

Efficiency of administering low dose aspirin to prevent pre-eclampsia based on NICE guideline – a policy to practice gap in antenatal care in a rural Sri Lankan district

D M A Kumara^a, D Ayesmantha^a, D Karunarathne^a, L Senarathna^a

Abstract

The NICE guideline on managing pregnancy induced hypertension recommends a low dose aspirin as prophylaxis for pre-eclampsia. Eligibility for aspirin is assessed using risk factor-based evaluation using major and moderate risk factors. Understanding prevalence of risk factors as per guideline and the level of adherence of clinicians to guideline are important in managing pre-eclampsia. This study aimed to assess the prevalence of major and moderate risk factors for pre-eclampsia in this population as per NICE guidelines and to understand the clinician's level of adherence to the guideline.

A cross-sectional study was carried out in the professorial unit, Teaching Hospital, Anuradhapura, Sri Lanka using a structured data collection sheet to collect data from pregnant women admitted for delivery within a period of one month.

Out of 420 pregnant women, 20 (4.5%) had major or moderate risk factors and eligible for aspirin prophylaxis as per NICE guideline. But only seven (35%) of them were identified based on the guideline and given aspirin during antenatal care. There were 11 (2.6%) women with major risk factors but only five were identified and from nine women with moderate risk factors, only two were identified as eligible. Comparatively, identifying eligibility based on major risk factors was higher than moderate risk factors.

Although the prevalence of risk factors of preeclampsia is low, there is a gap between NICE guideline recommendations and the actual practice among clinicians in antenatal care from this rural district. Clinicians should be provided with updated information on NICE guideline to improve recognizing risk factors and prescribing aspirin.

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^a *Department of Obstetrics and Gynaecology, Faculty of Medical Sciences and Allied Health Sciences, University of Rajarata, Sri Lanka.*

Correspondence: DMAK, e-mail: kumaradissanayake75@gmail.com

 <https://orcid.org/0000-0003-4676-2011>

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Introduction

Pre-eclampsia can lead to significant maternal and fetal morbidity and mortality¹. Hypertensive disorders is the fourth leading cause of maternal mortality in Sri Lanka². Pre-eclampsia defined as development of hypertension after 20 weeks of gestation with significant proteinuria and it may exist as pregnancy induced hypertension without proteinuria³.

Low dose of aspirin for prevention of pre-eclampsia and its complications had been studied during past decades and proven that aspirin reduces the occurrence of hypertension in pregnant women who have historical risk factors for developing pregnancy induced hypertension⁴⁻⁶.

In a systematic review and meta-analysis, Bujold E et al have concluded that starting aspirin in early gestation was associated with significant reduction in incidence of pre-eclampsia and reduction of progression to severe pre-eclampsia compare to starting it late gestation⁷.

In a Cochrane review, Duley, Lelia et al confirmed that there is a 17% reduction in the risk of pre-eclampsia with use of antiplatelet drugs with 8% reduction in the relative risk of preterm birth, 14% reduction in fetal and neonatal deaths and 10% reduction in small for gestational age babies⁸. These evidences were reaffirmed by an updated review from the same authors in 2019⁹.

Although low dose of aspirin is effective for the prevention of pre-eclampsia, there are no serious complications or adverse reactions reported. Coomarasamy A et al have concluded that aspirin therapy did not show any harmful effects, particularly that there is no increased risk in placental abruption, fetal intraventricular hemorrhage or other neonatal bleeding^{9,10}.

Based on the evidences, the (National Institute of Clinical Excellence) NICE guideline published in 2010 recommended prescribing Aspirin 75 mg daily from 12 weeks of gestation and at least by 16 weeks until the delivery for pregnant women who have risk of developing pre-eclampsia¹¹.

International guidelines are commonly used by clinicians in Sri Lankan health care system. Obstetricians and Gynaecologists use and recommend the NICE guidelines in prescribing aspirin in antenatal care.

The decision to prescribe aspirin is based on risk factor-based patients evaluation using major and moderate risk factors¹². Hypertension during previous pregnancy chronic kidney disease, autoimmune disease such as systemic lupus erythematosus or antiphospholipid syndrome, type 1 or type 2 diabetes and chronic hypertension are considered as major risk factors. Pregnant women with at least one major risk factor are eligible for aspirin prophylaxis. Being the first pregnancy, forty years of age or older, more than 10 years gap with the previous pregnancy, body mass index (BMI) of 35 kg/m² or more at first visit, family history of pre-eclampsia and multi fetal pregnancy are considered as moderate risk factors. Pregnant women with more than one moderate risk factor are considered as eligible for aspirin treatment³.

Despite the recommendations from number of guidelines including NICE, there are evidences that a significant proportion of eligible pregnant women with major or moderate risk factors of pre-eclampsia do not receive aspirin^{13,14}. Similarly, there are several studies those have presented that adherence to NICE guidelines is not adequate in many settings^{15,16}. Nevertheless, there are no evidences about the level of adherence of Sri Lankan clinicians in antenatal care with the NICE guideline on prescribing aspirin for pre-eclampsia. Hence, understanding the existing level of adherence is vital in improving the utilization of the recommendations from guidelines to prevent pre-eclampsia. This study aimed to assess the prevalence of risk factors for pre-eclampsia among pregnant women delivered in Anuradhapura teaching hospital as per NICE guideline and also to evaluate the level of adherence of clinicians in providing antenatal care to the guideline for prescribing aspirin for pregnant women with risk factors for p re-eclampsia.

Materials and methods

Study design and setting

A cross-sectional study was carried out in the Professorial Unit, Teaching Hospital, Anuradhapura Sri Lanka during 2017. Data was collected from individual patients using a structured data collection sheet and there was no follow-up.

Study population

Pregnant women who admitted to professorial unit, teaching hospital, Anuradhapura for delivery were

considered for this study. Anyone who was not in a position to provide information due to mental health issues was excluded. All other women were approached for consent and only consented women were included into the study.

Sampling and sample size

There were no published data on the population prevalence of pre-eclampsia from Sri Lanka. Hence, sample size estimation was not done and all admissions for a period of one month to the study hospital considered as the eligible sample. The average monthly admissions have been recorded as over 400 in the study hospital.

Method of data collection

Data collection was done by clinically trained research assistants in the post-natal ward of the study hospital. This included extracting data from current and previous maternity records, previous obstetric notes and collecting information directly from participants using structured data collection form.

Data analysis

The analysis of data was mainly descriptive to summarize and describe the characteristics of participants. Comparisons of the proportions and significant tests were used where necessary. Statistical software SPSS was used as data analysis tools.

Ethics statement

Ethical clearance was obtained from ethical review committee of the Faculty of Medicine and Allied Health Sciences, Rajarata University of Sri Lanka (ERC/2017/16).

Informed written consent was obtained from all participants before the data collection. Interviews were conducted within the ward and when the mothers are comfortable and ready to provide information. Identifiable information was not collected and steps were taken to protect the confidentiality of the collected data. All records were coded before the analysis.

Results

Four hundred and twenty patients recruited to the study during April 2017. Out of 446 total admissions during

the month, 431 became eligible and 420 consented to participate for the study.

Characteristics of the study population

Majority (63.1%) of the study population from age group 26 to 40 years and 35.2% is from 18 to 25 years age group. Forty eight percent has had received education up to junior high school. Half of the study population had a family income of 30000 to 50000 rupees per month (Table 1).

Prevalence of risk factors for pre-eclampsia

From the total number of participants of 420, the prevalence of moderate or major risk factors according to NICE guideline was 4.7% (n=20). From this group with risk factors, only seven (35%) were identified as eligible and prescribed aspirin in antenatal clinics. Except one, all others took aspirin regularly (Table 2).

Major risk factors:

Eleven patients out of 420 (2.6%) had major risk factors. Having diagnosed with hypertension during a previous pregnancy (7/11) and diabetes mellitus (6/11) were the identified risk factors among study participants respectively. Two participants presented with both hypertension during previous pregnancy and diabetes mellitus. Five out of eleven women with major risk factors were identified as eligible and given aspirin during antenatal clinics (Table 2). All 11 women with major risk factors had registered for antenatal care before 16th week of gestation.

Moderate risk factors:

The prevalence of the presence of more than one moderate risk factor was 2.1% (9/420) among participants, so that they are eligible for aspirin according to the NICE guideline. Out of these 9 women, 3 presented as first pregnancy and with family history of pre-eclampsia as a risk factor. Other risk factors such as multiple pregnancies (n=4), BMI over 35kg/m² (n=3), time since previous pregnancy more than 10 years (n=4) and age over 40 years (n=3) were identified in this population. Only two out of these nine women were identified as eligible for aspirin as per NICE guideline and given aspirin in antenatal clinics. All 9 women with moderate risk factors had registered for antenatal care before 16th week of gestation.

Table 1. Demographic characteristics of study population

Characteristics	Frequency (%)
Age – in years (n=406) <ul style="list-style-type: none"> • < 18 • 18-25 • 26-40 • >40 	<p>5 (1.2)</p> <p>143 (35.2)</p> <p>256 (63.1)</p> <p>2 (0.5)</p>
Marital status (n=420) <ul style="list-style-type: none"> • Married • Unmarried 	<p>417 (99.3)</p> <p>3 (0.7)</p>
Educational level (n=414) <ul style="list-style-type: none"> • Up to grade 5 • Up to O/L classes • Up to A/L classes • Graduates 	<p>74 (17.8)</p> <p>184 (44.6)</p> <p>148 (35.7)</p> <p>8 (1.9)</p>
Monthly income (n=385) <ul style="list-style-type: none"> • <10000 • 10000-30000 • 30000-50000 • >50000 	<p>3 (0.7)</p> <p>113 (29.3)</p> <p>209 (54.5)</p> <p>60 (15.5)</p>
Contact with antenatal care <ul style="list-style-type: none"> • Registered before 16 weeks • Registered after 16 weeks 	<p>414 (98.5)</p> <p>6 (1.5)</p>

Table 2. The number of participants eligible for aspirin treatment with risk factors and the number given aspirin in antenatal clinics

	Major risk factors	Moderate risk factors	Total number
Number (%) of women eligible for aspirin treatment as per NICE guideline	11 (2.6)	9 (2.1)	20 (4.7)
Number (%) of women identified as eligible in antenatal clinics	5 (45.4)	2 (22.2)	7 (35)
Number (%) of participants who continue to take aspirin regularly	4 (36.4)	2 (22.2)	6 (30)

From the total number, considering both major and moderate risk factors, 20 women were eligible for aspirin as per NICE guideline and only 7 (35%) were identified as eligible and given aspirin.

Discussion

This study shows that the prevalence of risk factors for pre-eclampsia based on the NICE guideline is 4.7% in this population from a tertiary care hospital in a rural district of Sri Lanka. However, only 35% of this eligible group was identified as eligible and given prophylaxis aspirin in antenatal clinics. The rest of the group has not received any prophylaxis aspirin for pre-eclampsia. These findings emphasize that adherence to prescription of aspirin as per NICE guideline for pre-eclampsia prevention based on major or moderate risk factors is low among clinicians involved in antenatal care in study area.

Overall, 20 (4.5%) women were eligible for aspirin based on major and moderate risk factors. But only 7 (35%) of them were given aspirin during antenatal care. Comparatively, prescribing aspirin for pregnant women based on major risk factors is higher than moderate risk factors. Identifying moderate risk factors were largely missed out and adherence to guideline is lower when the women present with moderate risk factors for pre-eclampsia. Failure to identify risk factors and prescribe subsequent prophylaxis aspirin shows that there is a policy (guideline) to practice gap regarding adhering to NICE guideline. This creates a missed opportunity in antenatal care as all women in the study were in touch with antenatal care system and all but 6 had registered for antenatal care before 16th week. These findings emphasize that educating clinicians on assessing risk factors would be useful not to miss opportunities to prevent complications due to pre-eclampsia in antenatal care.

Prevalence of pre-eclampsia risk factors based on NICE guideline and adherence of medical professionals towards NICE guideline has not been systematically studied in Sri Lanka. This is the first study to evaluate use of guideline on using aspirin for pre-eclampsia and reports that the adherence of clinicians to NICE guideline is 35% in Sri Lanka. Findings from this study emphasized that continuous professional development programs should be encouraged, particularly in rural districts.

Findings from this study are useful and encourage clinicians and administrators to look at the gap between the existing policy and the practice and identify possible reasons for it. The health system in Sri Lanka follows the NICE guideline from United Kingdom as a standard. Any practice or policy changes based on this study would be a timely action as the guidelines were introduced in 2010³. Although there were updates to the guidelines in 2019, those changes were about an alteration to the dose¹².

The study was carried out at the professorial unit in a teaching hospital where pregnant women from semi urban and rural areas are reaching. The sample was representative for all demographic areas in Anuradhapura district. Data collection was conducted by trained research assistants who could deliver the questions accurately.

Sample size calculation was not done prior to this study as there is no data on the prevalence of pre-eclampsia in Sri Lankan population. Instead all women admitted to the study hospital during one month period were taken as the sample. The average number of monthly admission to study hospital has been more than 400. An ad-hoc sample size calculation was done based on the population prevalence of pre-eclampsia in India which is 5.4%¹⁷. The estimated sample was 88 participants including an adjustment for 10% dropout¹⁸. The recruited sample of 420 was approximately five times than this estimation and large enough to detect an even a smaller prevalence of risk factors. Considering all admissions for a period of one month allowed recruiting a sample of pregnant women representative to the target population from Anuradhapura district. However, recruiting participants from peripheral clinics could ensure a better representation in terms of social and economic characteristics.

While highlighting the policy to practice gap in the antenatal care of this rural district, there were no details from this study about the potential reason from clinicians for not following the guideline. It will be useful to explore these reasons in a future study to get an insight into this issue.

Conclusion and recommendations

This study found that only 30% of pregnant women with the risk of pre-eclampsia from study population

had been identified using risk factor based assessment recommended in NICE guideline during antenatal care. Hence, there is a gap between the available guideline on using aspirin for pre-eclampsia based on major and moderate risk factors and the actual practice among clinicians from rural district of Anuradhapura. Adherence of clinician in antenatal care with the NICE guideline should be improved as hypertensive disorders is a leading cause in maternal mortality and morbidity in Sri Lanka.

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