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Guideline

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Korean Clinical Practice Guideline of Korean Society for Research on Nicotine and Tobacco (KSRNT) and National Evidence-based Healthcare Collaborating Agency (NECA) on Treatment of Tobacco Use 2024

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ABSTRACT

Tobacco use is a leading cause of preventable death, disease, and disability worldwide. Thus, smoking cessation is a critical public health intervention globally. This clinical practice guideline was developed to provide recommendations on pharmacological and

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non-pharmacological treatments for smoking cessation, tailored strategies for smoking cessation in special populations, and interventions for users of electronic cigarettes and multiple tobacco products. Thirty key questions and corresponding evidence-based recommendations were derived from systematic reviews, meta-analyses, and de novo development. A multidisciplinary panel of experts participated in the development of this guideline, incorporating evaluation of evidence quality, benefit–risk balance, patient values and preferences, resource use, and feasibility in the development process. This guideline reflects the latest research on smoking cessation treatments and provides practical and adaptable strategies for clinical and policy implementation. In addition, this guideline is expected to support healthcare providers in improving cessation success rates and contribute to the reduction of smoking-related morbidity and mortality rates in Korea. This guideline will be updated periodically in response to emerging evidence and clinical needs.

Keywords: Tobacco; Tobacco Use Disorder; Smoking Cessation; Practice Guideline

INTRODUCTION

Tobacco use remains a major modifiable risk factor for preventable mortality, morbidity, and disability worldwide. It is causally linked to a wide range of diseases, affecting nearly every organ system. In addition, it is a leading contributor to conditions such as lung, esophageal, and pancreatic cancers, cardiovascular disease, chronic respiratory diseases, and diabetes.[1] Smoking cessation yields both immediate and long-term health benefits, with greater gains observed when cessation is achieved at a younger age.[2] In Korea, the socioeconomic cost of smoking in 2019 was estimated to exceed 12 trillion KRW,[3] underscoring the public health and economic burden of tobacco use. Recognizing the global importance of tobacco control, the World Health Organization (WHO) adopted the WHO Framework Convention on Tobacco Control (FCTC) in 2005, with 182 countries participating as of 2023. Korea signed the FCTC in 2003 and has implemented a range of tobacco control policies since then. As a result, the smoking rate among Korean adult men declined from 66.3% in 1998 to 30.0% in 2022.[4] However, the decline has plateaued since 2008, and the smoking rate among adult women has shown little change over the past two decades. Notably, the recent introduction of novel tobacco products, including liquid-based and heated tobacco products (HTPs), has contributed to increased usage among adolescents and adults. The overall tobacco use rate, including these new products, now exceeds that of conventional cigarette smoking.[5]

Due to nicotine dependence, manifesting as tolerance, withdrawal, and craving, achievement of smoking cessation through willpower alone is difficult. Therefore, as with other chronic conditions such as hypertension or diabetes, smoking requires long-term management supported with clinical interventions and social support systems. This clinical practice guideline was developed to offer evidence-based recommendations for the treatment of tobacco use tailored to the Korean context. The main objective of this guideline is to provide standardized, evidence-based treatment recommendations that healthcare professionals can apply when treating individuals who smoke. This guideline targets a broad range of users, including adult cigarette smokers, users of electronic cigarettes and HTPs, individuals with pulmonary tuberculosis, those diagnosed with lung cancer, and patients preparing for elective surgery. In addition, this practice guideline accounts for factors such as smoker preferences, treatment feasibility, costs, and health equity. By offering tailored strategies for high-risk groups and addressing emerging forms of tobacco use, this guideline is expected

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Disclosure

Yu-Jin Paek reported past non-financial COIs, including a previous leadership role and publications, and financial COI related to research funding received over three years ago. Sungwon Roh reported a non-financial COI related to publications. Kiheon Lee reported past non-financial and financial COIs, including publications and research funding received more than three years prior. All reported COIs were reviewed and judged not to have influenced the development process. Other authors have no potential conflicts of interest to disclose.

to support clinical decision-making, enhance the effectiveness of cessation programs, and inform future policy and research directions.

GUIDELINE DEVELOPMENT PROCESS

Guideline development group (GDG)

This clinical practice guideline for smoking cessation was developed through a systematic, evidence-based process divided into three stages: planning, development, and finalization. In the planning stage, the GDG was formed, and conflict of interest (COI) management procedures were established. The GDG included experts on smoking cessation, public health professionals, and methodologists, and was organized into the following subcommittees: the steering committee, working group, advisory committee, and COI committee (**Fig. 1**).

The steering committee was co-chaired by a principal investigator from the Korean Society for Research on Nicotine and Tobacco (KSRNT) and the National Evidence-based Healthcare Collaborating Agency (NECA). The committee included multidisciplinary experts on guideline development and their responsibilities encompassed setting

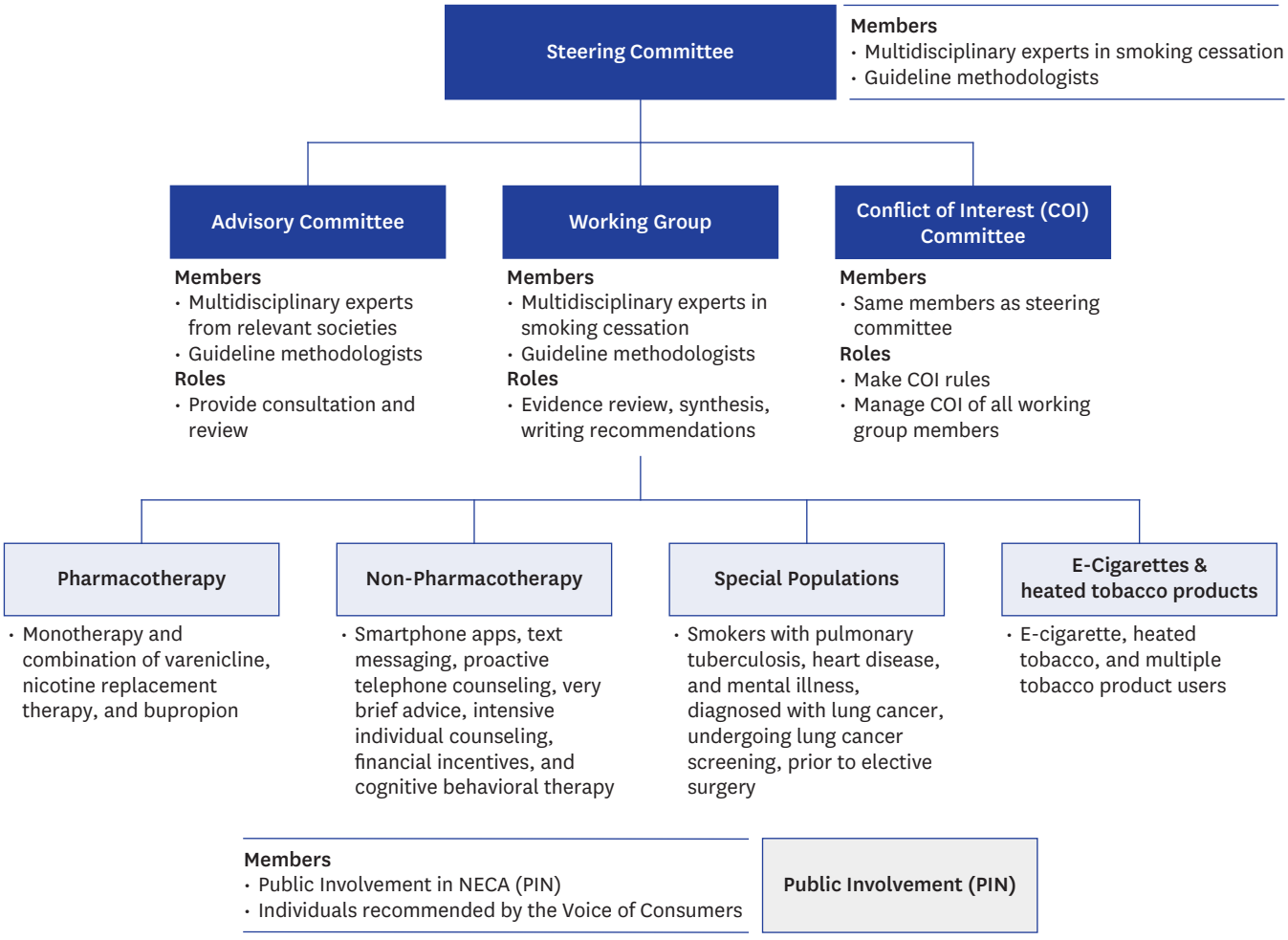

Fig. 1. Guideline development group.

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Author Contributions

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development principles, defining the scope of the guidelines, prioritizing clinical questions, and drafting recommendations. Monthly meetings were conducted to review the progress of each committee and discuss issues. The working group was divided into four subcommittees: pharmacotherapy, non-pharmacotherapy, special populations, and e-cigarettes and HTPs. Each subcommittee consisted of smoking cessation experts from KSRNT, methodologists from NECA, and participants from tobacco control organizations such as the Korea Health Promotion Institute. The members included professionals in disciplines such as medicine, public health, nursing, and psychology. The working group collaborated with NECA researchers to conduct literature searches, select studies, perform quality assessment, extract and synthesize data, and assess certainty of evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology. The COI committee, which comprised the same members in the steering committee, managed the COI status of all working group members. All members of the working group initially submitted their COI declarations before guideline development and updated them during the development process. The COI levels were categorized as 'No-COI,' 'Low,' 'Moderate,' or 'High.' When a COI was declared, the committee determined the appropriateness of involvement based on these categories (**Supplementary Table 1**). The advisory committee consisted of multidisciplinary experts nominated by the steering committee. They provided guidance on the content and methodology of this guideline and reviewed the draft recommendations.

The external review committee, which was separate from the GDG and composed of experts recommended by academic societies or the steering committee, reviewed the individual recommendations, as well as the entire guideline. Members of Public Involvement in NECA (PIN) reviewed and commented on the plain-language version of the guideline. PIN was established in 2018 as an independent group of 100 representatives, including patients, caregivers, and policymakers, who support evidence-based decision making.

Development of the guideline

The guideline was developed using the GRADE ADOLOPMENT framework, which supports the adoption, adaptation, or de novo development of recommendations. We formulated clinical questions, conducted systematic reviews, and evaluated the strength of recommendations using GRADE. The Evidence-to-Decision (EtD) framework was used to structure the final recommendations.

This guideline was developed to support healthcare professionals working in various clinical and public health settings. It was designed to target not only users of conventional cigarettes, HTPs, and e-cigarettes, but also special populations such as pregnant women and individuals with lung or cardiovascular diseases. The scope of this guideline was determined based on the PIPOH (Population, Interventions, Professionals, Outcomes, Healthcare setting) framework. Detailed elements of the framework are presented in **Supplementary Table 2**. The key questions were refined using the PICO (Population, Intervention, Comparator, Outcome) framework. Topics relevant to smoking cessation but not formally framed as clinical questions were described narratively. Outcomes were classified as "critical," "important but not critical," or "of limited importance" based on the GRADE methodology.[6]

To enhance efficiency, existing systematic reviews were initially identified for the formulation of all pharmacotherapy and most non-pharmacotherapy questions using the Cochrane Library and Epistemonikos. Review quality was assessed using A MeaSurement Tool to Assess

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systematic Reviews 2 (AMSTAR 2). When existing systematic reviews were not available, the working group conducted de novo systematic reviews. The PubMed, EMBASE, Cochrane Library, and Korean (KoreaMed, KMBASE) databases were searched for identification of relevant studies. In addition, a manual search was conducted for further identification of updated research. The inclusion/exclusion criteria for the selection of studies were based on the PICO framework. Studies that were not published in English or Korean, had no available full-text, or were only available as abstracts were excluded. Risk of bias was assessed using the Cochrane Risk of Bias (ROB) tool for randomized controlled trials (RCTs) and the Risk of Bias Assessment Tool for Non-randomized Studies 2.0.[7] For consistency, ROB 1.0 was used if applied in previous reviews, whereas the ROB 2.0 tool was used for de novo systematic reviews.[8,9] Two reviewers independently assessed each study, and any discrepancies were resolved through discussion. Covidence software was used to streamline the process.[10] The characteristics and outcomes of each study were extracted using internally developed forms. The results were synthesized narratively or through meta-analysis depending on the type of data. Heterogeneity was addressed using a random-effects model and subgroup analyses, and publication bias was assessed. Meta-analyses were conducted using Review Manager (RevMan) version 5.4,[11] and additional analyses were performed using R 4.2.2[12] and STATA 18.0.[13]

Certainty of evidence was assessed using the GRADE methodology (**Supplementary Table 3**). For each recommendation, the certainty of evidence was summarized in a Summary of Findings table, which included outcomes rated as 'critical' or 'important,' with effect estimates, number of studies/participants, and downgrade reasons noted in footnotes. The GRADE EtD framework was used to determine the strength and direction of recommendations. Seven key EtD criteria were selected by the steering committee: risk–benefit balance, certainty of evidence, patient values and preferences, resource requirements, acceptability, feasibility, and equity. Additionally, the committee considered factors such as risk–benefit balance, population preferences, implementation barriers and facilitators, alternative options, cost and resource use, and alignment with international guidelines. Based on these factors, the committee determined the direction of each recommendation, either for or against. In addition, the strength of each recommendation was classified as either strong or conditional. In some cases, strong recommendations were made despite the certainty of evidence being low or moderate, and even when acceptability or feasibility were judged as "probably acceptable" or "probably feasible." This is consistent with the GRADE framework, which allows strong recommendations when the overall balance of the EtD criteria, including substantial desirable effects, minimal harms, and patient values, clearly supports the intervention despite the presence of some residual uncertainty. The GRADE definitions are summarized in **Supplementary Table 4**.

Each working group conducted a peer review of the draft recommendations, which was followed by a secondary review conducted by the steering committee. Consensus was reached based on a two-thirds agreement through voting. If consensus was not achieved, a re-vote was held.

Finalization

The external review committee reviewed the necessity, appropriateness, methodology, rationality, feasibility of dissemination, and implementation of the developed clinical practice guideline. Comments and levels of agreement were reviewed by the working group and steering committee to decide whether the feedback should be incorporated into the guideline.

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Endorsement of the clinical practice guideline was requested from academic societies and institutions, including the Korean Academy of Family Medicine, the Korean Academy of Tuberculosis and Respiratory Diseases, the Korean Society of Cardiology, and the National Tobacco Control Center. The guideline booklet will be disseminated to national agencies, including the Ministry of Health and Welfare, the National Health Insurance Service, the Korea Disease Control and Prevention Agency, and the National Cancer Center. Approval of the guideline is under review by the Clinical Practice Guideline Committee of the Korean Academy of Medical Sciences. Several tools were developed to support the dissemination and implementation of this guideline, including a pharmacotherapy algorithm, the 5As and 5Rs frameworks, and the Korean version of the Fagerström Test for Nicotine Dependence. To improve accessibility for those who are trying to quit smoking, the recommendations were translated into plain language under the title 'Smoking Cessation Guideline for Tobacco Product Users,' and pictograms were included to illustrate each recommendation.

This guideline will be reviewed every five years to determine whether revisions are needed. The guideline will be fully or partially updated depending on the situation at the time of review. New evidence will be evaluated and integrated with existing results, and the certainty of evidence and strength of recommendations will be updated.

RECOMMENDATIONS

Clinical questions and corresponding recommendations were developed across four major areas: pharmacological treatment, non-pharmacological treatment, special populations, and users of e-cigarettes and HTPs. A summary of these recommendations is presented in **Table 1**.

Pharmacotherapy

The U.S. Food and Drug Administration has approved three pharmacological treatments for smoking cessation: nicotine replacement therapy (NRT), varenicline, and sustained-release bupropion. Although cytisine is prescribed in Europe and Canada, it has not yet been approved in the United States or Korea. This guideline addresses the use of pharmacotherapy for smoking cessation, including monotherapy and combination therapies that include varenicline, NRT, or bupropion. Based on these recommendations, the Korean Clinical Practice Guideline for Tobacco Cessation (2023),[14] and expert consensus from the development group, a pharmacotherapy algorithm was developed to support clinical decision-making. The overall treatment flow is illustrated in the figure below (**Fig. 2**).

Compared to placebo, is varenicline effective for smoking cessation?

Recommendation: We recommend varenicline as a first-line pharmacotherapy option for smoking cessation. (*Certainty of evidence: High; Grade of recommendation: A***)**

The systematic review by Livingstone-Banks et al.[15] was assessed using the AMSTAR2 tool, rated as "high" quality, and included for data synthesis. Forty RCTs that aligned with the PICO-SD criteria were selected from the systematic review,[16-55] and two more RCTs were added after an updated search.[56,57] The participants of these studies included general adult smokers (n = 23), patients with psychiatric conditions (n = 5), patients with pulmonary disease (n = 3), cardiovascular disease (n = 2), and other populations (n = 9). The results

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Table 1. Summary of recommendations for tobacco use treatment

Clinical questions	Recommendations	CoE	GoR
Pharmacotherapy for smoking cessation			
1. Varenicline	We recommend varenicline as a first-line pharmacotherapy option for smoking cessation.	High	A
2. NRT vs. Varenicline	We suggest considering combination NRT as a first-line pharmacotherapy option for smoking cessation. Clinical considerations - It can be considered when varenicline is ineffective or causes side effects.	Moderate	B
3. NRT	We recommend NRT as a first-line pharmacotherapy option for smoking cessation.	High	A
4. Bupropion	We recommend bupropion as a first-line pharmacotherapy option for smoking cessation.	High	A
5. Varenicline + Bupropion vs. Varenicline	We suggest considering combination therapy with varenicline and bupropion as an option for smoking cessation. Clinical considerations - Combination therapy may be beneficial for smokers, including those who previously failed to quit smoking using varenicline monotherapy. However, it should be carefully considered based on the individual's characteristics and preferences.	Moderate	B
6. Combination NRT vs. NRT monotherapy	We recommend combination NRT rather than monotherapy for smoking cessation.	High	A
7. NRT + bupropion vs. Bupropion only or NRT only	We suggest considering combination therapy with NRT and bupropion as an option for smoking cessation. Clinical considerations - Combination therapy with NRT and bupropion can be considered for smokers who failed to achieve smoking cessation with NRT or bupropion monotherapy.	Moderate	B
Non-pharmacotherapy for smoking cessation			
1. Smartphone app	We recommend the use of a smartphone app in addition to existing smoking cessation treatments for smokers. Clinical considerations - There is no significant difference in smoking cessation success rates between smartphone app interventions alone and standard smoking cessation support services. However, when combined with pharmacotherapy or behavioral therapies such as face-to-face counseling or text messaging, smartphone apps significantly improve smoking cessation outcomes, making such combined interventions beneficial. - A subgroup analysis based on the type of app service (chat-based, activity-based) incorporated into a smoking cessation app-integrated intervention showed that chat-based apps (messaging, chat) are effective for smoking cessation. Therefore, the type of app service should be considered when implementing a smoking cessation app-integrated intervention.	Moderate	A
2. Text message	We recommend providing personalized text messages for smoking cessation. Clinical considerations - The provision of text messages alone enhances smoking cessation success; however, combining text messages with face-to-face counseling, telephone counseling, or pharmacotherapy significantly improves smoking cessation outcomes. This suggests that a variety of smoking cessation interventions could be combined effectively.	High	A
3. Proactive telephone counseling	We recommend proactive telephone counseling for smoking cessation.	High	A
4. Very brief advice	We recommend providing very brief advice for smoking cessation. Clinical considerations - Very brief advice is defined as advice delivered by healthcare professionals between 30 seconds and 3 minutes per encounter, simply telling the smokers to quit, regardless of whether the harms of smoking are discussed or not.	High	A
5. Intensive individual counseling	We recommend intensive individual counseling for smoking cessation.	High	A
6. Cognitive behavioral therapy	We suggest considering cognitive behavioral therapy for smoking cessation. Clinical considerations - Cognitive behavioral therapy may provide additional benefits when combined with pharmacotherapy. In addition, its effects may be more pronounced in smokers with smoking-related diseases.	Moderate	B
7. Financial incentives	We suggest considering the provision of financial incentives for smoking cessation. We recommend offering financial incentives for smoking cessation in pregnant smokers. Clinical considerations - Financial incentives for smoking cessation should not be provided as a standalone treatment, but in combination with other smoking cessation interventions, such as pharmacotherapy and non-pharmacological therapies. - Pregnancy is a contraindication for smoking cessation medications. However, NRT may be considered when its benefits are deemed to outweigh the risks of smoking.	High High	B A

(continued to the next page)

Table 1. (Continued) Summary of recommendations for tobacco use treatment

Clinical questions	Recommendations	CoE	GoR
Special population			
1. Smokers with pulmonary tuberculosis	We recommend smoking cessation treatment for smokers with pulmonary tuberculosis.	High	A
2. Smokers diagnosed with lung cancer	We recommend smoking cessation to current smokers diagnosed with lung cancer to reduce mortality.	Low	A
3. Smokers undergoing lung cancer screening	We recommend active smoking cessation counseling and pharmacotherapy for smokers undergoing lung cancer screening.	Low	A
	Clinical Considerations - Research indicates insufficient evidence to support the effectiveness of low-dose chest CT screening alone in increasing smoking cessation rates.		
4. Smokers undergoing elective surgery	We recommend starting smoking cessation treatment prior to elective surgery for smokers.	Moderate	A
5. Smokers with heart disease.	We recommend varenicline as a first-line pharmacotherapy option for smoking cessation in smokers with heart disease.	Low	A
	We suggest considering NRT for smoking cessation in smokers with heart disease.	Low	B
	We suggest considering bupropion for smoking cessation in smokers with heart disease.	Moderate	B
	Clinical Consideration - Varenicline is recommended as a first-line treatment for smoking cessation in smokers with heart disease. However, NRT or bupropion may be considered if side effects occur or based on the smoker's preference.		
6. Smokers with mental illness	We recommend varenicline, bupropion, or NRT as a first-line pharmacotherapy option for smoking cessation in smokers with mental illness.	Moderate	A
	Clinical Considerations - Varenicline, bupropion, and NRT can be used for smoking cessation in smokers with mental illness. However, the potential side effects of each medication should be carefully explained to the smoker before making a choice.		
E-cigarettes and heated tobacco products			
1. E-cigarette users	We recommend both pharmacological and non-pharmacological interventions for quitting e-cigarettes.	Moderate	A
2. Heated tobacco product users	We recommend both pharmacological and non-pharmacological interventions for quitting heated tobacco products.	Good Practice Statement	
3. Multiple tobacco product users	We recommend both pharmacological and non-pharmacological interventions for complete cessation of all tobacco products among multiple tobacco product users.	Low	A
	Clinical considerations - Pharmacological and non-pharmacological interventions for smoking cessation can be applied to help quit e-cigarettes and multiple tobacco product use. - Based on research, effective interventions for e-cigarette cessation include varenicline and counseling, as well as tailored interactive text messages. For cessation of multiple tobacco products, effective interventions include varenicline, a combination of varenicline/bupropion + NRT + behavioral support, tailored interactive text messages, use of a smoking cessation app based on acceptance and commitment therapy, and smoking cessation booklets for dual users. However, additional research is needed to determine the efficacy of other interventions. - For e-cigarettes, relapse to combustible cigarettes upon cessation should be avoided.		

A: strong recommendation; B: conditional recommendation.
CoE = certainty of evidence, GoR = grade of recommendation, NRT = nicotine replacement therapy.

of the studies indicated that varenicline significantly increased smoking cessation success rates at six months compared to placebo (relative risk [RR], 2.24; 95% confidence interval [CI], 1.95–2.58). The incidence of serious adverse events associated with varenicline was slightly higher than that for placebo; however, the difference was not statistically significant (RR, 1.16; 95% CI, 0.95–1.40) (**Supplementary Table 5-1**).

Varenicline significantly increases smoking cessation rates but may cause side effects such as insomnia, abnormal dreams, and nausea. Although patient preference has not been directly assessed in any previous study, healthcare providers should inform patients about the benefits and risks of the therapy. Barriers to implementation of this therapy include treatment duration and side effects, which may discourage some users; however, its strong efficacy remains a key motivator. For patients who cannot tolerate varenicline, alternatives

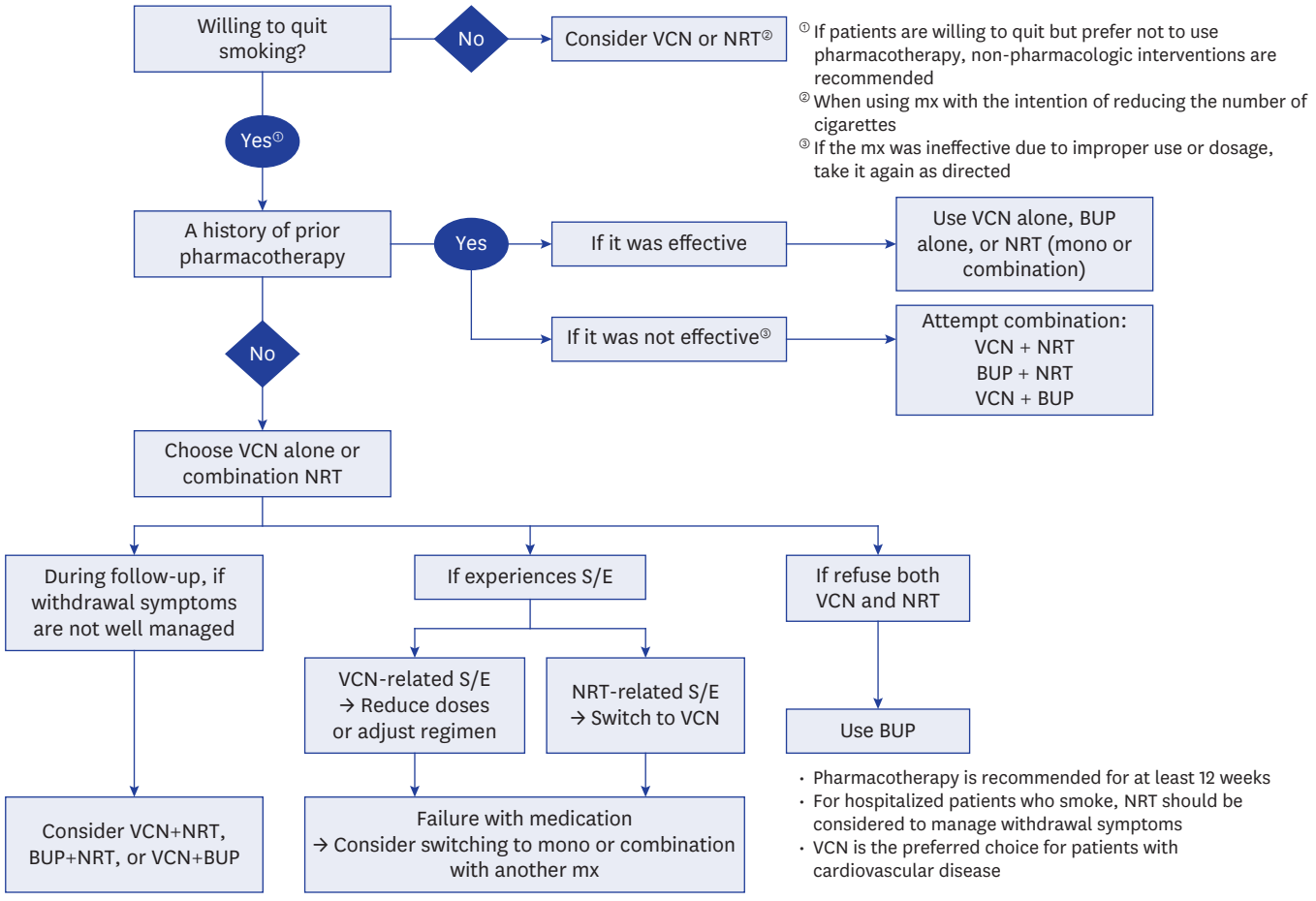

Fig. 2. Pharmacotherapy algorithm for smoking cessation.
VCN = varenicline, NRT = nicotine replacement therapy, BUP = bupropion, S/E = side effect, mx = medication.

such as NRT, bupropion, behavioral counseling, cognitive behavioral therapy (CBT), and mindfulness-based interventions should be considered based on individual needs and previous cessation attempts.

Compared to varenicline, is combination NRT effective for smoking cessation?

Recommendation: We suggest considering combination NRT as a first-line pharmacotherapy option for smoking cessation. (*Certainty of evidence: Moderate; Grade of recommendation: B***)**

Clinical considerations

It can be considered when varenicline is ineffective or causes side effects.

The systematic review conducted by Livingstone-Banks et al.,[15] which was assigned a "high" AMSTAR2 rating, included five RCTs that met the PICO-SD criteria.[20,44,58-60] Participants of the selected studies included general adult smokers (n = 3), smokers with medical or psychiatric conditions (n = 1), and methadone-treated smokers (n = 1). The combination

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NRT regimens evaluated in the studies included patch + lozenge (n = 2), patch + gum (n = 2), and patch + gum or inhaler (n = 1). No significant difference in smoking cessation success at six months (RR, 0.95; 95% CI, 0.73–1.22) or serious adverse events (RR, 1.16; 95% CI, 0.66–2.03) was observed between combination NRT and varenicline groups (**Supplementary Table 5-2**).

The benefits and risks of combination NRT compared to varenicline suggest no critical advantage of one over the other, making the choice dependent on side effects, administration convenience, and patient preference. Although no study has been conducted to directly examine patient preferences, combination NRT is associated with fewer gastrointestinal side effects and abnormal dreams than varenicline. However, practical challenges, such as the need for multiple NRT forms and additional costs (as insurance covers only one form), potentially limit the use of this therapy and emphasize the need for shared decision-making prior its initiation. Moreover, physicians' preference for prescribing oral medications, the focus of NHIS smoking cessation programs on varenicline, and the limited availability of combination NRT in public health centers further hinder its use. Policy advocacy for expanded insurance coverage to include combination NRT formulations and establishment of cost-sharing programs could improve accessibility and address these barriers to the use of combination NRT. Despite its comparable efficacy and the lower risk of nausea and abnormal dreams, increasing physician awareness and promoting combination NRT as an alternative when varenicline causes side effects are essential.

Compared to placebo, is NRT effective for smoking cessation?

Recommendation: We recommend NRT as a first-line pharmacotherapy option for smoking cessation. (*Certainty of evidence: High; Grade of recommendation: A***)**

The systematic reviews conducted by Hartmann-Boyce et al.[61] and Lindson et al.[62] were rated as "high" quality using the AMSTAR2 tool and were included in for data synthesis. A total of 83 RCTs that met the PICO-SD criteria were selected from the systematic reviews.[16,33,61,63-141] Five additional RCTs were identified to incorporate recent evidence,[142-146] resulting in a final selection of 88 studies. The results of the analyses indicated that at six months or longer, NRT achieved significantly higher smoking cessation success rates than placebo (RR, 1.64; 95% CI, 1.53–1.77) (**Supplementary Table 5-3**). Analysis of the results according to formulation revealed that all types of NRT achieved significantly higher cessation rates than placebo, with nicotine patches (RR, 1.63; 95% CI, 1.48–1.79) and gum (RR, 1.51; 95% CI, 1.32–1.72) demonstrating notable effectiveness. Additionally, nicotine oral spray (RR, 2.48; 95% CI, 1.24–4.94), inhalers (RR, 1.85; 95% CI, 1.32–2.60), nasal sprays (RR, 1.97; 95% CI, 1.44–2.70), and lozenges (RR, 1.98; 95% CI, 1.53–2.55) were all more effective than placebo in promoting smoking cessation. Regarding serious adverse events, two studies reported no occurrences in either the NRT or placebo groups.

The benefits of NRT for adult smokers generally outweigh its risks; however, caution should be applied for individuals who had recent acute cardiovascular events due to potential sympathetic stimulation. NRT significantly improves smoking cessation success rates compared to placebo; however, it may cause mild side effects such as nausea, sleep disturbances, and skin reactions from patches. NRT can be purchased independently as an over-the-counter medication or accessed through public smoking cessation programs, with

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financial support available for one formulation through the NHIS smoking cessation support program. However, use of self-purchased NRT often lacks proper follow-up. In addition, its multiple formulations require complex explanations, which may discourage physicians from actively recommending it. Despite these barriers, the accessibility, mild side effect profile, and formulation variety of NRT make it a viable smoking cessation option.

Compared to placebo, is bupropion effective for smoking cessation?

Recommendation: We recommend bupropion as a first-line pharmacotherapy option for smoking cessation. (*Certainty of evidence: High; Grade of recommendation: A***)**

A systematic review conducted by Hajizadeh et al.[147] was assessed using the AMSTAR2 tool, rated as "high" quality, and included in the analysis. Forty-two RCTs that met the PICO-SD criteria were selected from the systematic review.[16,23,29,31,39,47,104,117,142,148-180] The results showed that bupropion significantly increased smoking cessation success rates at six months or longer compared to placebo (RR, 1.57; 95% CI, 1.42–1.73). However, there was no statistically significant difference in the incidence of serious adverse events between bupropion and placebo (RR, 1.09; 95% CI, 0.84–1.42) (**Supplementary Table 5-4**).

Bupropion provides significant benefits for smoking cessation, with risks that are generally manageable in the general smoking population. However, it is contraindicated for individuals with seizure disorders or those prone to neuropsychiatric side effects, such as insomnia. Given its efficacy, healthcare providers should weigh its benefits against potential risks and ensure patients are well-informed before prescribing. Although bupropion effectively reduces withdrawal symptoms and may alleviate smoking-related depressive symptoms, it requires physician consultation and gradual dose escalation, which may limit accessibility compared to over-the-counter options. Implementation of streamlined prescription protocols, telemedicine consultations for follow-up visits, and enhanced training for primary care physicians on bupropion management could be beneficial for addressing these barriers. Alternative approaches include dose adjustment for insomnia management or switching to varenicline or behavioral interventions if the medication if needed. Despite the additional costs of bupropion, national smoking cessation programs offer substantial reimbursement, making it a cost-effective option for many patients.

Compared to varenicline monotherapy, is combination therapy with varenicline and bupropion effective for smoking cessation?

Recommendation: We suggest considering combination therapy with varenicline and bupropion as an option for smoking cessation. (*Certainty of evidence: Moderate; Grade of recommendation: B***)**

Clinical considerations

Combination therapy may be beneficial for smokers, including those who previously failed to quit smoking using varenicline monotherapy. However, it should be carefully considered based on the individual's characteristics and preferences.

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The systematic review conducted by Hajizadeh et al.[147] was rated as "high" quality based on the AMSTAR2 assessment. Four RCTs that met the PICO-SD criteria were selected from the review for analysis.[22,181-183] The results indicated that the combination therapy group (varenicline + bupropion) showed higher six-month smoking cessation success rate than the varenicline monotherapy group; however, the difference was not statistically significant (RR, 1.21; 95% CI, 0.95–1.55). Similarly, there was no statistically significant difference in the incidence of serious adverse events between the two groups (RR, 1.22; 95% CI, 0.61–2.44) (**Supplementary Table 5-5**).

Combination therapy may be beneficial for individuals who have a history of depression or failed to achieve smoking cessation on varenicline monotherapy. The potential risks of the therapy do not appear to be critical in certain patients. However, its use should be considered based on individual characteristics and preferences. Barriers to implementation include concerns regarding drug interactions, increased costs, and adherence challenges due to regimen complexity. However, combination therapy may provide a personalized approach for motivated individuals. Expanding insurance coverage could facilitate broader use.

Is combination NRT more effective than NRT monotherapy for smoking cessation?

Recommendation: We recommend combination NRT rather than monotherapy for smoking cessation. *(Certainty of evidence: High; Grade of recommendation: A)*

The systematic review conducted by Theodoulou et al.[184] was assessed using the AMSTAR2 tool, rated as "high" quality, and included in the analysis. An additional literature search was conducted to ensure the inclusion of the most up-to-date evidence, resulting in the selection of 16 RCTs.[58,108,117,185-198] The results showed that combination NRT group showed significantly increased smoking cessation success rates at six months or longer compared to the NRT monotherapy group (RR, 1.26; 95% CI, 1.15–1.39). Regarding serious adverse events, no statistically significant difference was observed between the combination NRT and NRT monotherapy groups (RR, 3.27; 95% CI, 0.28–38.66) (**Supplementary Table 5-6**).

The benefits of combination NRT outweigh its risks, as it significantly improves smoking cessation success rates compared to monotherapy, with nausea being the only adverse event reported at a higher rate. In addition, existing evidence suggests no significant differences in serious adverse events, sleep disturbances, depression, or cardiovascular issues between combination NRT and NRT monotherapy. Barriers to implementation of combination NRT include limited financial coverage, complex guidance requirements, and the need for clinic visits. However, combination NRT stabilizes nicotine levels and effectively reduces cravings, making it a strong option for managing withdrawal symptoms. Although it incurs higher costs, its superior cessation success rates may reduce long-term healthcare expenses. Expanding reimbursement policies to cover combination NRT formulations and developing patient assistance programs could help overcome these financial barriers.

NRT + bupropion vs. Bupropion only or NRT only

1) Is combination therapy with NRT and bupropion more effective for smoking cessation than bupropion monotherapy?
2) Is combination therapy with NRT and bupropion more effective for smoking cessation than NRT monotherapy?

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Recommendation: We suggest considering combination therapy with NRT and bupropion as an option for smoking cessation. (*Certainty of evidence: Moderate; Grade of recommendation: B***)**

Clinical considerations

Combination therapy with NRT and bupropion can be considered for smokers who failed to achieve smoking cessation with NRT or bupropion monotherapy.

Seven RCTs were selected from previous systematic reviews and an updated literature search to compare NRT + bupropion combination therapy vs. bupropion monotherapy.[104,117,142,169,197,199,200] The results indicated that the NRT and bupropion combination group showed a higher six-month smoking cessation success rate than the bupropion monotherapy group; however, the difference between the two groups was not statistically significant (RR, 1.15; 95% CI, 0.91–1.46). Regarding serious adverse events, a meta-analysis of two studies showed no statistically significant difference between the combination therapy and monotherapy groups (RR, 0.33; 95% CI, 0.03–3.17) (**Supplementary Table 5-7**). Fourteen RCTs were selected from previous systematic reviews and an updated literature search to compare NRT + bupropion combination therapy vs. NRT monotherapy.[104,117,142,197,199-208] The results showed that the NRT and bupropion combination group showed a higher six-month smoking cessation success rate than the NRT monotherapy group; however, the difference between the two groups was not statistically significant (RR, 1.18; 95% CI, 0.95–1.47). Subgroup analyses conducted according to NRT formulation revealed no statistically significant differences between groups. In addition, no significant difference in adverse events was observed between groups (RR, 1.01; 95% CI, 0.24–4.19) (**Supplementary Table 5-8**).

The analysis showed no significant difference in smoking cessation rates between combination therapy and monotherapy; however, nausea, sleep disturbances, and dry mouth were reported more frequently with use of the combination therapy. Given the added inconvenience, cost, and potential side effects, combination therapy should be considered primarily for individuals with high nicotine dependence or repeated quit failures. Barriers to implementation of NRT + bupropion combination therapy include preference for single-agent therapy among physicians, additional counseling requirements, and lack of financial support for combination therapy in Korea's smoking cessation program. However, combination therapy may be beneficial for smokers who experience withdrawal symptoms or depression during smoking cessation.

Non-pharmacotherapy

Is a smartphone app effective for smoking cessation?

Recommendation: We recommend the use of a smartphone app in addition to existing smoking cessation treatments for smokers. (*Certainty of evidence: Moderate; Grade of recommendation: A***)**

Clinical considerations

- There is no significant difference in smoking cessation success rates between smartphone app interventions alone and standard smoking cessation support services.

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However, when combined with pharmacotherapy or behavioral therapies such as face-to-face counseling or text messaging, smartphone apps significantly improve smoking cessation outcomes, making such combined interventions beneficial.
- A subgroup analysis based on the type of app service (chat-based, activity-based) incorporated into a smoking cessation app-integrated intervention showed that chat-based apps (messaging, chat) are effective for smoking cessation. Therefore, the type of app service should be considered when implementing a smoking cessation app-integrated intervention.

Five RCTs were selected from a systematic review conducted by Whittaker et al.[209-213] In addition, 14 additional RCTs published more recently were identified.[214-227] Analysis of smoking cessation success rates at six months or longer revealed that the intervention group that received smoking cessation support via a smartphone app showed a significantly higher quit rate than the control group (RR, 1.18; 95% CI, 1.01–1.37). The subgroup analysis revealed no statistically significant difference between the app-only intervention and control groups (RR, 0.98; 95% CI, 0.83–1.15). However, the app-combined intervention group demonstrated a significantly higher cessation success rate than the control group (RR, 1.43; 95% CI, 1.23–1.65) (**Supplementary Table 6-1**).

Smoking cessation apps are accessible to any smoker using a smartphone, regardless of time or location. However, their effective use requires a certain level of digital literacy, including the ability to navigate smartphones and utilize online information. In Korea, many commercially developed apps for smoking cessation are available; however, they vary in quality. Therefore, it is important to promote and enhance the use of evidence-based apps, such as the government-supported app, through continuous service updates and public awareness efforts.

Are text messages effective for smoking cessation?

Recommendation: We recommend providing personalized text messages for smoking cessation. *(Certainty of evidence: High; Grade of recommendation: A)*

Clinical considerations

- The provision of text messages alone enhances smoking cessation success; however, combining text messages with face-to-face counseling, telephone counseling, or pharmacotherapy significantly improves smoking cessation outcomes. This suggests that a variety of smoking cessation interventions could be combined effectively.

Sixteen RCTs were selected from a systematic review conducted by Whittaker et al.,[228-243] and seven additional RCTs were identified in an updated search.[244-250] The intervention groups were classified into two subgroups based on whether text messaging was provided alone or in combination with other smoking cessation treatments. The text-only intervention group included the participants of 14 studies, who primarily received personalized text messages. The text-combined intervention group included the participants of nine studies who received text messages in addition to pharmacotherapy, in-person counseling, or telephone support. Overall, the text messaging interventions significantly improved smoking cessation success compared to the control intervention (RR, 1.43; 95% CI, 1.18–1.73). Subgroup

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analysis showed that both text-only (RR, 1.36; 95% CI, 1.02–1.80) and text-combined interventions (RR, 1.53; 95% CI, 1.18–1.98) were significantly more effective than the control (**Supplementary Table 6-2**).

Text messaging for smoking cessation can be delivered anytime and anywhere. Unlike apps, which require users to engage voluntarily, text messages are passively received, allowing for broader population reach and potentially greater accessibility. However, implementing such services requires a system that can develop personalized messages aligned with each individual's quit schedule, send them automatically, and track performance through message history. As digital environments evolve, the reach and effectiveness of text messaging alone may decline; therefore, it should be integrated as a component within broader interventions such as mobile apps or AI-based programs.

Is proactive telephone counseling effective for smoking cessation?

Recommendation: We recommend proactive telephone counseling for smoking cessation. (*Certainty of evidence: High; Grade of recommendation: A*)

Twenty-nine RCTs were selected from a systematic review conducted by Matkin et al.,[251-279] and two more recent RCTs were added to reflect updated evidence.[280,281] Analysis of smoking cessation success rates at six months or longer showed that proactive telephone counseling by trained counselors significantly increased quit rates compared to the control interventions (RR, 1.30; 95% CI, 1.17–1.44). Subgroup analyses showed consistent results across different types of controls. Cessation rates were significantly higher in the intervention group than in both the minimal intervention control group (RR, 1.32; 95% CI, 1.15–1.52) and the usual care control group (RR, 1.25; 95% CI, 1.09–1.41). Additionally, telephone counseling without pharmacotherapy demonstrated a significant benefit over control interventions (RR, 1.35; 95% CI, 1.19–1.53), whereas counseling combined with pharmacotherapy showed a non-significant trend toward increased smoking cessation (RR, 1.19; 95% CI, 0.98–1.44) (**Supplementary Table 6-3**).

Proactive telephone counseling offers high accessibility and low barriers to use, making it suitable for the general population. It is particularly effective for individuals who may have difficulty accessing or are reluctant to participate in face-to-face smoking cessation programs, such as women, adolescents, older adults, workers, and people with disabilities. However, users with speech or language impairments may face difficulties using this intervention. In addition, those who prefer pharmacological interventions may exhibit lower acceptance of the intervention. For individuals with communication barriers, alternative formats such as text-based counseling platforms or video consultations with sign language interpretation could enhance accessibility. Proactive referral to telephone counseling as part of follow-up care in clinical smoking cessation programs can help promote its utilization.

Is very brief advice (VBA) effective for smoking cessation?

Recommendation: We recommend providing VBA for smoking cessation. (*Certainty of evidence: High; Grade of recommendation: A*)

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Clinical considerations

- Very brief advice is defined as advice delivered by healthcare professionals between 30 seconds and 3 minutes per encounter, simply telling the smokers to quit, regardless of whether the harms of smoking are discussed or not.

Eleven RCTs were included in this analysis, three selected through a systematic search[282-284] and eight identified from more recent publications.[275,285-291] Analysis of smoking cessation success rates at six months or longer showed that the intervention group that received VBA demonstrated a significantly higher quit rate than the control group (RR, 1.36; 95% CI, 1.16–1.59) (**Supplementary Table 6-4**).

VBA is a low-intensity intervention that can be broadly applied across the general population and may be particularly suitable for individuals who are not yet motivated to quit, as it is associated with a low risk of resistance. Its simplicity and feasibility make it acceptable to both healthcare providers and patients. However, implementation barriers exist when clinicians feel unprepared to deliver cessation advice or fail to perceive a clear link between smoking and the patient's primary condition.[292-294] Provision of feedback on cessation outcomes from patients who received VBA may reinforce clinicians' perceived value of the intervention. In addition, a team-based approach may enhance the delivery and sustainability of this intervention in busy clinical settings.

Is intensive individual counseling effective for smoking cessation?

Recommendation: We recommend intensive individual counseling for smoking cessation. (*Certainty of Evidence: High; Grade of Recommendation: A***)**

Forty-four RCTs were selected from a systematic review conducted by Lancaster et al.[167,268,295-336] In addition, seven more recent RCTs were identified in an updated search,[337-343] yielding a total of 51 RCTs included for data synthesis. Evaluation of smoking cessation success rates at six months or longer indicated that high-intensity individual counseling was associated with significantly higher quit rates than control interventions (RR, 1.47; 95% CI, 1.29–1.67). No serious adverse events were reported in the studies. In addition, subgroup analyses showed consistent benefits of the counseling. High-intensity counseling significantly increased quit rates compared to minimal intervention controls (RR, 1.53; 95% CI, 1.31–1.79) and low-intensity counseling controls (RR, 1.33; 95% CI, 1.06–1.69). Further analysis stratified according to pharmacotherapy use revealed significant effects of high-intensity counseling both in the absence of pharmacotherapy (RR, 1.60; 95% CI, 1.34–1.90) and when pharmacotherapy was used in both the intervention and control groups (RR, 1.29; 95% CI, 1.08–1.54) (**Supplementary Table 6-5**).

High-intensity individual counseling has been shown to be effective in the general population and in specific populations such as pregnant women, individuals with mental illness, and patients with myocardial infarction. Although high-intensity individual counseling requires longer and more frequent sessions than low-intensity counseling, it yields higher cessation success rates and may be particularly beneficial for smokers who are not receiving pharmacotherapy and rely solely on counseling support.[344] Facilitating referrals from

primary, secondary, and tertiary healthcare providers to public health centers or regional smoking cessation support centers can increase access to high-intensity counseling services.

Is CBT effective for smoking cessation?

Recommendation: We suggest considering CBT for smoking cessation. (*Certainty of Evidence: Moderate; Grade of Recommendation: B*)

Clinical considerations

- Cognitive behavioral therapy may provide additional benefits when combined with pharmacotherapy. In addition, its effects may be more pronounced in smokers with smoking-related diseases.

Eleven RCTs selected through a systematic search and screening[172,330,331,345-352] and five identified through supplementary searches[332-334,353,354] were included for synthesis. The results of the analyses indicated that adult smokers, CBT significantly increased smoking cessation success rates at six months or longer compared to minimal intervention (RR, 1.52; 95% CI, 1.21–1.92). In addition, subgroup analysis showed that CBT combined with pharmacotherapy significantly improved cessation outcomes (RR, 1.40; 95% CI, 1.03–1.91). CBT alone without pharmacotherapy was similarly effective (RR, 1.73; 95% CI, 1.19–2.50). Further subgroup analysis conducted according to population type showed that CBT was effective for smoking cessation in patients (RR, 1.84; 95% CI, 1.35–2.50) and healthy adults (RR, 1.42; 95% CI, 1.07–1.89) (**Supplementary Table 6-6**).

The effectiveness of CBT may vary depending on the condition and characteristics of the population.[355] Patients with underlying diseases may demonstrate stronger motivation to quit, enhancing the impact of the intervention. Development of a standardized CBT program tailored to the severity and risk level of smoking could enable the delivery of more personalized and effective sessions, ultimately promoting smoking cessation among diverse populations.

Financial incentives

1) Are financial incentives effective for smoking cessation in adult smokers?
2) Are financial incentives effective for smoking cessation in pregnant smokers?

Recommendation

1) We suggest considering the provision of financial incentives for smoking cessation. (*Certainty of Evidence: High; Grade of Recommendation: B*)
2) We recommend offering financial incentives for smoking cessation in pregnant smokers. (*Certainty of Evidence: High; Grade of Recommendation: A*)

Clinical considerations

- Financial incentives for smoking cessation should not be provided as a standalone treatment, but in combination with other smoking cessation interventions, such as

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pharmacotherapy and non-pharmacological therapies.
- Pregnancy is a contraindication for smoking cessation medications. However, NRT may be considered when its benefits are deemed to outweigh the risks of smoking.

Forty RCTs were selected from a systematic review conducted by Notley et al.,[335,356-395] and nine additional RCTs were identified to reflect updated evidence.[396-404] Subgroup analyses of the general adult population and pregnant smokers were performed. For the general adult population, the pooled analysis of smoking cessation success rates at six months or longer showed that provision of financial incentives significantly increased quit rates compared to no incentive (RR, 1.46; 95% CI, 1.26–1.69) (**Supplementary Table 6-7**). In pregnant smokers, financial incentives also significantly improved cessation success compared to no incentive (RR, 2.34; 95% CI, 1.73–3.18) (**Supplementary Table 6-8**).

Financial incentives should not be used as a standalone intervention for smoking cessation but rather as an adjunct to other non-pharmacological and pharmacological treatments. Existing evidence suggests that combining financial incentives with pharmacotherapy may produce synergistic effects, resulting in higher cessation success rates. Financial incentives can serve as a particularly important intervention in pregnant smokers, for whom pharmacological treatments are generally contraindicated. Smoking cessation during pregnancy has both direct and indirect health benefits for the mother and fetus and may contribute to improved maternal health outcomes and reduced healthcare costs.

Special populations

Is smoking cessation treatment effective for smokers with pulmonary tuberculosis?

Recommendation: We recommend smoking cessation treatment for smokers with pulmonary tuberculosis. (*Certainty of Evidence: High; Grade of Recommendation: A***)**

Twelve RCTs were included for the systematic review.[145,405-415] A meta-analysis of eight studies (three pharmacological intervention groups and six non-pharmacological groups, including one study with two intervention arms) was conducted to analyze smoking cessation outcomes. The results demonstrated significantly higher quit rates in the intervention group than in the control group (RR, 1.31; 95% CI, 1.12–1.54). Four additional studies (two pharmacological and two non-pharmacological) were not included in the meta-analysis. In the studies by Malhotra et al. and Sharma et al., both intervention groups received NRT combined with behavioral counseling and showed higher cessation rates than control groups that received counseling alone (70.2% vs. 46.7%; 47.8% vs. 32.4%, respectively). In addition, Nichter et al.[413] and Goel et al.[408] reported that individuals who received non-pharmacological interventions showed higher quit rates than those in the intervention groups (80.2% vs. 57.5%; incidence rate ratio, 1.52; $P < 0.001$). Regarding tuberculosis treatment success rate, data on pooled analysis from three studies showed no significant difference between the intervention and control groups (RR, 1.00; 95% CI, 0.96–1.03). Regarding tuberculosis conversion rate, only the study Dogar et al.[406] included results on this outcome, indicating no significant difference between groups. Serious adverse events were reported in the same study, with no significant difference between the intervention and control groups (RR, 1.04; 95% CI, 0.79–1.37) (**Supplementary Table 7-1**).

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There is a lack of adequate resources and knowledge in healthcare settings to provide tailored smoking cessation counseling for patients with tuberculosis. This highlights the need for additional support and training to facilitate the provision of personalized smoking cessation counseling for this patient population. Tuberculosis care providers can help address patient-related barriers to quitting smoking during anti-tuberculosis treatment and simultaneously contribute to improved treatment outcomes. Strengthening collaborations between national TB and tobacco control programs within an integrated healthcare system may serve as an important facilitator.

Does smoking cessation reduce mortality in current smokers diagnosed with lung cancer?

Recommendation: We recommend smoking cessation to current smokers diagnosed with lung cancer to reduce mortality. (*Certainty of Evidence: Low; Grade of Recommendation: A***)**

Eighteen studies were initially selected after systematic screening, and six additional studies were identified through supplementary searches, resulting in a total of 24 cohort studies included in the analysis.[416-439] All studies included comparison of mortality outcomes between patients with lung cancer who quit smoking at the time of or within one year of diagnosis and those who continued smoking. A meta-analysis of 17 studies that included data on adjusted hazard ratios (HRs) showed that quitting smoking at or shortly after diagnosis significantly reduced mortality risk compared to continued smoking (HR, 0.73; 95% CI, 0.67–0.80) (**Supplementary Table 7-2**). Subgroup analyses conducted according to cancer type showed similar results (for all lung cancer types combined: HR, 0.82 [95% CI, 0.73–0.93]; for small-cell lung cancer: HR, 0.61 [95% CI, 0.51–0.72]; for non-small cell lung cancer: HR, 0.72 [95% CI, 0.63–0.83]). A separate meta-analysis of nine studies that reported unadjusted HRs also showed a significant reduction in mortality among those who quit smoking around the time of diagnosis compared to those who continued smoking (HR, 0.77; 95% CI, 0.67–0.88).

For current smokers, smoking cessation at the time of lung cancer diagnosis offers greater benefits than risks, particularly in terms of improved survival. Given that smoking is the leading cause of lung cancer, a cancer diagnosis may serve as a powerful motivator for smoking cessation. Further research is needed to explore both pharmacological and non-pharmacological smoking cessation interventions tailored to current smokers diagnosed with lung cancer.

Smokers undergoing lung cancer screening

1) Is low-dose computed tomography (LDCT) screening effective for smoking cessation in smokers undergoing lung cancer screening?
2) Is smoking cessation treatment effective for smokers undergoing lung cancer screening?

Recommendation: We recommend active smoking cessation counseling and pharmacotherapy for smokers undergoing lung cancer screening. (*Certainty of Evidence: Low; Grade of Recommendation: A***)**

Clinical Considerations

- Research indicates insufficient evidence to support the effectiveness of low-dose chest CT screening alone in increasing smoking cessation rates.

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Four RCTs were selected through a systematic search and identification of primary studies that addressed the key question of whether LDCT promotes smoking cessation.[440-443] Evidence synthesis showed that smoking cessation rates at 12 months or longer did not significantly differ between the LDCT group and the non-LDCT group (four studies; RR, 1.11; 95% CI, 0.91–1.36) (**Supplementary Table 7-3**). To assess the effectiveness of smoking cessation interventions in smokers undergoing lung cancer screening, 10 RCTs (reported across 12 publications) were selected through a systematic search and screening process.[281,336,444-453] Pooled analysis of nine studies revealed no statistically significant difference in smoking cessation rates at three months or longer between the intervention group and the control group that received minimal or usual care (RR, 1.56; 95% CI, 0.90–2.69) (**Supplementary Table 7-4**). In a cluster RCT conducted by Foley et al., there was no significant difference in odds ratio between groups (OR, 0.97; 95% CI, 0.65–1.45). In the subgroup analyses, smoking cessation interventions that included pharmacotherapy achieved significantly higher cessation success than control interventions (RR, 2.41; 95% CI, 1.32–4.39). Similarly, interventions classified as intensive smoking cessation treatments achieved significantly greater quit rates than less intensive or usual care interventions (RR, 2.00; 95% CI, 1.20–3.34). Serious adverse events did not differ significantly between groups in the single study that reported them (RR, 0.93; 95% CI, 0.63–1.36) (**Supplementary Table 7-4**).

The benefits of smoking cessation are particularly significant for individuals with a high risk for lung cancer, such as those undergoing lung cancer screening. The risks associated with implementing cessation interventions during the screening process are comparable to those of standard cessation treatments, whereas the potential benefits are substantial. A systematic review of patients' perspectives on the "teachable moment" of lung cancer screening indicated that the screening experience heightened intrinsic motivation, increased awareness of smoking-related health risks, and encouraged smoking reduction.[454] In Korea's national lung cancer screening program, smoking cessation counseling is intended to be delivered during follow-up result consultations. However, attendance rates for follow-up visits are declining, prompting discussions on strategies to improve counseling uptake. Most physicians who conduct result consultations report limited time and experience to provide in-depth counseling. Therefore, delivering brief, motivational messages that highlight the clear benefits of quitting smoking, followed by referrals to specialized cessation services, may optimize intervention effectiveness.

Is initiating smoking cessation treatment prior to elective surgery effective for achieving smoking cessation in smokers?

Recommendation: We recommend starting smoking cessation treatment prior to elective surgery for smokers. (*Certainty of evidence: Moderate; Grade of recommendation: A***)**

Nine publications (seven unique studies) were identified through systematic screening,[54,455-460] and five additional RCTs (four unique studies) were retrieved through supplementary searches,[461-467] resulting in a total of 14 RCTs (11 studies) included in the analysis. The meta-analysis showed that smokers who underwent preoperative smoking cessation interventions had a significantly increased likelihood of quitting at six months or longer compared to controls (RR, 1.71; 95% CI, 1.20–2.44). Analysis stratified according to follow-up time indicated that quit rates remained significantly higher in the intervention group (RR at 6 months, 1.42; 95%

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CI, 1.06–1.90; RR at 12 months, 1.84; 95% CI, 1.31–2.59). Regarding postoperative outcomes, the intervention group had a significantly lower risk of developing any complication (RR, 0.79; 95% CI, 0.63–0.98) (**Supplementary Table 7-5**).

Smokers awaiting elective surgery may be more receptive to preoperative cessation treatment when informed that it can reduce postoperative complications and improve surgical outcomes. Unlike emergency procedures, the preoperative period for elective surgeries offers a valuable "teachable moment" for initiation of smoking cessation interventions. Similar to hospitalization for non-surgical reasons, this controlled setting encourages smokers to reflect more deeply on their health and the pros and cons of continuing smoking.

Smokers with heart disease

1) Compared to placebo, is varenicline safe and effective for smoking cessation in smokers with heart disease?
2) Compared to placebo, is NRT safe and effective for smoking cessation in smokers with heart disease?
3) Compared to placebo, is bupropion safe and effective for smoking cessation in smokers with heart disease?

Recommendation

1) We recommend varenicline as a first-line pharmacotherapy option for smoking cessation in smokers with heart disease. (*Certainty of Evidence: Low; Grade of Recommendation: A*)
2) We suggest considering NRT for smoking cessation in smokers with heart disease. (*Certainty of Evidence: Low; Grade of Recommendation: B*)
3) We suggest considering bupropion for smoking cessation in smokers with heart disease. (*Certainty of Evidence: Moderate; Grade of Recommendation: B*)

Clinical Consideration

- Varenicline is recommended as a first-line treatment for smoking cessation in smokers with heart disease. However, NRT or bupropion may be considered if side effects occur or based on the smoker's preference.

For the analysis of varenicline as a pharmacotherapy option for smoking cessation in smokers with heart disease, four publications (three RCTs) selected from a previous systematic review and through updated search were included for synthesis.[43,53,468,469] The results showed that among smokers with cardiovascular disease, varenicline significantly increased smoking cessation rates at six months or longer compared to placebo (RR, 2.35; 95% CI, 1.15–4.80). Subgroup analysis conducted according to disease phase (acute vs. non-acute) showed no statistically significant differences between the intervention and control groups (acute, RR, 1.44; 95% CI, 0.97–2.12; non-acute, RR, 4.36; 95% CI, 0.97–19.53). The incidence of cardiovascular adverse events did not differ significantly between groups (RR, 1.11; 95% CI, 0.71–1.73). In addition, no statistically significant difference in serious adverse events was observed (RR, 1.11; 95% CI, 0.80–1.56) (**Supplementary Table 7-6**).

For NRT, two publications were selected from a previous systematic review and through an updated search.[105,469] The results of the analysis showed that among smokers with

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cardiovascular disease, NRT increased smoking cessation success rate at six months or longer compared to placebo; however, the difference between groups was not statistically significant (RR, 1.39; 95% CI, 0.74–2.60). In the only study that includes data on cardiovascular adverse events, no statistically significant differences in the incidence of myocardial infarction (RR, 0.33; 95% CI, 0.01–8.04) or cardiac arrest (RR, 0.99; 95% CI, 0.06–15.70) were observed between the NRT and placebo groups. Regarding serious adverse events, no statistically significant difference was observed between smokers with cardiovascular disease in the NRT and placebo groups (RR, 1.01; 95% CI, 0.70–1.46) (**Supplementary Table 7-7**).

For bupropion, five publications were selected from a previous systematic review and through an updated search.[154,170,171,178,469] Among smokers with cardiovascular disease, the bupropion group showed a higher six-month smoking cessation success rate than the placebo group; however, the difference was not statistically significant (RR, 1.51; 95% CI, 0.99–2.31). The subgroup analyses showed that among patients hospitalized for acute myocardial infarction or acute coronary syndrome, there was no statistically significant difference in smoking cessation rates between the bupropion and placebo groups (RR, 1.17; 95% CI, 0.91–1.51). However, among smokers with stable cardiovascular conditions, bupropion significantly increased cessation rates compared to placebo (RR, 2.75; 95% CI, 1.23–6.15). Regarding cardiovascular adverse events, there was no significant difference between the groups overall (RR, 1.35; 95% CI, 1.00–1.83). In addition, the findings were consistent in both the acute (RR, 1.26; 95% CI, 0.89–1.77) and non-acute subgroups (RR, 1.71; 95% CI, 0.90–3.25). Similarly, no statistically significant difference in serious adverse events was observed between the bupropion and placebo groups (RR, 1.30; 95% CI, 0.48–3.52) (**Supplementary Table 7-8**).

Some previous studies have highlighted the potential cardiovascular risks of varenicline in patients with heart disease. However, subsequent research has shown no association between varenicline and increased cardiovascular risk, with some studies even indicating a reduction in all-cause mortality. In this meta-analysis, varenicline was the only pharmacological treatment to achieve a statistically significant improvement in smoking cessation rates among smokers with cardiovascular disease compared to placebo. Although NRT and bupropion did not demonstrate statistically significant efficacy, their relative risk values were modestly elevated (RR 1.39 and 1.51, respectively). In addition, they were not associated with increased risks of cardiovascular or serious adverse events compared to placebo. Therefore, NRT or bupropion SR may be considered as alternative options for patients who cannot tolerate varenicline.

Smokers with mental illness

1) Compared to a placebo, is varenicline safe and effective for smoking cessation in smokers with mental illness?
2) Compared to a placebo, is bupropion safe and effective for smoking cessation in smokers with mental illness?
3) Compared to a placebo, is NRT safe and effective for smoking cessation in smokers with mental illness?

Recommendation: We recommend varenicline, bupropion, or NRT as a first-line pharmacotherapy option for smoking cessation in smokers with mental illness. (*Certainty of evidence: Moderate; Grade of recommendation: A***)**

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Clinical Considerations

- Varenicline, bupropion, and NRT can be used for smoking cessation in smokers with mental illness. However, the potential side effects of each medication should be carefully explained to the smoker before making a choice.

For evaluation of varenicline as a pharmacotherapy option for smoking cessation in smokers with mental illness, 15 articles (13 RCTs) were selected from a previous systematic review and updated evidence and included for data synthesis.[16,17,21,30,36,40,44,51,55,56,470-474] The results indicated that varenicline was significantly more effective than placebo in achieving smoking cessation at six months or longer (RR, 2.17; 95% CI, 1.79–2.64). There was no statistically significant difference in serious adverse events between the varenicline and placebo groups (RR, 0.95; 95% CI, 0.66–1.37). Subgroup analyses conducted according to psychiatric disorders yielded consistent findings. However, the results for individual disorders were not statistically significant due to the wide CIs observed (major depressive disorder [RR, 0.82; 95% CI, 0.44–1.53], substance or opioid use disorder [RR, 1.77; 95% CI, 0.51–6.18], bipolar disorder [RR, 1.40; 95% CI, 0.44–4.47], and schizophrenia/schizoaffective disorder/bipolar disorder [RR, 0.76; 95% CI, 0.23–2.55]) (**Supplementary Table 7-9**).

For bupropion, 11 studies (9 RCTs) were selected from a previous systematic review and an updated search.[16,155,156,158,162,165,176,179,470-472] In smokers with mental illness, bupropion was significantly more effective than placebo in achieving smoking cessation at 6 months or longer (RR, 1.67; 95% CI, 1.30–2.14). There was no significant difference in serious adverse events between bupropion and placebo (RR, 1.12; 95% CI, 0.67–1.87). Bupropion was associated with a significantly higher risk of neuropsychiatric adverse events (RR, 1.23; 95% CI, 1.10–1.37). However, no statistically significant differences in serious neuropsychiatric events (RR, 1.30; 95% CI, 0.86–1.95) or individual symptoms including anxiety (RR, 1.26; 95% CI, 0.63–2.51), insomnia (RR, 1.27; 95% CI, 0.62–2.60), seizure (RR, 2.61; 95% CI, 0.11–60.51), suicidal ideation or intent (RR, 0.49; 95% CI, 0.06–3.75), and depression (RR, 0.90; 95% CI, 0.61–1.33) were observed between the two groups (**Supplementary Table 7-10**).

For NRT, four studies (two RCTs) were selected from a previous systematic review and an updated search.[16,99,470,471] Among smokers with mental illness, NRT was significantly more effective than placebo in achieving smoking cessation at six months or longer (RR, 1.55; 95% CI, 1.22–1.99). There was no significant difference in serious adverse events between the NRT and placebo groups (RR, 0.96; 95% CI, 0.55–1.67). Regarding neuropsychiatric adverse events, there were no significant differences in depression (RR, 1.00; 95% CI, 0.60–1.45), irritability (RR, 0.91; 95% CI, 0.65–1.27), or agitation (RR, 0.95; 95% CI, 0.62–1.46) between the groups. However, NRT was associated with a significantly higher risk of anxiety (RR, 1.47; 95% CI, 1.08–2.01), having abnormal dreams (RR, 2.64; 95% CI, 1.95–3.58), and insomnia (RR, 1.57; 95% CI, 1.17–2.12) than placebo (**Supplementary Table 7-11**).

Varenicline, bupropion, and NRT are all considered first-line pharmacotherapies for smoking cessation. The results of the studies on smokers with mental illness indicated notable differences in cessation efficacy among these agents; however, no significant differences in serious adverse events among them were observed. According to the 2020 clinical practice guideline from the American Thoracic Society, varenicline is recommended over nicotine patches for adults with mental health conditions.[475] Similarly, Ireland's National Clinical

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Guideline No. 28 (2022) recommends that mental health professionals prioritize varenicline as the first-line treatment.[476] If a smoker does not tolerate or respond to one medication, switching to one of the other first-line agents may be an appropriate alternative.

E-cigarettes and HTPs

Is smoking cessation treatment effective for e-cigarette users? (1)
Is smoking cessation treatment effective for heated tobacco users? (2)
Is smoking cessation treatment effective for multiple tobacco product users? (3)

Recommendation

(1) We recommend both pharmacological and non-pharmacological interventions for quitting e-cigarettes. (*Certainty of evidence: Moderate; Grade of recommendation: A*)
(2) We recommend both pharmacological and non-pharmacological interventions for quitting HTPs. (*Good Practice Statement*)
(3) We recommend both pharmacological and non-pharmacological interventions for complete cessation of all tobacco products among multiple tobacco product users. (*Certainty of evidence: Low; Grade of recommendation: A*)

Clinical considerations

- Pharmacological and non-pharmacological interventions for smoking cessation can be applied to help quit e-cigarettes and multiple tobacco product use.
- Based on research, effective interventions for e-cigarette cessation include varenicline and counseling, as well as tailored interactive text messages. For cessation of multiple tobacco products, effective interventions include varenicline, a combination of varenicline/bupropion + NRT + behavioral support, tailored interactive text messages, use of a smoking cessation app based on acceptance and commitment therapy, and smoking cessation booklets for dual users. However, additional research is needed to determine the efficacy of other interventions.
- For e-cigarettes, relapse to combustible cigarettes upon cessation should be avoided.

For analysis of smoking cessation for e-cigarette users, four studies were selected through a literature search and screening. Of the four studies, three were RCTs[477-479] and one was a non-randomized study (NRS) that included a post-hoc analysis of users of liquid-based e-cigarettes.[245,480] Regarding smoking cessation success rates, intervention groups who received smoking cessation treatment showed significantly higher quit rates than control groups. In the RCTs, the intervention groups were 73% more likely to achieve smoking cessation than the control groups (RR, 1.73; 95% CI, 1.07–2.79). In the NRSs, the intervention groups showed a 29% higher likelihood of smoking cessation (RR, 1.29; 95% CI, 1.04–1.58). Regarding serious adverse events, an RCT conducted by Caponnetto et al.[477] indicated that such events were rare and the cases recorded in either group were not treatment-related (**Supplementary Table 8-1**).

For analysis of smoking cessation among users of HTPs, no eligible studies were identified through the systematic search; however, two excluded cohort studies provided relevant data on the comparison of smoking cessation outcomes between users of conventional cigarettes and HTPs.[481,482] Nomura et al.[482] analyzed the efficacy of a telemedicine

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cessation program that included optional use of a varenicline or nicotine patch. Higher abstinence was observed in the HTP group at 24 weeks (OR, 1.12; 95% CI, 1.02–1.23) and borderline significance was recorded at 52 weeks (OR, 1.09; 95% CI, 0.99–1.19). Noda et al.[481] evaluated the use of an app-based program with educational and behavioral features and reported a significantly higher 24-week abstinence in the HTP group (OR, 1.17; 95% CI, 1.12–1.22). No serious adverse events were reported. Although direct clinical evidence from studies such as RCTs is limited, the balance of benefits and harms, patient values and preferences, and resource implications, as well clinical experience and expert consensus, support the recommendation of smoking cessation treatment for users of HTPs. The lack of high-quality evidence on the efficacy of HTP cessation treatment represents a critical gap in current tobacco control research. Given the substantial and growing prevalence of HTP use in Korea, there is an urgent need for prospective studies and RCTs specifically designed to evaluate the effectiveness of pharmacological and behavioral interventions in this population. Future research should be focused on head-to-head comparisons of different cessation modalities and investigation of the need for HTP-specific cessation strategies beyond conventional smoking cessation approaches.

Eight studies were selected for analysis of smoking cessation for users of multiple tobacco products. These included four RCTs,[478,483-485] two post-hoc analyses of previous RCTs,[245,486] and two cohort studies.[487,488] The studies were primarily focused on evaluation of dual or poly-use of conventional cigarettes and other tobacco products (e-cigarettes, waterpipes, cigars). No study on HTP-related multiple use was identified. Smoking cessation outcomes were analyzed separately for complete cessation of conventional cigarettes and other tobacco products, and cessation of conventional cigarettes only. For complete cessation of all tobacco products, both RCTs (RR, 1.39; 95% CI, 1.16–1.65) and NRSs (RR, 1.59; 95% CI, 1.12–2.24) indicated significantly higher quit rates in the intervention group than in the control group. For cigarette-only cessation, the RCTs did not show a statistically significant difference (RR, 1.17; 95% CI, 0.95–1.45); however, the results of the NRSs favored the intervention group. No serious adverse events were reported (**Supplementary Table 8-2**).

The effectiveness of behavioral and pharmacological interventions for tobacco and nicotine dependence is well established, and the interventions are widely used in clinical practice. Recent studies suggest that these interventions may also help users of e-cigarettes, HTPs, and multiple tobacco products. However, more large-scale RCTs are needed to confirm the effectiveness the existing interventions in these populations, especially through the comparison of treatment modalities. Although the prevalence of conventional smoking is declining in Korea, the use of e-cigarettes and multiple tobacco products is projected to increase.[5] Many users view e-cigarettes as less harmful and use them to quit smoking, reduce cigarette use, or for economic reasons.[489] When treating e-cigarette users, clinicians should assess tobacco use history, dual use with cigarettes, and perceptions of harm. Providing evidence-based information and engaging in shared decision-making are essential for achievement of satisfactory cessation outcomes.

CONCLUSION

This clinical practice guideline is the first developed in Korea to comprehensively address pharmacological and non-pharmacological treatments for smoking cessation, interventions for special populations, and smoking cessation strategies for users of electronic cigarettes.

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Developed through multidisciplinary collaborations among experts in medicine, public health, nursing, and psychology, it reflects the latest research and provides evidence-based recommendations tailored to individual smoker characteristics and needs. In addition, this guideline was developed by systematically evaluating the benefits and harms of each intervention and considering smokers' values and preferences, resource use, acceptability, feasibility, and equity. This guideline also includes practical tools, such as a pharmacotherapy algorithm and Korea's first cessation guidance for diverse tobacco product users, enhancing its clinical and policy relevance. Furthermore, the guideline presents tailored approaches to smoking cessation for special populations and specific guidance for e-cigarette users to ensure inclusivity and applicability across diverse groups. By increasing the likelihood of successful cessation and reducing smoking-related disease burden, this guideline is expected to improve public health outcomes. Moreover, it will serve as a key reference for informing health policies, supporting smoking cessation efforts, and guiding future research.

SUPPLEMENTARY MATERIALS

Supplementary Table 1
Level of conflict of interest and participation decisions

Supplementary Table 2
Population, Interventions, Professionals, Outcomes, Healthcare setting (PIPOH) framework

Supplementary Table 3
Certainty of evidence definitions based on Grading of Recommendations Assessment Development and Evaluation (GRADE) approach

Supplementary Table 4
Definition of grade of recommendation based on the Grading of Recommendations Assessment Development and Evaluation (GRADE) approach

Supplementary Table 5
GRADE summary of findings for pharmacotherapy

Supplementary Table 6
GRADE summary of findings for non-pharmacotherapy

Supplementary Table 7
GRADE summary of findings for smoking cessation in special populations

Supplementary Table 8
GRADE summary of findings for E-cigarettes and heated tobacco products users

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