably due to the enhancement of quality of methodologies and the increased interest in observational research, which complement and build on the evidence base established by RCTs.

Figure 2. Obs designs published in PubMed-Indexed Journals between 1980 and 2018

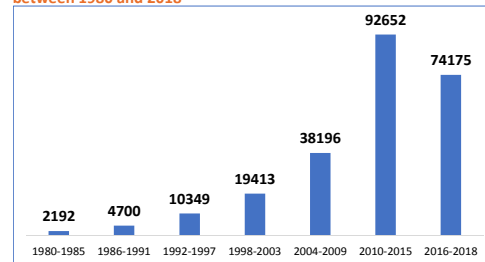
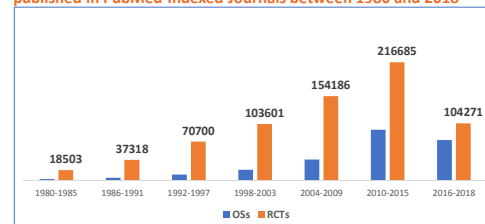


Figure 3. Number of publications per 5-year period of Obs and RCTs published in PubMed-Indexed Journals between 1980 and 2018



The ratio between number of articles related to RCTs and to Obs started to decrease in a continuous manner around 1995 (see red point in **Figure 4**).

Figure 4. Ratio between number of publications related to RCTs and to Obs from 1980 to 2018

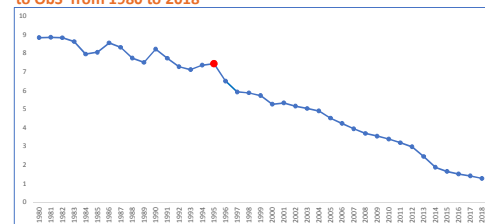
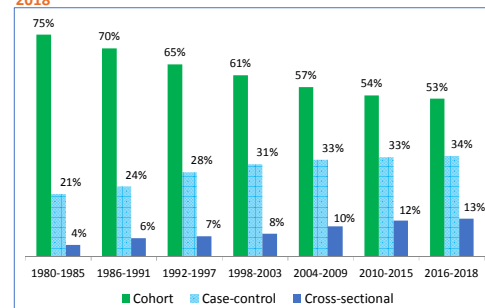


Figure 5 shows at each time the quote of published papers by study design. **Cohort studies** made up 75% of all reports in the early eighties (1980-1985) and decreased to 54% of reports in the years 2010-2015. **Case-control studies** represented an initial 21% of all reports in the period 1980-1985 and slightly increased to 33% in the last period 2010-2015. An increase was seen for **cross-sectional study** design, from 4% to 12%.

Figure 5. Publication trend of Obs by design and year from 1980 to 2018



Proportions were computed separately in each period of time over the total number of publications.