Evidence Synthesis Program

Orthopedic Surgery Complication Risk Associated with Smoking Cessation and Use of Nicotine Replacement Therapies

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Author roles, affiliations, and contributions to the present report (using the CRediT taxonomy) are summarized in the table below.

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This report was prepared by the Evidence Synthesis Program Coordinating Center located at the **VA Portland Health Care System**, directed by Mark Helfand, MD, MPH, MS and funded by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development.

PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted health care topics of importance to clinicians, managers, and policymakers as they work to improve the health and health care of Veterans. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The program comprises 4 Centers around the US and a Coordinating Center, which are led by VA clinicians and scientists who are recognized leaders in the field of evidence synthesis. The Coordinating Center, located in Portland, Oregon, was created to manage program operations, ensure methodological consistency and quality of products, engage with stakeholders, and address urgent evidence synthesis needs. To ensure responsiveness to VA decision-makers, the ESP is governed by a Steering Committee of health system leadership and researchers. Nominations for ESP reviews are submitted via the program website.

The present report was developed in response to a request from Veterans Health Administration (VHA) National Surgery Office. The scope was further developed with input from Operational Partners (below) and the ESP Coordinating Center review team.

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Operational Partners

Operational partners are system-level stakeholders who help ensure relevance of the review topic to the VA, contribute to the development of and approve final project scope and timeframe for completion, provide feedback on the draft report, and provide consultation on strategies for dissemination of the report to the field and relevant groups.

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Peer Reviewers

The Coordinating Center sought input from external peer reviewers to review the draft report and provide feedback on the objectives, scope, methods used, perception of bias, and omitted evidence (see Appendix E for disposition of comments). Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The Coordinating Center works to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

EXECUTIVE SUMMARY

Key Findings

- Little evidence is available on the impact of smoking cessation interventions on complication risk following elective orthopedic surgery.
- One randomized controlled trial (RCT) reported a lower risk of wound-related complications among patients offered counseling and nicotine replacement therapy (NRT) before undergoing total knee arthroplasty or total hip arthroplasty, compared with usual care. Findings from 3 observational studies are at substantial risk of bias.
- Important questions remain about the degree to which short-term tobacco cessation interventions among active tobacco users mitigate the risk of complications after elective orthopedic surgery and whether reduction in risk varies according to the duration and severity of tobacco use, timing of cessation relative to surgery, and/or use of NRT.
- Whether to require tobacco cessation in the immediate preoperative period may be best determined using shared decision-making and considering the totality of each patient's risk factors and potential benefits of surgery. It is possible that for some patients, requiring tobacco cessation prior to elective orthopedic surgery may be unduly burdensome and delay improvements to their quality of life without conferring a meaningful reduction in their surgical risks.

In a 2022 survey, more than 1 million Veterans enrolled in VHA care reported currently using tobacco (defined as cigarette smoking every day or some days), equating to almost 13% of all VHA enrollees. Professional societies including the American College of Surgeons recommend tobacco cessation prior to undergoing elective surgery to improve overall health and reduce the risk of surgical complications. In the case of elective orthopedic surgery, the American Academy of Orthopaedic Surgeons urges patients to quit smoking prior to surgery, citing tobacco use as a cause of poor wound healing, infection, and worse overall outcomes.

While requiring tobacco cessation prior to elective orthopedic surgery may lower complication risks, overly restricting the option of surgery also has the potential to worsen outcomes. Patients who are required to quit smoking prior to surgery but are unable to do so may seek out another surgeon with different requirements (delaying care) or ultimately decide to forgo surgery, even when the symptoms that led them to seek surgery in the first place become more severe or functionally limiting. To best determine if tobacco cessation prior to elective orthopedic surgery should be recommended or required, improved understanding of the degree of risk reduction associated with tobacco cessation interventions in the preoperative period is needed. The aim of this review was to synthesize evidence on the effectiveness of preoperative smoking cessation interventions and use of nicotine replacement therapy (NRT) at reducing complication risk associated with elective orthopedic surgery.

From 265 potentially relevant articles, 1 randomized controlled trial (RCT) and 3 observational studies met eligibility criteria. The most informative study was an older RCT conducted in Denmark of 120 adult tobacco users undergoing total knee arthroplasty (TKA) or total hip arthroplasty (THA) who were randomized to counseling and NRT versus usual care in the 6-8 weeks prior to surgery. The trial found that smoking cessation resulted in a lower risk of wound-

related complications including infection. Notably, the trial excluded those with a weekly alcohol intake of more than 35 units and participants had a mean body mass index (BMI) of 26-27 and low rates of diabetes (2% in the intervention group and 5% in the control group). Without data from other trials, it is unknown whether a similar intervention would lead to the same benefit in populations with a higher burden of comorbidities.

The 3 observational studies we identified contribute little useful information to address the review question. A retrospective cohort study of patients undergoing TKA or THA, which found a lower risk of infection associated with participation in a smoking cessation program, was at risk of selection bias because not all eligible patients were offered the intervention. Further, those who participated in the voluntary smoking cessation program may have had important differences from those who declined the program, and the study did not employ methods to minimize bias due to confounding. The remaining 2 observational studies used an all-payer claims database and had large sample sizes but were not designed to capture participants' lifetime tobacco use history (including duration and severity), use of NRT, actual rate of smoking cessation, or duration of smoking cessation prior to surgery. Understanding these characteristics is important for applying findings of these studies. More critically, these characteristics may be key drivers of complication risk that if not understood and accounted for when assessing the association between smoking (or smoking cessation) and complication risk, could distort the apparent size and direction of that association.

An additional limitation of available evidence is a lack of information on whether nicotine exposure in the form of NRT is an independent risk factor for worse outcomes. Participants in the smoking cessation groups of all 4 included studies were offered NRT, although no study reported whether or to what extent participants used NRT. In a study of adults undergoing anterior cervical discectomy and fusion, active tobacco use was associated with *lower* odds of dysphagia, which the authors speculated could have been due to the irritant effects of nicotine replacement products among participants in the smoking cessation group. However, no conclusions can be drawn regarding the effect of NRT based on this study. A well-conducted trial that captures in detail the extent and duration of participants' tobacco use history as well as their use of nicotine replacement and/or other medications relative to the timing of surgery is needed to understand the effects of NRT on surgical outcomes (if any).

Importantly, the purpose of this review was not to gauge the overall health benefits of tobacco cessation: available evidence is unequivocal about the harm of tobacco use across the lifespan and the benefits of stopping tobacco use at any age. It also seems clear that patients who have never smoked are, on the whole, at lower risk of complications following elective orthopedic surgery than patients who currently smoke. But in the absence of conclusive evidence establishing that active tobacco users who stop smoking in the *immediate* preoperative period have a reduced risk of surgical complications, whether to require tobacco cessation prior to elective orthopedic surgery may be best determined using shared decision-making and considering the totality of each patient's risk factors and potential benefits of surgery. It is possible that for some patients, requiring tobacco cessation prior to elective orthopedic surgery may be unduly burdensome and may delay improvements to their quality of life without conferring a meaningful reduction in their surgical risks.