research

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ORIGINAL RESEARCH Multicentre, double blind, RCT

Effects of intravaginal conjugated oestrogen on pessary continuation for pelvic organ prolapse

Zhou Y, Yin R, Zhang Y, et al

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Study question Does the use of vaginal oestrogen cream improve pessary continuation and satisfaction in women with pelvic organ prolapse?

Methods This trial recruited participants from 12 academic medical centres in China from May 2020 to June 2023. A total of 420 postmenopausal women with symptomatic pelvic organ prolapse (stage 2-4) and successfully fitted with ring pessaries were included and randomly assigned in a 1:1 ratio to receive oestrogen cream or placebo cream. One gram of conjugated oestrogen cream (0.625 mg/g) or placebo cream was inserted vaginally every night for the first two weeks after successful pessary fitting, followed by twice weekly for 12 months. The primary outcome was satisfaction with continued pessary use, defined as the proportion of participants who continued using the pessary and reported a response of very much better or much better on the Patient Global Impression of Improvement questionnaire at 12 months. Secondary outcomes were self-reported pelvic floor symptoms and adverse events. All analyses were based on a modified intention-to-treat approach and included 411 participants who had at least one follow-up visit.

Study answer and limitations Pessary continuation rate with satisfaction did not differ significantly between the oestrogen group and the placebo group (181/208 (87.0%) *v* 176/203 (86.7%); risk difference 0.3%, 95% confidence interval −6.2% to 6.9%; P=0.92). Excessive discharge (34/208 (16.3%) *v* 52/203 (25.6%); −9.3%, −17.1% to −1.4%), vaginal erosion or ulcer (4/208 (1.9%) *v* 14/203 (6.9%); −5.0%, −8.9% to −1.0%), and vaginal bleeding (3/208 (1.4%) v 13/203 (6.4%); −5.0%, −8.7% to −1.2%) were less common in the vaginal oestrogen group. Limitations included focusing exclusively on ring pessaries with support, a relatively short 12 month follow-up, and partial telephone follow-up.

What this study adds Vaginal oestrogen did not significantly improve pessary continuation rate and satisfaction in women with pelvic organ prolapse compared with placebo.

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Trial registration ClinicalTrials.gov NCT04393194.

Continuation rate with satisfaction in oestrogen group and placebo group in modified intention-to-treat population

Primary outcome	Oestrogen group, No (%)	Placebo group, No (%)	Risk difference (95% CI)	P value
Continuation rate with satisfaction	181/208 (87.0)	176/203 (86.7)	0.3 (−6.2 to 6.9)	0.92
Pessary continuation	186/208 (89.4)	182/203 (89.7)	−0.2 (−6.1 to 5.7)	0.94
Feeling satisfied	181/186 (97.3)	176/182 (96.7)	0.6 (−2.9 to 4.1)	0.73

CI=confidence interval

Sex differences in antithrombotic therapy for CAD

ORIGINAL RESEARCH Systematic review and meta-analysis

Sex related differences in efficacy and safety of antithrombotic therapy in patients with coronary artery disease

Piccolo R, Laino A, Vitale AP, Franzone A, Esposito G

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Find this at doi: 10.1136/bmj-2024-082974

Study question. Do sex related differences exist in the treatment effect of antithrombotic therapy in patients with established coronary artery disease?

Methods This systematic review and meta-analysis included randomised controlled trials reporting sex stratified outcomes, including ischaemic and major bleeding events, and comparing any experimental versus control antithrombotic strategies in coronary artery disease. The main outcomes were all cause death, myocardial infarction, and major bleeding. A within trial framework was developed to evaluate sex related heterogeneity in the treatment effect of antithrombotic therapies. Sex specific risk estimates were reported as hazard ratios with 95% confidence intervals (CIs), whereas trial level ratios of hazard ratios were pooled with an inverse variance model.

Study answer and limitations A total of 33 trials enrolling 274 433 participants (72 601 (median proportion 25%) women) were included. The relative risk of all cause death was comparable for more intensive versus less intensive antithrombotic therapies in both women and men, without sex based interaction (interaction hazard ratio 1.06, 95% CI 0.94 to 1.19; P for interaction=0.33; I^2=0.00%; P for heterogeneity=0.76). More intensive antithrombotic therapies were associated with a reduced risk of myocardial infarction by ~15% in both sexes (interaction hazard ratio 1.05, 0.95 to 1.17; P for interaction=0.36; I^2=14.05%; P for heterogeneity=0.28). Conversely, major bleeding was significantly higher by ~40% with more intensive versus less intensive antithrombotic therapies irrespective of sex (interaction hazard ratio 0.99, 0.86 to 1.15; P for interaction=0.93; I^2=33.56%; P for heterogeneity=0.06). Women were underrepresented and sex specific outcomes were underreporting across the otherwise eligible trials.

COMMENTARY Balanced trial recruitment is needed to build the evidence base for sex stratified care

Antithrombotic therapies, comprising antiplatelet agents and anticoagulants, are a cornerstone of secondary prevention in patients with established coronary artery disease. Many randomised controlled trials have evaluated various intensities and combinations of antithrombotic therapy, showing reduced risks of recurrent ischaemic events. However, longstanding concern has existed about the generalisability of these findings to female patients, given the underrepresentation of female patients in cardiovascular trials and the sex based biological differences in response to antithrombotic agents.[1] Sex differences in platelet reactivity, vascular biology, and pharmacokinetics have raised the hypothesis that female and male patients may experience different benefit-risk profiles with antithrombotic therapies. Clinically, concern has existed that female patients are more prone to bleeding complications and are therefore less suitable for more intensive treatment strategies. Observational data have also suggested potential sex based inequalities in treatment allocation and outcomes, with female patients less likely to be referred for intervention.[2]

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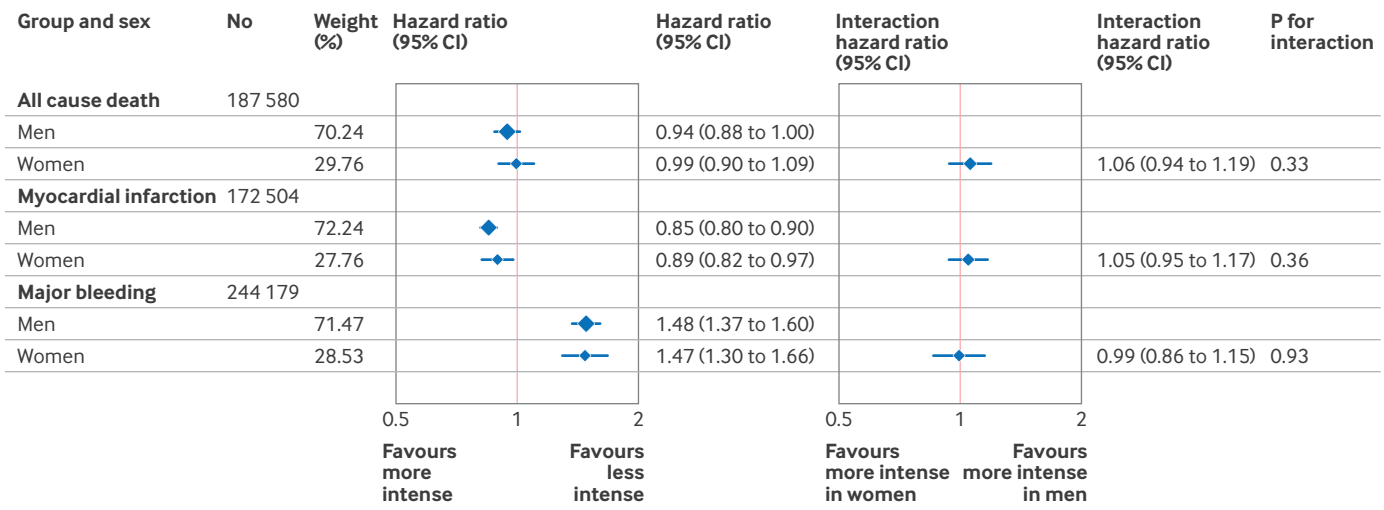
Female and male patients derive similar benefits and risks from more intensive antithrombotic strategies

In their systematic review and meta-analysis, Piccolo and colleagues examined whether the efficacy and safety of antithrombotic therapy in patients with established coronary artery disease differed between sexes.[3] Their analysis synthesised data from 33 randomised controlled trials, including more than 270 000 participants, of whom approximately 25% were female. The findings suggest that treatment effects of more intensive versus less intensive antithrombotic strategies are consistent in both female and male patients with coronary artery disease.

The researchers evaluated sex stratified outcomes for all cause mortality, myocardial infarction, major bleeding, stroke, cardiovascular death, and stent thrombosis. The primary analysis showed no statistically significant interaction between sex and treatment effect for any of these outcomes.[3]

Specifically, more intensive antithrombotic therapy was associated



Overall results of subgroup analysis for all cause death, myocardial infarction, and major bleeding, stratified by antithrombotic strategies. Left: forest plot with subgroup specific hazard ratios with 95% confidence intervals (CIs) for men and women. Right: common effect meta-analysis of within trial interaction hazard ratios between women and men

What this study adds Antithrombotic therapies provided consistent efficacy and safety outcomes in female and male patients with established coronary artery disease.

Funding, competing interests, and data sharing
This work was supported by a research grant from the Italian Ministry of Education. See full paper on bmj.com for competing interests. Requests for data sharing should be sent to the corresponding author.

Systematic review registration PROSPERO CRD42024560908.

with a relative reduction in myocardial infarction (~15%) and stent thrombosis (~30%) in both sexes. Conversely, the risk of major bleeding was increased by approximately 40% in both sexes. Modest reductions were seen in all cause and cardiovascular mortality with more intensive therapy, which seemed more pronounced in male patients; however, interaction testing did not reveal significant sex based heterogeneity.

Study implications

The results of this meta-analysis support the application of antithrombotic treatment strategies without modification on the basis solely of patient's sex in people with established coronary artery disease. This has practical relevance, given that female patients are often perceived to be at higher bleeding risk and consequently may receive less intensive antithrombotic therapy.

No data support the differential management of acute and chronic coronary syndromes on the basis of sex. The study findings are in line with the recommendations from the 2023 and 2024 European Society of Cardiology guidelines on the management of acute and chronic coronary syndromes, respectively—namely, that the same guideline recommended cardiovascular preventive therapy should be provided to women and men.[4 5]

However, these recommendations are brief, reflecting the limited evidence base, and a meta-analysis is only as good as the evidence base it draws on. The consistent underrepresentation of female patients in the included cardiovascular trials is particularly striking, with female participants comprising a median of 25% of participants in this meta-analysis. To build the evidence base for sex stratified care, we need balanced trial recruitment.

In this meta-analysis, more than half of the eligible trials failed to report sex stratified outcomes over a 20 year period, limiting the precision and applicability of subgroup analyses. Despite increasing awareness in the community, from journals, academics, and funders (for example, MESSAGE[6]), the inclusion and reporting of sex disaggregated data remain inconsistent.

Although this study is methodologically rigorous, its limitations must be acknowledged. The analysis is based on aggregate data, and individual patient level data were not available. The inability to adjust for covariates limits assessment of potential confounding. The subjectivity of intensive versus less intensive therapy, plus the inclusion of heterogeneous populations, antithrombotic agents, and endpoints, limits the specific clinical applicability of the various comparisons.

Next steps

Of note, no included trial was prospectively designed to assess treatment effect by sex, and many were underpowered for such analyses. The findings therefore speak to the absence of evidence for a sex-treatment interaction, rather than definitive evidence of equivalence. Sex specific management strategies are generally not provided in cardiovascular care guidelines because the evidence base to guide sex stratified care is limited. Future research, including meta-analyses of individual participant data and sex specific randomised trials, are needed to further clarify these observations.

Piccolo and colleagues provide the most extensive analysis to date on sex related outcomes of antithrombotic therapy in coronary artery disease.[3] Based on the evidence to date, their findings indicate that female and male patients derive similar benefits and risks from more intensive antithrombotic strategies. These results support the continued use of guideline directed therapies irrespective of sex but should be viewed as a call to action for greater inclusion of female patients in cardiovascular research and consistent sex based reporting in future cardiovascular trials.

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Potatoes and risk of type 2 diabetes

ORIGINAL RESEARCH Results from three US cohorts and a substitution meta-analysis

Total and specific potato intake and risk of type 2 diabetes

Mousavi SM, Gu X, Imamura F, et al

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Study question Are total and specific potato intake associated with risk of type 2 diabetes (T2D)?

Methods This study analysed data from three large US prospective cohorts: the Nurses' Health Study (1984-2020), Nurses' Health Study II (1991-2021), and Health Professionals Follow-up Study (1986-2018). A total of 205 107 participants free of diabetes, cardiovascular disease, and cancer at baseline were followed for up to 36 years, contributing more than 5.1 million person years of follow-up and documenting 22 299 diagnoses of incident T2D. Potato intake was assessed through validated food frequency questionnaires. Associations between total potato intake and intake by specific type (French fries; baked, boiled, or mashed) and diabetes risk were evaluated using Cox proportional hazards models, adjusting for lifestyle and dietary factors. Substitution analyses estimated the effect of replacing potatoes with alternative carbohydrate food sources. A dose-response and substitution meta-analysis was also conducted using data from 13 prospective cohorts (587 081 participants and 43 471 diagnoses of T2D).

Study answer and limitations For every increment of three servings weekly of total potato, the rate for T2D increased by 5% (hazard ratio 1.05, 95% confidence interval (CI) 1.02 to 1.08) and for every increment of three servings weekly of French fries the rate increased by 20% (1.20, 1.12 to 1.28). Intake of combined baked, boiled, or mashed potatoes was not significantly associated with T2D risk (pooled hazard ratio 1.01, 95% CI 0.98 to 1.05). In substitution analyses, replacing three servings weekly of potatoes with whole grains was estimated to lower T2D rates by 8% (95% CI 5% to 11%) for total potatoes, 4% (1% to 8%) for baked, boiled, or mashed potatoes, and 19% (14% to 25%) for French fries. In a meta-analysis of 13 cohorts, the pooled hazard ratio for risk of T2D with each increment of three servings weekly of total potato was 1.03 (95% CI 1.02 to 1.05) and of fried potatoes was 1.16 (1.09 to 1.23). In substitution meta-analyses, replacing three servings weekly of total, non-fried, and fried potatoes with whole grains was estimated to lower the risk of T2D by 7% (95% CI 5% to 9%), 5% (3% to 7%), and 17% (12% to 22%), respectively. Limitations include residual or unmeasured confounding inherent to observational studies.

What this study adds Higher intake of French fries, but not combined baked, boiled, or mashed potatoes, was associated with a higher risk of T2D. The T2D risk linked to potato intake seemed to depend on the food being replaced: replacing potato with whole grains was associated with lower risk, whereas replacing with white rice was associated with increased risk.

Funding, competing interests, and data sharing
Funded by the US National Institutes of Health. No competing interests declared. Data are not publicly available but can be requested through established cohort collaboration procedures.

Associations between potato intakes and risk of diabetes in NHS (n=72 712), NHSII (n=90 232), and HPFS (n=42 163)

	Frequency of potato consumption (servings/week)					P for trend	Hazard ratio* (95% CI)
Total potato	**<1**	**1**	**2-4**	**5-6**	**≥7**		
No of participants with T2D/person years	788/270 016	2172/676 037	11 458/2 645 546	6705/1 338 773	1176/245 130		
Model 1	Ref	1.05 (0.97 to 1.14)	1.29 (1.19 to 1.38)	1.57 (1.45 to 1.69)	1.85 (1.68 to 2.03)	<0.001	1.30 (1.27 to 1.33)
Model 2	Ref	0.99 (0.91 to 1.08)	1.05 (0.98 to 1.13)	1.13 (1.05 to 1.22)	1.25 (1.14 to 1.38)	<0.001	1.10 (1.07 to 1.13)
Model 3	Ref	0.97 (0.90 to 1.06)	1.00 (0.92 to 1.07)	1.03 (0.95 to 1.11)	1.12 (1.02 to 1.24)	<0.001	1.05 (1.02 to 1.08)
Baked, boiled, or mashed potatoes	**<1**		**1**	**2-4**	**≥5**		
No of participants with T2D/person years	1917/594 299		4204/1 196 275	12 754/2 731 261	3462/653 665		
Model 1	Ref		1.05 (0.99 to 1.10)	1.16 (1.11 to 1.22)	1.25 (1.18 to 1.33)	<0.001	1.13 (1.10 to 1.16)
Model 2	Ref		1.00 (0.95 to 1.06)	1.01 (0.96 to 1.07)	1.06 (1.00 to 1.13)	0.008	1.05 (1.02 to 1.08)
Model 3	Ref		0.97 (0.92 to 1.02)	0.96 (0.91 to 1.01)	0.99 (0.93 to 1.05)	0.62	1.01 (0.98 to 1.05)
French fries	**Almost never**	**1-3/month**	**1**	**2-4**	**≥5**		
No of participants with T2D/person years	2952/985 067	10 803/2 542 718	5234/1 103 370	3130/517 430	180/26 919		
Model 1	Ref	1.40 (1.34 to 1.46)	1.77 (1.69 to 1.86)	2.26 (2.14 to 2.40)	3.17 (2.71 to 3.71)	<0.001	2.18 (2.09 to 2.28)
Model 2	Ref	1.14 (1.09 to 1.19)	1.22 (1.16 to 1.28)	1.29 (1.22 to 1.37)	1.44 (1.23 to 1.69)	<0.001	1.35 (1.27 to 1.44)
Model 3	Ref	1.09 (1.04 to 1.13)	1.12 (1.06 to 1.18)	1.15 (1.09 to 1.23)	1.27 (1.08 to 1.49)	<0.001	1.20 (1.12 to 1.28)
Potato or corn chips	**Almost never**	**1-3/month**	**1**	**2-4**	**≥5**		
No of participants with T2D/person years	2763/787 691	8361/1 945 784	4893/1 112 988	5435/1 137 550	847/191 488		
Model 1	Ref	1.12 (1.07 to 1.17)	1.22 (1.16 to 1.28)	1.23 (1.17 to 1.29)	1.23 (1.14 to 1.34)	<0.001	1.15 (1.11 to 1.19)
Model 2	Ref	1.02 (0.97 to 1.06)	1.05 (1.00 to 1.10)	1.04 (0.98 to 1.09)	1.07 (0.99 to 1.16)	0.01	1.07 (1.03 to 1.11)
Model 3	Ref	0.98 (0.94 to 1.03)	0.98 (0.93 to 1.03)	0.95 (0.90 to 1.00)	0.97 (0.89 to 1.06)	0.50	1.02 (0.98 to 1.06)

NHS=Nurses' Health Study; NHSII=Nurses' Health Study II; HPFS=Health Professionals Follow-up Study; MET-h=metabolic equivalent tasks per hour; T2D=type 2 diabetes.
Dietary intakes were cumulative averages from the baseline food frequency questionnaire to the start of each four year follow-up interval.
Model 1 was stratified by age (months) and calendar time (two year interval) and adjusted for total energy intake. Model 2 was additionally adjusted for race/ethnicity (white, non-white), smoking status (never, past, and current (cigarettes/day): 1-14, >15-24, >24), alcohol intake (0, 0-4.9, 5-9.9, 10-14.9, 15-29.9, >30 g/day), physical activity (<3, 3.0-8.9, 9.0-17.9, 18.0-26.9, ≥27 MET-h/week), multivitamin use (yes/no), menopausal status and hormone use (NHS or NHSII), family history of type 2 diabetes (yes/no), antihypertensive use (yes/no), cholesterol lowering drug use (yes/no), history of hypertension at baseline (yes/no), socioeconomic status, and time varying body mass index (<21, 21.0-22.9, 23.0-24.9, 25.0-26.9, 27.0-29.9, 30.0-32.9, 33.0-34.9, 35-39.9, ≥40). All covariates (except race/ethnicity, family history of diabetes, and baseline hypertension) were updated every two years. Model 3 was adjusted for the covariates in model 2+updated cumulative average intake of servings daily (fifths) of total red meat, poultry, fish, egg, total dairy, nuts and legumes, fruits, vegetables, sugar sweetened beverages, whole grains, and refined grains, and mutual adjustment for baked, boiled, or mashed potatoes and for French fries.
*For three servings weekly.

The potato is a carbohydrate rich tuberous vegetable that traditionally has been used as a staple in many food cultures. Compared with other carbohydrate rich comestibles such as rice, potatoes also have a lower environmental impact, including low carbon dioxide emissions, terrestrial acidification, eutrophication, and freshwater use.[1] Amid a global climate crisis and with our food system contributing 21-37% of global greenhouse gas emissions,[2] potatoes could be considered for reintroduction as a more environmentally sustainable carbohydrate source, provided the health impacts and preparation methods are appropriately addressed. But because of their high carbohydrate content, and resulting increasing effect on blood glucose,[3] potatoes have been linked to a higher risk of type 2 diabetes. Although previous reviews have found no clear evidence of an association,[4] in its 2019 report, the EAT-Lancet Commission argued that potato intake increases the risk of type 2 diabetes and other health risks and recommended the intake of whole grains instead, putting health concerns at the centre of the debate.[5] However, neither the preparation method for potatoes nor specific foods that potatoes would replace were considered, both of which are central to evaluating the overall health impact of potatoes.

In their study, Mousavi and colleagues comprehensively investigated the association between intake of potatoes prepared by different methods (boiled, baked, or mashed versus French fries) and type 2 diabetes in three large US cohorts.[6] The cohorts followed more than 205 000 health professionals in the US with repeated dietary intake assessments every four years over almost four decades, documenting more than 22 000 people with incident type 2 diabetes. In addition, the authors performed an updated systematic review and meta-analysis of this association. Overall, both the cohort analysis and the meta-analysis found no association between intake of boiled, baked, or mashed potatoes and risk of type 2 diabetes, whereas a higher intake of French fries was associated with a higher risk, highlighting the importance of evaluating the health effects of potato intake separately by preparation type. This finding also corresponds to the observed associations between high intake of ultra-processed foods and high risk of type 2 diabetes—French fries are often ultra-processed, whereas baked, boiled, or mashed potatoes are often minimally processed.[7]

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Potatoes can be part of a healthy and sustainable diet

Meaning of the findings

While the association between intake of French fries is clear, the answer is more complicated for boiled, baked, or mashed potatoes. To estimate type 2 diabetes risk by substituting baked, boiled, or mashed potatoes with other foods, Mousavi and colleagues performed substitution analyses in the three US cohorts.[8] They found that replacing boiled, baked, or mashed potatoes with equal amounts of whole grains was associated with a lower risk of type 2 diabetes, whereas replacing them with refined grains, white rice, or brown rice was associated with a higher risk. Replacing with different types of vegetables was not associated with type 2 diabetes risk. These findings suggest that the association between intake of boiled, baked, or mashed potato and type 2 diabetes may depend on what foods they replace. For individuals who consume boiled, baked, or mashed potatoes as a staple carbohydrate source, this dietary habit might help to reduce intake of refined grains and should be encouraged. If feasible, however, partial substitution with whole grains could offer additional metabolic benefits. Conversely, if boiled, baked, or mashed potatoes are consumed as vegetables, dietary changes may not be necessary, provided these potatoes are a part of a balanced and diverse vegetable intake.

A lower risk of type 2 diabetes related to substituting boiled, baked, or mashed potatoes with whole grains was supported by meta-analysis. However, these findings are based on statistical modelling of observational data rather than the intervention studies that directly evaluate the health effects of replacing potatoes with whole grains. Besides, the meta-analyses relied on indirect methods rather than the substitution analysis directly, and the methodology for estimating such substitution effects remains to be standardised.[9 10] Nevertheless, replacing French fries with whole grains, refined grains, non-starchy vegetables, starchy vegetables, or legumes was associated with a lower risk of type 2 diabetes.

Study limitations

Other limitations should be acknowledged. Firstly, owing to the observational nature of the study, causal inference cannot be established, and measurement error is inevitable when measuring food intake with food frequency questionnaires. Secondly, most participants were health professionals of European ancestry with high educational attainment, whose potato intake amount, cooking methods, and overall health profiles differ from those of individuals from other racial/ethnic or social backgrounds.

Are potatoes back on the plate? Well, it depends. Two key considerations are important when guiding the public or informing policy: the food should be defined clearly (eg, the method of potato preparation), as should be the type of carbohydrate rich food to be replaced by minimally processed potatoes.[11] With their relatively low environmental impact and their health impact, potatoes can be part of a healthy and sustainable diet, although whole grains should remain a priority. Future cohort studies from more diverse populations that account for both preparation methods and substitution analysis are needed. In addition, future meta-analyses should extend beyond comparisons limited to whole grains.

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Effect of universal no-cost coverage on use of long acting reversible contraception and all prescription contraception

Schummers L, Cheng L, Odendaal M, et al

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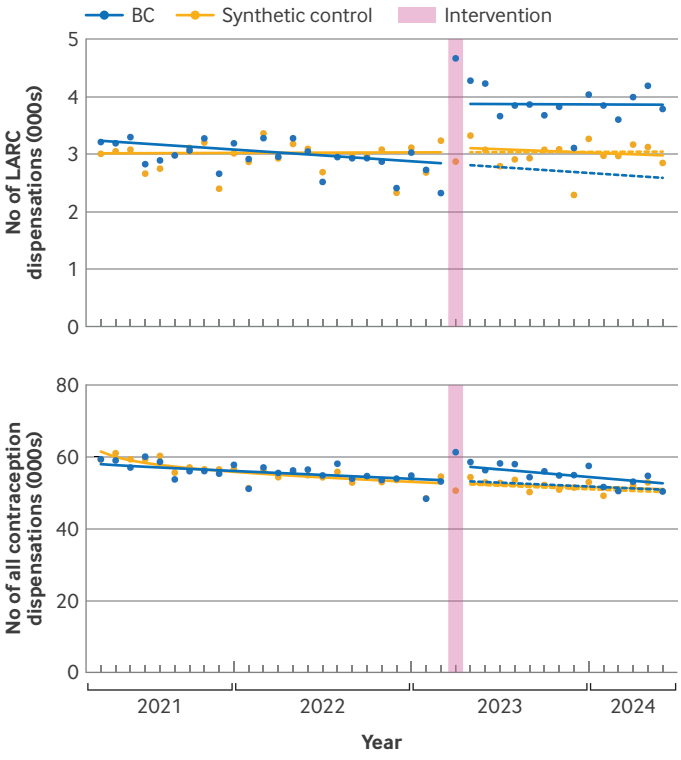
Find this at doi: 10.1136/bmj-2024-083874

Study question What effects did the introduction of a policy for first-dollar coverage of prescription contraception have on the use of long acting reversible contraception (LARC) and all prescription contraception in British Columbia, Canada?

Methods In a controlled, quasi-experimental, interrupted time series analysis, dispensation volumes for LARC and all prescription contraception in British Columbia were compared with a synthetic control derived from the nine other Canadian provinces, using a national prescription database. An interrupted time series analysis using population health data from British Columbia, including a cohort of female residents of reproductive age (15-49 years), examined changes in LARC use and all prescription contraception use. The study period was between 1 April 2021 and 30 June 2024.

Study answer and limitations Dispensations for LARC increased by 1050 (95% confidence interval (CI) 942 to 1487) immediately after British Columbia's policy change and showed a stable increasing trend. An additional 1273 (963 to 1698) monthly LARC dispensations were found 15 months after the policy compared with the expected volume, representing an estimated 1.49-fold (95% CI 1.34-fold to 1.77-fold) increase. Dispensations for all prescription contraception (including LARC) increased by 1981 (356 to 3324) per month or by 1.04-fold (1.01-fold to 1.07-fold). In the study population cohort, 9.1% of the 859 845 female residents aged 15-49 years were using LARC in April 2021. At 15 months after the policy, 11 375 (95% CI 10 273 to 13 013) more female residents used LARC than expected without the policy, representing an additional 1.3% (95% CI 1.2% to 1.5%) of female residents aged 15-49 years. The policy led to an additional 1.7% (1.5% to 2.3%) of individuals using any prescription contraception. Although use cannot be directly measured, it was assumed that participants in this analysis used all contraception dispensed.

What this study adds Universal, no-cost public coverage in British Columbia increased prescription contraception use overall, driven by increased LARC use. This policy providing universal, no-cost coverage for all prescription contraception methods (without other behavioural or informational interventions) significantly increased use of prescription contraception and prompted shifts to the most effective methods use in a large, diverse population.



Controlled interrupted time series analysis in British Columbia (BC) and in a synthetic control derived from Canada's other nine provinces before and after the introduction of BC's universal, no-cost contraception coverage in April 2023. The top graph shows the number of monthly LARC dispensations. The bottom graph shows monthly prescription contraception dispensations (for all types, including LARC). Solid lines indicate observed trends before and after the policy; dashed lines indicate expected (or counterfactual) trends after the policy

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