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Effect of bariatric surgery on cancer risk: identifying appropriate non-exposed controls for a cohort study

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Abstract

With the Observational Health Data Sciences and Informatics (OHDSI) network we can address important questions such as whether cancer risk is reduced after bariatric surgery that would not be feasible with traditional research data collection methods. OHDSI tools can implement target trials when comparing two groups both with a clear exposure, but there is no established approach when the control group receives no intervention, which occurs when we study the effect of bariatric surgery on cancer risk. Our aim is to briefly describe a protocol to study specific-site cancer risk after bariatric surgery in the OHDSI network and address the issue of identifying appropriate non-exposed controls.

Introduction

Real-world data (RWD) promises to vastly expand clinical research, providing data for large-scale studies that would not be feasible or timely with traditional research data collection methods. However, when observational studies are not properly designed they can yield biased results. Target trial emulation using RWD can help overcome this limitation and produce unbiased estimates of our observational analyses. An important research question that can be addressed using RWD is whether the risk of specific cancer types is reduced after bariatric surgery (BS). Previous studies addressing this question have mostly found non-significant or inconsistent results, in part due to lack of statistical power and to the use of different methodological approaches.(1–6) The Observational Health Data Sciences and Informatics (OHDSI) offers a unique opportunity to study BS and cancer risk as it includes over 1.5 billion individual records from 20 countries with highly detailed information on patients. OHDSI tools can implement target trials when comparing two groups with a clear exposure (e.g. alternative medications or surgeries), but there is no established approach when the control group receives no intervention, which occurs when we study the effect of BS on cancer risk. In particular, defining an appropriate index date for individuals who did not have a BS (but would have been eligible for one) is challenging. Our aim is to briefly describe a protocol to study specific-site cancer risk after bariatric surgery in the OHDSI network and address the issue of identifying appropriate non-exposed controls.

Study methodology

This study is a matched cohort study based on prospectively collected health data from databases that have been mapped to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM). The study start dates vary according to each participating database. The earliest start date of the study is 01/01/2000 and the latest end date of the study is 31/12/2019.

We will build two mutually exclusive cohorts: patients with BS and patients without BS (non-BS). To be included in these cohorts patients have to be aged ≥ 18 years, with a record of body mass index (BMI) ≥ 35 kg/m² or an obesity diagnosis, without history of BS nor cancer, have been on the database for 1 year before study entry and have at least 1 year of follow-up. Patients on the BS cohort also have a record of BS (index date). The index date of the non-BS cohort is assigned to the patients in the matching process.

The exposure of interest is BS (defined using OMOP-CDM procedure codes). The outcomes of interest are incident diagnoses of obesity-related cancers (defined using OMOP-CDM condition codes) assessed 1 year after the study entry date. We identify covariates related to sociodemographic characteristics of patients, diagnoses, procedures, measurements and devices from 365 days before the patient's index date up to, and including the index date.

A matching process to emulate a target trial

To conduct the matching process we divide the study period in 1-year windows starting in “01/01/2000 to 31/12/2000” until “01/01/2018 to 31/12/2018” (19 windows maximum). At each 1-year window, we identify eligible patients from the BS cohort and from the non-BS cohort. We search for BS patients and assign them the date of the surgery as their index date. For the non-BS cohort, we identify patients with a record of BMI ≥ 35 kg/m² or an Obesity diagnosis up to 5 years previous to the start of the 1-year window and assign them a random index date in the window. For both cohorts, we identify the covariates from 365 days previous to their index date. We match 1 patient with BS up to 5 patients without BS. An example of the matching process for Period 1 (year 2000) is provided in Figure 1. This approach will best emulate a target trial, since patients who are in the non-BS cohort in any of the 1-year windows could still undergo a BS over their follow-up (analogous to in a target trial, where participants randomized to not receiving a BS could still go on to undergo one in the future).

With the index date assignment to non-surgical patients, we will estimate propensity scores and do a matching adjustment (without replacement) to control for potential confounding. We will fit Cox proportional hazard models to estimate the risk of developing each cancer type and check for residual confounding using negative control outcomes.

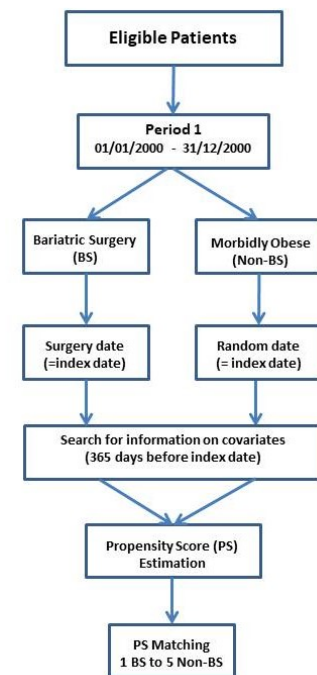


Figure 1. Matching process

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