



WILL YOUR STUDY BE COMPLETED ON TIME?

“Completion and Publication Rates of Total Knee Arthroplasty Studies Over Time: An Observational Study on Registered Trials”

INTRODUCTION

Total Knee Arthroplasty is a widely performed orthopedic procedure that is growing rapidly due to the increasing prevalence of knee arthritis. Clinical studies are vital in establishing the most up-to-date and evidence-based patient treatment for Total Knee Arthroplasty. Trial discontinuation and selective reporting may significantly impact evidence-based clinical practice and introduces research waste. Various guidelines, recommendations, and studies focused on improving successful completion and publication of newly initiated trials in the last decade.

AIM

We aim to assess the successful finalization (within 5 years), timely publication (within 7 years), consistent publication of preregistered primary outcomes, and the associated factors of total knee arthroplasty studies registered between 2000-2015 over time.

METHODS

We searched ClinicalTrials.gov for Total Knee Arthroplasty studies registered between 2000-2015 and extracted required and optional elements. We searched Embase, Cochrane Library, Web of Science, PubMed, and Google Scholar to identify published literature on the included studies and extracted the published primary outcome. We used Kaplan-Meier curves to visualize the time to publication of the preregistered primary outcome, and Cox regression analyses to explore associations between the variables and on-time-publication of preregistered primary outcomes.

RESULTS

We included 1,014 registered studies on Total Knee Arthroplasty (816 interventional; 198 observational). We found 634 unique references linked to included studies.

Percentage successfully finished interventional trials
 2000-2001: 9.1%
 2014-2015: 61.2%

Percentage successfully finished observational studies
 2002-2003: 20.0%
 2014-2015: 49.1%

Percentage successfully published interventional trials
 2002-2003: 22.2%
 2014-2015: 52.3%

Percentage successfully published observational studies
 2004-2005: 12.5%
 2014-2015: 43.4%

Industry-funded interventional trials were associated with a smaller chance of on-time publication (HR 0.73[95% CI 0.53 to 1.02]).

The association of a single-group assignment with on-time-publication reversed after adding this to the multivariable analysis, implicating assignment and allocation interfere.

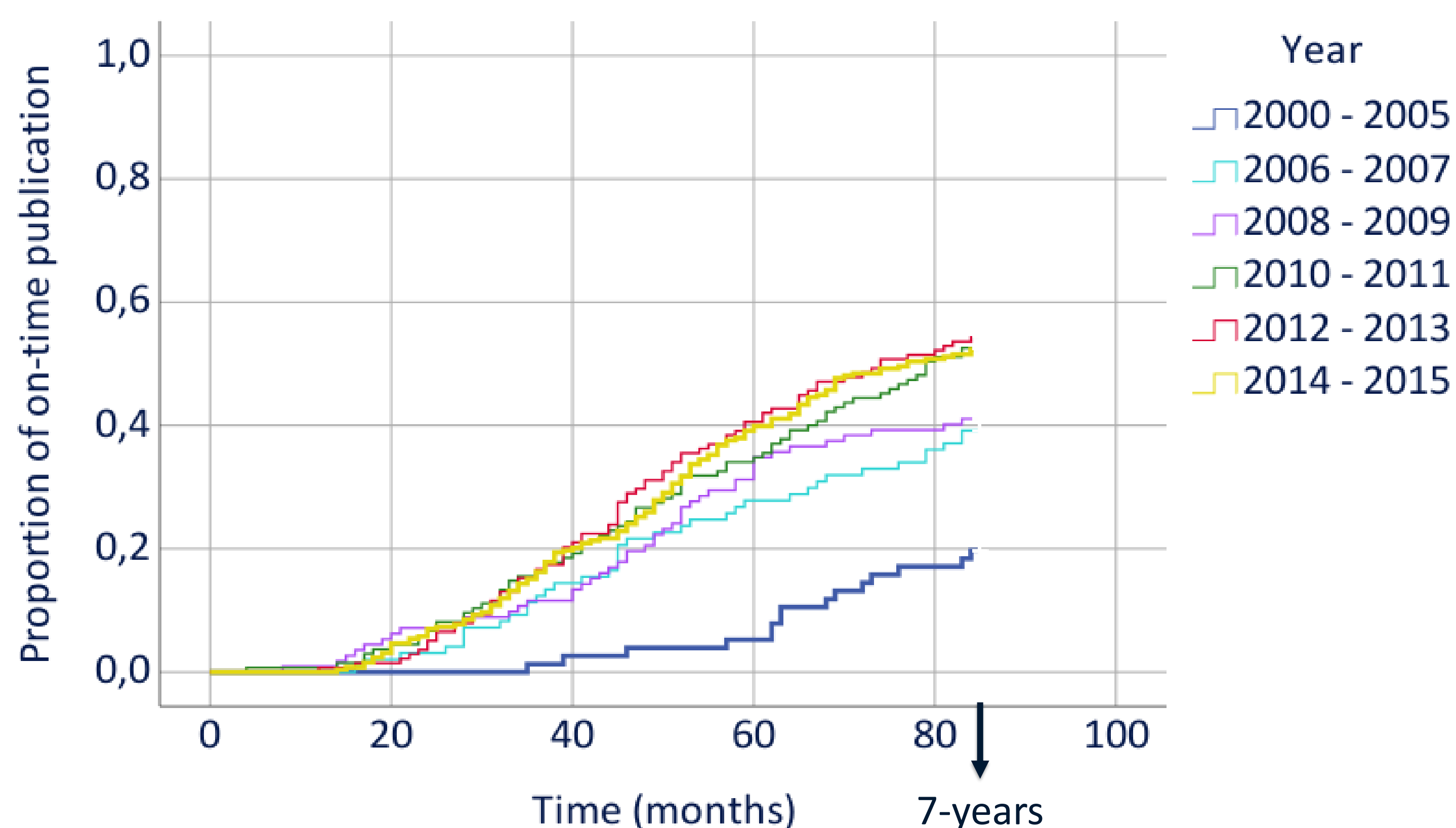
CONCLUSIONS

Our study showed that discontinuation and nonpublication were frequent, as were challenges in the timely and consistent publication of preregistered primary outcomes. While there was an improvement over time, the frequency remained substantial.

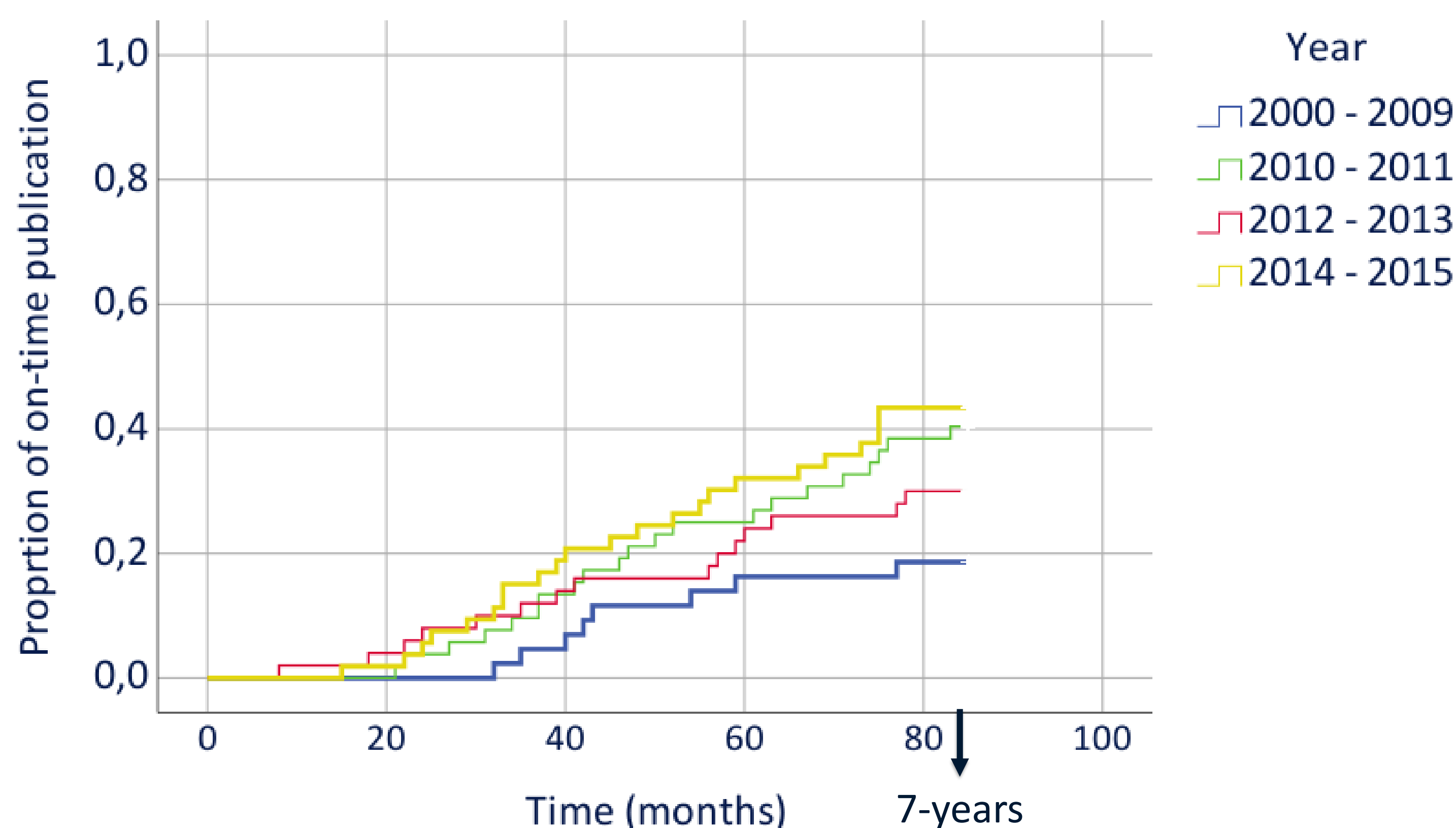
This emphasizes the need for better adherence to reporting guidelines and comprehensive information in registries, protocols, and results reports.

Figure 1A + B: Timely publication of the preregistered primary outcome*

A. Interventional trials



B. Observational studies



* Kaplan Meier curves for the timely publication (within 7-years) of interventional trials and observational studies. The preregistered primary outcome is the primary outcome registered in the protocol on ClinicalTrials.gov.

