INPLASY

Beef Consumption and Cardiometabolic Risk Factors: A Systematic Review and Meta-analysis of Randomized Controlled Trials with an emphasis on study quality

INPLASY202420013

doi: 10.37766/inplasy2024.2.0013

Received: 03 February 2024

Published: 03 February 2024

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ADMINISTRATIVE INFORMATION

Support - Beef Checkoff.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - This study is funded by the Beef Checkoff. MB Clinical Research and Consulting has also received funding in the past from the Pork Checkoff.

INPLASY registration number: INPLASY202420013

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 February 2024 and was last updated on 03 February 2024.

INTRODUCTION

Review question / Objective This project will perform a systematic review and meta-analysis of randomized controlled trials evaluating the effects of beef intake on cardiometabolic risk factors in adults. The primary goal is to identify the effect of beef intake on cardiometabolic risk factors and if this effect differs by study quality (rigor, risk of bias, transparency, and reproducibility). Cardiometabolic risk factors include blood pressure and blood lipids (e.g., LDL-c, triglycerides).

Condition being studied Cardiometabolic health - blood lipids and blood pressure.

METHODS

Participant or population Adults ≥ 18 y, no pregnant or lactating females; free from chronic disease at baseline with the exception of overweight/obesity, type 2 diabetes, prediabetes, metabolic syndrome, hyperlipidemia, or hypertension.

Intervention Diet intervention includes fresh or minimally processed beef.

Comparator Control diet without beef or with a lower level of fresh/minimally processed beef.

Study designs to be included Randomized Controlled Trials.

Eligibility criteria Inclusion Criteria: 1) Quantitative randomized controlled trials that assesses beef intake and cardiometabolic risk factors 2) Studies in human adults (≥ 18 y) 3) Subjects are healthy, have overweight/obesity, have type 2 diabetes, prediabetes, metabolic syndrome, hyper/dyslipidemia, or hypertension 4) Fresh/minimally processed beef as the main intervention compared to a control diet without beef, or with a lower level

of beef 5) Baseline and post-treatment measures of cardiometabolic risk factors 6) A measure of variability (standard deviation [SD] or standard error [SE]) of the cardiometabolic risk factors 7) Acute or chronic interventions 8) Publication in English language. Exclusion criteria: 1) Cross-sectional, retrospective, or prospective cohort study, or any other observational, case-control or single-arm study (i.e., interventions with no control condition) 2) In vitro or animal studies 3) Trials examining a mixture of red meats and not beef exclusively 4) Trials examining red meat and the type of red meat is not specified 5) Trials based on beef components or dietary supplement, not a beef food 6) Trials with only processed beef 7) Trials where the intervention is given via tube feeding 8) Trials in children (<18 y) or pregnant/lactating females 9) Trials that include participants with chronic disease at baseline with the exception of type 2 diabetes, prediabetes, obesity, metabolic syndrome, hyperlipidemia or hypertension 10) Trials that do not report quantitative outcomes of cardiometabolic risk factors.

Information sources A comprehensive literature search will be conducted using the PubMed and CENTRAL databases. The search will be limited to English language publications. The search will not be limited by geography. The reference lists from collected papers and other reviews will be evaluated to identify additional studies.

Main outcome(s) The primary outcome of the review will be the difference between beef intake and control conditions on blood lipids.

Additional outcome(s) The study will also evaluate the difference between beef intake and control conditions on blood pressure.

Data management Qualitative and quantitative data will be extracted from each publication meeting the inclusion criteria and none of the exclusion criteria. All data from eligible studies will be abstracted by two independent scientists and cross-checked. Any discrepancies will be resolved by discussion with an additional scientist and by referencing the original publication.
Data extraction will include the study design, geographical location of the study, sample size, population or participant demographics and health status, amount and description of beef consumed, frequency of consumption (if applicable), the comparator or control, follow-up time frame or duration of intervention, outcomes measured, risk of bias questions based on Cochrane ROB tool, reporting of withdrawals with reason, funding source, and quantitative outcome data for meta-analysis.

Quality assessment / Risk of bias analysis The Cochrane Risk of Bias tool for parallel and crossover RCTs will be used to assess risk of bias. The presence of publication bias will be assessed visually by examining funnel plots, as well as statistically by using Egger's regression method.

Strategy of data synthesis Statistical analyses will be carried out by personnel from Midwest Biomedical Research or designee. For selected cardiometabolic risk factor outcomes where sufficient published results are available (at least 3 RCTs), meta-analysis will be completed using Comprehensive Meta-Analysis (CMA) Software version 3 (Biostat, Englewood, NJ). Means, sample sizes, and associated variability (SD or SE) for each condition (beef vs. control) will be extracted directly from the study. The primary analysis will use pooled standardized mean difference (SMD) estimates or weighted mean differences (WMD) and 95% confidence intervals (CIs). Statistical significance for individual study and pooled SMDs or WMDs will be declared when the 95% CI does not include the null value of 0 (i.e., p-value <0.05). Studies will be weighted according to the inverse of the variance of each study's effect using random or fixed effects models based on a priori judgment regarding which is the most appropriate given the characteristics of the dataset. Statistical heterogeneity will be assessed using Cochran's Q and the I2 statistic. The Cochrane Handbook (2011) defines an I2 value of 0% to 40% as low heterogeneity, which "might not be important." An I2 value of ≥40% will be used to designate moderate or higher heterogeneity.
The outcome measures of the meta-analysis will be the difference between the beef and control conditions in cardiometabolic risk factors.

Subgroup analysis Subgroup analyses will be performed based on available data (e.g. gender, amount or type of beef, health condition, duration of testing, study quality score, etc.) from the selected studies.

Sensitivity analysis Sensitivity analyses will be performed based on conditions in the trials (e.g., weight loss vs stable weight, age of the study, use of different blood lipid cut-offs over time).

Language restriction English only.

Country(ies) involved United States.

Keywords blood lipids; beef; cardiometabolic health; blood pressure.

Dissemination plans The results of the review will be summarized into a manuscript for submission to a peer reviewed journal. The manuscript will summarize the quality of the current research, effects on cardiometabolic risk factors and recommendations for future research.

Contributions of each author

Author 1 - Lisa Sanders - Develop protocol and inclusion/exclusion criteria, database search, screen title/abstract, full text review and data extraction, risk of bias assessment, data interpretation, drafting manuscript.
Email: lisa@mbclinicalresearch.com
Author 2 - Orsolya Mezei - screen title/abstract, full text review and data extraction, risk of bias assessment, drafting manuscript.
Author 3 - Meredith Wilcox - statistical analysis.
Author 4 - Kevin Maki - Supervision, protocol development, resolve disputes over inclusion/exclusion of certain papers, data interpretation, editing manuscript.
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