

Clinical Trials Quality: Medical Journal Publication involvement

CPC-031

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Background

Clinical Trials (CT) resulting in biomedical journals publication constitute a strategy to guarantee good quality research. Clinical research promoters are obligated to publish either positive or negative results. Regretfully, this good practice is not as common as it should be. Cardiology and Oncology boards are the highest number of CTs carrying services in Hospital del Mar, Barcelona.

Purpose

The aim of this study is to check the publication index of CTs carried out by Cardiology and Oncology Clinical Services and to analyze the impact factor (IP) of the journals where CTs have been published. Finally, we aim to evaluate if the published results were positive or negative.

Materials and methods

A retrospective observational study was carried out considering all data gathered in the Pharmacy CT unit within the period 2002-2007. The study only assessed clinical trials of Cardiology and Oncology services.

A systematic search of Medical Journals indexed in PubMed and Clinicaltrials.gov databases until Oct 2012 was performed.

The following variables were collected for each CT: code, journal, publication data, IP and CT results. Every CT not proving the hypothesis described in the initial protocol was considered as a negative result (NR).

Results

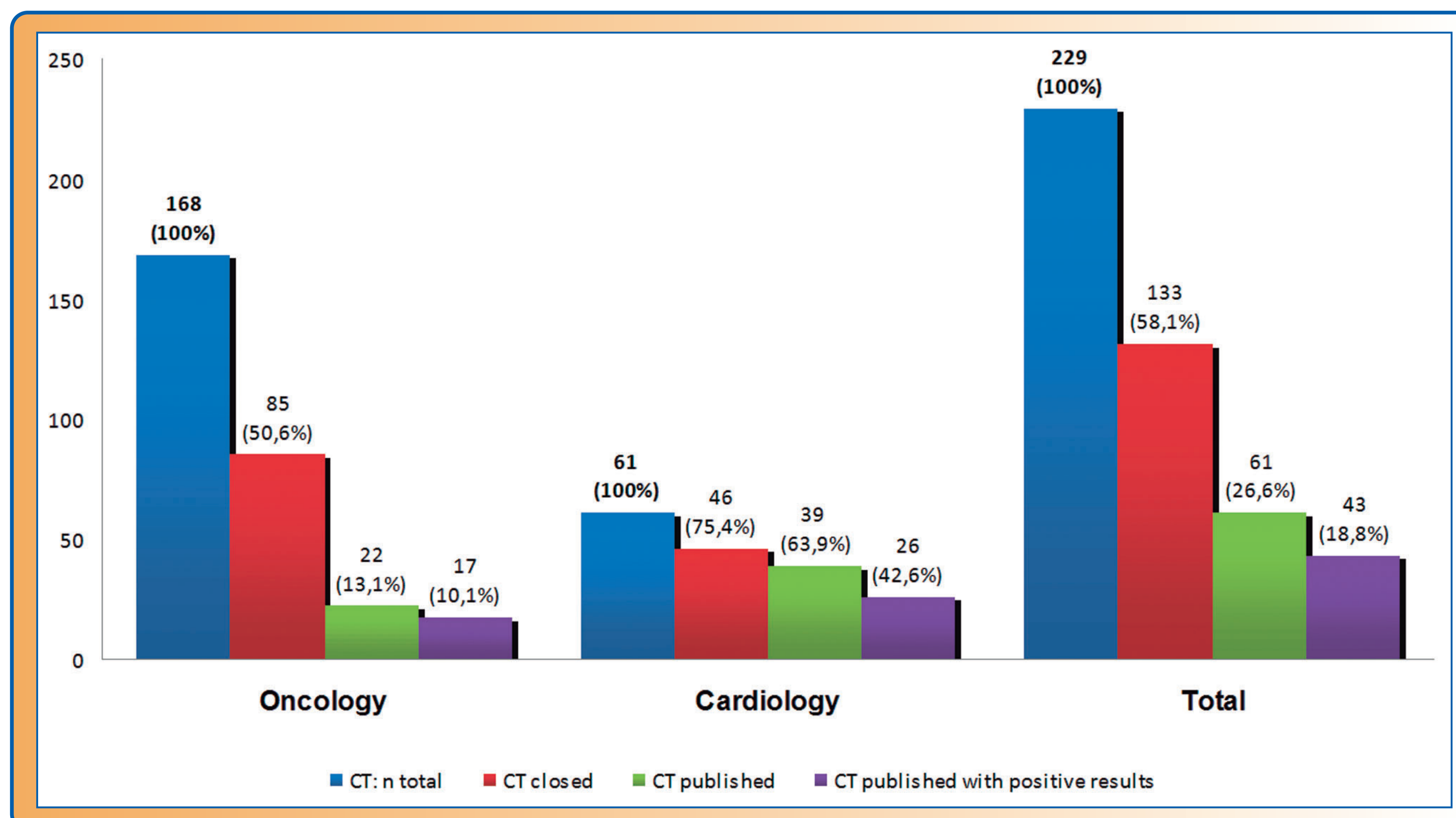
229 CT were analyzed. Distributed by medical clinical services: oncology-168 (73.4%), cardiology-61 (26.6%).

- CT already closed: 133 (58.1%); oncology-85 (50.6%), cardiology-46 (75.4%).
- CT already published: 61 (26.6%); oncology-22 (36.1%), cardiology-39 (63.9%).
- CT published with positive results: 43 (70.5%); oncology-17 (77.3%), cardiology-26 (66.7%).

Positive clinical assays results in cardiology conferred relative risks ranging at 4.88 for the occurrence of a closed study. CTs were published in journals with IP between 2.02 and 53.30. Mean IP was 18.48 (17.41 SD).

Clinical Trials	Oncology (n=168)	Cardiology (n=61)	Total (n=229)
Published vs. Closed	22/85 (25.9%)	39/46 (81.3%)	61/133 (45.9%)
Published vs. total	22/168 (13.1%)	39/61 (63.9%)	61/229 (26.6%)
Positive vs. published	17/22 (77.3%)	26/39 (66.7%)	43/61 (70.5%)

Mean IP = 18.48 (17.41 SD)



Conclusions

- Considering both Oncology and Cardiology services, less than 26.6% of initiated CTs were finally published.
- A high percent of initiated CTs has not been published up to date.
- Only 29.5% of all published CTs were published with a NR. This fact suggests a low level of NR resulting in Journal publications.
- Publication IP has a wide range between low and high scores. Nevertheless, we consider IP mean as a high standard level of publication.