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3. Kuczmarski RJ, Ogden CL, Grammer-Strawn LM, Flegal KM, Guo SS, Wei R, et al. CDC growth charts: United States. Advance data from vital and health statistics. No. 314. Hyattsville, Md: National Center for Health Statistics, 2000. (DHHS publication no. (PHS) 2000-1250 0-0431)

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Chronic Diseases Journal

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Editorial

Importance of patient education in the management of chronic diseases

Patient education is the process of enabling individuals to make informed decisions about their personal health-related behavior.[1] Patient education regarding the control and management of diseases is an inseparable part of healthcare services and requires careful consideration and planning. In spite of the plethora of literature and theories on the issues of behavior and change of behavior, such as the Health Belief Model, self-efficacy theory, Locus of Control Theory, Social Learning Theory, Stress and Coping Theory, and Adult Learning Theory, in practice, there are few consensuses on who is eligible to educate patients with chronic disease and how this education should be practiced.

We must educate patients to actively participate in the control and management of their disease for the following reasons (to mention but a few):

- Lack of patient and community participation undermines expensive and time consuming healthcare services.
- All patients, particularly those who suffer from a chronic disease, are actually involved in the management of their problems, and if they are not educated, they may commit medical errors and mismanage their problems.
- Without active, deliberate, and informed participation of patients, as a trained team member, in the process of management of their chronic diseases all efforts of healthcare providers and patients may become less effective, more expensive, and sometimes, unsatisfactory for both parties.
- The informed participation of patients in their own healthcare activities leads to a sense of ownership and control on their life and destiny for patients.

Based on the abovementioned points, patient education is a necessity for the professional endeavor of chronic disease management. However, training the trainers in the field of patient education remains a matter of debate and concern. Many healthcare disciplines provide patient education, yet few receive specific training in the field.[2] Moreover, regardless of the disciplines, it is important to be clear about who can be trained to train the patients. For various reasons, often with good intentions, many people, including patients and health professionals, get involved in patient education both formally and informally.[3] The involvement of people who are not professionally eligible and appropriately trained in the process of patient education not only may harm the patients, but also may hinder the effectiveness of healthcare services.[4]

The following criteria may be useful for selecting patient educators:

1. Possessing knowledge and expertise in the field of the diseases
2. Favorable attitude toward his or her professional limits and boundaries
3. Familiarity with educational theories and practices of patient education

To summarize, patient education can play an important role in the management of chronic diseases. There are theories and educational principles to inform patient education practices. Moreover, patient educators must be educated in the field of the diseases and on educational and theoretical principles. Research and debate on patient education must be encouraged among professionals and researchers.

Yadollah Zarezadeh,
Assistant Professor, Research Center for Social Determinants of Health, Kurdistan University of Medical Sciences, Sanandaj, Iran; Email: zaremspt@yahoo.com

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The relationship between spontaneous abortion among nurses and its related factors

Sholeh Shagheibi[1], Nasrin Soufizadeh[2], Ghobad Moradi[3], Erfan Azadpour[4], Shayan Naghshbandi[5]

1 Professor, Infertility Research Center, Kurdistan University of Medical Sciences, Sanandaj, Iran
2 Assistant Professor, Infertility Research Center, Kurdistan University of Medical Sciences, Sanandaj, Iran
3 Associate Professor, Social Determinants of Health Research Center, Kurdistan University of Medical Sciences, Sanandaj, Iran
4 Student of Medicine, Student Research Committee, Kurdistan University of Medical Sciences, Sanandaj, Iran
5 General Practitioner, Department of Medicine, School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran

Original Article

Abstract

BACKGROUND: Abortion is the most common complication of pregnancy which occurs in 15% of pregnancies. The aim of this study was to determine the incidence of spontaneous abortion and its related factors among nurses working in the hospitals.

METHODS: This cross-sectional study was conducted on 431 nurses working in hospitals in Sanandaj City, Iran, in 2014. A researcher-made questionnaire was used to collect the data. Data were analyzed via Stata software using descriptive statistics, mean, and standard deviation, and chi-square, t, and Fisher exact tests.

RESULTS: Mean age of participants was 33.45 ± 7.49 years; mean working hours per shift was 6.26 ± 2.50 hours; mean working hours per month was 201.63 ± 93.54 hours; and the mean work experience was 9.53 ± 7.37 years. The history of abortion among the participants was 22.23%. There was statistically significant relationship between age, working hours, working shifts, working ward, and work experience with spontaneous abortion ($P < 0.05$ for all).

CONCLUSION: The rate of spontaneous abortion among nurses working in the hospitals of Sanandaj City is higher than other studies. Therefore the decisions must be made to minimize adverse pregnancy outcomes in nurses.

KEYWORDS: Spontaneous Abortion, Nurse, Pregnancy Outcomes

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Introduction

Spontaneous abortion is a common complication at the beginning of the pregnancy.[1] Spontaneous abortion is involuntary termination of a non-viable intrauterine pregnancy before 28 weeks of pregnancy.[2] About 15% of pregnancies are at risk of abortion in first trimester.[1] Common causes of spontaneous abortion are chromosomal abnormalities, congenital or acquired abnormalities, thyroid and anti-phospholipid antibodies, and mothers' infection.[3] However, the main cause of abortion in spontaneous abortion is unknown.[1]

Among external factors affecting spontaneous abortion, occupational exposures could be noted.[4] Health care providers including nurses have the most occupational exposures.[5] More than two million women are employed as nurse annually that 4% of them are in the United States.[6,7] Nurses work in a unique working

Corresponding Author:
Sholeh Shagheibi
Email: shahgheibi@yahoo.com

environment which can require rotating and night shifts, long hours, prolonged standing, heavy lifting, and exposure to chemicals and X-ray radiation. They also encounter with various hazards during pregnancy including anesthetic gases, anticancer drugs, antiviral medicines, disinfectants, and X-ray.[8]

Many of the previous studies on nurses' exposure and spontaneous abortions lack sufficient number of exposed cases in order to adjust confounding variables. Although knowledge for exposure to dangerous drugs has increased, but the rules to reduce health care professionals' exposure to these dangerous drugs is not enough.[9-11]

Since the role of nurses as educated people who are among health care providers and also are in contact with many occupational exposures is very important, the previous studies often reflects the need for more studies on this topic and presenting strategies for prevention. Therefore, the aim of this study was to determine the incidence of spontaneous abortion and its related factors among nurses working in the hospitals of Sanandaj City, Iran, in 2014.

Materials and Methods

In this descriptive analytical cross-sectional study, the study population consisted of 431 married nurses working in all hospitals in Sanandaj City that at least had one pregnancy.

A researcher-made questionnaire was used to collect the data. Data were analyzed via Stata software (Version 11, StataCorp, College Station, TX, USA). Descriptive statistics, mean, and standard deviation, and chi-square (for qualitative variables), t (for quantitative variables), and Fisher's exact tests at the significant level of $P < 0.05$ were used to analyze the data.

Results

The mean age of participants was 33.45 ± 7.49 years. The mean hours of standing in a shift were 6.26 ± 2.50 hours, the mean of working hours per month was 201.63 ± 93.54 hours, and the mean work experience was 9.53 ± 7.37 years.

57.17% of nurses had worked more than 170 hours per month, 42.92% of them aged 20-30 years, and 36.89% of nurses had less than 5 years of work experience (Table 1).

48.14% of nurses had a history of pregnancy for 1-3 times, of which 77.67% had no history of abortion. Among those with a history of abortion, 15.58% had a history of at least one abortion (Table 2).

There was a statistically significant association between abortion during pregnancy and shift work ($P = 0.017$); so that the highest rate (47.62%) was related to nurses who had been working in the evening shift. There was also a statistically significant relationship between having an abortion during pregnancy with the working ward ($P = 0.012$). The highest percentage of abortions was observed in the age group of over 50 years ($P = 0.001$) (Table 3).

Table 1. Frequency distribution of quantitative variables in participants

Variables		n (%)	Confidence interval (95%)
Working hours in a month	170 hours and less	107 (24.83)	20.73-28.92
	More than 170 hours	324 (75.17)	71.07-79.26
Standing hours in a shift	6 hours and less	244 (56.67)	51.95-61.39
	More than 6 hours	187 (43.33)	38.60-48.04
Age (year)	20-30	185 (42.92)	38.23-47.61
	30-40	172 (39.91)	32.26-44.54
	40-50	69 (16.01)	12.53-19.48
	> 50	5 (1.16)	0.14-2.17
Work experience (year)	< 5	159 (36.89)	32.31-41.46
	5-10	127 (28.77)	24.47-33.06
	10-20	59 (13.69)	10.34-16.94
	> 20	44 (10.21)	7.33-13.07

Table 2. Frequency distribution of qualitative variables in participants

Variables		n (%)	Confidence interval (95%)
Number of pregnancies	No history of pregnancy	202 (46.90)	42.24-51.71
	1-3	207 (48.14)	43.39-52.88
	4-6	20 (4.65)	2.65-6.64
	More than 6	2 (0.47)	0.22-0.68
Number of abortions	No history of abortion	334 (77.67)	73.72-81.66
	1	67 (15.58)	12.13-19.02
	2	23 (5.12)	3.02-7.20
	3	4 (0.93)	0.01-1.84
	4	2 (0.47)	0.18-1.11
	5	1 (0.23)	0.22-0.68
Working shift	Morning	112 (25.99)	21.28-30.14
	Evening	21 (4.87)	2.83-6.91
	Night	26 (6.03)	3.77-8.28
	Rotating	272 (63.11)	58.29-67.45

Between having an abortion and work experience, a statistically significant association was found, and the highest risk of miscarriage was in nurses who had work experience of more than 15 years ($P < 0.001$).

There was no significant relationship between abortion and educational degree of nurses ($P = 0.637$). There was also no significant relationship between abortion and hours standing in a shift ($P = 0.269$).

There was significant relationship between abortion and work hours per month, and nurses with more than 170 hours per month of work time had the highest history of abortion ($P = 0.017$).

Discussion

The results of this study showed that most nurses aged 20-30 years, and had less than 5 years of work experience; they worked 7 hours per shift on average, and about 300 hours per month. Most participants in this study had no history of abortion, and among those with a history of abortion, 15.58% had a history of at least one abortion.

In a study by Lawson et al., the nurses' abortion rate was reported as 11%[8], which was more than our findings. Knutsson in a study described the effect of shift work on physiological function of health professionals. Knutsson also showed the strongest association between shift work with peptic ulcer disease, coronary heart disease, and compromised pregnancy outcome.[9] Axelsson et al. also reported increased risk of miscarriage in women who worked irregular hours or rotating shifts compared with day workers [Relative risk (RR):1.44, 95% Confidence interval (CI): 0.83-2.51].[10]

Table 3. The relationship between shift work, age groups, and hours standing in shift with spontaneous abortion among nurses

Variables		n (%)			χ^2	P
		Yes	No	Total		
Shift work	Morning	29 (25.89)	84 (74.11)	113	10.25	0.017
	Evening	10 (47.62)	11 (52.38)	21		
	Night	5 (19.23)	21 (80.77)	26		
	Rotating	52 (19.19)	219 (80.81)	271		
Age (year)	20-30	16 (8.65)	170 (91.35)	186	42.74	< 0.001
	30-40	48 (28.07)	123 (71.93)	171		
	40-50	29 (42.03)	40 (57.97)	69		
	> 50	3 (60.00)	2 (40.00)	5		
Hours standing in shift	6 hours and less	60 (24.38)	184 (75.62)	244	1.09	0.269
	More than 6 hours	37 (20.11)	150 (79.89)	187		

In a study by Uehata and Sasakawa which conducted on 2264 women, the results showed that irregular menstruation and abortions were more common in shift workers.[12] Shift work is a factor which possibly related to a risk of spontaneous abortion and reduced fertility.[13] Knutsson found an association between shift work and pregnancy outcome in terms of miscarriage, low birth weight, and preterm birth.[9]

Valanis et al. compared the rates of spontaneous abortion and stillbirths for pregnancies without antineoplastic exposure and exposed pregnancies in which the pregnant woman or her husband handled antineoplastic agents either before or during the pregnancy. Considering age during pregnancy, prior gravidity, maternal smoking during the pregnancy, and occurrence of a spontaneous abortion or stillbirth in a prior pregnancy, exposure of the mother to or the handling of antineoplastic agents during the pregnancy was investigated. Results showed that the risk of spontaneous abortion was significantly increased.[14]

The results of the present study showed that there was a statistically significant relationship between abortions during pregnancy with the working ward; so that nurses who worked in high stress hospital wards such as emergency and intensive care unit (ICU) had the highest abortion rate. Between abortion and work experience, a statistically significant association was found, and the highest risk of miscarriage was in nurses who had work experience of more than 15 years. It seems that more exposure in stressful wards affects the reproductive health of nurses.

In our study, the highest rate (47.62%) of abortion was related to nurses working in the evening shift. Moen et al. showed that the permanent night-shift workers had experienced significantly more abortions than the other shift groups and the three-shift rotation workers had the lowest number of abortions.[13]

Conclusion

The results of this study showed that the prevalence of abortion in nurses working in Sanandaj City hospitals was high. Working hours, shift work, age, and working ward had associated directly with spontaneous abortion in nurses, and these factors increased the risk of miscarriage. Therefore, decisions must be made to minimize adverse pregnancy outcomes in nurses. It is recommended that nurses who are pregnant and nurses who are at higher risk, work in low-stress wards, their working hours reduce as much as possible, and they work in fixed shifts instead of rotating shifts.

Conflict of Interests

Authors have no conflict of interests.

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Association between response to the medical treatment and predicting factors in ectopic pregnancy

Sholeh Shahgheibi[1], Saman Nasrollazadeh[2], Nasrin Soufizadeh[3], Mobin Naghshbandi[4]

1 Professor, Infertility Research Center, Kurdistan University of Medical Sciences, Sanandaj, Iran
2 Student of Medicine, Student Research Committee, Kurdistan University of Medical Sciences, Sanandaj, Iran
3 Assistant Professor, Infertility Research Center, Kurdistan University of Medical Sciences, Sanandaj, Iran
4 Student of Medicine, Department of Medicine, School of Medicine, Iran University of Medical Sciences, Tehran, Iran

Original Article

Abstract

BACKGROUND: Ectopic pregnancy (EP) is the leading cause of maternal death in the first trimester of pregnancy. There are many variables which can predispose EP. The aim of this study was to evaluate the possible association between individual's response to given medical treatment and predicting factors of ectopic pregnancy among pregnant women.

METHODS: In this cross-sectional study, 277 patients with ectopic pregnancy who were admitted to obstetrics and gynecology ward of Besat hospital, Sanandaj, Iran, were evaluated. The necessary information was obtained from all women diagnosed with EP during 2008 to 2013. Patients who received any medication before study or those who could not use methotrexate (MTX) were excluded from study.

RESULTS: In this study, 205 (74.1%) patients responded to the medical therapy. There was a significant association between successful response to the treatment and beta human chorionic gonadotropin (β-hCG) serum level less than 5000 mIU/ml, pregnancy sac size less than 4 cm and lack of fetal heart rate (FHR) in transvaginal sonography (TVS).

CONCLUSION: In conclusion, it was found that β-hCG serum level, pregnancy sac size and presence of FHR play a key role in predicting the response to the medical treatment in women with ectopic pregnancy, and might be helpful in selecting appropriate therapeutic scheme.

KEYWORDS: Ectopic Pregnancy, Pregnant Women, Methotrexate

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Introduction

Ectopic pregnancy (EP) is a major health problem for women in child-bearing age. It states the pregnancy occurring outside the uterine cavity that constitutes 1.2–1.4% of all reported pregnancies.[1] In this phenomenon blastocyst implants outside the uterine cavity endometrium, mostly (95.5%) in the fallopian tube.[2,3] The other most common implantation sites are ovarian (3.2%) and abdominal (1.3%) sites.[4]

Treatment for EP includes surgical or medical treatment which is usually systemic or through local route, or by expectant treatment.[5] According to the American College of Obstetricians and Gynecologists (ACOG) guideline, when beta human chorionic gonadotropin (β-hCG) level is < 200 mIU/ml, which is further in decline phase, expectant management may play a role.[6]

The favourable prognostic signs of ectopic pregnancy for successful expectant management

Corresponding Author:
Sholeh Shahgheibi
Email: shahgheibi@yahoo.com

are absent or there are minimal clinical symptoms with no evidence of haemodynamic and low initial β-hCG serum level.[7]

Previously, it has been reported that the medical treatment is quite less expensive than surgery.[8] Different medications have been tried to treat ectopic pregnancies, including systemic or local methotrexate (MTX), local potassium chloride, hyperosmolar glucose, prostaglandins, danazol, etoposide, and mifepristone.[9,10] Today, therapies mainly focus on MTX treatment. This agent was first used for supporting the surgical removal of the placenta from its abdominal implantation sites in second and third trimester cases.[11] MTX treatment causes severe abdominal pain and side effects; therefore, patient should be monitored closely. In addition, the serum β-hCG concentration should be assayed every week. In 15–20% of patients the serum β-hCG concentration has not declined by at least 25% in first week after drug use, and the next dose should be administered.[12] Regarding MTX treatment, there are two regimens: multi-dose (MTX 1.0 mg/kg intramuscularly (IM) daily; days 0, 2, 4, and 6 alternated with folinic acid 0.1 mg/kg orally on days 1, 3, 5, 7) and single dose (MTX 0.4 to 1.0 mg/kg or 50 mg/m^2 IM without folinic acid).[11] Researchers compared both regimens and concluded that the multi-dose regimen was more effective than the single-dose regimen.[13] According to the above information, this study was aimed to verify the possible association between response to the medical treatment and predicting factors in ectopic pregnancy among pregnant women referred to the Besat hospital, Sanandaj, Iran, during 2008–2013.

Materials and Methods

In a cross-sectional study, all women admitted to the obstetrics and gynecology ward of Besat hospital, Sanandaj City, during 2008 to 2013, who were diagnosed with EP, were included. Patients who received any medication before study or those who could not use MTX were excluded from study. The data were collected from patients' dossiers.

A logistic regression model was used to associate the contribution of underlying factors in predicting the serum level of β-hCG after the medical intervention. The outcome was defined on the basis of β-hCG levels. The absolute value of the β-hCG was not of great importance; rather, β-hCG level less than 2000 mIU/ml indicated a high chance for ectopic pregnancy. Thus, the nature of the medical outcome is dichotomous: either β-hCG falls below 2000 mIU/ml threshold or it is above this cut-off point. If the probability of changing the serum level of β-hCG follows a logistic function, then its probability can be estimated by:

$$p(y = 1|X) = \frac{1}{1+e^{-X\beta}}$$

Where X is the list of predictors and β is their corresponding coefficients to be estimated.

Results

In this retrospective study, 277 patients with ectopic pregnancy were evaluated. 197 (71.1%) patients were younger than 35 years, and 205 (74.1%) patients were successfully treated with medical treatment with MTX, while 72 (25.9%) patients required surgery. For each participant, several variables which were believed to influence the outcome of MTX treatment were recorded. The complete list of predictors is shown in table 1.

The question of interest was whether there is any association between the probability of β-hCG serum level less than 2000 mIU/ml with absence or presence of predictors. If there is not any association, then the determination of β-hCG would not be useful for prediction. To account for this, the significance of the fitted logistic regression with full list of predictors (full model) was tested against a model without predictors (null model).

Table 1. List of predictors included in logistic regression model

Predictor	Meaning	Nature of predictor
Response		
β-hCG	1 - β-hCG over 2000 mIU/ml; 0 – less than 2000 mIU/ml	Dichotomous
Predictor		
EP	1 - History of EP present; 0- no history of EP	Design
PLSUR	1 - History of pelvic surgery; 0 – no history of pelvic surgery	Design
PID	1 - History of pelvic inflammatory disease; 0 – no History of pelvic inflammatory disease	Design
INFER	1 – Infertility problem present; 0 – no infertility problem	Design
IVF	1 - In vitro fertilization; 0 - no in vitro fertilization	Design
INTCRS	1 - First intercourse before 18; 0 – no intercourse before 18	Design
ABORTION	1 - History of abortion; 0 – no history of abortion	Design
CS	1 – Birth by caesarean surgery; 0 – normal delivery	Design
Age	Age of subject	Continuous
Sac4	1 - Pregnancy sac over 4cm; 0 – pregnancy less than 4cm	Design
FHR	1 - Fetal heart rate present; 0 – no fetal heart rate	Design
β-hCG 5000	1 - β-hCG level over 5000 mIU/ml; 0 – β-hCG under 5000 mIU/ml	Design

EP: Ectopic pregnancy; PLSUR: Pelvic surgery; PID: Pelvic inflammatory disease; INFER: Infertility; IVF: In vitro fertilization; INTCRS: Intercourse; CS: Caesarean surgery; FHR: Fetal heart rate; β-hCG: Beta human chorionic gonadotropin

The result was highly significant, showing that there was a significant difference between the full model and the null model ($\chi^2 = 152.53$, degree of freedom (df) = 2, $P < 0.00001$), which indicates the good prediction power of predictors.

The results of fitting multiple logistic regression model showed that at $\alpha = 0.05$ level, the pregnancy sac larger than 4 cm (Sac 4), fetal heart rate (FHR), and β-hCG level over 5000 mIU/ml are statistically significant, infertility problem and individual's age are marginally significant, and other variables do not influence the level of β-hCG. To evaluate the goodness-of-fit of the logistic model, McFadden's pseudo R-square was used.[14] For a good fit, this index should be between 0.2 and 0.4.[15] For multiple logistic regression model, McFadden's pseudo R-square was obtained 0.46 which indicates a good fit. Table 2 represents the coefficients and odds ratios of the logistic regression model containing all predictors.

Table 2. Estimated coefficients and odds ratios for the logistic regression model containing all predictors

Predictor	Coefficient	Standard Error	Odds ratio	Wald Statistics	P
EP	0.062	0.061	1.064	0.993	0.321
PLSUR	-0.102	0.062	0.903	-1.624	0.105
PID	0.052	0.054	1.054	0.970	0.332
INFER	0.032	0.061	1.032	0.522	0.602
IVF	-0.206	0.113	0.813	-1.823	0.067*
INTCRS	-0.039	0.049	0.962	-0.791	0.429
ABORTION	0.082	0.051	1.085	1.614	0.108
CS	0.058	0.053	1.060	1.115	0.266
Age35	-0.090	0.047	0.913	-1.905	0.058*
Sac4	-0.211	0.051	0.809	-4.119	< 0.001
FHR	-0.316	0.085	0.728	-3.719	< 0.001
β-hCG 5000	-0.423	0.053	0.655	-7.950	< 0.001

EP: Ectopic pregnancy; PLSUR: Pelvic surgery; PID: Pelvic inflammatory disease; INFER: Infertility; IVF: In vitro fertilization; INTCRS: Intercourse; CS: Caesarean surgery; FHR: Fetal heart rate; β-hCG: Beta human chorionic gonadotropin

* $P < 0.100$ based on Wald test

Table 3. Estimated coefficients and odds ratios for the logistic regression model containing three predictors

Predictor	Coefficient	Standard Error	Odds ratio	Wald Statistics	P
Sac 4	-0.208	0.051	0.812	-4.037	< 0.001
FHR	-0.306	0.085	0.736	-3.606	< 0.001
β-hCG 5000	-0.441	0.053	0.643	-7.374	< 0.001

FHR: Fetal heart rate; β-hCG: Beta human chorionic gonadotropin

For ease of interpretation and practical use, it is recommended to construct a reduced model with fewer predictors as possible. Thus, to eliminate the less significant variables form the full model (Table 2), the top-down strategy of Diggle was followed.[16] Starting with the full model, the least significant covariate was determined based on Wald statistics and was dropped from the model. Likelihood ratio test (LRT) was applied to compare the initial and reduced model. The procedure proceeded until the LRT showed significant p-value, indicating no need for further reduction. The procedures led to excluding all marginal and non-significant design variables and ended up with a model including only the pregnancy sac larger than 4 cm (SAC 4), FHR, and β-hCG level over 5000 mIU/ml. For this model, McFadden's pseudo R-square reduced to 0.42 but still indicated a good fit. Table 3 represents the coefficients and odds ratios of the reduced logistic regression model.

Interaction and confounding effects: The interaction effects of three variables (i.e. Sac 4, FHR, and β-hCG 5000) were added to the final model to investigate whether there was any improvement in predicting the probability of increasing β-hCG level after medical intervention or not. In the same manner as discussed above, the LRT was used to discriminate between succeeding models. The process began with three significant predictors and their interactions. Top-down strategy found no significant interactions; as well as no confounding effects.

Model interpretation: Increasing the β-hCG level due to medical intervention tends to be linked with pregnancy sac larger than 4 cm (Sac 4). The estimated odds ratio is 0.812 or 1/1.231 (95% CI: 0.05-0.78) which is less than 1.0, indicating that the probability of increasing the level of β-hCG for a women with pregnancy sac larger than 4 cm is less than the probability of increasing the level of β-hCG for a women with pregnancy sac less than 4 cm. Specifically, the odds ratio of β-hCG growth would decrease by 0.231 for a woman with a sac less than 4 cm. The logistic regression model also suggests that the absence of FHR increases the level of β-hCG. The odds ratio of 0.736 (or 1/1.358) indicates that the probability of increase in the β-hCG is 1.358 times more than the probability of increasing the β-hCG if FHR is detected. Furthermore, the baseline β-hCG also affects the β-hCG level after medical treatment in similar manner. The odds ratio of 0.643 (or 1/1.555) indicates that the probability of increasing the level of β-hCG for a treated women with baseline β-hCG over 5000 mIU/ml is 1.555 times more than that of for a treated women with baseline β-hCG less than 5000 mIU/ml.

Discussion

The findings of this study showed that there was an association between the pregnancy sac ≥ 4 cm and failure to the treatment. In this regard, Kimiaei et al. reported that pregnancy sac ≥ 3.5 cm is the most important predicting factor in response to the treatment.[17]

In addition, according to the results it was found that the primary β-hCG serum level ≥ 5000 mIU/ml may be a predicting factor for treatment failure. This finding was in agreement with Saadati et al., who reported that in patients with higher serum level of β-HCG, the successful treatment increased by using double dose of MTX method. They showed that using double dose also could

decrease the necessity of operation, re-administration of MTX, and duration of hospitalization.[18] In another study, serum level of β-hCG ≥ 6000 mIU/ml was the only predicting factor of treatment failure.[19]

In agreement with the findings of the present study, Potter et al. reported that the median primary β-hCG serum level was lower in women with successful treatment compared to those women with treatment failure.[20]

Another finding was the rate of successful treatment with MTX. In this study, 72 (25.9%) patients required surgery. In accordance with these results, Mirbolouk et al. reported that among 370 patients, 285 (77.1%) patients were successfully treated with MTX and 85 (22.9%) patients required surgery.[21]

Furthermore, comparing to the present findings, compelling evidence suggests that there was no significant difference between groups regarding the age of patients, history of EP, infertility, abortion and location of ectopic mass; therefore, none of these factors could predict the success of drug treatment in this population.[13,21,22]

In addition, in the present study, it was revealed that presence of FHR in patients was associated with reduced rate of successful medical treatment, which was in line with the findings of Lipscomb et al., who indicated that FHR in sonography is a predictor of treatment failure.[22]

Conclusion

Taking together, the results of this study suggest that there is a significant association between successful response to the treatment and β-hCG serum level, pregnancy sac size or presence of FHR; while age, history of infertility, number of abortion, history of EP, history of pelvic infection or surgery, nulliparity, history of smoking, and caesarean were not predictors of treatment failure.

Conflict of Interests

Authors have no conflict of interests.

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The impact of perineal massage during pregnancy on perineal laceration during childbirth and postpartum: A randomized clinical trial study

Roonak Shahoei[1], Lila Hashemi-Nasab[2], Golbahar Gaderkhani[2], Farzaneh Zaheri[2], Faranak Shahoei[3]

1 Associate Professor, Clinical Care Research Center AND Department of Midwifery, School of Nursing and Midwifery, Kurdistan University of Medical Sciences, Sanandaj, Iran
2 Lecturer, Department of Midwifery, School of Nursing and Midwifery, Kurdistan University of Medical Sciences, Sanandaj, Iran
3 Besat Hospital, Kurdistan University of Medical Sciences, Sanandaj, Iran

Original Article

Abstract

BACKGROUND: This study was aimed to investigate the effect of perineal massage during pregnancy on perineal pain and lacerations.

METHODS: This randomized clinical trial study was conducted at Besat Hospital of Sanandaj, Iran, from June 2014 to July 2015, on 115 women. Subjects in the intervention group practiced a daily 8-minute perineal massage with olive oil, starting from the 34th week of gestation until delivery. A questionnaire, made by researchers, was used to collect data through interviews and observations as well as reading the women's health files. The collected data was analyzed using SPSS software. The descriptive results were reported in terms of frequencies, means and standard deviations (SD).

RESULTS: The incidence of episiotomy was 53.33% and 57.33% in interventional and control groups, respectively, reflecting the significant difference ($P < 0.050$). In the interventional group, the frequency of first and second-degree and urethra tears was 81.82%, 9.09%, and 9.09%, respectively. The frequency of the first and second-degree, urethra and vestibule tears was 72.23%, 11.11%, and 16.66%, respectively, in control group. Comparing the degrees of pain between two groups revealed the significant difference in severity of pain at 3 days, 10 days and 3 months after childbirth ($P < 0.001$).

CONCLUSION: Antenatal perineal massage has a significant effect on the incidence of intact perineum, episiotomy and postnatal perineal pain.

KEYWORDS: Laceration, Episiotomy, Pregnancy, Pain, Postpartum, Massage

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Introduction

Women regularly suffer from perineal trauma during childbirth process, particularly for the first delivery. Any damage to the perineum during childbirth may occur spontaneously or after episiotomy.[1] Approximately, 85% of women experience perineal trauma during childbirth and more than two-thirds of them need perineal repair.[2] Perineal injury during labor is accompanied with short- and long-term complications such as bleeding, infection, the need for surgical repair, urinary and fecal incontinence, dyspareunia, persistent pain and pelvic floor muscle weakness. Such complication rarely is seen in women with an intact perineum. Perineal pain after childbirth can damage the interaction between the mother and child, breastfeeding, childcare, sexual and emotional relationships and even interfere with recovery.[3] About 22% of women have reported the

Corresponding Author:
Roonak Shahoei
Email: rshaho@yahoo.com

continuance of perineal pain for eight weeks that sometimes lasts for one year or more.[1] Perineal trauma is associated with dyspareunia during the first 3 months after childbirth. The women with an intact perineum are more likely to start an early sexual activity and report less pain during sexual intercourse. Also, they may report orgasm in the first six months after childbirth.[4]

Nowadays, low-risk strategies such as complementary and alternative medicine, acupressure, aromatherapy and massage during pregnancy and childbirth have been suggested for reducing labor pain, and perineal trauma and pain.[5] Perineal massage by the husband a few weeks before childbirth increases elasticity and lowers the risk of perineal trauma induced by episiotomy or spontaneous ruptures.[6] Perineal massage also increases blood flow and the ability to stretch the perineum during childbirth that reduces pain associated with passing out the child from the birth canal. It also can reduce perineal trauma and pain after childbirth.[7]

The most common complication of childbirth, especially in nulliparous women, is a postpartum perineal pain. It has consequences such as insomnia, anxiety, delays in establishing the relationship between the mother and child prevents the romance between them and hinders the correct posture for breastfeeding.[8,9] Perineal pain debilitates the mother in childcare and its persistence endangers marital relationships.[10]

Several studies have reported that perineal massage during pregnancy can be an effective strategy for prevention of perineum trauma after vaginal delivery, especially in nulliparous women.[11,12] In America, a study with 368 nulliparous and multiparous women revealed that perineal massage during pregnancy reduced the frequency of laceration and episiotomy after childbirth.[11] However, it is reported that perineal massage during pregnancy had no protective effect on the perineum with no prevention of perineal trauma.[12] Although the study supports the claim that perineal massage during pregnancy decreases the need for episiotomy, perineal tear and pain after childbirth, nevertheless, there are still doubts that need to be addressed by further studies.[4] The mother's factors influencing perineal tear during childbirth are age, parity, gain of weight during pregnancy, hematocrit during pregnancy, childbirth position, the second stage of labor duration, history of episiotomy in previous births, history of tear in previous delivery and perineal massage during pregnancy. The newborn's factors are weight, fetal position during delivery, nuchal arm and the size of fetus.[11] The main purpose of this study was to evaluate the effect of massage during pregnancy on perineal trauma during childbirth and postpartum pain in women who referred to Besat hospital of Sanandaj, Iran.

Materials and Methods

This randomized clinical trial was conducted in an Iranian governmental educational hospital (Besat), from June 2014 to July 2015. Besat hospital is the referral center in Kurdistan Province, affiliated to Kurdistan University of Medical Sciences. The research population included the pregnant women attending to childbirth preparation class at Besat hospital.

The inclusion criteria of this study were singleton pregnancy, cephalic presentation, gestational age of 34 weeks, and lack of premature rupture of membranes, narrow pelvis, fetal distress and placental abruption, and eagerness to participate in this study. Those women with multiple pregnancies, previous cesarean childbirth with the forceps and vacuum, the history of administration of oxytocin, shoulder dystocia, posterior occiput, fetal distress, macrosomia, opioid drugs and a lack of labor progression were excluded from this study.

The principal investigator chose a specialist in the field of midwifery who was working in the labor room at the hospital as the research assistant and taught her how to massage the perineum, choose samples, fill out data collection

forms and obtain the written informed consent. The research assistant provided the women participating in childbirth preparation classes at the hospital with information about perineal exercise and the study process. Those women who willingly agreed to participate in this study were asked to sign written informed consent and undergone verbal and written education on perineal massage. Massage should be performed with the thumb through the vagina in a semi-sitting position and using olive oil drawing a U-shape. The intervention group was asked to perform perineal massage using olive oil from the 34th week of pregnancy to childbirth in an everyday manner and for eight minutes in each session. The women in the intervention group were asked not to provide any information about performing perineal massage during pregnancy to labor staff.

The samples size for this study consisted of 150 women who were considered eligible after reviewing of list. They were randomly assigned to two 75-woman groups. The statistical factors incorporated into formula were as follow: 95% confidence interval (CI), p1 = 70% and p2 = 91% as perineal rupture in the intervention and control groups reported by a previous study (11) and $\bar{p}$ as the mean of ratios.

The research assistant used the closed envelope to select the control group of those women who had the inclusion criteria with yes or no written on paper inside the envelope. In the control group, no intervention was performed during pregnancy and they received routine antenatal care.

Childbirth in both intervention and control groups was managed by a midwife in charge of deliveries who also filled out the questionnaires. The midwife in charge of deliveries was not informed of the allocation of the women into the groups. In both groups, the decision for episiotomy during childbirth was based on the detection of indications of labor and episiotomy. After childbirth, the perineal and vaginal tear and the indications for episiotomy were assessed by the delivery agent and the required forms were completed. A questionnaire was used to collect data through interviews and observation as well as reading the women's health files.

This questionnaire which was made by researchers consisted of three parts. The first part was the demographic characteristics of the samples including age, education, occupation, history of abortion, gestational age and maternal body mass index (BMI). The second part was related to information about childbirth such as episiotomy, the laceration grade, weight and sex of the child, head circumference, chest circumference and Apgar score. The third part was related to pain on the third and tenth days and three months after childbirth. The first-grade tear was defined as a damage to skin and perineal mucous. The second-grade tear consisted of the first-grade tear and the muscle tear. The third-grade tear was the second-grade tear along with damage to the anal sphincter.

Questionnaire validity was confirmed by content validity (questioner assessed by 10 midwifery lecturer of nursing and midwifery school) and its reliability was evaluated by test-retest method (r = 0.74). The samples were taught to assess and report their pain using the pain measurement ruler. Telephone follow-ups by the researcher were conducted on the third and tenth days and three months after childbirth to ensure of recording pain and its severity by the samples.

The collected data was analyzed using descriptive and inferential statistics via the SPSS software (version 21, IBM Corporation, Armonk, NY, USA). The descriptive results were reported in terms of frequencies, means and standard deviations. Also, Student's independent t-test, chi-square test and Fisher's exact test were used to compare the groups. $P < 0.050$ was considered statistically significant.

The research proposal of this study was approved by the Research Council and Ethics Committee of Kurdistan University of Medical Sciences. Considering the ethical issues in this

study, the participants were clearly informed about the objective and nature of the study. Moreover, prior to the study, the participants provided us with their written consents in the formal language (Persian). Ethically, we have met a commitment to keep all of the participants' information confidential. The ethical consideration of this study complies with the code of ethics issued by the Ministry of Health and the declaration of Helsinki.

Results

The mean and standard deviation (SD) of the age of the samples in the intervention and control groups were 26.25 ± 4.35 and 26.42 ± 3.65 years, respectively. The highest percentage of the age group in both groups belonged to the age group of 26-30 years old. Also, 88.00% (66) and 96.00% (72) of the women in the intervention and control groups were housewife, respectively. The majority (45.33%) of the women in the intervention group had an academic education, while 44% of the women in the control group had a diploma degree. The majority of the women in both groups had no history of abortion, 89.30% (67) in the intervention group and 93.30% (70) in the control group, respectively (P = 0.380). In the intervention group, the majority of the women 48% (36) were nulliparous, but 49.30% (37) of the women in the control group experienced their second pregnancy. The mean of gestational age of the women in the intervention group was 39.92 ± 0.84 weeks and in the control group was 39.34 ± 0.80 weeks.

The majority of infants in intervention and control groups were boy (53.30%) and girl (50.67%), respectively. The mean of the newborn weight in the intervention group was 3000 ± 760 g and in the control group was 3000 ± 570 g. The mean of head circumference of infants in the intervention and control group was 34.61 ± 1.68 and 34.32 ± 1.23, respectively. Also, the same figures for the infants' chest circumferences were 33.52 ± 1.2 and 32.85 ± 1.09, respectively.

The mean of the Apgar score in the first and fifth minutes after birth in both groups was 9 and 10, respectively. The maternal BMI in the intervention group was 23.49 ± 2.81, and in the control group was 23.60 ± 2.75 kg/m^2.

No statistically significant differences were observed between the groups in terms of age (P = 0.089), occupation (P = 0.073), education (P = 0.076), birth weight (P = 0.065) (Table 1).

Table 1. Demographic characteristic of participants (n = 150)

Characteristic		Group		P*
		Intervention	Control	
Age (year)	≤ 20	5 (6.70)	5 (6.70)	0.089
	21-25	14 (18.70)	27 (36.00)	
	26-30	41 (54.70)	28 (37.30)	
	≥ 31	15 (20.00)	15 (20.00)	
Occupation	House wife	66 (88.00)	72 (96.00)	0.073
	Employed	9 (12.00)	3 (4.00)	
Education	Primary school	9 (12.00)	16 (21.30)	0.076
	Diploma	32 (42.67)	33 (44.00)	
	Academic	34 (45.33)	26 (34.70)	
History of abortion	Yes	8 (10.70)	5 (6.70)	0.380
	No	67 (89.30)	70 (93.30)	
Gravida (n)	1	36 (48.00)	33 (44.00)	0.060
	2	15 (20.00)	37 (49.30)	
	≥ 3	24 (32.00)	5 (6.70)	
Newborn sex	Girl	35 (46.70)	38 (50.67)	0.180
	Boy	40 (53.30)	37 (49.33)	
Birth weight (g)	< 2500	1 (1.30)	1 (1.30)	0.065
	2500-3000	32 (42.70)	22 (29.30)	
	3001-3500	21 (28.00)	37 (49.30)	
	3501-4000	17 (22.70)	11 (14.70)	
	≥ 4001	4 (5.30)	4 (5.300	

Data are shown as number (%); * Chi-square test

The incidence of episiotomy in the intervention and control groups was 53.33% and 57.33%, respectively, which were statistically significant (Table 2).

Table 2. Comparative episiotomy rate among groups

Group	Episiotomy		P*
	Yes	No	
Intervention	40 (53.33)	35 (46.67)	< 0.001
Control	43 (57.33)	32 (42.67)	

Data are shown as number (%); * Chi-square test

Also, in the intervention group, 81.82% of the women experienced the grade-one tear, 9.09% the grade-two tear, and 9.09% had urethral rupture. The same figure in the control group was as follows: 72.23% the grade-one tear, 11.11% the grade-two tear and 16.66% had urethral and vestibule ruptures, which were reported statistically significant (P < 0.050) (Table 3).

Perineal pain after childbirth on days 3 and 10 and three months after childbirth was statistically significant. With regard to the severity of pain, pain on days 3, 10 and three months after childbirth in the groups was statistically significant (P < 0.001) (Table 4).

Discussion

Our investigations in this study have depicted that perineal massage during pregnancy protected the perineum during childbirth, as the incidence of episiotomy in the intervention group was lower in comparison with the control group. This finding is pretty in line with the findings of a bunch of studies.[1,4,11,13] One of the important factors during labor and childbirth care is the prevention of any damage to the perineum. Studies in the 1970s and 1980s showed that episiotomy not only did not stop perineal rupture, but also increased its frequency and intensity. Also, the only benefit of episiotomy was the prevention of anterior ruptures. The episiotomy technique is not effective in the prevention of perineal tear. Therefore, perineal massage can be considered a preventive intervention for perineal lacerations.[11]

In a systematic review of four studies conducted on 2497 patients concluded that perineal massage during pregnancy was associated with the reduction of trauma, the need for perineal stitches and treatment as well as episiotomy.[14] A systematic review on three clinical trials about perineal massage involving 1941 nulliparous women and 493 multiparous women concluded that perineal massage reduced the prevalence of trauma to the perineum and the need for episiotomy and perineal stitches in nulliparous women.[15]

No third and fourth-grade ruptures were reported among the women in the current study. Perineal massage reduced the third and fourth-degree tears.[5,16] A study in Australia revealed that perineal massage during pregnancy from the 34th week to childbirth reduced perineal lacerations and the incidence of episiotomy, concluding that that perineal massage during pregnancy diminished the possibility of damage to the perineum, lowered the need for episiotomy and perineal pain after childbirth.[4] Perineal massage with fingers in the last month of pregnancy is well-tolerated and safe by those women who had no previous history of vaginal delivery. Also, those women who used this method experienced fewer traumas to the perineum as well as episiotomy in childbirth.[17]

Table 3. Comparative perineal injuries rate among groups

Group	Tear				P*
	Urethra	Vestibule	First-degree tear	Second-degree tear	
Intervention	1 (9.09)	0 (0)	9 (81.82)	1 (9.09)	0.010
Control	2 (11.11)	1 (5.55)	13 (72.23)	2 (11.11)	

Data are shown as number (%); * Fisher's exact test

Table 4. Comparative perineal pain and its severity among groups after birth

Variable			Group		P*
			Intervention	Control	
Perineal pain	3 days after birth		35 (46.70)	59 (78.70)	0.001
	10 days after birth		7 (9.30)	53 (69.30)	0.001
	3 months after birth		0 (0)	15 (20.00)	0.001
Pain severity	3 days after birth	No pain	40 (53.33)	46 (61.34)	0.001
		Mild	25 (33.33)	8 (10.66)	
		Moderate	10 (13.34)	8 (10.66)	
		Sever	0 (0)	13 (17.34)	
	10 days after birth	No pain	70 (93.33)	23 (30.67)	0.001
		Mild	4 (5.33)	29 (38.66)	
		Moderate	1 (1.34)	21 (28.00)	
		Sever	0 (0)	2 (2.67)	
	3 months after birth	No pain	75 (100)	60 (80.00)	0.001
		Mild	0 (0)	15 (20.00)	
		Moderate	0 (0)	0 (0)	
		Sever	0 (0)	0 (0)	

Data are shown as number (%); * Independent t test

In a clinical trial study on the impact of perineal massage on the increased likelihood of intact perineum during delivery reported that perineal massage before childbirth did not protect the perineum and had no significant impact on perineal trauma.[12] The results of the study showed that perineal massage had no effect on the perineum, the need for episiotomy and perineal laceration.[18] A clinical trial in Japan, performed perineal massage four times a week for more than three weeks, reported that the need for episiotomy was reduced by 21%. However, the rate of perineal tears in the intervention group was slightly more than that in the control group.[19]

Another finding of this study was the decreased perineal pain in the intervention group, in the third day and three months after childbirth. Also, as compared to the control group, the severity of pain on day 3 and 3 months after childbirth in the intervention group was less. Our findings are in line with those of other studies.[1,4,20] Perineal pain after vaginal birth affects healing. Also, both episiotomy and perineal pain are associated with perineal injuries during pregnancy and three months after childbirth.[21]

A study concluded that those women who had an intact perineum after childbirth experienced less perineal pain following childbirth and experienced less sexual dysfunction three months after childbirth.[22] Perineal massage in the last weeks of pregnancy reduced perineal pain, the need for episiotomy and tears grade two and three.[1] In a study, researchers asked the intervention group to perform perineal massage during the 34th week of pregnancy to childbirth. They reported that those women older than 30 years old in the intervention group were more likely to give birth with an intact perineum (P = 0.029). The authors concluded that perineal massage significantly contributed to reducing perineal pain after childbirth.[20] Also, it is mentioned that perineal massage in nulliparous women was followed by the lower levels of pain three months after childbirth.[15]

The results of this study depicted that perineal massage during pregnancy was accompanied by less perineal tear and pain, and the need for episiotomy. Although evidence confirmed these results, perineal massage during pregnancy was not recommended by any clinical guideline. It is believed that this approach is safe and acceptable by women. Since there is no strong

evidence globally to support this technique, family physicians can suggest it to those women who are interested in using such methods for reducing perineal trauma and pain after childbirth.[17]

The strength of this study was telephone follow-ups by the researcher for three months after childbirth.

Conclusion

The antenatal perineal massage was found to have a significant effect on the incidence of intact perineum, episiotomy and postnatal perineal pain. Therefore, conducting this study with a larger sample size and comparison of the effect of perineal massage between nulliparous and multiparous women are suggested. Also, this study can be repeated in hospitals in which physiologic childbirth is carried out to prevent possible consequences of not conducting.

Conflict of Interests

Authors have no conflict of interests.

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Writing and presenting a systematic review emphasizing the Cochrane Handbook for systematic reviews

Fariba Khayyati[1], Zahra Fathifar[2], Shaiesteh Shirzadi[3], Tahereh Pashaei[4]

1 Social Determinants of Health Research Center, Kurdistan University of Medical Sciences, Sanandaj, Iran
2 Library, School of Health, Tabriz University of Medical Sciences, Tabriz, Iran
3 PhD Candidate, Department of Health Education and Health Promotion, School of Health, Tabriz University of Medical Sciences, Tabriz, Iran
4 Assistant Professor, Department of Health Education and Health Promotion, School of Health, Kurdistan University of Medical Sciences, Sanandaj, Iran

Review Article

Abstract

BACKGROUND: The systematic review is a scientific method for identifying and presenting early research, quality assessment, and integration of their results. This study aimed to describe the principles of systematic reviews and inscribe related articles emphasizing the Cochrane Handbook, for using of medical and health students.

METHODS: This study was a library review and a compilation of materials on how to conduct review studies in medical sciences and health with emphasis on the Cochrane Handbook.

RESULTS: The findings of this study indicated that review studies have different types, most notably systematic reviews. The Cochrane Handbook provides valuable information collections for conducting these studies in medical sciences, and allows systematic reviews to step by step facilitate and publish relevant articles.

CONCLUSION: Writing a systematic review involves defining the purpose and protocols, systematically searching for primary studies, critical assessment, selection of the studies, and then, analysis and integration of the final results.

KEYWORDS: Meta-Analysis, Systematic Review, Public Health

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Introduction

The systematic review is a scientific method of searching and finding the results of primary studies and evaluating and integrating their results on a certain topic, and it is considered to summarize and combine quantitative and qualitative studies. This method is different from the traditional review study which includes explanation of studies, but not the systematic identification of studies, qualitative evaluation, and integration of results.[1] In other words, the systematic review is an allocation process, critical review, and systematic integration of evidence retrieved from scientific studies in order to obtain a general, short, and reliable description of an issue.[2]

A systematic review is not a mere list of studies, but it integrates and interprets the results of studies in a way that increases understanding. Moreover, it is a key method for bridging over the gap between research and practice.[3] It is a special methodology for the evaluation and synthesis of the results of primary studies and foundations to improve evidence-based policies and performance.[4]

Review studies comprehensively cover a certain biomedical subject and justify the path to future studies for successful master, doctorate, and postgraduate programs.[5]

Corresponding Author:
Fariba khayyati
Email: khayati.f@muk.ac.ir

Unlike narrative reviews, the feature of the systematic review is that all its procedures and methods are designable and clear, and if other researchers adopt the same procedures and methods to review the same set of data, they will obtain identical results. In other words, such reviews are reproducible without the effect of the researcher, which indicates the internal consistency of such studies.[6]

Systematic reviews can lead to more reliable scientific achievements by saving time for researchers, therapists, and planners. It has been estimated that over 2 million articles are published in over 20,000 journals every year (2014), and it is impossible for a researcher to be aware of all scientific developments and productions even in a limited field of specialty. The systematic review, however, summarizes the best accessible evidence and provides a conclusion to help therapists and planners choose the right treatment for patients.[7] Therefore, the systematic review aims to respond to a question based on the most scientific published or unpublished evidence available[1] and is the basis for evidence-based medicine.[7] On the other hand, a systematic review can not only provide good reasons for clinical decision taking, but can also play an important role in determining future research needs. In this regard, the most important advantages of systematic reviews are:

1. Having certain methods to select and reject studies, which reduce biases or deviant results and increase the reliability of results,
2. Generalizability of results, consistency, and lack of dispersion of results by comparing the results of different studies[8] and increasing the statistical strength of smaller studies[9],
3. Comprehensive access of researchers, health services providers, or policymakers to exploitable information[8],
4. Updating the results of the most recent studies,
5. The possibility of designing evidence-based guidelines (action guides) to provide therapeutic and preventive interventions[7], and
6. Avoiding duplication and waste of time and resources on issues whose evidence has been clarified before.

Given the difference between decision making and decision taking, scholars usually help with decision taking, and executives and policymakers are responsible for taking the final decision. Like other health and healthcare decisions, policymaking should be based on the best and latest evidence available, and review studies are also useful in this field.

In this regard, the Cochrane Collaboration is an international organization which primarily aims to help individuals take informed healthcare decisions by preserving and enhancing access to systematic reviews of evidence. The Cochrane Collaboration was founded in 1993 and currently includes over 15,000 contributors from more than 100 countries, easily making it the largest organization involved in this kind of work. The international collaboration was launched one year after the establishment of the Cochrane Centre in Oxford (now the UK Cochrane Centre), founded by Sir Iain Higgins and Green and named after British epidemiologist Archie Cochrane. The Cochrane Collaboration is now an internationally renowned initiative.[10]

The present writing aims to introduce the principles of conducting systematic reviews in medicine and health. Such studies are highly reliable among other scientific articles. Given the development of knowledge in Iran and researchers' need for extensive studies in a certain field, it is expected that researchers take steps toward summarizing and providing effective scientific achievements by becoming familiar with the principles of review studies.

Materials and Methods

This was a review study on how to conduct review studies in medical sciences and health, with especial emphasis on the Cochrane Handbook.

Introducing and categorizing review studies: Review studies, which are also called secondary studies, are the result of scientific review, synthesis, and integration of several primary studies and are classified into the following methods.

In a classification, they were divided into two types: systematic articles and unsystematic (narrative) articles. These two types have different features and aims. The systematic review utilizes precise and extensive searches for texts on the subject in question using a critical investigation, and due to its precise methods of evaluating the available texts, it is considered as the gold standard of reviews. Systematic reviews are divided into qualitative and quantitative reviews. In both qualitative and quantitative reviews, authors try to retrieve all primary studies, search multiple databases, search the relevant studies manually, contact the authors of grey (unpublished) studies, examine the texts systematically, and critically evaluate the studies included in the review.

An unsystematic review is an overview of materials that are easily readable.[11] This type of review is more traditionally seen in nonmedical sciences, and is usually extensively used by the main practitioners in a field and generally on an issue. They use informal, unsystematic, and mental methods to search, collect, and interpret data that are mostly summarized through a hypothesis, without critical evaluation, and with an easy narration. Although review studies in every field are carried out by experts, they may be based on biased views.[12] Unsystematic review articles do not list the varieties of databases and methodological approaches used to carry out studies and the inclusion criteria of the retrieved articles, while searching the databases.[13] The results of such studies are more qualitative than quantitative.[14]

In another classification, review studies are classified as follows:

A) Narrative review articles (categorized as editorials, commentaries, and unsystematic narrative reviews),

B) Qualitative review articles or systematic review, and

C) Quantitative review or meta-analysis

A) Narrative and unsystematic review articles were explained above. An editorial is a kind of article which explains the view of an individual[15] or a group of individuals.[16] An editorial can be on any topic, but it usually deals with social issues. In order for editorials to be validated, they need to be supported by realities and evidence.[15] Similar to a lawyer on a debate that has already been made, the author of an editorial tries to convince the reader of a current result. Therefore, an editorial is a viewpoint with a predictive orientation.[17]

A commentary is a kind of review study in which individuals express their opinions about a person, thing, or event (for example, a sports event).[18] In the Cambridge Dictionary, it is stated that this type of review is used in radio or television or it is the comments written on an event, a book, or a person, which deal with the topic of that book or event.[19]

B) As stated, a qualitative systematic review is a comprehensive review that is based on primary research studies and has obtained certain standards with regard to its methodology. These studies should be clear and possess appropriate inclusion and exclusion criteria.[20] Systematic reviews are mainly characterized by searching all main reports on the topic in question, evaluating the reports of studies critically, and concluding based on integration of studies that have the qualitative features in question.[21] Other key features of such studies are developing clear goals and predetermined criteria and designing explicit methodology which leads to the reproduction of systematic reviews.[10]

C) The meta-analysis is regarded as equal to systematic review, but researchers use meta-analysis that has a quantitative scientific

analysis method to combine and summarize the results of studies in a quantitative way.[1] Therefore, conducting a meta-analysis is a step beyond review studies and is neither necessary nor possible in all systematic reviews, because conducting complex statistical comparisons requires similarity among the participants, trials, and interventions and their outcomes.[6] In other words, it is a mathematical combination of the results of at least two primary studies with similar hypotheses and methods.[9] According to the Cochrane Handbook, meta-analysis is using statistical methods to summarize the results of independent studies by combining the data from relevant studies. The meta-analysis can provide a more accurate assessment of the effects of health care compared to the case in which such assessments are conducted alone. Meta-analyses also increase the strength of evidence and facilitate the revelation of discrepancies among studies.

The method of conducting a systematic review: The systematic review is similar to primary scientific researches in which an instruction including the research question needs to be answered and the proposed methods should be developed.[1] In order to achieve and present the results of a systematic review to be published in the Cochrane Database of Systematic Reviews (CDSR), it is necessary to minimize bias, which is possible when the researchers do not allow their personal judgments to interfere with the selection and report of the studies. Protocol development is the first step in writing systematic reviews, which is like the proposal in primary studies and clarifies the path of the next steps. In addition, bias in selecting the studies to be included in a systematic review and reporting the data of all articles and studies, the results of which may include bias, need to be minimized. Since writing the protocol before reviewing the texts determines the research question and the characteristics of the included studies, it minimizes the probability of bias to a large extent. To write a systematic review, first, its protocol should be registered and agreed on in one of the thematic groups of the Cochrane subset. Protocols that are not converted into systematic reviews 2 years after confirmation will be eliminated from the Cochrane groups.

According to the Cochrane Handbook, a protocol includes the following parts: topic, background, aims, methods, characteristics of the studies that are selected for review including the type of study, participants, interventions, scales of results, search methods to determine the studies, data collection, analyses, acknowledgments, references, and additional information in appendices.[10]

A systematic review is carried out in a number of phases.

King's College London (2014) has introduced the following 8 phases: specifying the topic and whatever is needed to be known (developing an answerable question), searching articles (finding relevant studies), selecting articles based on the inclusion and exclusion criteria to enter into the review study, evaluating the selected articles with regard to bias, statistical analysis (summarizing and integrating the relevant studies), controlling bias in the inclusion method of studies (for example, whether the emphasis is on positive results and negative results receive less attention, and vice versa), introducing the statistical outline, presenting the results and their summary in tables, expressing and interpreting the results and the conclusion.[7] Similar phases have been introduced in other references including the Cochrane Handbook.[1,3,9,10,13]

Main and important stages of a review study

A) Specifying the topic and developing an answerable question: One of the most important characteristics that differentiate systematic reviews from typical studies is that, in systematic reviews, the review topic and inclusion and exclusion criteria or qualification criteria are precisely determined. These criteria

are usually a combination of the clinical question and characteristics of different varieties of studies that deal with the clinical question.[10] However, if the research question is more specifically posed, the study will be carried out more scientifically. Therefore, more useful and relevant data can be filtered from useless data.[14]

The proposed method to review the text of most questions can be divided into 4 main sections which are determined based on the PICO framework.

P (Patient/Population/Problem): This section determines the individuals related to the problem in question.

I (Intervention or exposure): This is related to the method of management, intervention, or test of what is aimed to be obtained. This section can include a method of therapy, surgery, or diet or factors that may affect the health outcomes.

C (Comparison or control): This is related to the method of control, replacement, placebo, or conducting of the test in order to compare in a correct and exact manner.

O (Outcome): This section shows what is more important than others or what the patient is most concerned about.[2] The first three parts of the clinical question (population, interventions, and comparisons) are usually the decisive criteria for selecting the studies to be entered into the review study, while the results of a study do not play a decisive role in the inclusion or exclusion of a study in the review.[10]

It is important that the study question is posed based on the abovementioned components to the extent possible; however, sometimes it is not necessary to consider all of them.

B. Searching and finding relevant studies: The best evidence is obtained from the studies whose method has minimized the probability of bias.[2] Based on the type of question (in fact, the type of problem that is to be resolved), the type of the selected articles can differ (Table 1).

In order to ensure the discovery of all of the conducted studies related to a topic, it is necessary to develop a systematic strategy to search the texts. The first step is to determine whether the systematic review can be conducted or not. After making sure that there is no review on the topic in question in the Cochrane Library, searching into the desired references will begin. The easiest way for this is to utilize bibliographic databases of studies.

In all systematic Cochrane reviews, the three databases of MEDLINE, Embase, and the Central Register of Controlled Trials (CENTRAL) need to be searched to find the required studies.[10] Moreover, appropriate for the topic under research, specialized thematic databases like the Cumulative Index of Nursing and Allied Health (CINAHL),

Table 1. Types of questions related to public and clinical health, types of ideal studies, and types of major evaluations[1]

Type of question	Types of ideal studies	Types of major evaluations
Intervention	Randomized clinical trial	Randomization, completion with follow-up, and blinding (patients and clinical factors)
Frequency/rate (disease)	Cross-sectional study or sequential sample	Sample framework, case affirmation, sufficient follow-up, or appropriate reaction
Etiology and risk factors	Cohort study	The groups are only different in terms of presentation, evaluation of the consequences, and acceptable evidence of the causes.
Prediction and precaution	Cohort study	Main cohort, and sufficient follow-ups
Diagnosis precision	Randomized or sequential sampling	Independent blind comparison using "gold standard", and correct selection of patients
Hypothesis	Qualitative research	Appropriate selection of topic and research methods

Information Center (ERIC) can be utilized. Searching a single database is not sufficient, and different databases should be used. There is no formal law that determines how many databases are required for searching; however, a view beyond the standard databases of health care is needed in interdisciplinary topics. In fact, the whole process of a good search is to find the best balance between sensitivity (finding the highest number of articles possible) and feature (ensuring that the articles are relevant).[7]

In order to reduce bias, it is necessary to search grey studies[13] such as synopses of conferences, technical or governmental reports, dissertations, and theses. In order to find grey literature, the websites of relevant organizations can be searched and the experts can be contacted.[1]

With regard to search strategy, first, it is useful to formulize the topic under search into smaller topics, and search the components and combine them with each other, and second, to utilize synonymous and relevant words. Specialized glossaries available in databases or keywords of articles can also be used for this purpose. Medical Subject Headings (MeSH) are the most famous of these glossaries. Moreover, it should be noticed that using keywords of glossaries should be as a supplement to free keywords not their substitute.

- Using Boolean operators: Using the operators "AND", "OR", and "NOT" make the search more limited, wider, or more specific.

- Using limiters and filters: On databases, filters such as language and year can be used. Moreover, searching the keywords can be restricted in a special field such as title, author, and abstract, and the types of retrieved documents, type of study, and age can be utilized according to the features of each database in order to make the searches more specialized.

C. Evaluating the quality of the retrieved studies and selecting them: The Cochrane systematic review is reviewing studies that possess the inclusion criteria.[10] The method of selecting the articles is typically presented as a diagram[8] and their specifications, including the method, the population, interventions, and various outcomes, are determined.[6]

The following measures are taken in order to select the required studies:

- The search results are entered into resource management software (such as Reference Manager and Endnote) and repeated articles are crossed out.

- The topics and abstracts of the articles are checked, and irrelevant cases are specified.

- The full text of the relevant articles is retrieved, and different reports of a single research are integrated.

- In the case of incomplete articles, the full text of the articles is requested from their authors in order to evaluate the rate of relevance regarding the topic of the review.

- The final decision on selecting or rejecting the study is taken.[10]

First, the abstract of the article should be reviewed. Subsequently, if it is relevant to the topic in question, its methodology is taken into account, and if the methodology is accepted, the results are considered. There is typically no need to study the introduction, discussion, and conclusion.[22] Due to the importance of the correct selection of the studies, at least two analysts should independently read and score all of the relevant studies. Then, the analysts find a solution for the probable discrepancies between the given scores by discussing and justifying every single score that they have given.[1]

In addition to the tool introduced in the Cochrane Handbook, the methods proposed by Jadad et al.[23] and Moher et al.[24] are among other ways to evaluate the quality of articles. These two standard methods are utilized to evaluate the quality of interventional studies, especially clinical trials, and the method of their report. Other available tools to assess and evaluate the quality of meta-analyses and systematic reviews

are QUORUM[25] and PRISMA[26], and to measure the quality of observational studies such as cross-sectional studies, case-control studies, and cohort studies are STROBE[26] and MOOSE.[24]

Since using predetermined and abridged scales can be problematic in assessing the quality of trials, it is recommended that authors evaluate trials from 5 perspectives: making sure that the trial has employed a randomized method, the therapeutic interventions are secretly distributed among the subjects, the study is double-blind, the patients are followed up for a long period of time, and the results of the intervention are analyzed.[6]

D. Extracting the data of the selected articles: In this phase, it is helpful to prepare a (paper or electronic) form in order to extract and summarize the data of the selected articles. This form should include the following parts:

- Reference (including journal name, title, author, volume, and page number),
- Topic of the study (as written by the author),
- Design of the study (trial),
- Population (the participants' demographics)
- Control (explaining the control group or the alternative intervention), and
- Results (the results of the intervention and the method of measuring them).[9,10]

E. Summarizing and combining the studies: If the studies are homogenous enough with regard to their questions and methods, it is appropriate to combine the results in order to present a summarized assessment, and a meta-analysis will be carried out, which has various statistical methods. The method of combining the studies can differ based on the type of their questions and the criteria of assessing the outcomes.

Various factors can lead to the emergence of differences in the results of a systematic review. For example, it is possible that the effect of a type of therapy appears different in different studies. These differences can be due to the patients or the disease (e.g., the phase or severity of the disease), intensity or duration of the intervention, simultaneous interventions (e.g., other treatments or measures that the patient is going though), evaluating the outcomes, and timing.

Difference among various studies is not only limited to these factors, but other characteristics, including the quality of the study, acceptance of the intervention, and suitability of the utilized criterion in assessing the outcome, can also lead to contradictions in the treatment results, which leads to differences in results.[1]

At the end of this section, it should be noted that systematic reviews are carried out on both quantitative and qualitative studies. As opposed to quantitative studies, qualitative studies consider the patient as a complete human, and attempt to attain a correct understanding of the experiences of patients and reasons for which the patients perform some activities in certain conditions.[27] A qualitative study examines experimental, emotional, and social phenomena, and is defined as any type of study whose results are not obtained from quantitative investigations and statistical calculations.[28-30] Qualitative synthesis is regularly used in the systematic review of professional health texts; however, it is mainly employed in general texts.[31] It is evident that separate qualitative studies have limitations such as generalizability; therefore, combining these studies can help overcome such limitations. There are many methods for synthesizing qualitative evidence, which are appropriate for the aims and prospects of Cochrane interventional reviews. The synthesis of qualitative research is a controversial and developmental field, and the Cochrane Qualitative Methods Group has founded a committee to discuss the future methodological developments in this field.[32]

F. The method of reporting systematic review articles: The structure of systematic review articles is as follows:

Title: The title should be short, interesting, clear, and general. The titles of such articles are usually shorter than those of research articles. Like research articles, using abbreviations is not allowed in this type of article. It is recommended that the terms "review" or "overview" be used in the title so that the type of article is clear.[8] A title with more accurate and specific explanation is more likely to be referred to.[5]

Abstract: It is typically written as a structure and in the IMRAD framework (introduction, methodology, results, and discussion). In other words, it is written in the sections of introduction (aim), method, results, discussion, and conclusion. The content of this section is presented in about 250 to 400 words. The keywords range from 3 to 10 words, including the term systematic review.[6,8]

Introduction: It includes background (epidemiological and clinical background of the topic) and different therapeutic approaches or interventions. In this phase, there is an attempt to convince the reader of the necessity or aim of the research.

Methodology: In this section, the method of retrieving the articles from the databases and the complete name of the utilized databases are included. The utilized keywords, time limit, and the language of the data references should also be specified. Moreover, the research question and inclusion and exclusion criteria should be included. In fact, it deals with the method of evaluating the methodological quality of the studies. If the systematic review article is accompanied with meta-analysis, statistical indicators and tests should also be included in this section.

Results: In systematic review articles, the results are actually the same as the selected articles obtained from the search and evaluation. In addition to referring to the number of the articles, the following sections are also included in the "Results" section.

Combining the data (studies): It should be noticed that the studies are appropriately combined based on certain and valid criteria.

Similarity of the data: This section deals with examining the similarity among the populations under investigation, the administered interventions, and the outcomes of the articles.

Moreover, the reasons for discrepancy between studies should be taken into consideration.[8] Furthermore, it is necessary to provide a short explanation of the main results, the level of the evidence, strengths and weaknesses of each study, and relationship with each section. Readability of a review can be improved by the inclusion of some tables without explanation, synthesis of the main data, and conveyance of the main messages.[5]

Discussion: In this section, a hypothesis is tested. The data, results, and analyses are summarized, and the application of the results is evaluated and interpreted according to the research question (aim).[14] This section actually deals with the interpretation of the results. When the examined cases are more similar, there will be an increase in the probability of obtaining highly reliable results, which in turn enhances the generalizability of the results. The results of the content of the articles under investigation should be expressed with a logical sequence and in clear purposeful phrases. In the "Discussion" section, the issue of what concept has been obtained should be referred to. The author needs to deal with any certain opinion relevant to the issue, if there is any.

In addition to the criticisms and analyses presented in the text, the results obtained from examining and discussing different opinions should be linked with the study's aims referred to in the introduction, but phrases and conclusions that are irrelevant should be avoided. In this section, the expenses, safety of the treatment (or intervention) compared to similar studies, limitations, and weaknesses should be included. Moreover, recommendations for future studies should be

provided based on the current study.[8]

Conclusion

The systematic review is a scientific method for searching, finding, evaluating, and combining the results of primary studies regarding a certain issue. The results of the present study show that review studies are of different types, and the most important type is the systematic review whose method of preparation and performance was presented in the current study. In order to optimally carry out review studies and prevent bias, developing the relevant protocol is the first step. Subsequent steps are searching systematically for primary studies, evaluating and selecting the right studies, and analyzing, combining, and interpreting the final results. The Cochrane Handbook is a collection of valuable information on how to carry out systematic reviews in medicine and health, and facilitates their performance and publication.

Conflict of Interests

Authors have no conflict of interests.

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Reducing the incidence of cancers in Iran with more attention to personal and environmental risk factors

Ali Poormohammadi[1], Manoochehr Karami[2], Keivan Saedpanah[3]

1 PhD Candidate, Social Determinants of Health Research Center AND Department of Environmental Health Engineering, School of Public Health, Hamedan University of Medical Sciences, Hamedan, Iran
2 Associate Professor, Social Determinants of Health Research Center AND Department of Epidemiology, School of Public Health, Hamedan University of Medical Sciences, Hamedan, Iran
3 MSc Student, Department of Occupational Health Engineering, School of Public Health, Hamedan University of Medical Sciences, Hamedan, Iran

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Editor in Chief

Cancer is a generic name for a large number of diseases associated with abnormal growth of cells. It is estimated that one out of every three people will develop cancer at different stages during their lifetime. In addition, one of four patients will die from the disease. In recent years, the number of cancer patients has increased considerably.[1] Cancer is recognized as the second cause of death in developed countries and as the third cause of death in Iran.[2] The incidence of cancers and their resulting mortality have been reported by the American Cancer Society.[3] To qualify as a common cancer, the estimated annual incidence for 2016 had to be 40,000 cases or more. Based on the list provide by the American Cancer Society, the most common type of cancer is breast cancer, with more than 249,000 new cases in the United States in 2016.[3] The next most common cancers are lung cancer and prostate cancer. A similar growing trend is seen in Iran. Most common cancers in Iran include cancer of the breast, stomach, esophagus, colon rectal, bladder, and leukemia.[1] Most cancers are attributed to genetic factors, lifestyle, and exposure to occupational and environmental carcinogenic compounds. Most of these mentioned factors can be controlled or prevented. Tobacco smoking, dietary factors, overweight, and alcohol consumption account for 34% of total cancers occurring in 2010 in the United Kingdom.[4] Breast cancer is one of the most commonly diagnosed cancers among women in Iran. The prevalence of this cancer was lower in Asian countries than developing countries, but in these countries it is increasing. In Iran, 76% of the most common cancers in women were related to breast cancer.[1-5] Age, history of breast disease, genetic factors, and environmental factors are among the risk factors associated with the development of breast cancer.[5] Among these risk factors, alcohol consumption, obesity, and physical inactivity are considered as the main preventable risk factors for 21% of the total number of deaths due to breast cancer in the world. Changes in lifestyle and eating habits in recent years have caused breast cancer to become more common at younger ages and in urban communities.[5] Unnecessary radiation

Corresponding Author:
Manoochehr Karami
Email: ma.karami@yahoo.com

exposure is one of the avoidable risk factors for cancer breast,[2] while other factors can also be controlled and are avoidable. Leukemia is recognized as a commonly diagnosed cancer in children. In Iran, the prevalence of leukemia is 7.7 and 4.0 per 100000 people/year among men and women, respectively.[1] It is reported that chronic exposure to benzene and ionizing radiation are the main risk factors for leukemia. Exposure to benzene and ionizing radiation are generally attributed to individual's jobs and are partly avoidable in workplaces.[6] Skin cancer alone includes 5.2–32.7 percent of all cancers in Iran.[1,7] The incidence of skin cancer has been increasing in recent decades in Iran. Most cancer cases are associated with exposure to sunlight, changes in climate, thickness of the ozone layer, and personal and social habits that can also explain this increase. Studies indicated that there is a significant association between latitude of a region and incidence of skin cancer. Thus, in more southern latitudes, the number of skin cancer cases is remarkably higher.[7] Bladder cancer is the second and third most common cancer among men in Markazi and Kurdistan provinces, and the fourth most common in Iran.[8] Known risk factors associated with bladder cancer are urinary tract infections, diabetes, water pollution, dietary factors, fluid intake, coffee drinking, drugs, exposure to aromatic amines, smoking, and a family history.[8] In addition, low intake of fruits and vegetables, and consumption of opium and hot drinks are associated with esophageal cancer. Esophageal cancer is the second and third most common malignancy in Iranian men and women, respectively.[9] Colon cancer can be prevented by reducing the intake of red and processed meat and increasing the consumption of fruits and vegetables (fibre). On the other hand, the presence of high concentrations of nitrate in vegetables and the overuse of chemical fertilizers can cause stomach cancer. The use of chemical fertilizers can be decreased, and thus, it can be considered as an avoidable risk factor. The incidence of colorectal cancer is lower in Iran than in Western countries. Colorectal cancer is the fifth and third most common cancer in men and women in Iran.[10] Two out of ten cancer deaths in Iran can be prevented through not smoking.[11] Physical activity is associated with reduced risk of lung, colon, and breast cancers.[11,12] It has been reported that strenuous physical activity reduces the risk of stomach cancer.[9] In recent years, a dramatic increase in the prevalence of smoking, obesity, inactivity, and improper diet has been observed in Iranian cities.[12-14] On the other hand, with the increasing population of the elderly in Iran, it is expected that new cases of various cancers will increase in the next decades.

In conclusion and in line with the scope of this journal, it is necessary to pay further attention to studies assessing public awareness level regarding the role of risk factors in the prevention of cancers and offering solutions to improve individuals' lifestyle in terms of cancer prevention.

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