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Impact of educational preeclampsia prevention booklet on knowledge and adherence to low dose aspirin among pregnant women with high risk for preeclampsia

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Abstract:
Background: Postpartum bleeding and pregnancy induced hypertension – including preeclampsia – remain to be a great cause of maternal mortality. The use of aspirin for preventing preeclampsia has been practiced recently by fetomaternal specialists in Indonesia. This study aimed to analyze the impact of education using an aspirin booklet provided by pharmacists on knowledge and adherence in taking aspirin among pregnant women with high risk for preeclampsia.
Methods: This was one group of pretest-posttest study. We enrolled all pregnant women with high risk for preeclampsia screened at 11^{+0}–13^{+6} weeks' gestation at Fetomaternal Clinic, Dr. Ramelan Naval Hospital, Surabaya. All subjects prescribed with low-dose aspirin (100 mg) for preeclampsia prevention received oral and written education using the aspirin booklet and had been followed up for 2 months. Knowledge about aspirin for preeclampsia prevention was measured by a validated questionnaire developed for this study. Adherence to aspirin was measured by pill count method.
Results: A total of 12 pregnant women with high risk for preeclampsia were included during the study period. This study showed a statistically significant difference on knowledge of preeclampsia prevention before and after receiving oral and written education using aspirin booklet (p-value = 0.020), as well as aspirin adherence (p-value = 0.011).
Conclusion: The use of oral education and written aspirin booklet provided by pharmacists had impact on knowledge of preeclampsia prevention and adherence in taking aspirin among pregnant women with high risk for preeclampsia. We recommend to conduct randomized control study of adequate number of subjects.

Keywords: educational booklet, knowledge, low dose aspirin adherence, pharmacist, preeclampsia prevention
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Introduction

Preeclampsia is pregnancy-specific hypertensive disease with multisystem involvement. It usually occurs after 20 weeks gestation, most often near term, and can be superimposed on another hypertensive disorder [1]. A woman in developing countries is considered to be seven times more likely to develop preeclampsia than women in developed countries. About 10–25% of preeclampsia will cause maternal death [2].

According to the Fetal Medicine Foundation (FMF), preeclampsia preventions should be undertaken by screening pregnant women at 11^{+0}–13^{+6} weeks' gestation to determine the risk for preeclampsia [3], [4]. Low-dose aspirin is included in the category of non-steroidal anti-inflammatory drugs that have the pharmacological activity as an anti-platelet and prevention for preeclampsia [5], [6]. Aspirin at dosage of 75–100 mg was sufficient to inhibit platelet formation from thromboxane A2 (TXA 2) and produced an antithrombotic effect [7]. Other research suggest that low-dose aspirin starting at gestational ages between 7 and 16 weeks can significantly reduce severe preeclampsia in pregnant women who were identified as high risk for preeclampsia [8].

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A meta-analysis research intended to analyze the role of aspirin in the prevention of preeclampsia with low-dose aspirin (75–150 mg) per day concluded that there was a decrease in the incidence of preeclampsia, severe preeclampsia, and fetal growth retardation with the administration of aspirin starting at ≤16 weeks [9]. Aspirin use in pregnant women with high risk for preeclampsia can be started from 12 weeks to 36 weeks of gestational age [10].

Preeclampsia is the major cause of maternal death according to the Ministry of Health. The use of low dose aspirin for preeclampsia prevention has been practiced recently by fetomaternal specialists in Indonesia. The obstacle in screening the risk for preeclampsia was the limited number of FMF certified sonographers in secondary and tertiary care, as well as limited number of pregnant women who have been referred to secondary and tertiary care for any medical reasons. First trimester screening is a comprehensive procedure for early identification of preeclampsia risk which combines maternal characteristics (including demographic data, medical and obstetric history), with uterine artery pulsatility index (PI), mean arterial blood pressure (MAP) and placental-like growth factor (PlGF) at 11–13 weeks' gestation. This procedure to assess preeclampsia and fetal growth restriction risks which is done by FMF certified sonographers leads to a better and earlier identification of pregnancies at high risk for preterm preeclampsia. Such early identification of the high-risk group for preterm preeclampsia is important because the risk is substantially reduced by the prophylactic therapy of low-dose aspirin tablet once daily [3], [4]. Thus, the simple method for preeclampsia screening based on clinical conditions (blood pressure, obesity, protein urine, history of preeclampsia) will be done when there is a lack of FMF certified sonographer in Indonesian healthcare facilities.

Pregnant women with high risk for preeclampsia should take aspirin tablets every day at bedtime to prevent the constant release of platelets to the circulation, so that it requires patients' medication adherence [11]. Most pregnant women reluctantly take this medicine, because they are concerned about the adverse effect of the drugs on the fetus. This emphasized the need for collaboration between patients and healthcare professionals. Knowledge and medication adherence of the patients can be improved by giving patient education. Good oral and written communication between health workers and patients is needed to increase patients' adherence [12].

A booklet is one of the written health educational media. It can last for a long time and contains written information which is completed with pictures and colors to improve patient's understanding. Such knowledge on specific information will lead to patients' concordance and thus will have impact on patients' behavior, especially in medication adherence [13]. In this recent research, the natural setting of education about the importance of aspirin as preeclampsia prevention in high-risk pregnant women was delivered orally. Pharmacists in this research team play an important role in developing written education material to improve patients' knowledge and aspirin adherence. This aspirin booklet can be integrated with the usual booklet on maternity care. The objective of this study was to analyze the impact of the use of aspirin booklet on knowledge and adherence in taking low dose aspirin tablets among pregnant women with high risk for preeclampsia.

Subjects and methods

Subjects

This was a pre-experimental study using one group pre-test post-test design, conducted during September 2018 and December 2018 at Dr. Ramelan Naval Hospital, Surabaya, Indonesia. The inclusion criteria for pregnant women were (1) a gestational age of 11^{+0}–13^{+6} weeks based on ultra-sonography, who underwent first trimester screening at Dr. Ramelan Naval Hospital, (2) a high risk for preeclampsia based on the results of screening by FMF certified sonographer and (3) candidate for low dose aspirin therapy able to read, hear and communicate well. We excluded pregnant women who were not willing to be involved in this study. Dropout criteria were (1) inability to manage completion of the procedures of the study for any reason before the end of the study, (2) fetuses died of other causes instead of preeclampsia, eclampsia, or a diagnosis with hemolysis, elevated liver enzyme, and low platelet count (HELLP) syndrome before the end of the study, and (3) those who suffered from aspirin side effects.

Methods

This research was performed in accordance with protocols and was given ethical approval from Medical Research Ethics Commission of Dr. Ramelan Naval Hospital, Surabaya, Indonesia. Pregnant women who met the inclusion criteria received a full explanation of this research and signed informed consent forms.

A pre-test in the form of a validated questionnaire based on the content of the booklet was delivered to the subjects before education had been started. The validated questionnaire contained seven questions in the

knowledge domain, which were (1) signs of preeclampsia, (2) effect of preeclampsia on pregnant women and the fetus, (3) preeclampsia prevention by administering low dose aspirin tablets regularly, (4) aspirin dosage administration, (5) how to avoid adverse drug reaction on gastrointestinal tract, (6) how to store aspirin tablet correctly, and (7) safety issue of aspirin tablet. This is a "true or false" questionnaire, which was scored '1' for each correct answer and '0' for each wrong answer.

Each of the pregnant women received a booklet and oral education delivered by the researcher. The content of the oral educational material were in accordance with the content of the booklet. Pharmacist in the research team showed the content of the booklet to the subjects for about 15 minutes. The content of the booklet given to the pregnant women included definitions, signs and symptoms of preeclampsia, the effect of preeclampsia on the mother and fetus, prevention for preeclampsia with low dose aspirin tablets, dosage regimen and administration of low dose aspirin therapy, information about benefit of low dose aspirin therapy for mother and her fetus, and the importance of self-adherence to low dose aspirin therapy.

Eligible subjects of the research were prescribed with 30 low dose aspirin tablets which was to be taken once daily. At the second hospital visit (28 days apart from the first visit), assessment of aspirin adherence domain was performed by pill count method. Subjects of the research were asked to bring along their remaining aspirin at second and third hospital visits for pill counting. The remaining aspirin tablets were counted, and matched to the number of tablets that should have been left. Adherence was defined as the patient's ability and willingness to carry out low dose aspirin therapeutic regimen along the pregnancy period which had been clinically assessed by practitioners as high risk for preeclampsia. Furthermore, a second oral and written education using aspirin booklet, which was exactly the same education topic as the first hospital visit, was given to the subjects of the research. The objective of these repeated interventions was to improve the subjects' knowledge, so that subjects were in concordance with the researcher about the importance of adherence in taking low dose aspirin tablets.

At third visit (28 days after the second visit), at Fetomaternal Clinic, Dr. Ramelan Naval Hospital, all subjects were evaluated for their adherence domain in taking low dose aspirin tablets by pill count method. At the end of the study, the pregnant women were given post-test questionnaire, which had exactly the same contents as those of the pre-test questionnaire. The questionnaire contains seven questions in the knowledge domain, scored '1' for each correct answer and '0' for each wrong answer.

SPSS 23.0 for Windows version analysis was used to analyze the validity of each question item and reliability of questionnaire. There were two questions on the first version of the questionnaire which had correlation value less than 0.553 (r table of 13 samples), which was thus removed from the questionnaire. The two questions removed were about headache as one of preeclampsia symptoms and how to obtain aspirin tablet for preeclampsia prevention. The valid and reliable final questionnaire are listed in the Table 1. Normality test used was Shapiro-Wilk, because of limited number of subjects of the research (<30 subjects), and test of difference used was nonparametic Wilcoxon match paired, because the data distribution of the knowledge (based on questionnaire's scoring system) and adherence (based on pill count) were not normal ($p = 0.000$ for both pre- and post-questionnaire test; $p = 0.016$ and 0.116 for pill count).

Table 1: Questionnaire of preeclampsia prevention with low dose aspirin tablets

No.	Question	Yes	No
1	Preeclampsia is pregnancy-specific hypertensive disease with the sign of protein in urine		
2	Preeclampsia has an impact on mother: kidney failure, liver and eclampsia while to fetus has an impact on low birth weight and fetal death		
3	Taking aspirin tablets regulary can prevent pregnant women from preeclampsia		
4	Pregnant women should take the aspirin tablets everyday at bedtime until 36 weeks' gestation		
5	Pregnant women should take the aspirin tablets after dinner to prevent gastrointestinal disorder		
6	Aspirin tablets should be stored at dry place and out of reach of children		
7	Aspirin tablets are dangerous substances for mother and fetus		

Results

The validity and reliability tests were carried out in January to July 2018. Content and construct validation were carried out on 13 pregnant women suitable to the research criteria, but not the sample of the research. SPSS 23.0

for Windows version analysis was used to analyze the validity of each questionnaire item with a value of >0.553 (r table of 13 samples = 0.553), reliability test with Cronbach's α was 0.808 > 0.553, and each of the questions had a value of total correlation = 0.778 or more, and thus the questionnaire was valid and reliable.

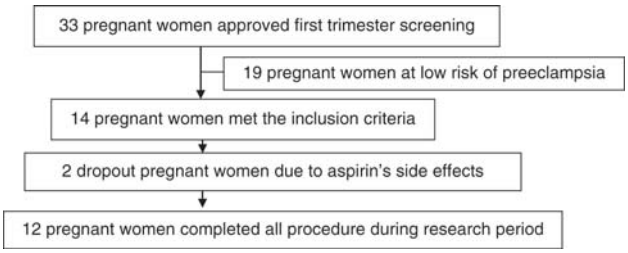

Figure 1: Flow diagram showing the recruitment process of pregnant women.

During the study period, we enrolled 33 pregnant women who underwent first-trimester screening. We excluded 19 pregnant women who had mild risk of preeclampsia, based on the results of screening by FMF certified sonographers. Thus, the sample size of this research was 14 pregnant women who met the inclusion criteria. Two pregnant women were unable to complete this study, because they experienced side effects of low dose aspirin, i.e. nausea, vomiting, and melena (Figure 1).

The characteristics of pregnant women who participated in the research based on the FMF algorithm can be seen in Table 2. The mean score of pregnant women's knowledge increased by 0.67 points after the second education. The mean score in knowledge domain before and after the education was 6.08 and 6.75, respectively (Figure 2). The adherence of pregnant women based on mean percentage of low dose aspirin tablets consumption after education increased by 6.0%. There was a significant difference (p = 0.020) in the knowledge of the pregnant women with high risk for preeclampsia before and after oral and written education using aspirin booklet. The mean percentage of low dose aspirin adherence in the first and the second evaluations was 89.8% and 95.8% consumption of aspirin, respectively (Figure 3). There was a significant difference (p = 0.011) in aspirin adherence between the first and second education.

Table 2: Characteristic of pregnant women with high risk for preeclampsia.

Characteristic	(n = 12), Mean ± SD
Age, years	28.6 ± 3.8
Weight, kg	60.3 ± 10.7
Height, m	1.6 ± 0.0
BMI	24.6 ± 3.9
Gestational age, week	12.5 ± 0.8
MAP	90.2 ± 14.9
Mean UTPI	2.1 ± 0.4
n, %	
Cigarette smoker	
1. Yes	0
2. No	12 (100.0)
Obstetric history	
1. Nulliparous	6 (50.0)
2. Parous with no previous preeclampsia	4 (33.3)
3. Parous with previous preeclampsia	2 (16.7)
Conception method	
1. Spontaneous	12 (100.0)
2. Ovulation induction	0
3. In vitro fertilization	0
Family history of preeclampsia	
1. Yes	2 (16.7)
2. No	10 (83.3)
Medical history	
1. Chronic hypertension	2 (16.7)
2. Diabetes mellitus Type 1	0
3. Diabetes mellitus Type 2	1 (8.3)
4. Systemic lupus erythematosus	0

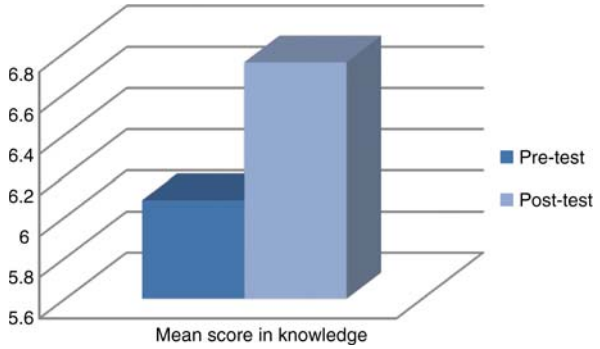

Figure 2: Mean score in knowledge domain of the pre- and post-education.

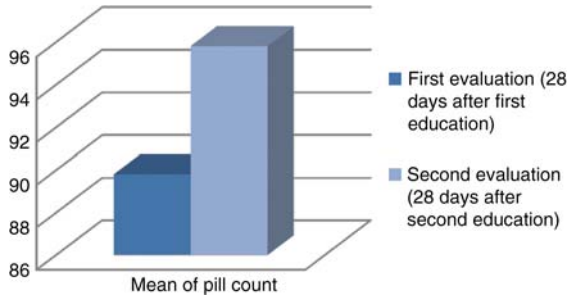

Figure 3: Mean percentage of aspirin adherence after first and second education.

Discussion

Most of the pregnant women had their first trimester visit to a midwife at primary care. According to the national health insurance scheme, all pregnant women with high risk or preeclampsia from primary and secondary health care facilities must be referred to tertiary care to get screened by a certified sonographer. Dr. Ramelan Naval Hospital, Surabaya, Indonesia is a tertiary care hospital that has carried out first trimester screenings by FMF certified sonographers since December 2011. Lack of the FMF certified sonographer at several secondary and tertiary health care facilities at the time of this research contributed to the underdiagnosed pregnant women with high risk for preeclampsia. Solution for this conditions was the use of simple method for preeclampsia screening based on clinical conditions (blood pressure, obesity, protein urine, history of preeclampsia) which had been done in primary care facilities . This causes the small number of pregnant women visiting the FMF certified sonographers at hospital in their first trimester, thus resulting in the relatively small number of our research sample. This condition is reflected in the number of pregnant women participating during the questionnaire's validation (first half year of 2018) compared to the sample of the research (September–December 2018). We did not use the same subjects for validation and samples, because it had taken several months for testing and retesting the first and the second versions of the questionnaire, before we could develop a valid and reliable one. The first version of the questionnaire consisted of nine questions, which were (1) signs of preeclampsia, (2) headache as one of the symptoms of preeclampsia, (3) effect of preeclampsia on pregnant women and the fetus, (4) preeclampsia prevention by administering low dose aspirin tablets regularly, (5) how to obtain aspirin tablet as preeclampsia prevention, (6) aspirin dosage administration, (7) how to avoid adverse drug reaction on gastrointestinal tract, (8) how to store aspirin tablet correctly, and (9) safety issue of aspirin tablet. We removed questions number 2 and 5, due to their correlation value ($r = -0.63$ and $r = -1.63$, respectively) which were less than 0.533 (r table of 13 samples). The second version of the questionnaire contained the remaining seven questions in the knowledge domain with the Cronbach α of 0.749; thus, it was concluded to be a valid and reliable questionnaire.

The efficacy of the first trimester screening in detecting preterm and term using maternal risk factors for preeclampsia is approximately 50%, while using mini-combinations [maternal factors with MAP and pregnancy-associated plasma protein-A (PAPP-A)] is 60%, maternal factors with biochemical markers is 65%, maternal factors with biophysical markers is 70%, and maternal factors with a combination of biophysical and biochemical markers is 75%. The choice of which type of the test was used for screening does not only depend on the efficacy but the feasibility of implementation, availability of the FMF certified sonographer, and the economic consideration of health services in the primary and secondary levels [14]. In this study, screening was done by combining maternal factors and biophysical markers, so that the results of measurements on pre-

dictions of preterm preeclampsia risk are more comprehensive. Components of the FMF screening test used in this research included maternal history (including ovulation-induced conception, race, body mass index (BMI), age, and mother with pre-eclampsia); MAP; uterine artery Doppler PI (UTPI); and PAPP-A and PlGF multiples of the median.

Maternal age is one of the preeclampsia risk factors. A study of the effect of the age of pregnant women on the development for preeclampsia resulted in the conclusion that under 20 years of age and those over 35 years old had an increased risk for preeclampsia [15]. Another reported that the risk for preeclampsia developed at the age of above 40 years [10]. Another study on the relationship between the age of pregnant women and adverse pregnancy outcomes resulted in the conclusion that the risk for preeclampsia had increased at the age of 35 years old [16]. In this recent research, maternal age was 28.6 ± 3.8 years old and should not be at risk of preeclampsia. But other risk factors such as past medical history, nulliparous, and current medical problems should be considered as risk factors for preeclampsia.

The appropriate BMI values for the Asian population according to WHO are as follows: underweight (<18.5), normal (18.5–22.9), overweight (23.0–27.5), and obesity (>27.5) [17]. Among pregnant women with high risk for preeclampsia, severe preeclampsia occurs in women who are overweight or obese even though the discrepancy between the body weight before pregnancy and the increase in weight during pregnancy is not statistically significant [18]. Overweight and obesity are considered as chronic inflammatory conditions that cause clinical symptoms of preeclampsia. The risk for preeclampsia occurs in women who happen to be obese before being pregnant [10].

Preeclampsia develops in pregnant women with nulliparous status compared to mothers with parous status [15]. Another study has shown that nulliparous status increases the risk of hypertension in pregnancy and preeclampsia, while the incidence of preeclampsia and eclampsia is low in parous women [19]. In this study 50% of pregnant women were nulliparous, thus increasing the risk to develop preeclampsia.

The high risk for preeclampsia occurred in women with chronic hypertension and preeclampsia history in the previous pregnancy [10]. Women with a family history of preeclampsia increase the risk of preeclampsia by 24%. This is related to genetic and environmental factors that exist in pregnant women [20]. This study included 16.7% of pregnant women who had preeclampsia history in their previous pregnancy and had a family history of preeclampsia. Chronic hypertension of 16.7% and diabetes mellitus of 8.3% were also found in this study.

The MAP and UTPI indicated by multiple of median values increased significantly at the first trimester of pregnant women with high risk for preeclampsia [21], [22], [23]. There was a significant relationship between the value of MAP and UTPI on the development of the risk of preeclampsia combined with maternal factors for the screening process. The estimation of preeclampsia development was detected using maternal factor, MAP, and UTPI of 80% and was able to detect preeclampsia before 34 weeks' gestation (preterm preeclampsia), and 55% was able to detect preeclampsia before 37 weeks' gestation (term preeclampsia) [24].

In vitro fertilization increased preeclampsia risk and pregnancy hypertension compared to other conception methods [25]. All the pregnant subjects of this study underwent spontaneous fertilization. This type of fertilization should not be considered as a risk for developing preeclampsia.

All pregnant women declared at high risk for preeclampsia by the sonographer received low dose aspirin (100 mg) tablets as preeclampsia prevention. One meta-analysis study concluded that the administration of low-dose aspirin before 16 weeks' gestation can significantly reduce the risk of severe preeclampsia but not for mild preeclampsia [8]. Pregnant women with a high risk for preeclampsia in screening results was more than 1:100. The administration of low-dose aspirin has been shown to reduce the incidence of preterm preeclampsia by 62% compared to placebo [26].

The use of low dose aspirin 100 mg tablet during pregnancy does not increase maternal bleeding complications. Research conducted by Bujold et al. [27] showed that gastrointestinal discomfort was reported to occur in 10% of pregnant women taking aspirin daily. There was no increased risk of bleeding and placental abruption [28], [29]. Pregnant women who experience preeclampsia developed significant increase in thromboxane A2, but the level of prostacyclin dropped sharply [30].

Research conducted by Abheiden et al. showed that non-adherence to low dose aspirin (80 mg) at 24–36 weeks gestation was as high as 46.3% and 21.4%, measured respectively by Simplified Medication Adherence Questionnaire and Beliefs and Behaviour Questionnaire [31]. This high incidence of aspirin non-adherence could increase risk of developing preeclampsia and thus endanger maternal and fetus' health.

Aspirin adherence can be enhanced by improving the knowledge about preeclampsia and low dose aspirin therapy as preeclampsia prevention. Education and communication can improve patient knowledge. Good communication between health workers and patients is needed to increase their adherence. Health workers can provide support in the form of education, discussion, or changes to drug regimens [12]. Research by Adawiyani showed that the use of booklets as a written educational media could increase the knowledge and drug adherence among anemic pregnant women supplemented with iron tablets in the experimental group compared to the control group (oral education) [32]. Another study using booklets as educational media to improve chil-

dren's knowledge and parents' and classroom teachers' nutrition knowledge with a pre-post design resulted in significant differences in nutrition knowledge after intervention using booklets [33].

This recent research served all pregnant women with both oral and written education using aspirin booklet which already received a copyright from the Indonesian Ministry of Law. In the natural setting before this research was conducted, education about the importance of administration of low dose aspirin tablet had been delivered orally without written materials at fetomaternal clinics. Pharmacist in this research team had been managed to developed the specific aspirin booklet as written educational material This emphasized the important role of pharmacists in supporting aspirin adherence among pregnant women with high risk for preeclampsia.

Education should be given when pregnant women at first screening are diagnosed as at high risk for preeclampsia. We provided all pregnant women with education materials consisting of knowledge about the importance of adherence in taking low dose aspirin tablets during the pregnancy as preeclampsia prevention, served as both oral and written education. Thus, the design of this study was a one group pretest and posttest research, as it was related to research ethics and could endanger pregnant women at high risk for preeclampsia if education is given orally without support of written materials. Preeclampsia is an emergency maternal condition that leads to maternal mortality in hours. This study showed that oral and written education served by pharmacist could increase the knowledge and adherence of pregnant women in taking low dose aspirin in statistically significant manner.

The limitation of the study is the small number of subjects enrolled in this research. Improvement on the knowledge and motivation to aspirin adherence could be the result of historical changes unrelated to the provision of booklet and oral communication. Any other source of information received by the pregnant women unrelated to our intervention, such as from newspaper and other media, could probably be a source of bias in this research. The conditions that are potential confounding factors are difficult to control in this outpatients setting; thus, extreme caution is needed in interpreting and generalizing the results of this pre-experimental research. We recommend further investigation about knowledge and aspirin adherence in randomized control study design with the adequate number of subjects involved in such research.

Conclusions

The use of oral education and written aspirin booklet provided by pharmacists had impact on knowledge of preeclampsia prevention and adherence in taking aspirin among pregnant women with high risk for preeclampsia.

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Informed consent: Informed consent was obtained from all individuals included in this study.

Ethical approval: Research involving human subjects complied with all relevant national regulations, institutional policies and is in accordance with the tenets of the Helsinki Declaration (as revised in 2013), and has been approved by the authors' institutional review board.

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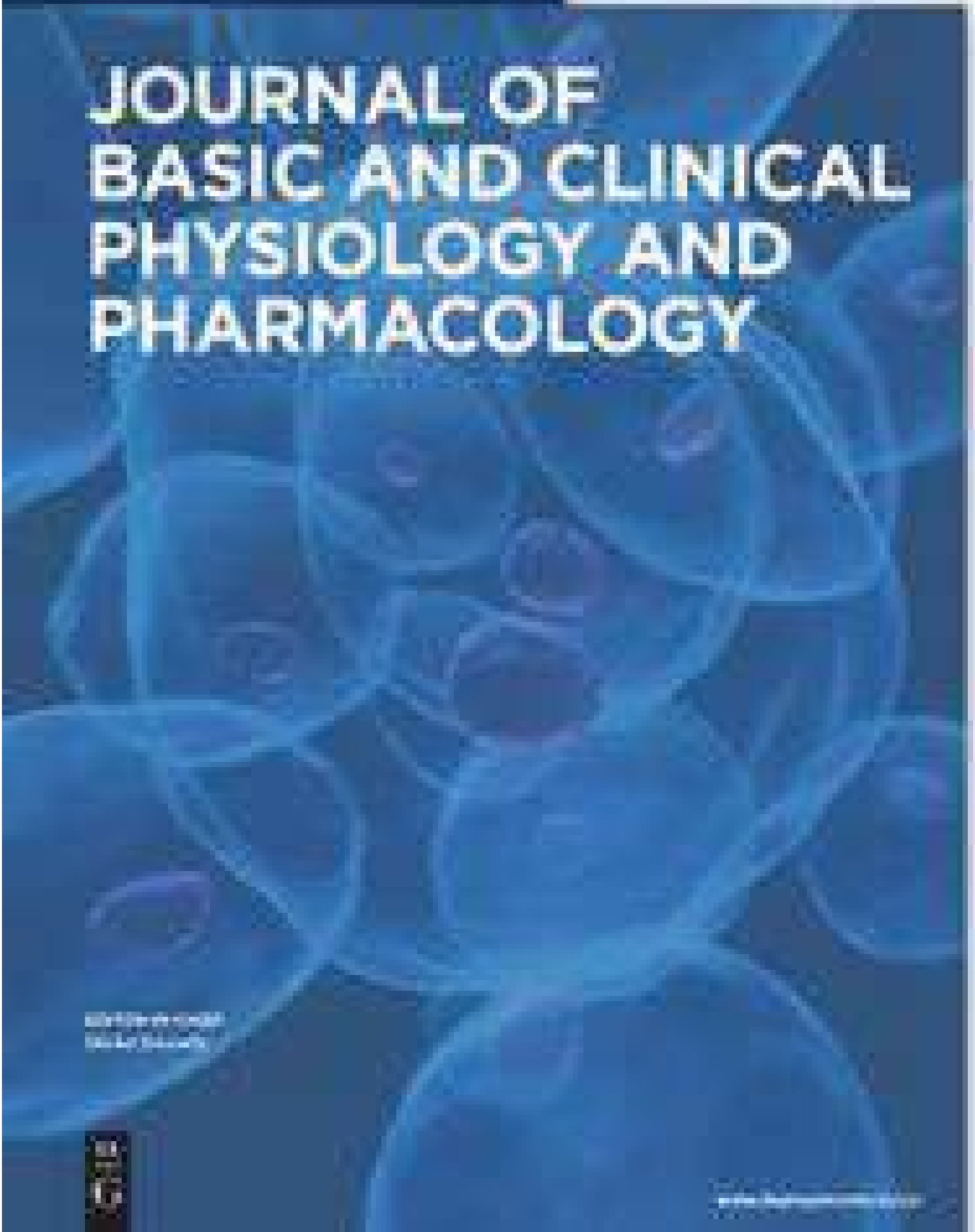

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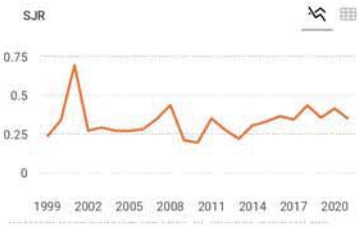

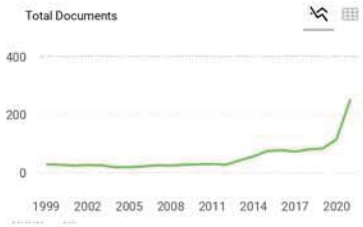

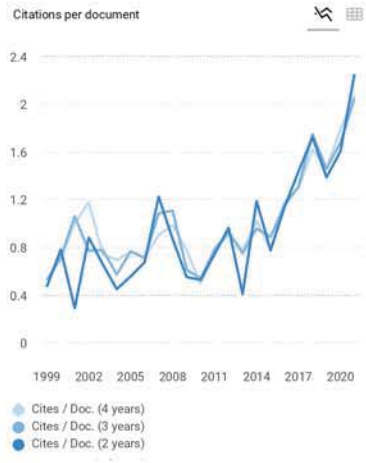

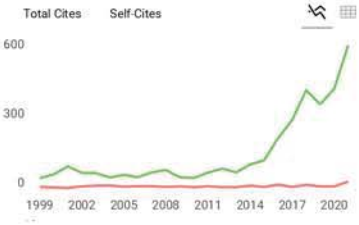

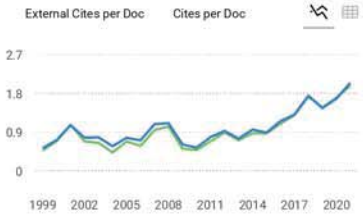

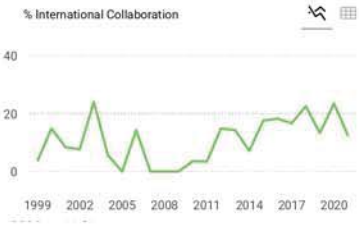

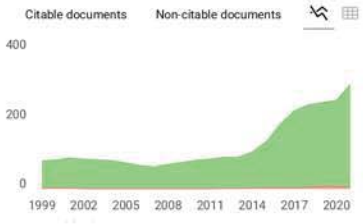

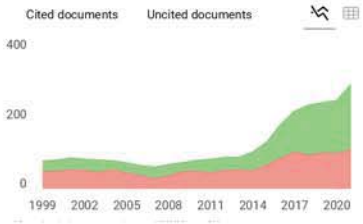

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