Aims and Scope

The Korean Journal of Women Health Nursing is the primary source of information for meeting the challenges of providing optimum healthcare for women. This authoritative peer-reviewed journal publishes the latest clinical and research papers on health issues that affect women throughout their lifespan. The Journal aims to be the core resource for cutting-edge advancements and clinical applications of new nursing practice, therapeutic protocols for the management of health problems in women, and innovative research in gender-based issues that impacts treatment and nursing care.

The emphasis of the journal is on clinical nursing practice and education on the social science components relevant to women’s health issues. Topics covered include nursing care, education and research methodology for ante-, intra-, and post-partum women, for middle aged and elderly women’s health, and for socio-cultural issues and therapies.

About the Journal

The Korean Journal of Women Health Nursing (KJWHN) is a peer-reviewed official journal of the Korean Society of Women Health Nursing of the Republic of Korea (South Korea). It was launched in 1995 under its previous title, the Journal of Korean Women’s Health Nursing Academic Society (Vol. 1, no. 1, 1995 - Vol. 6, no. 1, 2000, pISSN: 1225-9543), and the Journal of Korean Academy of Women’s Health Nursing (Vol. 6 No. 2, 2000 - Vol. 7 No. 2, 2001, pISSN: 1225-9543).

Since June 2012 it has continued under the current title, the Korean Journal of Women Health Nursing (Vol. 18 No. 2, 2012 - present, pISSN:2287-1640, eISSN:2093-7695). The official abbreviated title is Korean J Women Health Nurs. It is published quarterly on the last day of every March, June, September, and December. Any supplementary or special issues may be published. The number of print copies per issue is 60. The copyright, including the right of online transmission, is owned by the Korean Society of Women Health Nursing. This journal is supported by a Korean Federation of Science and Technology Societies grant funded by the Korean government (Ministry of Science and ICT).

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Published on March 31, 2021

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This paper meets the requirements of KS X ISO 9706, ISO 9706-1994 and ANSI/NISO Z39.48-1992 (Permanence of paper)
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In December 2020, the Korean government announced the 2021–2025 Fourth Basic Plan for Low Fertility and Aged Society [1]. Reflecting social and environmental changes, the fourth plan includes a comprehensive lifelong guarantee of sexual and reproductive health rights. The plan supports healthy pregnancy and childbirth by strengthening social support for healthy and safe contraception, maintenance and termination of pregnancy, expanded resources for high-risk pregnancies, and safe infertility care centered around consumers. The Issues and Perspectives [2] published in this issue highlights the background of the plan and reviews the phenomenon of the low birth rate in detail. In particular, a suggestion is made to improve the safety of infertility treatments for the health of mothers and children and to provide psychological/emotional support such as information provision and counseling. In this article, I would like to summarize the present state of infertility support, including financial support for infertility treatment and psychological/emotional support such as information provision and counseling, as well as sharing my thoughts on the relevant arrangements.

Korea’s infertility support policy

The number of people diagnosed with infertility in Korea increased from 185,000 in 2010 to 200,000 in 2014 [3], and further grew to over 230,000 in 2019 [4]. Against this backdrop, the government initiated a project to provide financial support for infertility treatment in 2006, thereby standardizing infertility treatment procedures that were not previously covered by insurance. Health insurance coverage for infertility treatment procedures was subsequently applied from October 2017. Accordingly, from October 2017 to September 2018, approximately 120,000 patients benefitted from health coverage for infertility treatment, to the tune of 1.2 million USD (based on the amount reviewed and determined by the Health Insurance Review and Assessment Service excluding duplicate patients) [5].

In response to strong public advocacy supporting the expansion of health insurance coverage to include infertility treatment, the government abolished the restriction on the age of women to 44 years or younger (international age) for insurance-covered infertility treatment in July 2019, and expanded coverage so that women aged 45 years or older (international age) could benefit from health insurance for infertility treatment if considered necessary based on the medical assessment of a physician. Furthermore, the number of in vitro fertilization (IVF) and intrauterine insemina-
tion (IUI) procedures covered by health insurance was increased to a limited extent (by increasing the co-pay for additional procedures from 30% to 50%) and efforts to relieve women’s economic and psychological burden were made by establishing infertility/depression counseling centers.

In other words, in 2019, health insurance coverage for fertility-related counseling/education and examinations was promoted to encourage couples thinking of having children to actively monitor their physical condition before being diagnosed as infertile and to prevent infertility in advance. In addition, the government developed a plan to apply health insurance coverage to basic infertility tests at medical institutions, steps taken to achieve an appropriate physical condition for pregnancy, and education and counseling on conception for any couples planning to conceive a child, as well as a comprehensive plan to create a safe, healthy delivery environment for couples struggling with infertility and to address social needs.

The government is striving to improve the standard for the number of transplanted embryos, devise a plan to improve the safety of procedures, provide information necessary before and after infertility procedures on the public information portal, strengthen psychoemotional support such as counseling for infertile couples, offer health information on women who underwent infertility treatment and their babies, provide information on the status of use of infertility/depression counseling centers, and present evaluations of satisfaction on the comprehensive parenting portal. Furthermore, steps are being taken to support childcare and extended leave for infertility treatment, all of which are measured aimed at strengthening consumer-centered safe infertility support.

Provision of infertility-related information and psychological/emotional support

The emotional difficulties experienced by women during infertility treatment, combined with experiences of pain, discomfort, and physical fatigue during assisted reproductive procedures such as ovarian stimulation and invasive ovum aspiration, may contribute to low infertility treatment success rates, reduced quality of life [6,7], and decisions to discontinue treatment [8].

In light of the recognition that psychosocial support improves both the likelihood of conception and the quality of life of people experiencing infertility, thereby ultimately improving the effectiveness of infertility support, major advanced countries have assigned and managed infertility counseling as a main component of infertility procedures and treatment. For example, in the United Kingdom, Australia, and New Zealand, infertility counseling has been mandated through legislation so that prior to infertility treatment, sufficient general information on infertility and infertility-related procedures are sufficiently provided to aid in the decision-making process. In addition to providing medical information on infertility and supporting the decision-making process, these countries have expanded the scope of infertility counseling to a wide range of psychological health issues, including the psychological distress of infertile women, relationship problems between partners and with family members, and personal quality of life and satisfaction [9]. These psychological interventions have been reported to produce positive results in terms of relieving depression in women undergoing infertility treatment and improving marital intimacy, sexual satisfaction, fatigue [10], and pregnancy rates [11].

The provision of information and psychological support for infertile couples in Korea was mainly conducted at medical institutions providing infertility treatment in the past. However, the Korea Population, Health and Welfare Association conducted a pilot operation of an infertility counseling center in 2015 and opened the Central Infertility and Depression Counseling Center in June 2018. Subsequently, additional centers were opened in the Jeonnam, Incheon, and Daegu areas to provide information on mental health and improve emotional and psychological health, as well as supporting medical procedures related to infertility, pregnancy, and childbirth. As a result, statistically significant relief in depression, anxiety, and stress has been reported in women who received services at the infertility/depression counseling center [12].

Infertility nursing strategies

Women who receive infertility treatment experience both physical and psychological fatigue throughout the treatment process [13]. Physical fatigue due to frequent hospital visits and invasive procedures for the diagnosis and treatment of infertility may impose a burden on women receiving infertility treatment in combination with psychological difficulties and tension during ovulation induction, which is performed to assess the growth rate and number of follicles, as well as anxiety and tension during procedures such as IUI and IVF, and psychological fatigue as pregnancy is confirmed [13].

Women who undergo assisted reproductive technology treatment have higher levels of negative emotions before IVF than during IVF [14], and couples who undergo repeated cycles have higher levels of depression than those who have just started IVF for the first time [15]. In addition, the risk of depression is high until 1 year after successful IVF and childbirth [16], and women
who experienced IVF in the past were found to have a higher risk of depression 20 to 23 years later regardless of childbirth [17]. The quality of life of women undergoing IVF is lower when their level of depression is high, previous treatment has failed, and the cause of infertility is unknown; the latter two factors are particularly important contributors to the deterioration of quality of life [18]. Therefore, differentiated intervention strategies are required according to the cause of infertility, and more psychoemotional interventions are needed when infertility treatment fails.

When positive interactions do not occur in a marital relationship, stress and negative emotions related to infertility are directly transmitted without filtering, resulting in a vicious cycle of negative emotions involving conflict, regret, and feelings of guilt [13]. Such psychological discomfort and difficulties associated with infertility can be alleviated if women receiving fertility treatment understand their own emotions and express them appropriately through words and actions [13]. Indirect exposure of women undergoing infertility treatment to media has a negative correlation with infertility-related quality of life, whereas a positive association with overall quality of life has been demonstrated for the direct and gradual disclosure of methods that provide opportunities for face-to-face meetings, verbal expression, and immediate responses [19]. Therefore, women who undergo infertility treatment should be sensitive to their feelings and changes due to infertility, and at the same time, they should be able to express their feelings appropriately, for which interventions that help effective communication and positive interactions with their spouses are required.

In the meantime, a high level of stigma perceived by women is related to a low quality of life associated with infertility. In light of the fact that 88.1% of patients receiving infertility treatment need psychological counseling [20], it is necessary to improve perceptions of infertility in individuals and in society, along with providing psychological support [21], in order to reduce the stigma of infertility and improve quality of life.

Numerous studies have reported physical, psychoemotional, and socioeconomic difficulties among women diagnosed with infertility and receiving treatment in Korea. These difficulties are similar for women with female factor infertility and for those with unknown causes of infertility [13], and the burden of male factor infertility is also imposed on women [22]. Infertility should be understood as a situational difficulty that requires more effort than other challenges because of the possible or actual presence of factors that make it difficult to succeed in pregnancy, rather than being understood as a woman's individual defect or insufficiency. It would also be desirable to use the terms “women receiving infertility treatment” and “women receiving IVF” instead of “infertile women,” which has the effect of stigmatizing them. Furthermore, the main strategy for overcoming infertility could be to make ongoing efforts to positively change the perceptions of women who are diagnosed with infertility and those of Korean society toward infertility.

With a multifaceted policy that helps alleviate socioeconomic difficulties accompanying the process of diagnosis and treatment of infertility, medical institutions that provide infertility treatments and local communities should establish strategies to reduce physical difficulties for women receiving infertility treatment and to improve psychoemotional well-being at the personal and interpersonal levels throughout the process of planning infertility treatment, failure, and further attempts. In other words, it is necessary to examine patients’ psychoemotional status, as well as physical difficulties, experienced during the infertility treatment process and to provide counseling accordingly. Couples should also be included as recipients of infertility nursing care throughout the process of infertility treatment; they should be provided sufficient information, and it is necessary to develop and apply multifaceted interventions at the individual, family, and society levels to help people overcome infertility together with active support from their spouses.

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**Conflict of interest**
The author declared no conflict of interest.

**Funding**
None.

**Data availability**
Please contact the corresponding author for data availability.

**Acknowledgments**
None.
References


Korea’s low birth rate issue and policy directions

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Introduction

In early 2021, the South Korean media poured out discouraging articles on the natural decrease in the nation’s population. The low birth phenomenon has continued for almost two decades since 2002, when the total fertility rate (TFR)—defined as the average number of children that a woman would bear during her reproductive lifespan between ages 19 and 49 years—dropped below 1.3 [1]. In 2020, the number of births was surpassed by deaths, causing a natural population decline. To make the matter worse, young people are more likely to delay marriage or having children in the coronavirus disease 2019 (COVID-19) era, leading to an even lower number of expected births this year. It is a national task to slow the trend of low birth rates and an aging population by taking appropriate actions to bring about social, economic, cultural, and regional changes that can create a more sustainable society. In this paper, I would like to discuss the current status of low birth in South Korea (hereinafter, Korea) as well as the issues and future directions of the country’s population policy.

How serious is the birth issue in Korea?

The number of births in Korea has declined dramatically on three occasions since the end of the Korean War. The country boasted high fertility rates from the end of the Korean War until 1982, where the number of annual births was maintained between 800,000 and 1 million. In 1983, the nation’s TFR dropped below the population replacement level of 2.1, thanks to the government’s strong fertility regulation policy, widespread use of contraception, and normalization of smaller family sizes [1]. This is referred to as the first population change in Korea. Between 1983 and 2000, the number of annual births stayed at around 600,000; as such, this period has been labeled the low birth stage. In 2001, the number of births dropped dramatically to 400,000, with a TFR of 1.3 [1], corresponding to the second population change. The 1997 Asian financial crisis seems to have had ripple effects on the trend of individuals delaying marriage and subsequently having children. Low fertility continued through 2016, when the number of births further plunged to 300,000 (the third population change). In 2019, Korea became the only country in the world where a woman is expected to give birth to less than one child in her life, with a TFR of 0.92 [1].

The government has not been complacent regarding the issue of low birth. In 2005, the government enacted the Framework Act on Low Birth Rate in an Aging Society and organized the Presidential Committee on Ageing Society and Population Policy [2] which is led by the president and...
consists of ministers and experts, as very low birth rates have continued since 2001 with a TFR under 1.3. The government has renewed the Basic Plan for Aging Society and Population Policy every 5 years since 2006 and implemented policies across all walks of society. The first and second rounds of the plan included policies and measures to support pregnancy and childbirth, as well as childcare services to relieve couples’ financial burden of raising children. Starting in the third round, which came into effect in 2015, additional support was provided for job-seeking and housing for newlyweds to address the financial factors that contribute to getting married later and staying single longer. The government revised the third round in 2018, announcing the Policy Roadmap for an Inclusive Nation [3]. The new plan designed a transition to a policy aimed at improving the quality of life for all generations based on the criticism that previous plans have simply focused on the government’s role in encouraging childbirth without putting people at the center. Despite such efforts, the fertility rate seems far from ready to bounce back.

Why aren’t young Koreans having children?

When asked if they agreed with the statement “being a parent is an invaluable thing in life,” most Koreans (81.7%) agreed, including 67.0% of people in their 20s [4]. All age groups, including those in their 20s, reported thinking that having two children is ideal. In reality, the younger generation in Korea make dark jokes about having to give up three things in life, i.e., so-called “sam po”—dating, marriage, and having children. They feel like they do not have time, energy, or emotions that should go to surviving fierce competition in school and building qualifications to land a job in the tight job market. Korea has become a society where young people find it difficult to plan for a life where securing a job leads to getting married and having a family, because they are too anxious about obtaining a secure job, a stable income, and a place to live.

Exploring differences between men and women in how they see marriage and family may also provide insights into this phenomenon. The traditional gender roles of male breadwinners and female housekeepers are being challenged. A survey by the Korean Population, Health and Welfare Association [5] showed that six out of 10 single 30-somethings said they would like to get married. Two out of 10 responded they did not want to get married and the other two said they were not sure. Regarding the reason why they were hesitant to get married, 51.1% of male respondents said they found it difficult to agree on marriage terms such as housing and finances. Meanwhile, 25.3% of female respondents said they were “happy living alone,” and 24.7% said they were hesitant to tie the knot because of “the culture of patriarchy and gender inequality.” Five out of 10 respondents were positive about having children, while negative opinions were expressed through responses of “not [being] confident if I can do well in parenting” (24.6%), and “the financial burden of childcare” (24.3%).

In a 2019 survey by the Korean Women’s Development Institute on the priority of developmental tasks in life among young women and men in their 20s-30s [6], female respondents placed a higher priority on work and personal life than partnership and children. The results were not markedly different from those of their male peers. This shows that today’s young women choose to prioritize their career throughout their life cycle, as do young men.

A high percentage of young women also agreed that their partners’ participation in childcare, equal distribution of household chores, and partner’s maternity/paternity leave are prerequisites for them to consider having children. This is sharply distinct from the responses of their male counterparts, who pointed to their own financial situation and stable job as the biggest factors. This means that today’s young women will not tolerate traditional gender roles or unequal treatment, and would only choose to have children if their partners actively share the burden, allowing them to keep their careers without facing an existential crisis. These results provide a valuable perspective on what kind of environment is needed for today’s young women.

How should we approach low birth policies?

The international community has been discussing the most suitable way to approach population policies for a long time. In the 1970s and 1980s, governments around the world implemented strong population policies focused on family planning. Discussions were held about whether the population should be regulated in light of how population growth seemed to deter economic development. At the 1994 Cairo International Conference on Population and Development and the 1995 Beijing World Conference on Women, the paradigm for population policies shifted from controlling population size to acknowledging human rights [7].

The 1994 Cairo Conference confirmed that population policies should value the unique life of human beings rather than trying to regulate population size, acknowledging that reproductive rights are basic human rights. Governments committed to
goals to be met by 2015 to ensure universal access to reproductive health services, such as reducing infant/child/maternity deaths, universal education, and family planning to help empower women and improve their social status. The 1995 Beijing Conference advised governments to protect women's rights to reproductive health without unwanted pregnancy and birth, recognizing that women play a key role in socioeconomic development. Reproductive health and rights refer to the state of physical, mental, psychological, and social well-being free from illness, malfunctions, and/or disabilities. This acknowledgement helped the paradigm of population policy to move away from emphasizing economic development issues and to prioritize individual rights, health, and welfare. Since then, the global community has started to understand sexual and reproductive health and rights as part of human rights, and has protected comprehensive services that provide information, counseling, education, and healthcare.

How did this issue play out in Korea? The Korean government continued to implement measures to control population growth for a considerable time even after reaching its goal of curbing population growth by 1983, earlier than it had planned. It was only in 1996 that the fertility regulation policy was replaced by the goal of "improving the quality of the population." Concrete actions were taken to promote reproductive health such as providing sex education for teenagers and supporting mothers, infants, and children. With plummeting birth rates in the beginning of the 2000s, the government started to implement policies to encourage childbirth. Based on the diagnosis that the nation's low birth and population aging trends will aggravate social and economic crises, authorities put measures in place to promote childbirth and support childcare to achieve increased fertility [8]. However, not enough efforts were made to enhance gender equality, understand childbirth as women's individual right, and provide support for health and welfare. The younger generation saw this kind of policy as the government attempting to enforce traditional cultural norms by demanding that they have children. Korean women have expressed their repulsion against recent initiatives like the disclosure of the "birth map" and conducting the National Survey on Fertility and Family Health and Welfare, claiming that the government simply sees women as a tool for childbirth and is attempting to control population growth [9].

A paradigm shift is needed in low fertility policy

The Korean government released the Fourth Basic Plan for Ageing Society and Population Policy for the 5-year period beginning in 2021 [2]. The plan demonstrates a shift in paradigm in the government's population policy compared to the previous rounds. The Fourth Basic Plan presents a vision of creating "a sustainable society where all generations are happy together," acknowledging that current birth rates and demographic phenomena are the outcomes of individual choices and adaptation, not of governmental regulation and control. This plan makes it clear that the focus will be on bringing about structural changes at the individual, family, regional, and social levels. This is indeed a shift in policy direction and will be a welcome shift new beginning, no matter how overdue the change is.

The new plan envisions a society where we "work and care together" as a strategy to stop low birth [2]. Any woman who would like to work should be able to find employment, and not forced to discontinue their careers, endure job instability, or work in a low-paying job. Key strategies include creating gender-equal labor conditions so that all genders can plan stable careers, as well as improving current maternity/paternity leave policies so that everyone can share the labor of work and parenting. The COVID-19 crisis has shed light on the fact that the labor of caregiving plays a key role in sustaining families and society. Housekeeping, childcare, and elderly caregiving should not be underestimated or taken for granted as women's tasks. Homes, businesses, and local communities should all contribute to transform Korean society into one where people truly "work and care together.

It is also notable that the new plan penciled in the tasks of "guaranteeing the rights to sex and reproduction over the lifetime" and "legally embracing various types of families" in its strategies [2]. The government should support healthcare services from the point a woman gets pregnant, as well as providing health coverage for the entire life cycle, from adolescence to old age, covering sexual health, menstrual health, contraceptives, abortion, gender-based violence, sexually transmitted infections, and cancer control and prevention. Furthermore, Korean law only protects families that consist of "relationships based on marriage, blood, and adoption," while France and Germany have expanded their legal boundaries of family to embrace unions that emotionally and financially support each other without official marriage, through the Civil Solidarity Pact and the Life Companion Law, respectively [10]. In 2019, 2.3% births in Korea were out of wedlock [1], the highest percentage in the country’s history but the lowest among Organisation for Economic Co-operation and Development (OECD) nations—along with the lowest TFR. Korea should join the ranks of the global community in banning discrimination against diverse types of fami-
lies and should create an environment where all types of families and their children are respected and embraced.

The issue of low birth and aging population is caused by a combination of complex social issues that exist in Korean society. It is true that this phenomenon may affect our country’s socio-economic structure. As we see many countries overcoming the issue of low birth, Korea should restore trust within its society, so that everyone is respected and able to choose their own lifestyle, rather than focusing on this crisis that fuels public anxiety. Hopefully, Korea will evolve into a society where all residents can protect their own family and exercise reproductive rights with enhanced gender equality and quality of life. A stronger focus on women’s health is needed within public health and health-related policy. Moreover, as the impact of sexual and reproductive health on women’s lives and quality of life is paramount, active education, research, and policy development is more urgent than ever.

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All work was done by Kyung Ae Cho.

Conflict of interest

The author declared no conflict of interest.

Funding

None.

Data availability

Please contact the corresponding author for data availability.

Acknowledgments

None.

References

치정도구의 심리계량적 속성 1: 내용타당도

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Psychometric property of an instrument 1: content validity

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서론

측정이란 규칙에 따라 사물, 사건 또는 현상에 숫자를 부여하는 것을 의미하며[1]. 간호 현장에서 연구자나 실무자는 관심 개념을 직접적으로 측정하게 된다. 예를 들어 체중은 체중기를 사용해서 직접적으로 측정하지만, '희망' 같은 추상적인 개념은 간접적으로 측정하게 된다. 즉, 추상적 구성개념이 가지고 있는 속성을 측정가능한 지표(질문)로 만드어서 측정하는 것이다. 간호학에서 흔히 사용되는 간접적 측정방법은 자가보고형 도구(self-reported instrument)이다. 의학에서는 의료인이나 보호자가 아 닌 환자가 자신의 건강상태를 주관적으로 평가하는 도구를 환자보고결과 측정도구(patient-reported outcome measure, PROM)라고 명명하고 있다[2]. 자가보고형 도구 또는 PROM 사용에서 가장 중요한 것은 심리계량적 속성(psychometric properties)이 만족되었는지이다. 앞으로 본 학술지에서 심리계량적 측정속성에 대한 내용을 시리즈로 연재할 예정인데, 척도(scale), 검사(test), 도구(tool) 및 설문지(questionnaire)로 이를 붙여진 자가보고형 도구 또는 PROM 모두를 측정도구(instrument)라고 할 것이며, 그 첫 번째 측정속성으로 내용타당도에 대해 알아보고 한다.

내용 타당도

예비측정도구 개발 단계


개념적 정의가 규명되었으나, 그 다음으로는 구성 개념이 가지고 있는 속성을 파악한다. 속성을 도출하기 위해 문헌고찰, 면담(일대일 인터뷰, 포커스 그룹 면담), 질적연구 등을 통해 구성 개념이 가진 속성을 파악할 수 있다. 이렇게 파악된 속성을 이용하여 각 문항을 작성한다. 이때, 임기 수준은 초등학교 6학년에서 중학교 1학년이다. 문항은 다양하지 않게 기술해야 하며, 이중부정은 사용하지 않는 것이 좋다. 또한 문항용어나 외국어 사용은 피하는 것이 좋다[7]. 예를 들어, 암 환자 특이성 삶의 질 측정도구는 European Research Organization for the Treatment and Measurement of Cancer Quality of Life Questionnaire, Core Module (EORTC QLQ-C30)의 초기 문항문의 "TV"라는 단어가 사용되었는데[9]. 실제로 이 도구는 한국 암 환자에게 사용했던 연구에 의하면 경제적의 노동중 환자에서 많이 단어로 있던 문항을 이해하는 데 문제가 있었던 것으로 나타났다[10].


구성개념 반영에 대한 판단 단계

예비문항으로 이루어진 도구가 준비되었으면, 그 다음으로는 최종

또한 두 번째 단계는 개발된 측정도구의 내용이 정의된 구성 개념을 얼마나 반영하는지를 판단하는 단계라고 할 수 있다.

Korean J Women Health Nurs 2021;27(1):10-13

https://doi.org/10.4069/kjwhn.2021.01.31

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Lawshe[13]는 전문가 내용타당도를 판단하기 위해 내용타당도 비율(content validity index, CVI)의 사용을 제안하였다. 전문가에게 문항이 얼마나 관련 있는지를 3점 척도에(필수적, 사용 가능한 만족한 필수적은 아니야, 필요 없음) 응답하도록 요청하고, CVR=(mn - N/2)/(N/2)을 계산한다(100. 필수적이라고 응답한 답의 수; N. 총 질문의 수). CVR 값의 범위는 -1에서 +1이며, CVR의 임계치는 측정 전문가의 수에 따라 달라진다고 하였다. 예를 들어, 전문가 수가 5명, 10명일 때 각각 0.99, 0.62 이상이면 내용타당도를 만족한다고 보였다.

Lynn[4]가 제시한 내용타당도 지수(content validity index, CVI)는 간호학에서 가장 많이 사용하는 방법이다. 전문가에 게 문항을 등급에 4점 척도(1점, 관련 없음; 2점, 수준을 갖는 것 관련 있음) 3점, 관련이 있거나 4점, 관련이 있음) 다양성을 수신함. 4점, 해당 관련 없음) 답을 요구한다(12). 그리고 각 문항에 대해 3점 또는 4점에 답한 전문가의 비율의 CVI를 산출한다. 문항의 CVI (item-level CVI, I-CVI) 값은 전문가가 3-5명이면 1.00, 그리고 6-10명이면 0.78 이상이야하면 문항의 내용타당도가 만족된 것이라고 보았다. 전체 측정도구의 CVI (average of content validity index for scale, S-CVI/Ave) 산출은 I-CVI를 합해서 문항의 수로 나누어 산출하며, Polit와 Beck[14]는 0.90 이상을 권장하였다.

CVI는 일치 비율(portion agreement)에 대한 계산으로 간단하고 이해하기 쉽지만, “우연의 일치(chance agreement)”로 인한 과도한 가중성을 배제할 수 없다. 따라서 Wynld 등[15]은 이를 보정하는 다중평가자 카파계수(multi-rater Kappa coefficient)를 CVI와 같이 사용할 것을 권장하였다. 그러나, 카파계수는 측정도구의 안정성(stability)과 관련된 신뢰도를 반영하는 지표로 내용타당도 검증 중 사용에 적합하지 않을 뿐 아니라, 측정하고자 하는 구성 개념과 관련성이 없는(1점 또는 2점) 것도 함께 평가되어 계산되는 것이 문제가 되었다[16]. 이에 대해 대안으로, 관련성이 낮은 문항(1점 또는 2점의 문항)을 제외한 수신된 카파계수 $\kappa = (\frac{I - CVI}{P})/(1 - P)$가 제시되었다. 수식에서 $P$는 $[N/\sum(N/A - A)] \times 5^m$으로, N은 전문가의 수, A는 문항의 관련성을 3점 또는 4점에 응답한 수를 의미한다[16].

여러 연구자들이 내용타당도를 판단하기 위해 정량화에 노력력을 기울였지만, Beckstead[7]는 정량화를 위해서는 전문가 수가 총
분명 말이야 하고, 관련성에 대한 4점 척도 점수를 이분형(1-2점, 관련성이 없음; 3-4점, 관련성이 있음)으로 재구성하여 원래 가지고 있던 정보를 손실시키지 말아야 하며, 카파 또는 수정된 카파계수에 는 표준오차가 같이 제시되어야 한다고 지적하였다. 더 나아가 "타당도"란 연구자가 실제 대상자로부터 수집한 반응점을 가지고 추론하는 것이기 때문에 문항 자체에 대한 전문가 판단 결과에 타당도라는 용어를 사용하는 것은 적절하지 않다고 하였다. 따라서 내용타당도보다는 "조작적 정의에 대한 수용성(acceptability of an operational definition)"이라고 명명하는 것이 바람직하다고 하였다.


요약

내용타당도는 측정도구의 내용이 측정하고자 하는 구성개념을 얼마나 적절히 반영하고 있는가에 대한 것이다. 그 과정은 예비측정도구 개발 단계와 개발된 것이 측정하고자 하는 구성개념을 잘 반영하는지를 판단하는 단계로 나누어 볼 수 있다. 첫 번째 단계에서 측정하고자 하는 구성개념에 대한 개념화와 예비문항 개발이 이루어진다. 그 후, 전문가와 측정도구를 사용하고자 하는 대상자들 대상으로 개발된 예비문항의 관련성, 포괄성 및 이해성을 판단하게 된다.

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Author’s contributions

All work was done by Lee EH.

Conflict of interest

The author declared no conflict of interest.

Funding

This research was supported by a National Research Foundation of Korea (NRF) grant (NRF-2018R1A2B6001719). The funder did not play any role in the conduct or publication of the study.

Data availability

Not applicable.

Acknowledgments

None.

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Effects of nursing intervention programs for women with gestational diabetes: a systematic review of randomized controlled trials

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Purpose: This study aimed to identify the effects of nursing intervention programs for women with gestational diabetes mellitus (GDM) through a critical review of recent studies.

Methods: Studies related to effects of nursing intervention programs for women with GDM published in English or Korean between 2000 and 2019 were extracted from 10 electronic databases. The quality of the studies was evaluated and double-checked for accuracy by two reviewers using the Revised Cochrane Risk-of-Bias tool for randomized controlled trials.

Results: Twenty studies were selected, of which 19 had a low risk of bias and one had a high risk of bias. Interventions fell into six main groups: (1) integrated interventions, (2) self-monitoring of blood glucose levels, (3) dietary interventions, (4) exercise, (5) psychotherapy, and (6) complementary therapy. This review found that nursing interventions for GDM were of many types, and integrated interventions were the most common. However, low-carbohydrate diets and blood glucose monitoring interventions did not show statistically significant results. Evidence shows that various nursing intervention programs applied to GDM improved diverse aspects of maternal, fetal, and neonatal health, including both physical and psychological aspects.

Conclusion: The composition and delivery of integrated interventions continue to evolve, and these interventions affect physical and psychological indicators. Although interventions affecting physical health indicators (e.g., blood glucose levels, diet, and exercise) are important, many studies have shown that programs including psycho-emotional nursing interventions related to anxiety, depression, stress, self-efficacy, and self-management are also highly useful.

Keywords: Gestational diabetes; Nursing; Program; Randomized controlled trial; Systematic review
Introduction

**Research Background**

Gestational diabetes is on the rise worldwide, and various interventions have been reported to be effective in medicine, nutrition, and health. Integrated interventions composed of combinations of nutrition, exercise, lifestyle, and blood glucose management have been shown to be effective in terms of physical and psychological indicators.

**Implications for practice, education, and/or policy**

Evidence for constructing the most efficient program for gestational diabetes intervention was presented, making a practical contribution to improving the health indicators of women with gestational diabetes, both during pregnancy and postpartum, as well as neonatal health.

**Summary statement**

- **What is already known about this topic?**
  Gestational diabetes is on the rise worldwide, and various interventions have been reported to be effective in medicine, nutrition, and health.

- **What this paper adds**
  Integrated interventions composed of combinations of nutrition, exercise, lifestyle, and blood glucose management have been shown to be effective in terms of physical and psychological indicators.

- **Implications for practice, education, and/or policy**
  Evidence for constructing the most efficient program for gestational diabetes intervention was presented, making a practical contribution to improving the health indicators of women with gestational diabetes, both during pregnancy and postpartum, as well as neonatal health.

**Method**

- **Ethics statement:** This study was excluded from approval by the Institutional Review Board as a study using literature from previously published studies.

**Research Design**

The research design is the one that has been previously published and is based on the literature.

**Results**

The results of this study are presented in detail, including specific findings and implications for practice, education, and/or policy.
문헌 검색 전략
문헌 검색을 위한 구체적인 질문은 PICO-SD (Participants, Intervention, Comparisons, Outcomes, Timing, Study Design)를 포함하였고 구체적 기준은 다음과 같다.

• 대상자(participants): 임신성 당뇨병을 진단받고 다른 임신성 합병증이 없는 임산부
• 중재 (intervention): 임신성 당뇨병을 진단받은 임산부에게 적용된 간호중재프로그램
• 비교군(comparisons): 임신성 당뇨병 관련된 간호중재프로그램을 제공받지 않은 임산부
• 결과(outcomes): 임신성 당뇨병의 결과변수는 임산부, 태아, 신생아 측면에서 제시된다. 본 연구에서는 신체적 결과 지표(체중, 임신 기간 중 체중변화, 체질량지수 등), 진단대사성 결과 지표(혈당, 당뇨혈증, 출산 결과 지표(체내혈당, 난산, 유도분만), 심리적 안녕 결과 지표(우울, 불안, 스트레스, 자기효능감, 삶의 질, 모아 예측), 태아, 신생아 결과 지표(과체중아, 신생아 저혈당증 등)의 5가지 측면의 변수들을 모두 고려하고자 하였다.
• 연구용형(study designs): 무작위 대조군 실험연구(randomized controlled trial. RCT)만을 포함하였다.

문헌 검색 프로세스

검색어는 국내외의 경우 ‘임신성 당뇨병’ OR ‘임신성 당뇨’ OR ‘임신 중 고혈당’ OR ‘임신성 고혈당’ OR ‘임신 중 당뇨’ AND ‘식이’ OR ‘영양’ OR ‘식사’ OR ‘음飮’ OR ‘생활습관’ OR ‘ 자기관리’ OR ‘자가관리’ OR ‘심리’ OR ‘교육’ OR ‘중재’ OR ‘프로그램’ OR ‘간호’ 등으로 하였다. 국외의 경우 ‘Gestational diabetes mellitus’ OR ‘pregnancy diabetes’ OR ‘Hyperglycemia in pregnancy’ OR ‘gestational hyperglycemia’ OR ‘diabetes in pregnancy’ AND ‘self-management’ OR ‘programs’ OR ‘educational programs’ OR ‘life style’ OR ‘life-style intervention’ (diet OR exercise OR physical activity OR weight) OR ‘treatments’ OR ‘psychosocial manage-

개별 연구의 비둘림 위험 평가
두 명의 연구자가 선택된 문헌의 비둘림 위험 평가를 위해 RCT 평가 도구인 Revised Cochrane Risk-of-Bias tool (RoB2 [12])를 사용하였고 비둘림 위험 평가하였다. RoB2는 기존에 사용되고 있던 ROB를 2019년에 수정 보완한 도구로, 개별 무작위 평가를 위해 무작위 과정에서 발생하는 차우침, 의도된 개입으로 인한 차우침, 누락된 결과로 인한 차우침, 결과 측정의 차우침, 결과 보고 선택의 차우침의 5가지 영역으로 구성되어 있다. 각 영역마다 총 22개의 신호 점탈 질문이 포함되어 있으며 그 질문에 대한 응답은 ‘그렇다(yes)’, ‘아니요 아니이다(probably yes)’, ‘아니로 아닐 것이다(probably no)’, ‘아니다고(Not)’, ‘정보 없음(no information)’으로 평가하게 된다. 각각의 응답을 근거로 하여 비둘림 평가를 판단하는 알고리즘에 따라 ‘평양 위험은 낮음(low risk)’, ‘일부 위험 사항(some concerns)’, ‘평양의 위험성이 높음(high risk)’으로 총괄 위험 평가를 하게 된다. 연구자의 각의 비둘림 평가에 대한 의견 불일치는 토론을 통해 해결하였다.

자료 추출과 분석방법
체계적 문헌고찰을 위한 자료 추출 양식은 연구자들이 합의하여 항목을 결정하였으며, 이 양식에 연구 정보(저자, 출판연도, 연구국가, 연구 대상(연령, 임신 주수, 출생여자수), 이론 고찰, 중재 방법(중재집단 수, 중재 내용, 중재기간), 연구 결과 등을 포함하였다. 한편, 본 연구는 RCT만을 포함하였지만 연구의 이질성과 중재의 복합성으로 인해 중재 방법의 효과크기를 결정할 수 없어 메타분석을 실시하지 않았다.
Results

문헌 선정

국내외 데이터베이스 검색을 통해 중복된 연구를 제외하고 일치적으로 검색된 문헌은 총 454편이었다. 문헌 선정 기준인 대상자, 중재 및 비교군, 연구유형에 따라 검색된 문헌의 제목과 초록을 검토하여 34편이 선택되었다. 선정된 34편의 문헌은 전문을 확인하였고, 그 중에서 대상자가 부적합한 문헌 1편, 연구 설계가 선정기준에 부적합한 문헌 3편, 간호중재프로그램이 아닌 문헌 10편 등 총 14편을 제외하고 20편의 논문이 최종 선정되었다. 구체적으로 임신성 당뇨병 전중(prediabetic)의 임산부들을 대상으로 한 연구, 비등등성 대조군 유사 실험연구들, 의학적 중재프로그램 연구들이 제외되었다.

선정된 문헌의 특성

최종 체계적 문헌고찰에 포함된 연구는 총 20편으로 분석 대상 논문의 특성은 다음과 같다(Table 1). 연구 발표연도는 2002년부터 2019년까지 분포하였으며, 2015년 이후 발표된 연구가 15편(75%)이었고 2005년까지는 1편의 연구만 보고되었다. 연구가 진행된 나라들은 이란 6편(30%), 미국 5편(25%)으로 다수였고, 오스트레일리아와 중국이 각각 2편(10%) 등이었다. 20편의 연구들 중 이론적 고찰이 이루어진 연구는 3편(15%)이었다. 연구 장소는 20편(100%) 모두 병원이며, 중재가 개인별로 적용된 연구가 19편. 그룹별인 경우는 1편이었다. 대상자의 수는 38명부터 233명까지 다양하였고 대상자의 나이는 30대 이상을 대상으로 한 연구가 15편

<table>
<thead>
<tr>
<th>Variable</th>
<th>Categories</th>
<th>n (%)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publication year</td>
<td>2000–2004</td>
<td>1 (5.0)</td>
<td>[32]</td>
</tr>
<tr>
<td></td>
<td>2005–2009</td>
<td>2 (10.0)</td>
<td>[30,31]</td>
</tr>
<tr>
<td></td>
<td>2010–2014</td>
<td>2 (10.0)</td>
<td>[28,29]</td>
</tr>
<tr>
<td></td>
<td>2015–2019</td>
<td>15 (75.0)</td>
<td>[13–27]</td>
</tr>
<tr>
<td>Country</td>
<td>Iran</td>
<td>6 (30.0)</td>
<td>[13,15,20,22,27]</td>
</tr>
<tr>
<td></td>
<td>United States of America</td>
<td>5 (25.0)</td>
<td>[26,29-32]</td>
</tr>
<tr>
<td></td>
<td>Australia</td>
<td>2 (10.0)</td>
<td>[16,25]</td>
</tr>
<tr>
<td></td>
<td>China</td>
<td>2 (10.0)</td>
<td>[14,23]</td>
</tr>
<tr>
<td></td>
<td>Norway, Turkey, Spain, Croatia (each)</td>
<td>1 (5.0)</td>
<td>[17–19,28]</td>
</tr>
<tr>
<td></td>
<td>United Kingdom</td>
<td>1 (5.0)</td>
<td>[24]</td>
</tr>
<tr>
<td>Use of a theoretical framework</td>
<td>Yes</td>
<td>3 (15.0)</td>
<td>[14,17,30]</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>17 (85.0)</td>
<td>[13,15,16,18,29,31,32]</td>
</tr>
<tr>
<td>Intervention setting</td>
<td>Hospital</td>
<td>20 (100)</td>
<td>[13–32]</td>
</tr>
<tr>
<td>Intervention unit</td>
<td>Individual</td>
<td>19 (95.0)</td>
<td>[13-23,25-32]</td>
</tr>
<tr>
<td></td>
<td>Group</td>
<td>1 (5.0)</td>
<td>[24]</td>
</tr>
<tr>
<td>Sample size of each group</td>
<td>&lt; 50</td>
<td>10 (50.0)</td>
<td>[13,18-22,27,29,31,32]</td>
</tr>
<tr>
<td></td>
<td>50–79</td>
<td>9 (45.0)</td>
<td>[14-16,23-26,28,30]</td>
</tr>
<tr>
<td></td>
<td>≥ 80</td>
<td>1 (5.0)</td>
<td>[17]</td>
</tr>
<tr>
<td>Mean age of participants (year)</td>
<td>&lt; 30 in both the control and experimental groups</td>
<td>3 (15.0)</td>
<td>[22,27,31]</td>
</tr>
<tr>
<td></td>
<td>≥ 30 in both the control and experimental groups</td>
<td>15 (75.0)</td>
<td>[13,15-21,23-26,28-30]</td>
</tr>
<tr>
<td>Different range of mean age at each group</td>
<td>1 (5.0)</td>
<td>[32]</td>
<td></td>
</tr>
<tr>
<td>Not presented</td>
<td>1 (5.0)</td>
<td>[14]</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1. PRISMA flow chart. DB, database.

https://doi.org/10.4069/kjwhn.2021.03.02
(75%)인 반면, 각 군별로 평균 나이가 다른 경우가 1편(5%), 제시 되어 있지 않은 연구가 1편(5%)이었다. 대상자의 임신 주수는 12주부터 분만 시(intrapartum)까지 다양하게 나타났다.

문헌의 비뚤림 위험 평가
본 연구에 포함된 20편의 연구를 RoB2 도구를 이용하여 비뚤림 위험을 평가하였고, Cochrane 그룹에서 제공하는 Review Manager ver. 5.4 (Cochrane, London, UK)를 이용하여 분석하였다. 그 결과 1편(5%)은 무작위배정 과정(randomization process) 영역에서 무작위배정 과정을 상세히 기술하고, 중재군과 대조군의 기준선의 차이가 없어 'low risk'로 판단된 연구가 14편(70%), 무작위 과정에 대해 상세한 설명이 없지만 대상자에 대한 기준 또는 배정 비율은 'some concerns'로 판단된 연구가 6편(30%) [14,16,25,27,29,31]이었다.

의도된 중재(intended interventions), 누락된 결과(missing outcome data), 결과 보고(reported result) 영역에서는 모두 비-carousel의 위험이 낮다고 평가되었다.

결과 측정(measurement of the outcome) 영역에서는 결과 측정 방법이 부적절하여 연구 결과에 영향을 미칠 가능성이 크다고 판단하여 'high risk'로 판단한 연구가 1편(5%)이고 [23], 나머지 19편(95%)은 결과 측정 방법이 적절하여 'low risk'로 판단되었다(Figure 2A).

체계적 문헌고찰 결과
간호중재프로그램의 종류로는 단일 중재로 식이 2편, 운동 2편, 스

Figure 2. Risk of bias graph. (A) Risk of bias summary. (B) Risk of bias Risk of bias for selected studies.
통합 중재프로그램

영양, 운동, 생활 습관과 혈당 관련 주요 2가지 이상의 중재를 통합한 프로그램의 효과를 평가한 연구들도 모두 10편이었다. 혈당 관련 신생아 사후 결과지표와 스테레스, 자기효능감, 자기관리 관련 심리적 안녕 결과지표가 가장 두드러진 효과로 나타났다 (Table 2).

1) 직접적인 대면 교육을 통한 중재

중국 임산부 120명이 대상인 연구에서는 임신성 당뇨병 관련 지식, 운동, 혈당 모니터링 및 전신건강 교육 등을 제공받은 중재군의 혈당 조절, 생활습관 변화, 질환 관련 지식 인식률, 괴상 및 신체 4시간 간 혈당이 향상되었고, 조사, 수술 출혈, 양수과다증, 태아 곤란, 요로관련 발생률 및 신생아 관련 합병증도 통계적으로 낮게 나타났다 [23]. 백시코예 미국 임산부를 대상으로 한 연구는 임신성 당뇨병의 유형 및 위험요인, 영양, 운동 및 의학적 관리, 식품군과 측정 관련 영양요법에 대해 1시간 교육을 제공하고 3주 후 측정한 중재군의 건강 책임, 신체 활동, 영양, 영식 성장, 대인관계 및 스트레스 관련에서 통계적으로 유의한 차이가 있었다 [30]. 한편, 이한 임산부들을 대상으로 4주 동안 총 4회의 교육을 실시한 결과, 자기관리 행동과 혈당 수치에서 효과를 보였다 [21].

2) 디지털 영상자료(digital video disc, DVD), 웹 또는 모바일 기반 교육 프로그램 중재


3) 자기 관리 행동의 강화를 위한 중재

이란 임산부 151명을 대상으로 한 연구에서 자기 관리 페저지 및 3

Table 2. Characteristics of selected studies (N=20)

<table>
<thead>
<tr>
<th>First author, year [reference]</th>
<th>Country</th>
<th>Selection criteria</th>
<th>Int.</th>
<th>Cont.</th>
<th>Measurement / result (statistical significance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mirghafourvand, 2019 [13]</td>
<td>Iran</td>
<td>Age (&lt; 35 years), self-efficacy, weight, height, head circumference, preterm labor (–)</td>
<td>n=46</td>
<td>Usual care</td>
<td>Pre - Post 1 month: Maternal self-efficacy, birth weight, height, and head circumference, preterm labor (–)</td>
</tr>
<tr>
<td>Ly, 2019 [14]</td>
<td>China</td>
<td>Not presented</td>
<td>n=67</td>
<td>Usual care</td>
<td>Pre: UP 28-30 weeks</td>
</tr>
<tr>
<td>Koliyand, 2019 [15]</td>
<td>Iran</td>
<td>Age (&lt; 35 years), self-efficacy, weight, height, head circumference, preterm labor (–)</td>
<td>n=75</td>
<td>Usual care</td>
<td>Pre: UP 28-32 weeks</td>
</tr>
<tr>
<td>Conti-Olph, 2019 [16]</td>
<td>Australia</td>
<td>Age (&lt; 35 years), self-efficacy, weight, height, head circumference, preterm labor (–)</td>
<td>n=52</td>
<td>Usual care</td>
<td>Pre: UP 28-32 weeks</td>
</tr>
</tbody>
</table>

(Continued to the next page)
### Table 2. Continued

<table>
<thead>
<tr>
<th>First author, year [reference]</th>
<th>Country</th>
<th>Selection criteria</th>
<th>Int.</th>
<th>Cont.</th>
<th>Measurement: result (statistical significance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Borgen, 2019 [17]</td>
<td>Norway</td>
<td>&lt;IUP 33 weeks</td>
<td>n = 112</td>
<td>n = 121</td>
<td>IUP 36 weeks – Birth – PP 3 months: Proportion of emergency C/S (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The Pregnant+ app (healthy diet, being physically active and feedback on BG); Duration not presented.</td>
<td></td>
<td></td>
<td>PP OGTT 2-hour BG level, birth weight, breast feeding practice, obstetric complications or transfer to the intensive neonatal care unit (–)</td>
</tr>
<tr>
<td>Sklempe, 2018 [18]</td>
<td>Croatia</td>
<td>IUP 30–36 weeks</td>
<td>n = 18</td>
<td>n = 20</td>
<td>IUP 30th - 33rd - 36th week:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Regular supervised exercise and daily brisk walks of at least 30 min (20 min aerobic, 20–25 min resistance, pelvic floor, stretching, 10 min of relaxation); 2 weeks (50–55 min sessions)</td>
<td></td>
<td></td>
<td>PPG levels at end of pregnancy, neonatal BMI (+),</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diaphragmatic breathing exercise (5 minutes every morning; questionnaires twice a month); 30 days</td>
<td></td>
<td></td>
<td>Psychological state (depression, anxiety, stress), maternal–fetal attachment (+)</td>
</tr>
<tr>
<td>Bahramian, 2018 [20]</td>
<td>Iran</td>
<td>IUP 24–28 weeks</td>
<td>n = 38</td>
<td>n = 38</td>
<td>Every 2 weeks:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>500 mg ginger capsules twice a day; 8 weeks</td>
<td></td>
<td></td>
<td>Mean 2 hour PPG, insulin dose, and frequency of obstetrical visits (+); FBS, hemoglobin A1C (–)</td>
</tr>
<tr>
<td>Zandinava, 2017 [21]</td>
<td>Iran</td>
<td>IUP 28–30 weeks</td>
<td>n = 46</td>
<td>n = 46</td>
<td>Pre – Post 4 weeks:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Self-care educational with educational booklet; 4 weeks</td>
<td></td>
<td></td>
<td>Self-care behaviors, BG at 1 hour and 2 hours after GTT (+); FBS, quality of life (–)</td>
</tr>
<tr>
<td>Zaheri, 2017 [22]</td>
<td>Iran</td>
<td>IUP 24–32 weeks</td>
<td>n = 40</td>
<td>n = 40</td>
<td>Pre – Post 2 weeks:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cognitive-behavioral stress management; six 2-hour sessions; 3 weeks</td>
<td></td>
<td></td>
<td>Stress (+); FBS (–)</td>
</tr>
<tr>
<td>Liu, 2017 [23]</td>
<td>China</td>
<td>IUP 24–37 weeks</td>
<td>n = 60</td>
<td>n = 60</td>
<td>Every month:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Health education (mental health, exercise; medication guidance; BG monitoring; obstetric education; weight control); Duration not presented.</td>
<td></td>
<td></td>
<td>BG control, lifestyle change and knowledge on GDM (+); incidences of premature birth, PP hemorrhage, hydramnios, fetal distress, and urinary infection (+); Neonatal incidence of hyperbilirubinemia, severe asphyxia, hypoglycemia and pneumonia (+)</td>
</tr>
<tr>
<td>Draffin, 2017 [24]</td>
<td>United Kingdom</td>
<td>Not presented</td>
<td>n = 77</td>
<td>n = 73</td>
<td>Pre – 2 weeks later – at PP 6–8 weeks:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Patient-centered educational DVD (living with GDM, SMBG, administering insulin, calculating BMI post-pregnancy, healthy eating); 46 min</td>
<td></td>
<td></td>
<td>Maternal anxiety at 2 weeks, 1-hour PPG, pregnancy specific stress, emotional adjustment to GDM, self-efficacy, knowledge of GDM, risk perception for developing diabetes (–)</td>
</tr>
</tbody>
</table>

(Continued to the next page)
<table>
<thead>
<tr>
<th>First author, year [reference]</th>
<th>Country</th>
<th>Selection criteria</th>
<th>Int.</th>
<th>Cont.</th>
<th>Measurement: result (statistical significance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sayakhot, 2016 [25]</td>
<td>Australia</td>
<td>Not presented</td>
<td>n = 56</td>
<td>n = 60</td>
<td>Post: Knowledge of GDM (–), knowledge of food choice and exercise during pregnancy (–), knowledge of GDM management (–), association of education levels and knowledge of GDM (–)</td>
</tr>
<tr>
<td>Durnwald, 2016 [26]</td>
<td>United States</td>
<td>&lt; IUP 33 weeks</td>
<td>n = 49</td>
<td>n = 52</td>
<td>At PP 6–12 weeks: FBS and 2-hour PPG (–)</td>
</tr>
<tr>
<td>Bastani, 2016 [27]</td>
<td>Iran</td>
<td>IUP 20–42 weeks</td>
<td>n = 30</td>
<td>n = 30</td>
<td>At 3 days: Anxiety (+)</td>
</tr>
<tr>
<td>Moreno-Castilla, 2013 [28]</td>
<td>Spain</td>
<td>≤ IUP 35 weeks</td>
<td>n = 75</td>
<td>n = 75</td>
<td>At each follow up visit – after delivery: Differences in daily carbohydrate consumption (+), rate of requiring insulin, maternal weight gain, ketonuria, maternal hypertension, CS, small for gestational age, large for gestational age, macrosomia, newborn hypoglycemia (–)</td>
</tr>
<tr>
<td>Homko, 2012 [29]</td>
<td>United States</td>
<td>&lt; IUP 33 weeks</td>
<td>n = 40</td>
<td>n = 40</td>
<td>Every 2 weeks until IUP 36 weeks – then weekly: Maternal BG, neonatal birth weight (–)</td>
</tr>
<tr>
<td>Mendelson, 2008 [30]</td>
<td>United States</td>
<td>IUP 12–32 weeks</td>
<td>n = 49</td>
<td>n = 51</td>
<td>At 3 weeks – delivery admission day: Health Promoting Lifestyle Profile II scores (+): Glycemic control, macrosomia, or days of maternal or neonatal hospitalization (–)</td>
</tr>
<tr>
<td>Homko, 2007 [31]</td>
<td>United States</td>
<td>≤ IUP 33 weeks</td>
<td>n = 32</td>
<td>n = 25</td>
<td>Every 2 weeks until IUP 36 weeks – then weekly: Self-efficacy (+): FBS or PPG (although more women in the Int. group received insulin therapy), Pregnancy and neonatal outcomes (–)</td>
</tr>
<tr>
<td>Homko, 2002 [32]</td>
<td>United States</td>
<td>≤ IUP 33 weeks</td>
<td>n = 31</td>
<td>n = 27</td>
<td>Pre – at IUP 37 weeks: The Diabetes Empowerment Scale (–) At each visit: Dietary compliance, birth weight, gestational age at delivery, Apgar, neonatal complications, rates of macrosomia, CS, birth trauma (–)</td>
</tr>
</tbody>
</table>

BG: Blood glucose; BMI: body mass index; Con: control; CS: cesarean section; DVD: digital video disc; FBS: fasting blood sugar; GDM: gestational diabetes mellitus; GTT, glucose tolerance test; Int: intervention; IUP: intrauterine pregnancy; min: minutes; OGTT: oral glucose tolerance test; PP: postpartum; PPG: postprandial glucose; SMBG: self-monitoring of blood glucose.
본 연구는 임신성 당뇨병 임산부들을 대상으로 통합 중재요법을 개발하고 시도한 연구이다. 본 연구는 임산부들의 당뇨병 상태를 관리하는 데 있어 심리적, 정신적, 신체적, 일상생활적인 모든 측면을 고려하여 통합 중재요법을 개발하고 시도하였다. 본 연구의 대상은 임산부 중 당뇨병 환자 300명을 모집해 연구에 참여하였다. 연구는 4개월 동안의 통합 중재요법 시행 후 결과를 분석하였다. 통합 중재요법은 심리요법, 운동요법, 보완요법, 영양요법 등 다양한 요법을 통합한 통합중재요법으로 구성하였다. 조사 및 설문지, 당뇨병 관리지표, 심리적 건강지표를 사용하였다. 결과적으로, 통합 중재요법의 효과는 통계적으로 유의하게 나타났다. 한편, 본 연구의 한계로는 임산부들의 적절한 참여와 참여율이 낮다는 점이 있다. 통합 중재요법을 개발하고 시도하는 데 있어 이는 연구의 한계로 간주된다.
주간 실시한 감소시켰으나 연구는 인치하는 대상으로 복식, 경제·사회적, 희생단지, 산부인부의 사망 또는 재에 대한 효과를 측정하기 위한 반복 연구가 요구된다.

식이요법 중재의 효과를 종합한 결과, 저탄수화물 식이 중재가 인산성 당뇨병 임상부의 중요한 치료 전략이나 본 연구에서 가장 효과적인 식단은 저당부 식이로서 나타났다. 이는 식이요법 중재프로그램 고찰 연구에서 저당부 식이가 기저군[39], 신체적 압박 및 인슐린 사용 감소[40,41]에 의미가 있다는 결과와 일치하고 있다. 그러나 저탄수화물 식이 중재는 유의한 효과가 나타나지 않으나[28], 이는 저탄수화물 식이 중재에 오히려 혈당이 상승하고 태아 지방이 높아졌다는 결과와 일치한다[42]. 이러한 결과를 토대로, 보편적인 치료 전략인 저탄수화물 식이보다 저당부 식이가 효과적인 식이 전략으로 나타났는데, 국내 임신성 당뇨병을 가진 임신부들에게 더 적합한 식이 전략을 구현하기 위한 반복 연구가 요구된다.

예어로비과 저항운동을 결합한 프로그램은 혈당과 신생아 증후감에 효과적이었다[18], 이는 임신성 당뇨병을 가진 임산부를 대상으로 실시한 운동 요법 고찰연구에서 혈당 감소[43], 인슐린 요구량 감소[44,45], 거동이, 체중감소, 비율 감소[34] 효과와 일치하는 것으로 나타났다. 그러나 보다는 예측, 병발 및 추후에 효과적인 복식효과[19] 증가와 관련하여 저당부 식이를 대상으로 한 연구는 본 연구에서 다른 1편의 반복 연구가 요구된다.

인지행동요법은 스트레스 감소뿐만 아니라 혈당 감소에도 효과를 나타내는데[22]. 제2형 당뇨병 및 동반성 우울증이 있는 친구 환자들 대상으로 생활습관 상당한 통합 저지행동 치료요법을 실시하여 당화혈색소 수치가 감소된 결과가 일치한다고 할 수 있다[45]. 그러나 인지행동 요법과 관련한 임신성 당뇨병 임산부 대상 연구는 본 연구에서 다른 1편의 반복 연구가 요구된다.

보완요법으로 생장 캡슐 복용은 식후 혈당 및 인슐린 요구량을 감소시켰으나[46], 이는 신생아 중재는 혈당 및 인슐린 요구량의 감소에 어느 정도 효과가 있지만 볼 수 있다. 한편, 임산부 당뇨병으로 인한 불안감을 낮춘 데 효과적이며[27,30]의 임신성 당뇨병 임산부를 대상으로 해 이질 연구에서 12주간 실시 후 75 g 정구 당당하검사, 인슐린 저항성, 인슐린 수치 및 인슐린 치료 횟수가 상당히 감소한 것으로 나타났다[47]. 이는 현재 요법이 신체적, 심리적 결과 지표에서 효과를 나타내는 것으로 볼 수 있다. 이러한 결과를 토대로, 생장 캡슐 복용과 경제 요법과 같은 보완요법에 대한 국내 임신성 당뇨병을 가진 임산부들에 대한 효과를 측정하기 위한 반복 연구가 요구된다.

본 연구에서 비둘림 위험 평가 결과 비둘림의 위험이 높았던 연구는 외래의 5%로, 이로 인해 효과가 과대 추정될 가능성이 존재하므로 연구 결과 해석 시 주의해야 하며 이를 보완한 연구가 요구된다.

이상의 결과를 토대로, 임신성 당뇨병 임산부를 대상으로 한 간호중재프로그램의 기존 연구의 결과가 유의하고 대부분의 개입이 어느정도 가치가 있음을 발견하였다.

첫째, 통합 중재 프로그램의 구성이나 제공 방식이 계속 전환하고 있으며, 신생아생산 및 신체적 안녕 지표에서 효과를 나타내고 있다.

둘째, 혈당 모니터링 요법은 중요한 치료 전략이지만 그 효과성을 입증하지 못하고 있다. 그럼에도 불구하고, 계속적으로 다양한 중재 전략이 수립되어 연구가 시도되고 있는 것을 의미가 있는 것이다.

셋째, 혈당 모니터링, 영양, 운동 등 신체적 건강지표에 미치는 증후는 물론 중요하며 다수의 연구에서 임신성 당뇨병 임산부가 겪는 심리적 어려움 또한 드라마를 고려해야 할 필요. 구강, 스테레스, 자기효능감 및 자기 관리와 관련한 심리적 안녕 지표를 간호중재에 포함한 프로그램 또한 유용성이 높은 것으로 나타났다.

본 연구는 RCT로서 구성되었으나 전반적으로 낮은 비둘림 위험을 보여 연구의 질이 높은 것으로 평가된다. 또한 연구 간의 이질성도 통계적으로riet고 임신성 당뇨병을 가진 임산부들을 위한 단일 및 통합 간호중재에서 임산부, 태아, 신생아 측면의 결과가 발견하였으며, 효율적인 간호중재프로그램을 구축하기 위한 구체적인 증거를 제시함으로써 임신 중, 산후 및 신생아 임상을 개선하는 데 심리적으로 기여할 수 있는 방법을 제공하였다는 데 의미가 있다. 그러한 연구들은 적절한 연구가 서로 다른 중재 전략을 구현하고 있고 차별화되지 않은 결과 지표를 보고하고 있으므로 확실한 효과를 단정짓기 어렵고, 일반화된 중재프로그램을 제시하기에는 제한점이 있다. 고찰된 연구들은 국내 연구들로 구성되어 있어 국내 현실을 반영한 간호중재프로그램에 그 효과를 입증할 반복 연구들이 요구되고, 중재 전달 방식 또한 시대적 상황을 반영한 컨텐츠를 개발하고 효과를 증증할 것을 제언하는 바이다.

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Conceptualization, Data collection, Formal analysis: all authors; Writing-original draft: all authors; Writing-review & editing: Chung CW.

Conflict of interest

The authors declared no conflict of interest.

Funding

None.

Data availability

Please contact the corresponding author for data availability.

Acknowledgments

None.

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10.54773815579344


Birth cohort effects on maternal and child environmental health: a systematic review

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Purpose: This study aimed to review recent findings from birth cohort studies on maternal and child environmental health.

Methods: Birth cohort studies regarding environmental health outcomes for mothers and their children were investigated through a systematic review. A literature search was conducted in PubMed, CINAHL, the Cochrane Library, Embase, and RISS to identify published studies using the keywords using a combination of the following keywords: maternal exposure, environmental exposure, health, cohort, and birth cohort. Articles were searched and a quality appraisal using the Newcastle-Ottawa Scale for cohort studies was done.

Results: A review of the 14 selected studies revealed that prenatal and early life exposure to environmental pollutants had negative impacts on physical, cognitive, and behavioral development among mothers and children up to 12 years later. Environmental pollutants included endocrine disruptors, air pollution (e.g., particulate matter), and heavy metals.

Conclusion: This systematic review demonstrated that exposure to environmental pollutants negatively influences maternal and children's environmental health outcomes from pregnancy to the early years of life. Therefore, maternal health care professionals should take steps to reduce mothers' and children's exposure to environmental pollutants.

Keywords: Cohort studies; Environmental exposure; Environmental health; Pregnancy; Systematic review

주요어: 코호트 연구; 환경적 노출; 환경적 건강; 임신; 체계적 고찰

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Summary statement

• What is already known about this topic?
Endocrine disruptors (EDCs) are defined as substances that interfere with the production, release, metabolism, transport, signaling, activity, and elimination of hormones. Although pregnant women and children are known to be susceptible to EDCs, recent evidence from birth cohorts has not been reviewed.

• What this paper adds
Among pregnant women, exposure to environmental pollutants was associated with a shorter gestational period and less fetal growth. Among their children, exposure showed associations with higher blood pressure, poorer lung function, lower immunity, cytological changes, and impaired neuropsychiatric development.

• Implications for practice, education, and/or policy
Policy measures should be taken to protect pregnant women from environmental pollutants in light of the impact of environmental health on pregnant women and future generations.

Introduction

연구 필요성


임부와 태아에 대한 환경적 위협의 결과는 속속 밝혀지고 있다. EDC가 임부에게 주는 영향을 살펴보면 임부의 비스페놀 A (bisphenol A, BPA), 프탈레이트(phthalate), 살충제 노출이 태아의 난포 수를 감소시켰다[6]. 식사에 파라벤(paraben)과 BPA 같은 EDCs로 오염된 경우 조산의 비율이 1.6배 높았다[7]. EDCs 노출은 태아의 정신운동 발달 문제와 생식 건강 문제를 유발하였으며[8], 프탈레이트는 태아의 대뇌 발달 부정확성이 신생아의 피페, 2~5세 아동의 채식을 감소시키는 영향을 미쳤다[9]. 임신 중에 살충제 성분이 노출되면 태아가 아동기이 되었을 때 인지적 발달에 부정적 영향을 미쳤다[10]. EDCs로 인한 임신 초기에 임신기간에 노출된 임부의 경우 자연유산의 증가가 있었다[11]. 또한 증증수와 미세먼지도 임부와 태아의 건강에 영향을 주는 것으로 밝혀지고 있는데, 임부의 날

노출은 자연유산을 높였고[12]. 미세먼지가 높은 지역의 임부는 조산과 자연유산 비율이 높았다[13].

환경적 건강은 어디에나 존재하는(ubiquitous) 환경오염 물질의 화합이 어려운 점, 장기간 노출과 중복 노출의 특성, 건강문제 발현의 장기적 특성, 동물실험을 아니니에 인간에게 추정되기 어려운 특징을 가지고 있다[6]. 따라서 환경오염 물질의 효과를 증명하기 위해서는 노출 인구집단의 종단적 코호트 연구가 적합하므로 세계적으로 환경적 건강에 관한 출산 코호트 연구가 이루어지고 있다[14]. 하지만 최근 세계적으로 10년간 활발히 이루어지는 출산 코호트 연구의 결과를 파악하기 위한 세계적 고찰 연구는 찾아보기 어렵다[14]. 그러므로 본 연구는 임신기간 환경오염 물질에 노출된 모아를 대상으로 건강에 미치는 영향을 장기간 연구해 온 출산 코호트 연구의 주제와 결과를 고찰하고, 환경오염 물질이 임부와 자녀의 건강에 어떠한 영향을 미쳤는지를 유의성을 파악하고자 한다. 모아의 환경적 건강에 대한 출산 코호트 결과를 살펴봄으로써 인류에게 타산 환경오염의 건강 영향을 직시하고, 환경적 건강태세를 증진하고 예방할 수 있는 분야를 파악하며, 취약한 모아를 보호하게 될 간호의 시각을 얻게 될 것이다.

연구 목적

본 연구의 목적은 모아의 환경적 건강에 대한 출산 코호트 연구를 체계적으로 고찰하고 유효성을 파악하는 것으로, 구체적인 목표는 다음과 같다.

첫째, 모아의 환경적 건강에 대한 출산 코호트의 주제를 파악한다. 둘째, 모아의 환경적 건강에 대한 출산 코호트의 결과를 파악한다. 셋째, 임부의 환경오염 물질 노출이나 모아의 건강에 미치는 영향성 유의성을 파악한다.
Methods

Ethics statement: This study received an ethical approval ex-
emption from the Institutional Review Board of Kongju Na-
tional University (KNU-IRB-2020-93).

연구 설계

문헌 검색 전략
문헌 검색은 각 연구자가 모든 과정에서 case report를 작성하여 독
립적으로 임상의학 도서관(National Library of Medicine)에서 제시한 COSI (Core Standard, Idea-
al)의 영역이었다[17]. 검색식은 PubMed에서 Mesh 검색을 이용하
여 ("Maternal Exposure" OR "Child’s" OR "Maternal Exposures"
OR "Prenatal Exposures”) AND "Environmental Exposure"
"Health” OR "Cohort Studies” OR "Cohort” OR "Birth Cohort” OR "Chronic Library”에서 [Maternal Exposure] explode all trees AND (Maternal exposure): ab,kw, CINAHL에서 CINAHL Headings를 이용하여 (Maternal Exposure OR Prenatal Exposure OR Maternal Exposures OR Prenatal Exposures) AND (Environmental Exposure OR Environmental Exposures) AND Health AND (Cohort Studies OR Cohort OR Birth Cohort). Embase에서 EMTREE를 이용하
여 (maternal exposure'/exp OR prenatal exposure’/exp OR ‘en-
vIRONMENTAL exposure’/exp) AND ‘health’/exp AND ‘cohort analysis’/exp를 적용하였다. 국내 문헌 검색은 RISS에서 "출산코호트 OR 출산과오호트 AND 원장”의 키워드를 적용하였다. 연구의 비통
립 감소를 위하여 biography search를 포함하였다.
문헌의 선정기준은 (1) 모야의 환경적 노출에 대한 건강 효과를
측정한 출산 코호트 연구, (2) 영어나 한국어로 된 연구, (3) 개별 출
산 코호트 자료를 국가 간, 국가 내 데이터 뱅크로부터 합치 연구,
(4) full text 접근이 가능한 연구, (5) peer review로 된 저널 문헌, (6) 출판된 연구, (7) 1980-2020년 사이의 연구었다. 문헌의 제외기준은
(1) 학위논문, (2) 학회 발표, (3) 프로토콜 연구, (4) 서적, (5) 고찰 연구, (6) 보고서, (7) 결과가 보고되지 않은 논문, (8) 회
색 논문(conference abstract)이었다. 실험연구의 고찰에 사용하는
PICOST-SD의 핵심 질문 대신 환경적 과학문제에 관한 고찰에 사
용되는 Participant Exposure Comparison Outcome Setting Time-
Study Design (PECOST-SD)를 사용한 결과는 다음과 같다[18].

대상(participants)
대상자의 선정기준은 건강 문제가 없는 임신 전체 기간의 임부로
하였으며 임부와 자녀를 한 쌍으로 한 연구를 포함하였다. 대상자
의 제외기준은 임산 협증을 가진 고위험 임부인 경우와 자녀만을
대상으로 한 연구는 제외하였다.

노출(exposure)
환경오염 물질의 노출을 연구의 독립변인으로 한 연구를 선정하였
고, 환경오염 물질 노출에는 EDCs, 미세먼지를 포함한 공기오염,
중금속, 전자파, 방사선을 선정하였다.

비교 대상(comparison)
비교 대상은 코호트 연구의 설계에서 대조군을 설정한 연구와 환경
오염 물질의 노출에 따른 증후군의 차이 검정, 상관관계 분석, 회
귀분석 등의 통계 결과가 제시된 연구를 포함하였다.

결과(outcome)
연구 결과로 모체의 환경오염 물질 노출이 모체, 태아, 신생아, 영
아, 유아, 학령전기, 학령기의 자녀에게 임대를 미치는 영향을 포함
하였다. 건강문제로는 신체적, 인지적, 행동적, 정신적, 사회적 건
강문제를 포함하였다. 청년기 이상의 자녀를 추적 조사한 연구는
발견되지 않았으므로 제외 기준이 되었다.

장소(setting)
장소는 임부 관련 접근 가능한 자료로 지역사회, 의료기관, 웹사이트,
국가자료, 국제자료를 모두 포함하였다.

평가시점(time)
평가시점은 임신 1, 2, 3기, 출생 시, 신생아기, 영아기, 유아기, 학
령전기, 학령기에는 해당하는 모야의 생애주기 중 일 회, 수 회의 추
 후평가를 모두 선정하였다.

https://doi.org/10.4069/kjwhn.2021.03.12
연구설계(study design)

연구설계는 코호트 연구만을 선정하였으며 전형적 코호트와 후향적 코호트를 모두 포함하였다. 코호트 연구를 위한 프로토콜 연구 실험연구, 횡단적 조사연구, 질적 연구, 종합 및 문헌고찰 연구는 제외하였다.

분석문헌 선택과정

문헌 검색은 PubMed, CINAHL, Cochrane Library, Embase, RISS의 5개 검색 엔진으로부터 검색하였다. 검색 필터로 수집된 총 논문의 수는 605개(각각 244/10/57/281/13)였으며, hand search로 9편의 논문을 추가하였고, 증복 논문 198편이 제외되었다. 각 연구자는 독립적으로 총 416편의 논문의 초록을 읽어 이 중 선정기준에 적합하지 않은 398편을 제외하고 18편이 남았다. 18편 중 코호트 연구의 질 평가 도구로 추천되는 [19] Newcastle–Ottawa Scale (NOS)를 사용하여 [20] 각각의 질 평가 결과에 대한 연구 회의를 거쳐 4편을 제외한 총 14편을 선정하였다[21–34] (Figure 1). 14편의 연구는 질적 고찰을 활용하였으며, 메타 분석에 활용할 수 있는 공통적 종속변수가 발견되지 않아 이질적 이었으며 양적 유효성 평가는 수행하지 않았다.

문헌의 질 평가

논문의 질 평가 도구인 NOS는 호주의 Newcastle 대학과 캐나다의 Ottawa 대학이 협력하여 개발한 코호트 연구의 질 평가 도구로[20] 가장 흔히 사용되는 도구이다[19]. NOS는 코호트 선정(selection of cohorts), 코호트 비교(comparability of cohorts), 결과 사정(assessment of outcome)의 세 가지 평가 영역으로 구성되어 있다. 코호트 선정 영역은 노출 코호트의 대표성, 비노출 코호트의 선정, 노출의 확인, 연구시작 시 보고하지 않는 관심결과 제시의 4가지 세부 영역으로 이루어져 있으며, 세부 영역의 15개 답 중 6개 답의 점이 높은 항목에 별을 한 개씩 부여할 수 있고, 총 별의 수는 0–6의 범위를 가진다. 코호트 비교 영역은 연구설계나 분석의 기초한 코호트의 비교 1영역으로 이루어져 있으며, 2개의 항목에 응답하도록 되어 있고, 점이 높은 항목에 별을 한 개씩 부여할 수 있고, 총 별의 수는 0–2의 범위를 가진다. 결과 사정의 영역은 결과 사정, 결과 발생을 충분하게 오래 추후 관찰하였는지, 그리고 코호트 추후관찰의 적절성의 3가지 세부 영역으로 이루어져 있으며, 세부 영역의 10개 답 중 5개 답의 점이 높은 항목에 별을 한 개씩 부여할 수 있고, 총 별의 수는 0–5의 범위를 가진다. 별의 수가 많을수록 연구의 점이 높은 것을 의미하며, 3가지 영역에 대한 종합평가를 별의 수로 확인할 수 있다. 본 연구에서는 NOS 메뉴얼과 cohort star template을 사용하여[20] 각 연구자가 독립적으로 연구의 질 평가를 수행하고 결과를 대조하여 확정하였다. 별이 가진 항목은 연구자 간 회의를 거쳐 합의를 도출하였다(Table 1).

자료 분석

연구자들은 질 평가를 마친 선정된 총 14편의 논문에 대하여 독립적으로 case report를 작성하여 정성적 분석을 시행하였다. 사례보고의 항목은 출산 코호트 연구의 주제(저자, 연도, 국가, 코호트

Figure 1. PRISMA flow diagram for the literature search.
NOS: Newcastle-Ottawa Scale.
Table 1. Quality appraisal using the Newcastle-Ottawa Quality Assessment Form for selected cohort studies (N=14)

<table>
<thead>
<tr>
<th>Reference</th>
<th>First author</th>
<th>Publication year</th>
<th>Selection</th>
<th>Comparability</th>
<th>Outcome</th>
<th>Quality†</th>
</tr>
</thead>
<tbody>
<tr>
<td>[21]</td>
<td>Hong</td>
<td>2014</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>Good</td>
</tr>
<tr>
<td>[22]</td>
<td>Vafeiadi</td>
<td>2014</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>Good</td>
</tr>
<tr>
<td>[23]</td>
<td>Jiang</td>
<td>2015</td>
<td>??</td>
<td>***</td>
<td></td>
<td>Fair</td>
</tr>
<tr>
<td>[24]</td>
<td>Aker</td>
<td>2016</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>Good</td>
</tr>
<tr>
<td>[26]</td>
<td>Bougas</td>
<td>2018</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>Good</td>
</tr>
<tr>
<td>[27]</td>
<td>Fioravanti</td>
<td>2018</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>Good</td>
</tr>
<tr>
<td>[28]</td>
<td>Haug</td>
<td>2018</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>Good</td>
</tr>
<tr>
<td>[29]</td>
<td>Impinen</td>
<td>2018</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>Good</td>
</tr>
<tr>
<td>[31]</td>
<td>Clemente</td>
<td>2019</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>Good</td>
</tr>
<tr>
<td>[33]</td>
<td>Philippat</td>
<td>2019</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>Fair</td>
</tr>
<tr>
<td>[34]</td>
<td>Shah</td>
<td>2020</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>Good</td>
</tr>
</tbody>
</table>

†Good quality: 3 or 4 stars in the selection domain AND 1 or 2 stars in the comparability domain AND 2 or 3 stars in the outcome/exposure domain; fair quality: 2 stars in the selection domain AND 1 or 2 stars in the comparability domain AND 2 or 3 stars in the outcome/exposure domain; poor quality: 0 or 1 star in the selection domain OR 0 stars in the comparability domain OR 0 or 1 stars in the outcome/exposure domain.

고유명칭, 대상 인구집단, 모집 수/최종 분석 수, 모체 노출, 모아 결과, 추적 관찰 시점, 출산 코호트 연구의 결과(환경오염 물질, 결과변수, 연구 결과), 출산 코호트가 강화에 미치는 영향의 유효성의 결과 평가였다. Case report 작성 후 연구자 간 회의에서 일치도를 확인하였으며, 일치되지 않은 항목에 대하여 논문을 재평가하여 조정하였다.

Results

연구의 질 평가 결과

14편 논문의 질 평가를 NOS 체크리스트로 확인한 결과[20] 코호트 선정 영역은 별 2-3의 범위를 가지고 있었고, 코호트 비교 영역은 별 1-2의 결과. 결과 사정은 별 2-3의 범위를 나타내며 질적인 평가 영역이 모든 영역에서 결손되지 않았다. 그러므로 14편의 연구가 모두 분석에 포함되었다. 코호트 선정의 4가지 세부 영역 중 노출의 확인이 모든 연구에서 확보되어 표본의 선정이 정적으로 충족되었다. 코호트 비교 영역은 연구설계나 분석에 기초한 코호트의 비교 영역이 모든 연구에서 최소한 1개 이상을 충족하여, 노출 정도를 비교하였으나 혼란 변수의 조정이 있었음을 나타내었다. 결과 사정의 영역은 결과 사정, 결과 발생을 충분하게 오래 추출 관찰하였지만, 코호트 추후관찰의 적절성 중 적어도 2개 이상을 충족하여 결과 변수를 충분한 기간 사전이나 결과의 근거를 명확하게 측정하였음을 나타내었다(Table 1).

모아의 환경적 건강에 대한 출산 코호트 주제


https://doi.org/10.4069/kjwnh.2021.03.12
모자의 환경적 건강에 대한 출산 코호트 결과

출산 환경오염 물질은 구체적으로 다이옥신, 프탈레이트, 폐 살균, BPA 등 40개 이상의 EDCs의 6편[22,24,25,28,29,33], 미세먼지 등의 공기오염 5편[26,27,31,32,34], 낮은 수준, 맨간, 카드뮴 등의 준 금속 2편[21,34], 연료(석탄, 나무펄프, 전기스태브) 1편[23], 질소 화합물, 홍은 1편[30]이 있다. 모체의 결과변수는 구체적으로 태아 기간 1편[22], 태반 무게 1편[33], 에스트로겐, 프로게스테론, 성 호르몬 결합 글로불린, 갑상선 자극호르몬, 갑상선 호르몬 1편[24] 이었다. 자녀의 결과변수는 출생 시 체중과 신장 5편[21–23,27,33], 머리둘레, 허리둘레 2편[27,34], 태반과 출생 시 체중의 차 1편[33], 체중동반 면역글로불린 1편[25], 페놀 1편[26], 비만도 1편[27], 혈중 고밀도지질 1편[27], 백혈구의 테라모어 길이(lecocyte telomere length, LTL) 1편[31], 혈압 1편[32], 40개의 화학물질 채내 농도 1편[28], 아토피 피부염, 비만, 천식, 폐쇄성 호흡기 질환, 알리지, 호흡기 감염 1편[29], 주의력 결핍 과잉행동 장애 1편[30], 행동 문제, 신체발달지수, 저지, 자폐 행동 1편[34]이었다(Table 2).

임부의 환경오염 물질 노출이 모자의 건강에 미치는 영향의 유효성 연구 결과 EDCs의 노출 효과를 살펴보면, 모체의 다이옥신 노출이 높은 체계간기[22], 출생 시 자녀의 저체중[22]과 관련이 있었고, 프탈레이트와 폐 살균이 태반 무게 감소와 관련이 있었다[33]. 임부의 프탈레이트 노출은 태반과 출생 시 신체와 체중 사이의 관계 감소와 관련이 있었다[33]. 폐놀과 바른 노출은 모체의 심호르몬 결합 글로불린을 증가시키고[24], 에스트로겐과 프로게스테론을 감소시켰다[24], 에스트로겐과 프로게스테론의 비율을 감소시켰다[24]. 임부의 환경오염 물질 노출이 자녀의 정장 백신 글로불린의 효과를 높혀 면역 형성을 감소시켰다[25]. 40개의 모체 EDCs 농도는 자녀의 EDCs 농도와 관련이 있었고[28], 90% 이상의 물질이 모체에서 더 높은 농도로 나타났다[28]. 임부의 과분화물질(perfluorinated alkylated substances) 노출은 자녀의 면역 역제, 상기도, 하기도, 귀도장과 관련이 있다[29].

미세먼지를 포함한 공기오염 물질의 노출 효과를 살펴보면, 임부의 미세먼지 노출[27,34], 임신 시 석탄이나 나무 밀가루를 이용한 냉장하는 것이 출생 시 저체중[23]과 관련이 있었다. 이산화황소 노출은 자녀의 폐기능 중 간체폐활량(forced vital capacity)을 낮추었고[26] 26% 부분적으로도 감염과 알려진의 민감성을 높였다[26]. 임부의 미세먼지, 질소화합물 노출은 자녀의 비만과는 통계적으로 유의한 관계가 있었다[27]. 임부의 흡연은 자녀의 낮은 인지성과 관련이 있었다[30]. 임부의 미세먼지 노출은 자녀의 LTL 감소와 관련이 있었다[31]. 임부의 아산화질소 노출은 신생아의 높은 수축 기, 이완기 혈압과 관련이 있었다[32].

증속된 노출 효과를 살펴보면, 임부의 낮, 수온, 카드뮴, 맨간 노출은 자녀의 낮은 체중 증가[21,34], 낮은 인지적 발달 점수, 정신발달 점수, 신체발달 점수와 관련이 있겠다[34]. 높은 자폐행동과 행동문제 점수와 관련이 있다[34] (Table 3).

Discussion

본 연구는 세계적 고찰 방법에 의해 14편의 환경오염 물질 노출이 모자의 건강 문제에 미치는 영향을 비교하여 출산 코호트 연구들의 주제와 결과를 파악하고 모야 건강에 미치는 영향을 분석하였다. 14편의 결과 변수는 모야의 신체적, 인지적, 행동적 건강 상태에 유의한 영향을 주는 것으로 나타났다.

본 연구의 강점은 세계적으로 환경오염 물질이 모야의 건강에 미치는 영향에 관심을 가지고 출산 코호트가 국가단위 사업으로 활발히 수행되고 있는 시점에서, 연구 결과들을 통합하여 살펴 볼 수 있도록 계획적인 고찰이 이루어졌다는 점이다. 출산 코호트는 환경적 건강을 포함하여 다양한 모야 건강을 주제로 최근 10년 사이 유 률을 중심으로 11개 이상 활발히 진행되고 있는데[14], 1~10년의 연구 기간을 두고 진행되는 출산 코호트 연구의 특성상 결과 변수를 확인하기에 적절한 시점에 도달하였다. 본 연구 결과 모야의 환경적 건강 관련 코호트는 2014년 이후 유럽 지역 외에도 한국과 중국을 포함하여 다수 국가에서 이루어지고 있으며, 연구의 규모 도 매우 컸어서 대상자의 수가 1,000명 이상이 경험이 다수었다.

본 고찰 논문들은 NOS 점 평가 결과인 코호트 선정, 코호트 비교, 결과 사례 연구의 결과적으로 유수한 것으로 나타나[20], 모야 건강의 시사점을 제공하는 근거기반 확장에 기여하였다. 그러므로 출산 코호트 자료 결과를 통합하여 해석하면 임신 후 환경오염 물질 노출로 인한 모야의 환경적 건강 결과 관련 지식을 확장하는 데 도움을 줄 수 있다[14].

본 연구 결과 모야의 환경적 건강에 대한 출산 코호트 주제는 EDCs, 공기오염, 증속이 임신 기간 동안 모체에 촉진되어 모야와 출생자에게 어떠한 건강 영향을 주었는지 조사한 전체적 코호트 연구라고 요약할 수 있다. 환경오염 물질별 결과를 고찰 하면 다음과 같이 논의할 수 있다.

첫째, 연구물 6편으로 가장 많은 환경오염 노출물질로 조사된 EDCs는 호르몬의 생성, 방충, 대사, 전달, 연결, 활동, 세균을 방해하는 물질로 정의되고 있으며, 적은 양으로도 효과를 나타내며 환경보건학이나 부류한다[35]. 임신기간간은 EDCs에 취약한 시기로 태아에게 모체의 생활습관이 전달되고, 모야 수유를 통하여 물질을 전달하게 되어 미래 세대에 영향을 미치는 소리 없는 유해물질이다

https://doi.org/10.4069/kjwhn.2021.03.12
<table>
<thead>
<tr>
<th>Reference</th>
<th>First author</th>
<th>Selected</th>
<th>Country</th>
<th>Title of cohort</th>
<th>Study design</th>
<th>Participant</th>
<th>Recruitment/analysis (n)</th>
<th>Maternal exposure</th>
<th>Maternal or infantile outcome</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>[21]</td>
<td>Hong</td>
<td>2014</td>
<td>Republic of Korea</td>
<td>MOCEH</td>
<td>Prospective cohort</td>
<td>Mother-child pairs</td>
<td>1,475/1,150</td>
<td>Heavy metal</td>
<td>Physical development</td>
<td>At 6, 12, and 24 months</td>
</tr>
<tr>
<td>[22]</td>
<td>Vafeiadi</td>
<td>2014</td>
<td>Europe (5 countries)</td>
<td>NewGeneris</td>
<td>Prospective cohort</td>
<td>Mother-child pairs</td>
<td>967/289</td>
<td>Chemicals</td>
<td>Gestational age and weight</td>
<td>At birth</td>
</tr>
<tr>
<td>[23]</td>
<td>Jiang</td>
<td>2015</td>
<td>China</td>
<td>Lanzhou cohort</td>
<td>Prospective cohort</td>
<td>Mother-child pairs</td>
<td>14,359/10,542</td>
<td>Cooking fuel</td>
<td>Birth weight</td>
<td>At birth</td>
</tr>
<tr>
<td>[26]</td>
<td>Bougas</td>
<td>2018</td>
<td>France</td>
<td>PARIS</td>
<td>Prospective cohort</td>
<td>Mother-child pairs</td>
<td>3,840/788</td>
<td>Air pollution</td>
<td>Lung function</td>
<td>At 8–9 years</td>
</tr>
<tr>
<td>[27]</td>
<td>Fioravanti</td>
<td>2018</td>
<td>Italy</td>
<td>GASPII</td>
<td>Prospective cohort</td>
<td>Mother-child pairs</td>
<td>719/581</td>
<td>Air pollution</td>
<td>Obesity</td>
<td>At 4 and 8 years</td>
</tr>
<tr>
<td>[28]</td>
<td>Haug</td>
<td>2018</td>
<td>Europe (6 countries)</td>
<td>HELIX</td>
<td>Prospective cohort</td>
<td>Mother-child pairs</td>
<td>31,472/1,301</td>
<td>Chemicals and heavy metals</td>
<td>Chemicals and heavy metals</td>
<td>Between 6 and 12 years</td>
</tr>
<tr>
<td>[29]</td>
<td>Impinen</td>
<td>2018</td>
<td>Norway</td>
<td>ECA</td>
<td>Prospective cohort</td>
<td>Mother-child pairs</td>
<td>3,754/641</td>
<td>Chemicals</td>
<td>Immunosuppression</td>
<td>At 2 and 10 years</td>
</tr>
<tr>
<td>[31]</td>
<td>Clemente</td>
<td>2019</td>
<td>Europe (6 countries)</td>
<td>HELIX</td>
<td>Prospective cohort</td>
<td>Mother-child pairs</td>
<td>31,472/1,396</td>
<td>Air pollution</td>
<td>Cell aging</td>
<td>At 1 year</td>
</tr>
<tr>
<td>[33]</td>
<td>Philippat</td>
<td>2019</td>
<td>France</td>
<td>EDEN</td>
<td>Prospective cohort</td>
<td>Mother-son pairs</td>
<td>998/473</td>
<td>Chemicals</td>
<td>Physical development</td>
<td>At birth</td>
</tr>
<tr>
<td>[34]</td>
<td>Shah</td>
<td>2020</td>
<td>Republic of Korea</td>
<td>MOCEH</td>
<td>Prospective cohort</td>
<td>Mother-child pairs</td>
<td>1,751/442</td>
<td>Heavy metals and air pollution</td>
<td>Physical, neurologic, and behavioral development</td>
<td>At birth, 6 month, 1, 2, 3, 4, 5, and 6 years</td>
</tr>
</tbody>
</table>


*Denmark, Greece, Norway, Spain, and England; †England, France, Spain, Lithuania, Norway, and Greece.
### Table 3. Outcomes of birth cohort studies (N=14)

<table>
<thead>
<tr>
<th>Reference</th>
<th>First author</th>
<th>Selected Pollutant</th>
<th>Outcome measure</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>[21] Hong</td>
<td>2014</td>
<td>Lead</td>
<td>Infants' weight and height</td>
<td>Lead exposure was associated with low infantile weight and height.</td>
</tr>
<tr>
<td>[22] Vafeiadi</td>
<td>2014</td>
<td>Dioxin-like plasma activity</td>
<td>Birth weight and gestational age</td>
<td>Dioxin exposure was associated with low birth weight and short gestational age.</td>
</tr>
<tr>
<td>[23] Jiang</td>
<td>2015</td>
<td>Coal, biomass, and electromagnetic stove</td>
<td>Estradiol, progesterone, estradiol/progesterone, SHBG, TSH, FT3, and FT4</td>
<td>Phenol exposure was associated with decrease of progesterone. Paraben exposure was associated with increase of SHBG and decrease of estrogen and progesterone.</td>
</tr>
<tr>
<td>[24] Aker</td>
<td>2016</td>
<td>BPA, BP-3, 2,4-DCP, 2,5-DCP, TCS, MPB, BPB, and PPB</td>
<td>Weight, height, waist, hip circumference, BMI, and HDL</td>
<td>NO&lt;sub&gt;2&lt;/sub&gt;, NOx, PM&lt;sub&gt;10&lt;/sub&gt; and PM&lt;sub&gt;2.5&lt;/sub&gt; exposure was not associated with weight, height, waist, hip circumference, body mass index, and high-density lipoprotein.</td>
</tr>
<tr>
<td>[26] Bougas</td>
<td>2018</td>
<td>NO&lt;sub&gt;2&lt;/sub&gt;</td>
<td>Pulmonary function test index</td>
<td>NO&lt;sub&gt;2&lt;/sub&gt; exposure was associated with low forced vital capacity.</td>
</tr>
<tr>
<td>[27] Fioravanti</td>
<td>2018</td>
<td>NO&lt;sub&gt;2&lt;/sub&gt;, NOx, PM&lt;sub&gt;10&lt;/sub&gt;, and PM&lt;sub&gt;2.5&lt;/sub&gt;</td>
<td>Weight, height, waist, hip circumference, BMI, and HDL</td>
<td>NO&lt;sub&gt;2&lt;/sub&gt;, NOx, PM&lt;sub&gt;10&lt;/sub&gt; and PM&lt;sub&gt;2.5&lt;/sub&gt; exposure was not associated with weight, height, waist, hip circumference, body mass index, and high-density lipoprotein.</td>
</tr>
<tr>
<td>[28] Haug</td>
<td>2018</td>
<td>40 chemicals and heavy metals</td>
<td>40 chemicals and heavy metals</td>
<td>For persistent compounds and heavy metals correlations between maternal exposure and child outcomes were moderately high.</td>
</tr>
<tr>
<td>[29] Impinen</td>
<td>2018</td>
<td>PFAS (PFUnDA, PFOS, PFOA, PFOSA, and PFNA)</td>
<td>Atopic dermatitis, pulmonary function, rhinitis, asthma, obstructive airway disease, allergy, and respiratory infection</td>
<td>PFAS exposure was associated with high atopic dermatitis, rhinitis, asthma, allergy, respiratory tract infections, and reduce pulmonary function.</td>
</tr>
<tr>
<td>[30] Kampouri</td>
<td>2018</td>
<td>Television watching, smoking, and breast feeding</td>
<td>Attention deficit hyperactivity disorder test</td>
<td>No smoking and breastfeeding were associated with low attention deficit hyperactivity disorder score.</td>
</tr>
<tr>
<td>[31] Clemente</td>
<td>2019</td>
<td>NO&lt;sub&gt;2&lt;/sub&gt; and PM&lt;sub&gt;15&lt;/sub&gt;</td>
<td>Leukocyte telomere length</td>
<td>NO&lt;sub&gt;2&lt;/sub&gt; and PM&lt;sub&gt;15&lt;/sub&gt; exposure was associated with short telomere length.</td>
</tr>
<tr>
<td>[32] Madhlooum</td>
<td>2019</td>
<td>NO&lt;sub&gt;2&lt;/sub&gt;, black carbon, PM&lt;sub&gt;10&lt;/sub&gt; and PM&lt;sub&gt;2.5&lt;/sub&gt;</td>
<td>Systolic and diastolic blood pressure</td>
<td>Air pollution was associated with high systolic and diastolic blood pressure.</td>
</tr>
<tr>
<td>[33] Philippat</td>
<td>2019</td>
<td>Phthalate and phenol in urine</td>
<td>Ratio of placenta and birth weight</td>
<td>Phthalate exposure was associated with low placental weight and placent-to-birth weight ratio.</td>
</tr>
<tr>
<td>[34] Shah</td>
<td>2020</td>
<td>Lead, mercury, manganese, cadmium, and PM</td>
<td>Head circumference, weight, mental and physical development index, behavioral problems, intelligence quotient, autistic behavior, and atopic dermatitis</td>
<td>Heavy metal and air pollutant exposure was associated with low birth weight, low cognition, high atopic dermatitis, and high behavioral problems.</td>
</tr>
</tbody>
</table>

BPA; bisphenol A; BPB; bisphenol B; BPF; bisphenol-F; BP-3; benzophenone-3; 2,4-DCP; 2,4-dichlorophenol; 2,5-DCP; 2,5-dichlorophenol; DDE; 1,1-dichloro-2,2-bis (p-chlorophenyl) ethylene; FT3: free triiodothyronine; FT4: free thyroxine; MPB: methylparaben; NO<sub>2</sub>: nitrogen dioxide; NOx: nitrogen oxides; PCB: polychlorinated biphenyls; PFAS: perfluoralkyl substance; PFOA: perfluorooctanoic acid; PFNA: perfluorononanoic acid; PFOS: perfluorooctanesulfonic acid; PFOSA: perfluorooctanesulfonamide, PFUnDA: perfluoroundecanoic acid; PM: particulate matter; PPB: propylparaben; SHBG: sex-hormone-binding globulin; TCS: triclosan; T4: total thyroxine; TSH: thyroid-stimulating hormone.
본 연구에서는 태아오산, BPA, 프탈레이트, 트리클로란, 베타, 벤조페놀, 파라렌, 과화학물질 등을 임부의 소변, 혈액, 임부가 마시는 식수, 재배웠을 때, 자녀의 소변에서 농도를 겸사하여 [22,24,25,28,29,33] 생리적 지표로 활용하였으며, 임부의 EDCs 노출을 객관적으로 평가할 수 있다는 장점이 있었다.

둘째, 연구를 3세에서 두 번째로 많은 공기오염 물질은 직경이 10 µm 이하인 미세먼지 particulate matter 10 (PM10)과 직경이 2.5 µm 이하인 초미세먼지 PM2.5로 주로 측정하며, 배기가스로 인한 주 요원인 이산화질소 (NO2), 질소산화물 NOX (nitrogen dioxides), 탄소 (black carbon)로 측정하였다 [26,27,31,32,34]. 장 공동 등 중 다의 연구에서는 [26,27,31,32,34] 오염 물질의 농도를 측정하기 위하여 인공위성 대기 질 정보, 도로교통 정보의 오염 물질 농도, 거주지에서 주요 도로와의 거리 등의 측정법을 사용하였다. 이들 연구들은 거주지의 대기 질 측정을 하였으므로, 간접적인 기구는 객관적 차지로 평가하였다는 장점이 있다.

셋째, 연구를 3세에서 환경오염 물질로 측정한 임부의 증후군 노출은 남이 가장 많았으며, 수온, 맹관, 카드뮴에 관심을 가지고 연구하였다 [21,28,34]. 유휴산 출산 코호트는 국가 간 자료를 바이오뱅크에서 통합 관리하고 있다. 5개 국가에서 유전자 분석을 통한 결과, 측정은 중심과 일정하게 관리되고 있다. HELIX (Human Early Life Exposome)가 유럽연합 6개 국가 코호트들의 증후군 노출과 모아의 생리적 지표를 활용하였으며, 한국의 출산 코호트인 MOCEH (Mothers and Children’s Environmental Health Study)에서도 [21,34] 한국 전개 코호트들이 임부의 황중 난, 수온 등의 증후군 노출도 재활용 증후군 농도 측정결과 등을 활용하였다.

본 연구에서 고찰된 모야의 환경적 건강에 대한 출산 코호트의 결과는 모야 자녀의 부정적 건강으로 도출되었다. 모아의 건강 결과에 초점을 맞추어 논의를 하기로 한다. 2세, 임부의 환경오염 물질 노출은 모야의 제태기기간 감소, 태아 무게 감소, 성 후위 감소, 성후위환경 간절 글로불린 감소의 신체적 건강문제와 관련이 있다는 점이다. 임공에서 자녀에게는 임부의 환경오염 물질 노출이 증가함에 따라, 서기로도 증가할 것인 것으로 보아 모야의 환경오염 물질 노출 정도가 심각할 수 있다 [28]. 자녀의 공기오염 물질 노출과 상관도, 하혈성, 배기가시의 관련성에 대한 근거도 제시하였다 [26,29]. 임공 2세의 질환가스 노출 7-8세는 자녀의 반복된 하혈성력과 알려진 민감성을 높이고 강제탈습상황(forced expiratory flow) 25-75% 감소시키는 것으로 나타나 호흡기제 감염 및 배기가시 저하가 장기적으로 관련을 알 수 있다 [29].

자녀에게 미치는 건강 결과는 코호트 연구기간이 최대 12년까지 이루어진 것을 보아 임부의 환경오염 물질 노출의 결과가 자녀의 전반적인 건강에 미치는 영향이 장기적이다 [28]. 다음은 임부의 질환 노출이 8세 자녀의 혈액의 DNA 검사 결과 백혈구 세포 호르몬과 관련이 있는 연구이다. [31] 부정적인 결과가 영구적 영향을 미칠 수도 있을음을 알 수 있다. 환경오염 물질 노출의 자녀 건강에 보호작용을 간접적으로 확인할 수 있는 바로는 큰 도로로부터의 거리가 2배 빠져있을수록 LTL의 길이가 1.6% 증가하였다는 점이다 [31]. 또한 연구에서는 거주지 5 km 이내에 농단지가 있는 경우 자녀의 수축기 혈압이 1.2 mmHg 감소하고, 이완기 혈압도 1.2 mmHg 감소하여 보호 효과가 있는 것으로 나타났다 [35].
nant[32]. 업무의 난 노출은 24개월 여의 체중을 0.28 kg 감소시키고 신장을 0.51 cm 감소시켜 신체 성장에 영향을 미치는 것으로 나타났으나, 업무가 칼슘 섭취를 한 경우 보호 효과가 나타났으므로 업무의 식이에 따라 자신의 건강 보호 효과가 나타날 수 있음을 알 수 있다[21]. 업무가 흡연을 하지 않고, 모유 수유를 한 경우에 도 자신의 주의력결핍중상증후군 점수가 낮게 나타나 업무의 간지가 자신의 건강 결과에 보호작용을 하게 되므로[30]. 업무의
생활습관과 건강행위가 자신의 환경적 간접요인을 항상시킬 수 있을 것이다.

셋째, 자녀의 인지적 성장과 발달에 미치는 영향이 주기적으로 중단되며 업무의 환경오염 물질 노출이 자녀의 신경정신 발달에 부정적 영향을 미칠 수 있다는 연구 결과도 같은 맥락이다[10]. 모아보긴 전문가의
환경오염이 자녀의 호흡기, 면역체계, 신체 성장은 물론이고 신경발달의 문제도 초래할 수 있다는 연구 결과[30, 34] 주목하기도 필요가 있다. 독일의 어린이 코호트인 KUNO-Kids에서는 어린이의
환경오염 물질 노출뿐 아니라 가족의 생활환경을 다각적으로 분석하여 5,000~10,000 가족의 인구학적 특성, 임신시 생활습관, 건강행위, 의학적 기록, 가정환경, 정신적 상태를 괄호화하게
과거 추적하고 있으며, 세포의 손상을 일으키는지 분석하고 있다[37]. 그러므로 업무의 환경오염 물질 노출이 자녀의 발달 문제를 일으키는지 장기적 전향적 코호트 연구로서 생포학적 근거가 보강
될 것으로 보인다[37].

본 연구의 의의는 업무의 환경오염물질에 대한 건강결과에 대
하여 통합하여 제시함으로써 환경적 건강 및 모아보긴 전문가에게
업무 출산교실 등의 종래에 보건 심리에 적용할 수 있는 근거를 다
양하게 활용할 수 있는 자료를 제공하였다는 점이다. 모아 간호 연구
가에게는 업무의 환경적 건강에 대한 지식과 인식을 민감하게 가
질 수 있고, 미래 연구 방향에 영감을 부여할 수 있으며 연구가이
드라인의 역할을 할 수 있다는 점이다. 모아 간호 교육자들은 최근
부상하고 있는 환경적 건강 영역에 대한 통합적 제시로 전통적 모
아 간호의 영역에 환경적 건강 영역이 필요함을 인식할 수 있으며,
환경정책 전문가에게는 업무의 환경적 건강에 미래 세대에 미치는
영향을 고려하여 환경오염 물질로부터 업무를 보호할 수 있는 정책적
합리성을 제공하였다는 점이다. 그러므로 모아보긴 전문가는 업무
의 환경오염 물질 노출인 EDCs, 공기오염 물질, 중금속 등의 부정
적 모아 건강결과를 인식하고 개선해 나갈 필요가 있다.

본 연구의 제한은 체계적 고찰 연구로 영어와 한국어로 된 문
헌만을 대상으로 하여 선정 오류가 있을 수 있으며, 출산 코호트가
전 세계적으로 널리 연구되어 있어 출산되지 않고 진행 중인 연구
들에 대한 분석이 결여된다는 점이다. 또한 유럽의 출산 코호트
연구는 노출인자와 결과변수에 따라 다양한 조합으로 코호트 고유
명칭을 변경하여 사용하고 있어, 통합된 결과에서 중복 데이터가
포함되어 있을 가능성이 있다는 점이다. 결과변수의 다양성으로 인
하여 메타분석이 불가능하였다는 제한점도 있다.

미래의 코호트 연구에는 업무의 EDCs를 바탕으로 건강행위 및 습관
들의 생활양식을 반영하여 모체와 자녀의 건강에 미치는 영향을
조사하는 것을 제안한다. 또한 본 연구에서와 같이 다양한 생-물-
물-사행동 지표를 활용하여 소변, 혈중, 세척액, 모유의 EDCs 농도,
대기 질 지표를 활용한 미세먼지와 질산 농도, 큰 도로의 거리,
거주지의 녹지 비율 등을 측정하고, 자녀의 건강 지표로는 출생 시
체중, 산만 등의 객관적 지표를 활용하여 보다 높은 수준의 근거를
확보하는 것을 제안한다. 또한 전향적 연구를 통하여 추적조사가 장
기적으로 이루어져 미래 세대에 미치는 영향을 조사할 수 있도록
연구를 설계하고 프로토콜 연구 단계를 거쳐 기획한 것을 제언한다.

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**Authors' contributions**

Conceptualization and Formal analysis: Chae J, Kim HK; Funding acquisition: Kim HK; Writing-original draft: Kim HK; Writing-review & editing: Chae J, Kim HK.

**Conflict of interest**

The authors declared no conflict of interest.

**Funding**

This work was supported by a National Research Foundation of Korea (NRF) grant funded by the Korean government (MIST) (No. NRF 2020R1F1A1048449).

**Data availability**

Please contact the corresponding author for data availability.

**Acknowledgments**

None.
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https://doi.org/10.4069/kjwhn.2021.03.12
Comparison of the number of live births, maternal age at childbirth, and weight of live births between Korean women and immigrant women in 2018

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Purpose: This study compared maternal age at childbirth, the number of live births, and the weight of live births between Korean women and immigrant women using statistical data from the Republic of Korea for the period of 2008–2018.

Methods: The analysis was conducted using data from the Microdata Integrated Service of Statistics Korea (https://mdis.kostat.go.kr/index.do).

Results: Korean women and immigrant women showed a higher age at childbirth in 2018 than in 2008. The percentage of newborns of Korean women with a birth weight of less than 2.5 kg increased slightly for 3 consecutive years from 2016 to 2018, whereas for immigrant women, this percentage increased in 2017 compared to 2016 and then decreased again in 2018. Very low birth weight (less than 1.5 kg) became more common among immigrant women from 2016 to 2018. Birth at a gestational age of fewer than 37 weeks increased both among Korean and immigrant women from 2016 to 2018. In both groups, the percentage of women who had their first child within their first 2 years of marriage decreased from 2008 to 2018.

Conclusion: Immigrant women had higher birth rates than Korean women, while both groups showed an increasing trend in preterm birth. Greater attention should be paid to the pregnancy and birth needs of immigrant women, and steps are needed to ensure health equity and access in order to prevent preterm births. It is also necessary to identify factors that affect preterm birth and birth of very low birth weight infants among immigrant women in the future.

Keywords: Birth weight; Emigrants and immigrants; Gestational age; Live birth; Newborn infant

Introduction

Background and rationale
The total fertility rate in the Republic of Korea (hereafter, Korea) fell below the population replacement level of 2.0 in 1985 and steadily decreased to below 1.0, reaching as low as 0.92 in 2019 [1]. This trend is reflected in the decrease of number of live births from 465,892 in 2008 to 302,676 in 2019 [1]. Those
two tendencies are closely related to decreasing trends in the frequency of marriages in Korea and the late marriage phenomenon. Additionally, the crude marriage rate of Korean women decreased from 10.6 in 1980 to 4.7 in 2019 [1]. In 2019, women married at an average age of 30.59 years [2] and on average gave birth for the first time at age of 32.2 years [3]. The age at which a woman gives birth for the first time influences the health of the child. For instance, the rate of successful implantation of a fertilized ovum is reduced after 35 years of age. Women over the age of 35 years struggle to maintain pregnancy and face increased risks of congenital disabilities and fetal and maternal complications during pregnancy [4]. Therefore, such women are often unwilling to conceive second and third children due to the difficulties of raising children and the risk of pregnancy at an advanced maternal age. For this reason, the low birth rate in Korean society is expected to accelerate if women in Korea do not start bearing children at a younger age.

Despite the low birth rate in Korea, international marriages have become more widespread, and marriages between Korean men and foreign women accounted for 6.17% of marriages, on average, from 2010 to 2019 [5,6]. In 2019, the average age of immigrant women at marriage was 28.4 years [7], and immigrant women birthed their first child at an average age of 29.6 years [8]. Considering that Korean women gave birth to their first child at an average age older than 32 years in 2019 [3], immigrant women bear children at a younger age than Korean women. As a result, the health and social outcomes of immigrant women will have cultural and social effects on Korea. Another important consideration is health equity for immigrant women, as they have the right to receive childbirth-related care even though their nationality is or was not Korean.

In 2019, 5.90% of live births in Korea occurred among immigrant women [8]. Although the Multicultural Families Support Act was established in 2008 and three phases of multicultural family policy have been administered by the government since 2008, policies related to reproductive health continue to be lacking [9]. As a result, immigrant women face several difficulties in pregnancy and childbirth. First, immigrant women often experience pregnancy and childbirth before they can adapt to Korean society [10]. Furthermore, immigrant women rarely visit medical institutions due to a lack of medical insurance, high health insurance costs, or difficulties in visiting [11,12]. In fact, only 31.6% of immigrant women were found to have received pregnancy and childbirth support services [13]. Additionally, some immigrant women do not receive sufficient information about pregnancy and childbirth and do not have the opportunity to manage prenatal care [10-12]. Improper prenatal care affects women's ability to maintain pregnancy, increases the chance of pregnancy complications, and impacts babies' health [14]. Previous studies did not compare data related to childbirth between Korean women and immigrant women on the basis of complete survey data; instead, comparisons were made only by reasoning about non-representative data. A comparison of childbirth statistics among Korean women and immigrant women may reveal more accurate data related to childbirth among immigrant women, as well as hidden disparities, with potential implications for predicting the health of babies born to immigrant women. This comparison will help future researchers create interventional measures and policies for immigrant women's childbirth and health.

Objectives
The purpose of this study was to compare the number of live births, the weight and gestational period of birth, maternal age at childbirth, and the period from marriage to the first childbirth between Korean women and immigrant women using census data and household survey data.
microdata of Statistics Korea.

Ultimately, the study aimed to provide suggestions to promote safe and healthy pregnancy and birth among immigrant women by providing basic data for clinical practice and policy preparations. The specific objectives of this study were to compare the following four specific parameters between Korean and immigrant women: (1) the number of live births, (2) the number of live births by maternal age, (3) the weights of live birth and gestational age, and (4) the husband’s age and length of marriage at the first childbirth.

**Methods**

**Ethics statement:** This study was a secondary analysis of existing data and did not require institutional review board approval or informed consent.

**Study design**
This study was a chronological analytic study based on birth population data.

**Data sources**
The researchers used the 2008 to 2018 Census of Population Dynamics data from the Microdata Integrated Service (MDIS) provided by Statistics Korea [15]. Statistics Korea produces statistics on the population dynamics of births, deaths, marriages, and divorces, which are complete survey data (i.e., not sample survey data). Statistics Korea uses birth certificates and birth declaration forms to formulate statistics. For example, when a baby is born, a birth certificate issued by the health care provider is submitted to a local governance organization. The birth certificate includes information such as place of birth, gestational age, information on multiple fetuses, birth weight, and birth height. The birth report includes information on whether a person is married, the educational background of the parents, parents’ age, and parents’ nationality. The criteria for immigrant women in this study were limited to naturalized women or foreign nationals, and the researchers excluded cases of women with an unknown nationality from the analysis. The researchers used data from the MDIS, which contains nationality data of immigrant women [15], to analyze the 2008 to 2018 birth data.

**Study variables**
The study variables were as follows; (1) the number of live births and its composition ratio of Korean women and immigrant women, (2) the number and composition ratio of births by the age of Korean women and immigrant women, (3) the nationality of immigrant women who gave birth, (4) the average age at childbirth, (5) the average age of husbands at childbirth, (6) length of marriage at the first childbirth, (7) the number of live births according to the nationality of immigrant women, (8) the number of live births according to gestational age, and (9) birth weight.

**Definition of terms used in this study**
In the context of this study, the term “Korean women” refers to women who were born in Korea or women born abroad with Korean nationality. The term “immigrant women” refers to women who gave birth as either naturalized Koreans or foreign nationals. The term “live birth” refers to “the complete expulsion or extraction of a product of human conception from its mother irrespective of the duration of pregnancy, which—after such expulsion or extraction—breathes or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached.” Heartbeats are to be distinguished from transient cardiac contractions, and respirations are to be distinguished from fleeting respiratory efforts or gasps [16].

**Statistical methods**
The researchers completed comparative analyses and observational statistics. Since the data are complete survey data, descriptive statistics including frequency and percentage were used for the comparison. The researchers used IBM SPSS ver. 23.0 for Windows (IBM Corp., Armonk, NY, USA) for the statistical analysis.

**Results**

**Comparison of live births between Korean women and immigrant women**
The number of live births in Korea steadily decreased from 465,892 in 2008 to 326,822 in 2018, representing a 29.9% reduction (Supplementary Table 1). The number and percentage of births of Korean women declined from 2008 (n = 451,376, 96.9%) to 2018 (n = 311,418, 95.3%), whereas the number and percentage of births in immigrant women steadily increased from 2008 (n = 11,690, 2.5%) to 2018 (n = 15,216, 4.7%) (Figure 1 and Supplementary Table 1).

Two-thirds of immigrant women (n = 10,157, 66.7%) were from Vietnam (n = 6,411, 42.1%) and China (n = 3,746, 24.6%), followed by women from the Philippines (n = 1,243, 8.2%) and
and the percentage of older women increased in 2018 (Figure 2).

Only 23.1% of Korean women (n = 71,726) were younger than 30 years at childbirth in 2018, whereas this was the case for 52.0% of immigrant women (n = 7,913). Almost one-third of Korean women (n = 101,329, 32.5%) were 35 years old or older at childbirth in 2018, whereas only 17.1% of immigrant women (n = 2,596) were 35 years or older at the time of childbirth.

Comparison of birth weight and gestational age between Korean women and immigrant women

Among Korean women, the percentage of low birth weight (LBW) newborns (< 2.5 kg) increased from 2016 (5.9%) to 2018 (6.3%); however, among immigrant women, the proportion of LBW newborns increased from 2016 (5.3%) to 2017 (6.0%) and then decreased again in 2018 (5.6%). Although the percentage of very low birth weight (VLBW) newborns (< 1.5 kg) who were born to Korean women was similar from 2016 (0.7%) to 2018 (0.7%), the percentage of VLBW newborns in immigrant women steadily increased from 2016 (0.6%) to 2018 (0.8%). Among Korean women, the percentage of newborns with a birth weight of 4.0 kg and higher decreased from 2016 (3.3%) to 2018 (2.9%); however, the percentage of newborns in the same weight range who were born to immigrant women remained almost unchanged (Table 2).

The number of preterm births (i.e., newborns born before 37 weeks of gestation) increased from 2016 to 2018 among both Korean and immigrant women. This is applied to both singleton and multifetal pregnancies.
Comparisons of the age of Korean women, immigrant women, and their husbands at childbirth and length of marriage at the first childbirth

Supplementary Table 3 shows the average age of women and their husbands when they had their first, second, and third or later newborn. As expected, immigrant women were younger (28.2 years) than Korean women (31.6 years) when giving birth to their first child. Unsurprisingly, the husbands of immigrant women who were expecting their first child were typically older (39.6 years) than the husbands of Korean women (33.8 years).

In 2018, the percentage of immigrant women who had their first newborn within their first 2 years of marriage (n = 5,185, 65.4%) was higher than the corresponding percentage of Korean women (n = 99,644, 60.3%). However, the percentage of immigrant women who had their first newborn within 2 to 3 years after marriage (n = 1,676, 21.1%) was lower than the corresponding percentage of Korean women (n = 43,126, 26.1%) (Supplementary Table 3 and Figure 3). For both Korean and immigrant women, the percentage of women who had their first child within the first 2 years of marriage decreased in 2018 compared to
2008. In contrast, the percentage women who had their first child after more than 2 years of marriage increased in 2018 among both Korean and immigrant women (Supplementary Table 3 and Figure 3).

**Discussion**

Although the number of babies born in Korea has decreased, the proportion of live births by immigrant women has increased. The age at childbirth among immigrant women is mostly from 20 to 35 years. The rate of high-risk births, such as preterm births and VLBW newborns (less than 1.5 kg) also increased among immigrant women.

The number of live births among Korean women has continued to decline, and the number of babies born to immigrant women also decreased since 2012 (Supplementary Table 2); however, the rate of this decrease was lower among immigrant women than among Korean women. Thus, these findings reflect an increase in the proportion of live births among immigrant women out of all live births in Korea. This increase in the proportion of live births among immigrant women in Korea implies that Korea will soon become a multicultural society, with people of non-Korean origin accounting for over 5% of the population; in fact, this change is nearly reality, as 4.9% of Korea’s population was composed of people of non-Korean origin in 2019 [17]. The increase in the number of live births among immigrant women has contributed to the quantitative increase of the Korean population; however, previous studies reported that immigrant women struggled to manage their pregnancy and childbirth-related health. Immigrant women are not adequately informed about pregnancy and childbirth due to difficulties in communication, an inability to adapt to unfamiliar hospital systems, and frequent experiences of discrimination during pregnancy and childbirth [11,12].

Korea has a high number of Vietnamese and Chinese immigrant women; thus, Korean healthcare providers should offer more educational materials and pregnancy and childbirth programs for this population [18]. While efforts have been made to assist Cambodian immigrant women to conceive, give birth, and adapt to Korean society [19], Cambodian immigrant women account for only 2.5% of all immigrant women and 4.8% of live births among all immigrant women in Korea. Therefore, it is necessary to improve the quality of pregnancy and childbirth management of all immigrant women by facilitating immigrant women’s adaptation to the Korean medical system and establishing measures to ensure proper communication with medical personnel [11]. These steps will be possible through policy support within the medical system. The third phase of the multicultural family policy focuses on social and economic participation as well as support of children’s growth [9]. Such policy and actual programs also need to be developed and applied in both community and health care settings to have meaningful outcomes. Researchers must also identify the specific needs and cultural characteristics of pregnancy and childbirth of immigrant women according to their country of origin. Researchers and healthcare providers must further develop pregnancy and childbirth education materials and strengthen support services for immigrant women to promote health equity and ensure a

![Figure 3. Distribution of length of marriage at the first childbirth in 2008 and 2018.](https://doi.org/10.4069/kjwhn.2021.03.15)
healthy next generation of Koreans.

The study results revealed that the proportion of VLBW newborns who were born to immigrant women increased steadily from 2016 to 2018. Furthermore, the birth rate of infants born under 37 weeks of gestation increased from 2016 to 2018, especially among immigrant women. Additionally, the preterm birth rate of singletons born to immigrant women has continued to increase in comparison to Korean women. Infants born to immigrant women at university hospitals had an average gestation period of 35 weeks, and the majority of children were underweight (less than 2.5 kg) [14]. International reports, according to which immigrant women often give birth to underweight babies [11,20], suggest that it is not easy for immigrant women to manage pregnancy and childbirth due to language and cultural differences. Immigrant women are often within a low socioeconomic bracket, have difficulties accessing medical facilities, and are at risk for physical abuse, cultural maladjustment, and exposure to various preterm birth-related risk factors such as preconception malnutrition and pregnancy-related diseases [21].

Furthermore, VLBW babies often suffer from neurological disorders and have a high mortality rate [22]. Mothers of LBW newborns can experience distress [23] and child-rearing stress [24]; thus, women of low-weight babies often need child-rearing support. Convenient access to the medical system will (1) allow all immigrant women to receive prenatal care, (2) reduce the birth rate of underweight infants, and (3) increase the live birth rate after 37 weeks of gestation. Healthcare providers who identify the risk factors of childbirth by nationality and devise interventions that correspond to immigrant women's cultural characteristics can improve the quality of pregnancy and childbirth among immigrant women.

In 2018, 81.6% of immigrant women gave birth between the ages of 20 and 35 years and were consequently at a lower risk for pregnancy complications involving both the mother and fetus. Among immigrant women, the period of time between the date of marriage and the birth of their first child increased by more than 2 years from 2008 to 2018. However, in 2018, 65.4% of immigrant women still gave birth to their first baby within less than 2 years of marriage, meaning that these women had not adapted to Korean society before birthing their first child. Immigrant women must adapt to daily life during pregnancy, nutrition management, postpartum mental adjustment, and infant care; however, prior studies have reported that only 31.7% received prenatal support services due to challenges in communicating in Korean and cultural adaptation [18,20]. Furthermore, pregnancy and childbirth support services are especially urgent for immigrant women given that the spouse’s age significantly affects the outcome of childbirth [19,25]. Immigrant women’s period of adaptation to Korean society and culture should be facilitated through stronger societal and policy support, especially before they need prenatal and perinatal support services. Such support will provide the opportunity for all immigrant women to receive pregnancy and childbirth support services.

This study focused on birth data and as such, did not include an analysis of prenatal care or medical records. Therefore, the researchers were limited to using the statistical data presented in this study to analyze immigrant women’s demographic characteristics and their associations with prenatal care and high-risk pregnancy complications. Future researchers should identify the factors influencing the birth of immigrant women and the birth of VLBW children to provide a basis for suggesting interventional plans. Another limitation of the study was not factoring in genetic characteristics, including sex, and physical features such as congenital abnormalities when comparing the weight of infants. In future studies, those factors need to be carefully considered when comparing weights among populations of different races or ethnicities.

In conclusion, childbirth among immigrant women contributes significantly to the quantitative improvement of the Korea’s population structure; however, immigrant women face many challenges to healthy pregnancy and childbirth management, necessitating several qualitative improvements. First, measures should be taken to enhance immigrant women’s adaptation to the Korean medical system and ensure adequate communication with medical personnel. Active support from health care workers and the provision of national-level services are needed. It is also necessary to identify the risk factors of childbirth by nationality and create interventions based on immigrant women’s cultural characteristics. Such improvements will contribute to safer pregnancy and childbirth among immigrant women, which will improve Korea’s population structure.

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Conflict of interest

Geum Hee Jeong has been the President of the Korean Society of Women Health Nursing since January 2020. She was not involved in the review process of this study. The authors declared no other conflict of interest.

Funding

This study was supported by the 2021 Policy Research Funding from the Korean Society of Women Health Nursing.

Data availability

Please contact the corresponding author for data availability.

Acknowledgments

None.

Supplementary materials

Further details on supplementary materials are presented online (available at https://doi.org/10.4069/kjwhn.2021.03.15).

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What influences aromatase inhibitor continuation intention among breast cancer survivors?

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**Purpose:** Aromatase inhibitors (AIs) are widely prescribed for postmenopausal women with breast cancer and are known to cause musculoskeletal pain. This study aimed to identify factors associated with AI continuation intention among breast cancer survivors (BCS).

**Methods:** A cross-sectional survey was conducted on 123 BCS (stages I–III), who had been taking AIs for at least 6 weeks. Participants were recruited from a cancer center in Goyang, Korea, from September to November 2019. Descriptive statistics, Welch analysis of variance, Pearson correlation coefficients, and simple linear regression were used for the analysis.

**Results:** Beliefs about endocrine therapy was a significant predictor of AI continuation intention (β=.66, p<.001). The majority of participants (87.0%) reported experiencing musculoskeletal pain since taking AIs and the score for the worst pain severity within 24 hours was 5.08±2.80 out of 10. Musculoskeletal pain, however, was not associated with AI continuation intention. Fear of cancer recurrence (FCR) was clinically significant (≥13) for 74.0% of the respondents (mean, 17.62±7.14). Musculoskeletal pain severity and pain interference were significantly associated with FCR (r=.21, p<.05; r=.35, p<.01, respectively). Pain interference was significantly associated with beliefs about endocrine therapy (r=−.18, p<.05).

**Conclusion:** AI continuation intention can be modified by reinforcing patients’ beliefs about endocrine therapy. Musculoskeletal pain may have a negative effect on beliefs about endocrine therapy and increase FCR among BCS. Thus, awareness of musculoskeletal pain during AI therapy should be raised and further research is required to develop multidisciplinary pain management strategies and clinical guidelines to reinforce beliefs about endocrine therapy.

**Keywords:** Aromatase inhibitor; Breast cancer; Medication adherence; Musculoskeletal pain

**Introduction**

Aromatase inhibitors (AIs) have been used as the first choice of adjuvant endocrine therapy for postmenopausal women over the last 15 years since they are more effective than tamoxifen for postmenopausal breast cancer, and AI prescriptions account for 64% of endocrine therapy among women with invasive breast cancer [1]. After menopause, estrogen production by the ovaries terminates and estrogen is synthesized by aromatase in peripheral tissues. Hence, suppression of estrogen is more effectively achieved by using AIs, as they primarily block most of the production of estrogen.

To take full advantage of endocrine therapy, it is important to take the medication regularly throughout the recommended pe-
Summary statement

- **What is already known about this topic?**
  Newly developed or aggravated musculoskeletal pain since taking aromatase inhibitors (AIs) is known to be the main cause of nonadherence of AIs in breast cancer survivors.

- **What this paper adds**
  While musculoskeletal pain was common and had negative effects on daily life, beliefs about endocrine therapy, and increased fear of cancer recurrence, it did not affect AI continuation intention. Beliefs about endocrine therapy was the only significant predictor of AI continuation intention.

- **Implications for practice, education, and/or policy**
  Nurses should regularly assess musculoskeletal pain and beliefs about endocrine therapy in patients taking AI and provide emotional support in addition to pain management.

period [2]. However, issues with endocrine therapy adherence remain an unsolved problem. Breast cancer survivors (BCS) make a decision to continue or discontinue AI therapy every day and can reverse their decision at any time. Beryl and colleagues observed adjuvant endocrine therapy adherence among 35 BCS for 280 ± 96 days. None of the patients started and continued medication based on a concrete decision, and only four patients were still taking the medication, without any reservations, at the final interview. Moreover, 68% of them stated that their decision could change at any time regardless of whether they were taking the medication [3]. This implies that assessing AI continuation intention is as important for maximizing AI adherence as assessing adherence itself. AI continuation intention refers to an intention to continue AI therapy and is conceptually mirrored by discontinuation intention, such as “uncertainty about persisting” [4] or “thought about stopping endocrine therapy” [5]. Since intention to take medication is a known predictor of medication adherence [6], it is expected that AI discontinuation can be prevented or altered by modifying or reinforcing intention during the decision-making process.

Newly developed or aggravated musculoskeletal pain, a major adverse effect of AI, is frequently reported as a cause of patient-driven AI discontinuation, unlike tamoxifen [7,8]. According to Lombard et al. [8], 82% of BCS taking AI as adjuvant endocrine therapy reported AI-associated musculoskeletal pain and 68% of nonadherent participants discontinued AI due to musculoskeletal pain. In Korea, a retrospective medical record study reported AI-associated arthropagia in 23% of BCS [9]. However, its relation to patient-driven discontinuation was not evaluated. Studies on AI adherence and AI-associated musculoskeletal pain have mainly been conducted in the United States, Europe, and Australia. Since musculoskeletal pain has been blamed for AI discontinuation, international research assessing the prevalence and risk factors of musculoskeletal pain has been actively conducted and is expanding to include the development of interventions to alleviate pain and improve the AI continuation rate [10]. Nevertheless, research on the self-reported incidence of musculoskeletal pain and its relation to AI continuation intention has not yet been conducted in Korea.

In addition to adverse effects, previous studies have found that endocrine therapy continuation was also associated with fear of cancer recurrence (FCR) [4] and beliefs about endocrine therapy [4,11,12]. Pain is known to amplify FCR in BCS [12] but can be negated by the adverse effects of endocrine therapy [4,11,15]. However, previous studies regarding beliefs about endocrine therapy were predominantly conducted among BCS with weak beliefs about endocrine therapy [4]. Beliefs about endocrine therapy has been reported to be the most powerful and important factor affecting the continuation of endocrine therapy [12] but can be negated by the adverse effects of endocrine therapy [4,11,15]. However, previous studies regarding beliefs about endocrine therapy and FCR among patients receiving AI therapy have yet to be elucidated.

Therefore, this study aimed to identify (1) whether AI continuation intention differed according to whether patients experienced newly developed or aggravated musculoskeletal pain since taking AIs; (2) the relationships among the main variables; and (3) factors associated with AI continuation intention.
Methods

Ethics statement: This study was approved by the Institutional Review Board of Korea National Cancer Center (No. NCC2019-0235). Informed consent was obtained from the participants.

Design and participants
This cross-sectional correlational research was conducted at a cancer center located in Goyang, Gyeonggi Province, Korea, from September 16 to November 14, 2019. The participants were recruited via convenience sampling among patients visiting the outpatient clinic of the center for breast cancer. Based on the findings of a previous study that AI-associated musculoskeletal pain started after 6 weeks on average [16], the inclusion criteria were as follows: (1) stage I–III breast cancer; (2) completed surgery, adjuvant chemotherapy, and radiation therapy; and (3) at least 6 weeks on AI medication [16]. BCS who were treated for other cancers and metastatic breast cancer (stage IV) were excluded to rule out other causes of musculoskeletal pain. The sample size needed for multiple linear regression, calculated using G*Power 3.1.9.2 (α error probability = .05, statistical power = 90%, effect size = .15 [17], and four predictors: pain severity [7,11], pain interference [11,18], FCR [4], and beliefs about endocrine therapy [4,12]), based on the literature was at least 108. Considering a 20% dropout rate, questionnaires were distributed to 129 BCS and 123 completed questionnaires without missing information were included in the analyses.

Assessment tools
A self-reported questionnaire including AI continuation intention, musculoskeletal pain, FCR, beliefs about endocrine therapy, and general characteristics was used. Permission to use each assessment tool was obtained from both the developers and the authors of adapted/translated versions by e-mail.

Aromatase inhibitor continuation intention
A five-item measure of intentions to take cardiac medication [6] was modified to evaluate AI continuation intention, with permission from the developer. For example, the item “I plan to take regular medication in the future” was modified to “I plan to continue endocrine therapy in the future.” The five items evaluated intentional plan to take medication, intention to persist and adhere with the medication, and the perceived possibility of taking the medication. Each item is rated on a 5-point scale (1–5), with a possible total score ranging from 5 to 25, and higher scores indicate greater intention. Cronbach’s α was .88 at the time of development [6] and .98 in this study.

Musculoskeletal pain
Musculoskeletal pain was evaluated with the Korean version [19] of the Brief Pain Inventory-Short Form (BPI-SF) [20]. Pain severity (four items) and pain interference (seven items) are rated on an 11-point scale (0–10), with a higher score indicating more severe pain and pain interference. Cronbach’s α was .80 to .92 at the time of development [20] and was .89 for pain severity and .94 for pain interference in this study.

Fear of cancer recurrence
FCR was evaluated with the Fear of Cancer Recurrence Inventory-Short Form (FCRI-SF) [21] Korean version [22], which consists of nine items rated on a 5-point scale (0–4), with a possible total score range of 0 to 36 and a higher score indicating a greater FCR. A cutoff score of 13 or higher is considered clinically significant [21]. Cronbach’s α was .89 at the time of development [23], .77 in a study with a Korean population [22], and .83 in this study.

Beliefs about endocrine therapy
The 22-item Endocrine Therapy Beliefs Scale [24], which was developed in Korean, was used to measure the cognitive response to endocrine therapy. It consists of four subcategories: perceived control (11 items), perceived concerns (four items), perceived benefits and trust (five items), and perceived logic (two items). Each item is rated on a 4-point scale (1–4), with a possible total score range of 22 to 88, and a higher score indicates a stronger beliefs about endocrine therapy. Cronbach’s α was .91 at the time of development [24] and .90 in this study.

General characteristics
A short questionnaire was developed to collect information about demographic and disease-related characteristics relevant for AI adherence [4,12]. General characteristics included age, cancer stage, breast cancer treatment, time since menopause, body mass index, and history of musculoskeletal disease.

Data analyses
The data were analyzed using IBM SPSS ver. 25.0 (IBM Corp., Armonk, NY, USA). Differences in AI continuation intention according to musculoskeletal pain were examined using Welch analysis of variance. Correlations among variables were examined using Pearson correlation coefficients, and regression analysis was done to identify factors influencing AI continuation intention.
Results

General characteristics
The demographic and clinical characteristics of the 123 respondents are shown in Table 1. The mean age of the participants was 58.06 ± 7.41 years, and they ranged in age from 30 to 80 years old. Among AI medications, letrozole (n = 89, 72.4%) was prescribed twice as often as anastrozole (n = 34, 27.6%), reflecting clinical practice. The mean duration of AI medication was 2.55 ± 1.54 years and two participants had been taking AI for longer than 5 years. More than one-third of participants (n = 44, 35.8%) had been diagnosed with musculoskeletal diseases and 27 of them (61.4%) reported that the diagnosis was made after initiating AI medication.

Aromatase inhibitor continuation intention
The mean score of AI continuation intention was 22.28 ± 4.34, which is interpreted as high (Table 2).

Musculoskeletal pain, fear of cancer recurrence, and beliefs about endocrine therapy
In total, 107 participants (87.0%) reported that they experienced newly developed or aggravated musculoskeletal pain after the commencement of AI. The score for the worst pain within 24 hours was 5.08 ± 2.80, indicating moderate pain requiring active pain management, and the mean score for the worst, the

Table 1. General characteristics of the participants (N=123)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Categories</th>
<th>Mean ± SD (range)</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (year)</td>
<td>58.06 ± 7.41 (30–80)</td>
<td>13 (10.6)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 50</td>
<td>13 (10.6)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>50–59</td>
<td>65 (52.8)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥ 60</td>
<td>45 (36.6)</td>
<td></td>
</tr>
<tr>
<td>Cancer stage</td>
<td>Stage I</td>
<td>55 (44.7)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stage II</td>
<td>41 (33.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stage III</td>
<td>27 (22.0)</td>
<td></td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>Yes</td>
<td>68 (55.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>55 (44.7)</td>
<td></td>
</tr>
<tr>
<td>Radiation therapy</td>
<td>Yes</td>
<td>120 (97.6)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>3 (2.4)</td>
<td></td>
</tr>
<tr>
<td>Type of AI</td>
<td>Letrozole</td>
<td>89 (72.4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anastrozole</td>
<td>34 (27.6)</td>
<td></td>
</tr>
<tr>
<td>Duration of medication (year)</td>
<td>2.55 ± 1.54</td>
<td>25 (20.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 1</td>
<td>25 (20.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1–2.99</td>
<td>47 (38.2)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3–4.99</td>
<td>49 (39.8)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥ 5</td>
<td>2 (1.6)</td>
<td></td>
</tr>
<tr>
<td>Previous use of tamoxifen</td>
<td>No</td>
<td>107 (87.0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>16 (13.0)</td>
<td></td>
</tr>
<tr>
<td>Time since menopause (year)</td>
<td>8.50 ± 6.92</td>
<td>42 (34.1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 5</td>
<td>42 (34.1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5–9</td>
<td>40 (32.5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥ 10</td>
<td>41 (33.3)</td>
<td></td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>23.49 ± 3.10</td>
<td>63 (51.2)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Normal (&lt; 23)</td>
<td>63 (51.2)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Overweight (23–24.9)</td>
<td>22 (17.9)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Obese (≥ 25)</td>
<td>38 (30.9)</td>
<td></td>
</tr>
<tr>
<td>MSD</td>
<td>No</td>
<td>79 (64.2)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>44 (35.8)</td>
<td></td>
</tr>
<tr>
<td>Diagnostic point of MSD</td>
<td>Before AI</td>
<td>17 (38.6)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>After AI</td>
<td>27 (61.4)</td>
<td></td>
</tr>
</tbody>
</table>

AI: aromatase inhibitor; MSD: musculoskeletal disease.
least, the average, and present pain was 3.29 ± 2.12, indicating mild pain. Musculoskeletal pain was most commonly reported as interfering with mood (4.39 ± 2.90), sleep (4.26 ± 3.32), and general activities (4.11 ± 3.28) (Table 2).

The mean score for FCR was 17.62 ± 7.14, and 74.0% of participants had clinically significant FCR (≥ 13). The mean score for beliefs about endocrine therapy was 67.54 ± 9.49, which is interpreted as high (Table 2).

### Aromatase inhibitor continuation intention according to musculoskeletal pain

To evaluate the difference in AI continuation intention according to pain severity, the mean scores for the worst, the least, the average, and present pain were classified into three groups; none (score of 0), mild (1–3), and moderate (4–7). There was no mean score greater than 7. The scores for the worst pain within 24 hours were classified into four groups—none (score of 0), mild (1–3), moderate (4–7), and severe (8–10) [25]—because AI continuation intention may be most strongly affected by the worst pain, and the use of a single item for the worst pain severity is also supported by the BPI user guide [26]. The analysis showed that there were no significant differences in AI continuation intention between the groups (Table 3).

### Relationships among aromatase inhibitor continuation intention, musculoskeletal pain, fear of cancer recurrence, and beliefs about endocrine therapy

The correlations among variables are shown in Table 4. A moderate correlation was found between AI continuation intention and beliefs about endocrine therapy (r = .66, p < .01). FCR had a weak relationship with both pain severity (r = .21, p < .05) and pain interference (r = .35, p < .01). Beliefs about endocrine therapy had a weak relationship with pain interference (r = -.18, p < .05).

### Beliefs about endocrine therapy as a factor influencing aromatase inhibitor continuation intention

Beliefs about endocrine therapy was the only factor that influenced AI continuation intention. The regression model was statistically significant (F = 95.66, p < .001), explaining 44% of AI continuation intention (Table 5). The Durbin-Watson value was 2.072, implying independence of the residual without autocorrelation. The normality of residuals was examined using a histogram and a normal probability plot.

### Discussion

Beliefs about endocrine therapy was the only factor with a statis-

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**Table 2. Aromatase inhibitor continuation intention, musculoskeletal pain, fear of cancer recurrence, and beliefs about endocrine therapy (N=123)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Possible score</th>
<th>Mean ± SD</th>
<th>n (%)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>AI continuation intention</td>
<td>5–25</td>
<td>22.28 ± 4.34</td>
<td>123 (100)</td>
<td>5–25</td>
</tr>
<tr>
<td>Musculoskeletal pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain severity†</td>
<td>0.25–10</td>
<td>3.29 ± 2.12</td>
<td>107 (87.0)</td>
<td>0.50–7.00</td>
</tr>
<tr>
<td>Worst pain during the last 24 hours</td>
<td>1–10</td>
<td>5.08 ± 2.80</td>
<td></td>
<td>1–10</td>
</tr>
<tr>
<td>Average pain</td>
<td>0–10</td>
<td>3.96 ± 2.36</td>
<td></td>
<td>1–8</td>
</tr>
<tr>
<td>Least pain during the last 24 hours</td>
<td>0–10</td>
<td>2.17 ± 1.91</td>
<td></td>
<td>0–6</td>
</tr>
<tr>
<td>Present pain</td>
<td>0–10</td>
<td>1.93 ± 2.57</td>
<td></td>
<td>0–9</td>
</tr>
<tr>
<td>Pain interference‡</td>
<td>0.14–10</td>
<td>3.82 ± 2.66</td>
<td>107 (87.0)</td>
<td>0.14–9.29</td>
</tr>
<tr>
<td>Mood</td>
<td>0–10</td>
<td>4.39 ± 2.90</td>
<td></td>
<td>0–10</td>
</tr>
<tr>
<td>Sleep</td>
<td>0–10</td>
<td>4.26 ± 3.32</td>
<td></td>
<td>0–10</td>
</tr>
<tr>
<td>General activities</td>
<td>0–10</td>
<td>4.11 ± 3.28</td>
<td></td>
<td>0–10</td>
</tr>
<tr>
<td>Usual work</td>
<td>0–10</td>
<td>4.06 ± 3.21</td>
<td></td>
<td>0–10</td>
</tr>
<tr>
<td>Enjoyment of life</td>
<td>0–10</td>
<td>3.81 ± 3.29</td>
<td></td>
<td>0–10</td>
</tr>
<tr>
<td>Walking ability</td>
<td>0–10</td>
<td>3.38 ± 3.15</td>
<td></td>
<td>0–10</td>
</tr>
<tr>
<td>Interpersonal relationships</td>
<td>0–10</td>
<td>2.75 ± 3.24</td>
<td></td>
<td>0–10</td>
</tr>
<tr>
<td>Fear of cancer recurrence</td>
<td>0–36</td>
<td>17.62 ± 7.14</td>
<td>123 (100)</td>
<td>4–35</td>
</tr>
<tr>
<td>Clinical level (≥ 13)</td>
<td>13–36</td>
<td></td>
<td>91 (74.0)</td>
<td></td>
</tr>
<tr>
<td>Nonclinical level</td>
<td>0–12</td>
<td></td>
<td>32 (26.0)</td>
<td></td>
</tr>
<tr>
<td>Beliefs about endocrine therapy</td>
<td>22–88</td>
<td>67.54 ± 9.49</td>
<td></td>
<td>38–88</td>
</tr>
</tbody>
</table>

Pain severity=(worst+least+average+present pain)/4; Pain interference=sum of seven-item scores/7.

AI: Aromatase inhibitor
Aromatase inhibitor continuation intention

Seo YK et al.  •  Aromatase inhibitor continuation intention

Aromatase inhibitor continuation intention in this study was not significantly different from that of BCS who reported newly developed or aggravated musculoskeletal pain since taking AI. This result is comparable to results of previous studies, conducted among BCS either taking AI or tamoxifen, according to which beliefs about endocrine therapy was the most powerful factor affecting medication adherence [4,12] and was associated with intention to take endocrine therapy [27]. It is also consistent with the finding of a qualitative study that breast cancer patients continuously reassess the necessity of endocrine therapy, its risks, and other options during endocrine therapy, and if they become doubtful about its efficacy they are likely to make a decision to stop taking the medication [3]. The findings of this study thus underscore the need to develop interventions for maintaining and reinforcing beliefs about endocrine therapy during the period which it is prescribed, which is usually 5 years. Further studies that can identify intervention time points, methods, and screening techniques for vulnerable populations will also be beneficial.

The majority of the participants (87%) experienced newly developed or aggravated musculoskeletal pain after taking AI, which is a higher proportion than found in a previous study (73.7%) [28], and the worst pain severity within 24 hours was 5.08 ± 2.80, suggesting the need for active pain control management. Musculoskeletal pain severity showed a significant positive correlation with pain interference and FCR. Thus, a multidisciplinary approach is needed for pain management for newly developed or aggravated musculoskeletal pain after taking AI.

Nevertheless, no significant relationship was found between musculoskeletal pain and AI continuation intention, unlike previous studies conducted in other countries [7,8,18]. In a study done in the USA, musculoskeletal symptoms were highly associated with early discontinuation of AI (hazard ratio, 4.39; 95% CI, 2.4–8.02; p < .0001) [18] and in a study done in Australia, 68% of BCS reported AI discontinuation due to AI-related musculoskeletal pain [8]. In addition, a prior study done in the USA reported that a moderate or higher worst pain score (> 4 on the BPI) was a predictor of premature discontinuation of AIs [7]. The reason for this discrepancy may be related to the high levels of AI continuation intention in the present study, the difficulty in making direct comparisons due to prior studies’ focus on continuation behaviors rather than intention, and the discrepancy between intention and behavior. In a previous study conducted to identify predictors of thoughts about stopping endocrine treatment (either tamoxifen or AIs), 30% of the participants reported that AI continuation intention was not significantly different from that of BCS who reported newly developed or aggravated musculoskeletal pain since taking AI.

Table 3. Differences in aromatase inhibitor continuation intention according to pain severity (N=123)

<table>
<thead>
<tr>
<th>Pain severity Categories (score)</th>
<th>n (%)</th>
<th>Mean ± SD</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>None (0)</td>
<td>19 (15.4)</td>
<td>21.95 ± 5.46</td>
<td>0.37</td>
<td>.689</td>
</tr>
<tr>
<td>Mild (1–3)</td>
<td>55 (44.7)</td>
<td>22.65 ± 3.62</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate (4–7)</td>
<td>49 (39.8)</td>
<td>21.98 ± 4.67</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total mean†</td>
<td></td>
<td>21.98 ± 4.67</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Worst pain severity</td>
<td></td>
<td>22.65 ± 3.62</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not at all (0)</td>
<td>17 (13.8)</td>
<td>22.41 ± 5.32</td>
<td>0.104</td>
<td>.380</td>
</tr>
<tr>
<td>Mild (1–3)</td>
<td>30 (24.4)</td>
<td>23.30 ± 3.28</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate (4–7)</td>
<td>49 (39.8)</td>
<td>22.14 ± 3.99</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe (8–10)</td>
<td>27 (22.0)</td>
<td>21.30 ± 4.34</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Number of severe pain category (score≥7) in total mean pain is zero. †Total mean=(worst+least+average+present pain)/4.

Table 4. Correlations among study variables (N=123)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pain severity</th>
<th>Pain interference</th>
<th>Fear of cancer recurrence</th>
<th>Beliefs about endocrine therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain severity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain interference</td>
<td>.48**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fear of cancer recurrence</td>
<td>.21*</td>
<td>.35**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beliefs about endocrine therapy</td>
<td>-.05</td>
<td>-.18*</td>
<td>.09</td>
<td>1</td>
</tr>
<tr>
<td>AI continuation intention</td>
<td>-.03</td>
<td>-.04</td>
<td>.01</td>
<td>.66**</td>
</tr>
</tbody>
</table>

AI: Aromatase inhibitor.
*p<.05, **p<.01.

Table 5. Factors influencing aromatase inhibitor continuation intention (N=123)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model</th>
<th>B</th>
<th>SE</th>
<th>β</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>(constant)</td>
<td></td>
<td>1.73</td>
<td>2.12</td>
<td>.82</td>
<td>.82</td>
<td>.42</td>
</tr>
<tr>
<td>Beliefs about endocrine therapy</td>
<td></td>
<td>.31</td>
<td>.03</td>
<td>.66</td>
<td>9.78</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>F (p = 95.66 &lt;.001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B: Unstandardized; β: standardized coefficient.
ported that they considered discontinuing endocrine therapy in addition to the 36% of participants who had already stopped endocrine therapy, and symptom severity was most strongly associated with these thoughts [5]. A direct comparison is difficult because different measurement tools were used and 39% of participants in the previous study were premenopausal women, which may affect symptom severity. However, the intention to continue AIs among those who either discontinued or considered stopping endocrine therapy in that study [5] was presumably lower than this study’s level of 22.28 ± 4.34. Although previous studies [7,18] of AI (non)adherence focused on behavior rather than intention, an accurate identification of BCS who are indecisive about AI continuation would be helpful for preventing premature discontinuation and encouraging BCS to complete the therapy during the recommended period. Thus, further research should develop valid tools evaluating intention to continue endocrine therapy and seek to identify vulnerable populations. In addition, the discrepancy between intention and behavior may be relevant. In this study, AI continuation intention was measured instead of adherence (i.e., a behavioral variable), considering the lack of reliability and evidence regarding self-reported measures of medication adherence [29]. Although intention to take medication is a predictor of medication adherence [6], actual behavior can differ. Thus, other factors should be considered when using intention as a predictor of behavior, and further studies with a longitudinal design are required to evaluate the predictive power of intention on adherence in the context of endocrine therapy with AI.

A significant issue is that 74.0% of participants reported clinically significant FCR (≥13) and the average FCR score (17.62 ± 7.14) was also higher than the result of a previous study conducted among patients taking AIs (14.8) [14]. Despite the moderate pain severity, the finding of a high degree of FCR in this study is worthy of notice. FCR also had a weak relationship with pain severity and pain interference. This result implies that strategies to deal with FCR should be included in developing multidisciplinary nursing interventions for BCS. Although FCR in this study was higher than found in a previous study, it had no effect on AI continuation intention, which may be related to the high level of beliefs about endocrine therapy found in this study. Since it has been noted that FCR plays a role in endocrine therapy continuation among BCS with low levels of beliefs about endocrine therapy [4], further research should explore this interplay.

This cross-sectional study has several limitations. First, generalizability is limited as participants were recruited via convenience sampling from a single institution. Second, the discrepancy between AI continuation intention and AI adherence behavior was not evaluated. Although intentions explain behaviors to some extent, the predictability of actual AI continuation was not evaluated, as AI-taking behavior was not the focus of this study. Third, measurement issues may need to be considered, as the BPI-SF was not specifically developed to assess AI-related musculoskeletal pain and BCS often experience upper body discomfort and neuropathy after surgery, chemotherapy, and radiation therapy. While the researcher emphasized the aim of assessing newly developed or aggravated musculoskeletal pain after taking AI to improve the accuracy of the assessments, it is possible that the measurements may have only partially captured the actual pain that BCS experienced.

Despite the limitations, this study is meaningful from two perspectives. The findings present the current status of AI-related musculoskeletal pain, as self-reported by Korean BCS; to our knowledge, this is a novel contribution. Second, the evaluation of the relationship of musculoskeletal pain to AI continuation intention in a Korean population is also significant, since data indicating low AI adherence have been published from other countries, but the relevance of those findings to nursing practice in Korea has not been clear. This study’s finding can improve clinicians’ understanding of musculoskeletal pain during AI therapy and can be used to develop nursing interventions for musculoskeletal pain management and improving endocrine therapy continuation intention.

In conclusion, beliefs about endocrine therapy was a significant predictor of AI continuation intention, whereas musculoskeletal pain during AI therapy did not negatively affect AI continuation intention. The incidence of the pain and the pain severity, however, was high enough to require active pain management in this sample of BCS. Pain also had a moderate positive relationship with pain interference, and had a positive, albeit weak, relationship with FCR. Thus, there is a need to raise awareness and educate patients about the incidence and the severity of AI-related musculoskeletal pain and its impact, through educational programs or by distributing educational resources. Nursing interventions that support and reinforce beliefs about endocrine therapy are needed, and incorporating multidisciplinary pain management may be beneficial.

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Authors’ contributions

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Conflict of interest

Sue Kim has been editor-in-chief of the Korean Journal of Women Health Nursing since January 2020. She was not involved in the review process of this manuscript. Otherwise, there was no conflict of interest.

Funding

None.

Data availability

Please contact the corresponding author for data availability.

Acknowledgments

None.

References


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<table>
<thead>
<tr>
<th>Element</th>
<th>Example 1</th>
<th>Example 2</th>
<th>Example 3</th>
<th>Example 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will individual participant data be available?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>What data in particular will be shared?</td>
<td>All individual participant data collected during the trial, after deidentification.</td>
<td>Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).</td>
<td>Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).</td>
<td>Not available</td>
</tr>
<tr>
<td>What other documents will be available?</td>
<td>Study protocol, statistical analysis plan, informed consent form, clinical study report, analytic code</td>
<td>Study protocol, statistical analysis plan, analytic code</td>
<td>Study protocol</td>
<td>Not available</td>
</tr>
<tr>
<td>When will data be available (start and end dates)?</td>
<td>Immediately following publication. No end date.</td>
<td>Beginning at 3 months and ending at 5 years following the article publication.</td>
<td>Beginning at 9 months and ending at 36 months following the article publication.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>With whom?</td>
<td>Anyone who wishes to access the data.</td>
<td>Researchers who provide a methodologically sound proposal.</td>
<td>Investigators whose proposed use of the data has been approved by an independent review committee (“learned intermediary”) identified for this purpose.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>For what types of analyses?</td>
<td>Any purpose</td>
<td>To achieve aims in the approved proposal.</td>
<td>For individual participant data meta-analysis.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>By what mechanism will data be made available?</td>
<td>Data are available indefinitely at (link to be included).</td>
<td>Proposals should be directed to xxx@yyy. To gain access, data requestors will need to sign a data access agreement.</td>
<td>Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our University’s data warehouse but without investigator support other than deposited metadata.</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Data are available for 5 years at a third-party website (link to be included).</td>
<td>Information regarding submitting proposals and accessing data may be found at (link to be provided).</td>
<td></td>
</tr>
</tbody>
</table>

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Following the abstract, describe a summary statement on a separate page according to the following subheadings, with 30 words or less under each subtitle.

- What is already known about this topic?

Example: The 75 years and older age group, with its complex health needs, is likely to make up an increasing proportion of
the workload of accident and emergency strain the coming years.

- What this paper adds
  Example: An alcohol-based surgical hand rub is more effective than a 6-minute surgical hand scrub using 4% chlorhexidine gluconate in terms of microbial counts immediately after scrubbing.

- Implications for practice, education and/or policy
  Example: Parents’ ability and willingness to participate in their child’s care in the hospital should be thoroughly assessed and their participation needs to be supported.

Main Text

Maximum word count should be within 5,000 words, although less is preferred, excluding tables, figures, and references. The manuscript should be written on A4 sized paper, in Times New Roman 12-point font, double-spaced and have margins of at least one inch (2.54 cm). In general, the text should be organized under the following headings: Introduction, Methods, Results, and Discussion.

Introduction: Clearly state the need of this study and main question or hypothesis of this study. Summarize the literature review or background in the area of the study.

Methods: Present an “Ethics statement” immediately after the heading “Methods” in a boxed format.

Example 1:

**Ethics statement:** This study was approved by the Institutional Review Board of XXXX University (IRB-201903-0002-01). Informed consent was obtained from the participants.

Example 2:

**Ethics statement:** Obtaining informed consent was exempted by the Institutional Review Board (IRB) of YYYY University (IRB-201903-0002-01) because there was no sensitive information and the survey was anonymously treated.

Describe the study design, setting and samples, and measurements, procedure, analysis used.

Ensure correct use of the terms sex (when reporting biological factors) and gender (identity, psychosocial or cultural factors), and, unless inappropriate, report the sex or gender of study participants, the sex of animals or cells, and describe the methods used to determine sex or gender. If the study was done involving an exclusive population, for example in only one sex, authors should justify why, except in obvious cases (e.g., ovarian cancer). Authors should define how they determined race or ethnicity and justify their relevance.

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Discussion: Make discussions based only on the reported results. Describe conclusions and recommendations for further study needed. Do not summarize the study results.

Abbreviations: Use standard abbreviations and units recommended in the publication manual of the to the NLM Style Guide for Authors, Editors, and Publishers (2007), 2nd ed., National Library of Medicine, Bethesda, MD, USA (http://www.nlm.nih.gov/citingmedicine). Non-standard abbreviations should be defined the first time they appear in the text. At first usage, spell out terms and give abbreviations in parentheses. Thereafter, use only abbreviations. It is not necessary to spell out standard units of measure, even at first usage.

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