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# Cost-effectiveness analysis of first trimester screening for preeclampsia and early initiation of aspirin therapy for prevention of the disease in a private tertiary hospital

Carol Joanna G. Violago, Irene B. Quinio

## Abstract:

**Background:** Preeclampsia (PE) has significant health and economic burden. Early screening for PE through first trimester screening (FTS) can direct decision-making on early initiation of aspirin (ASA) therapy, which has been known to reduce the incidence of PE.

**Objectives:** The objective of the study is to evaluate the cost-effectiveness of FTS and early initiation of ASA for disease prevention.

**Methodology:** A population of 1916 women who delivered in a private tertiary hospital from January 2019 to March 2020 was categorized based on the risk of developing PE, results of FTS, initiation of ASA therapy, development of PE, and mode of delivery. Descriptive statistics using counts and percentages were used to summarize the data. Association between ASA therapy and PE was assessed using the Chi-square test. Costs of screening, ASA therapy, inpatient management, and delivery were computed.

**Results and Conclusion:** Results showed that PE was prevented in 71.4% of those high-risk patients who underwent FTS and started on ASA therapy. Total cost of urgent care of PE and delivery was P119,687.02 to P149,687.02 for early PE, and P103,587.02 to P133,587.02 for late PE. Prevention of early PE and late PE results in net cost savings of P69,694.02 and P53,594.02, respectively, with the investment of P9,993.00 on FTS and ASA therapy. Implementation of FTS and initiation ASA therapy is an effective and cost-saving approach that can prevent PE.

## Keywords:

Aspirin, cost-effectiveness, first trimester, preeclampsia

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## Introduction

Preeclampsia (PE) remains to be one of the leading causes of maternal and fetal morbidity and mortality complicating 3% of pregnancies worldwide.<sup>[1-3]</sup> Philippine Obstetrical and Gynecological Society (POGS) statistics report severe PE complicating 2%–5% of pregnancies.<sup>[4]</sup> In this institution, there is a 16%–17% incidence

of hypertensive disorders in 60% of high-risk women who delivered in 2014–2018 (Martin, M., Gonzaga, Z., 2018, unpublished).

The development of PE complicates both maternal and fetal health. Admission to intensive maternal unit, eclampsia, HELLP syndrome, postpartum hemorrhage, fetal growth restriction, oligohydramnios, preterm birth, and perinatal deaths are some of the most common complications of the disease.<sup>[1,2,3,5]</sup> In relation to this, maternal

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health-care costs related to PE significantly add to the burden of disease. Mallampati *et al.* estimated the costs of preterm PE and term PE in the United States (US) to have an additional \$4,410 and \$2,044 to maternal and neonatal health-care costs, respectively.<sup>[6]</sup> In a cost-of-illness analysis of PE by Hao *et al.*, of an integrated health-care system in the US, the maternal–infant cost of PE was \$28,603.<sup>[7]</sup> Zakzuk *et al.* evaluated the costs of care of patients with PE in Colombia and revealed expenses to increase seven times higher than what is covered by insurance. Extrapolated cost of disease is at \$1,474 per case with an economic burden of \$40,106,544 to \$60,159,078 annually.<sup>[8]</sup> In the Philippines, there is no published study on the economic burden of PE. The Philippine Health Insurance Corporation (PhilHealth) provides only a first case rate payment for PE of only P6,800 regardless of severity of the disease but does not provide a second case rate payment. The case rates for delivery are P6,500 and P19,000 for normal spontaneous delivery (NSD) and cesarean section (CS), respectively. Patients rely on out-of-pocket payment, coupled with private health-care insurance coverage if available, for the rest of their hospital expenditures.

In 2014, this institution established the first trimester screening (FTS) program to address the need for accurate and timely assessment of high-risk women and determine the need to initiate ASA therapy to prevent PE. The ASPRE trial (2017) and American College of Obstetricians and Gynecologists (ACOG) guidelines (2018) provided the evidence of the efficacy of ASA in preventing PE if initiated before 16-week gestation.<sup>[1,2,9]</sup> Despite these guidelines, implementation based on risk-based approaches falls short.<sup>[9]</sup> Evaluation of cost-effectiveness of FTS with the initiation of ASA therapy in this institution will further validate best practices in preventing PE and present data that will fill the knowledge gap of economic burden of PE in the Philippine setting. The objective of the study is to evaluate the cost-effectiveness of FTS (using maternal characteristics, placental growth factor, pregnancy-associated plasma protein A [PAPP-A], and ultrasound measurement of uterine artery pulsatility index [UtA-PI]), and early initiation of aspirin therapy for the prevention of the disease. The specific objectives are (1) to determine the rate of cases of PE prevented by undergoing FTS and ASA therapy, (2) to determine the cost of urgent care and delivery of patients with PE, (3) to determine the cost of FTS and ASA therapy, and (4) to determine the cost of maternal health-care savings based on Philippine peso.

## Methodology

### Population and sample

This is a retrospective study of 1916 singleton pregnant

patients with clinical risk factors for development of PE who delivered in this institution from January 2019 to March 2020. Patients with the following variables were excluded: (a) multiple pregnancies, (b) pregnancies complicated by fetal abnormality, (c) women taking low-dose aspirin and long-term nonsteroidal anti-inflammatory medications regularly, and (d) women who are not able to take ASA due to diagnosed bleeding disorder, peptic ulceration, and hypersensitivity to aspirin.

### Data collection process

Patient profiles and clinical courses of 1916 women who delivered from January 2019 to March 2020 were collected using the Orion and Midas hospital information management systems. Results of the FTS calculated using the Life Cycle Program were obtained from the High-Risk Pregnancy Clinic electronic records. The Life Cycle Program uses the Fetal Maternal Foundation (FMF) algorithm assessing maternal age, body mass index, MAP MoM, smoking history, PE history, parity, history of chronic hypertension, PIGF MoM, PAPP-A MoM, and UtA-PI.<sup>[10]</sup> Results of the data collected were inputted in Microsoft Excel to categorize patients based on: (1) clinical risk factors of developing PE, (2) results of FTS done at 11–13 6/7 weeks age of gestation, (3) initiation of ASA therapy, (4) development of PE, and (5) mode of delivery.

### Analysis

#### Data sets

The total of 1916 patients were evaluated using POGS clinical risk factors for developing PE and was divided into low risk and high risk.<sup>[3]</sup> Those who were high risk were divided based on two approaches. The first approach comprised those who underwent FTS, while the second approach comprised those who did not. Those under the first approach with high-risk results were started on ASA therapy before 16-week age of gestation, and those with low-risk results were not started on ASA therapy. Those under the second approach did not undergo FTS and were not started on ASA therapy. All patients were then followed up if they developed PE or not. Patients who developed PE were further categorized to early and late PE [Figure 1].

#### Analysis procedures

Descriptive statistics using counts and percentages were used to summarize the data into categories. Association between ASA therapy and PE was assessed using the Chi-square test. Tests of hypotheses were assessed at 5% level of significance. Decision analysis tree model [Figure 1] was created to present the patient profiles and clinical courses. The first approach represented the management of women screened as high risk for PE based on clinical factors during their first

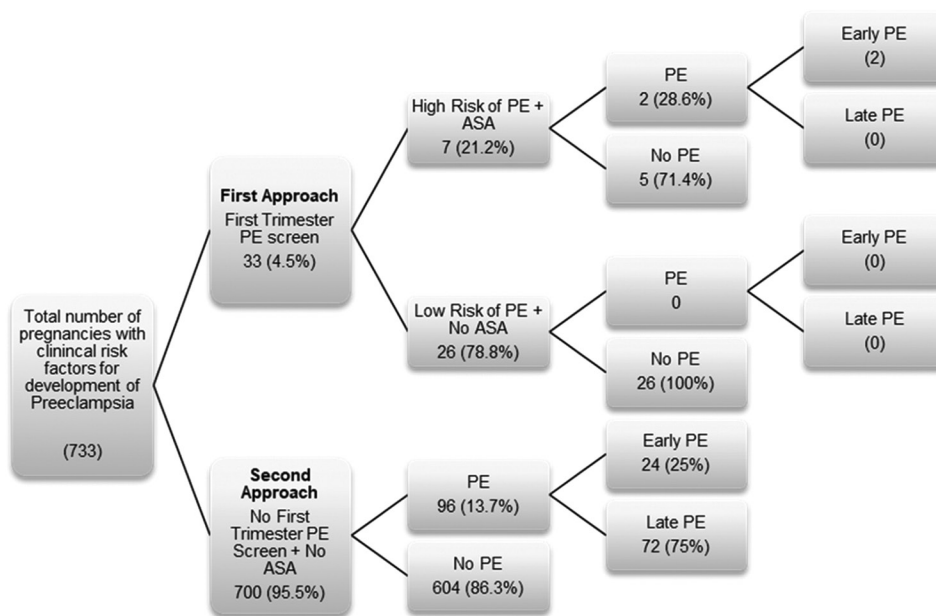


Figure 1: Decision analysis tree of two approaches for prevention of preeclampsia

prenatal checkup, then underwent FTS, and initiated on ASA therapy when FMF multivariate screening algorithm concurred the high risk of developing PE. The second approach represented clinically assessing patients at risk for developing PE but forgoing FTS and ASA therapy. Subsequent development of PE was then recorded.

Cost computations were done by identifying the expenses incurred using approaches described in the figures. The cost of FTS is based on institution's rate. The estimated cost of ASA therapy is based on standard market price of 80 mg/tablet 1 tablet daily taken from 12 weeks to 36 weeks age of gestation.<sup>[11]</sup> Other expenses were based on medications given to control elevated blood pressure, seizure prophylaxis, fetal lung maturity, and fetal neuroprotection. Moreover, included are the expenses for fetomaternal surveillance in the intensive maternal unit and the labor room, room rate, and average length of stay. Cost of NSD and CS delivery is based on institution's standards as well. Not included in cost computation are doctors' professional fees, prenatal care, neonatal care, and other indirect costs. All costs were normalized to December 2019 Philippine peso based on the Consumer Price Index. Microsoft Excel was used to do cross-sectional analysis. All variations based on the decision analysis performed. Cost-effectiveness was calculated using the following formula;<sup>[12]</sup>

Cost of FTS and ASA therapy – averted cost of urgent care of PE = net costs (negative value means cost-savings).

## Results

There were a total of 1916 patients who qualified for the

study. The population was divided into 1183 (61.7%) low-risk patients and 733 (38.3%) high risk for PE based on clinical assessment. Of the patients under the high-risk set representing the first group, 33 patients (4.5%) underwent FTS. FTS revealed seven patients (21.2%) were at risk of developing PE and were started on ASA therapy. Of the patients who were under ASA therapy, two (28.6%) developed PE, both of whom were categorized as early. Five (71.4%) did not develop PE. Twenty-six (38.8%) were low risk for developing PE and did not start ASA therapy, all of whom did not develop PE (100%). Of the patients under the second group, 700 (95.5%) did not undergo FTS and ASA therapy. Of these patients, 96 (.7%) developed PE, 24 (25%) and 72 (75%) developed early PE and late PE, respectively; 604 (86.3%) did not develop PE [Figure 1].

The cross-tabulation of PE status versus FTS and initiation of ASA ( $n = 33$ ) is shown in Table 1. Analysis reveals that there is a significant association between prevention of PE and ASA treatment ( $P = 0.04$ ).

Focusing on the cost of the two approaches, Table 2 shows the estimated cost for FTS, ASA therapy, cost of urgent care of PE, and cost of delivery. The cost of FTS is based on institution's rate of Php 9405.00. The estimated cost of ASA therapy of Php 588.00 is based on standard market price of 80 milligram per tablet taken once a day daily taken from 12 weeks to 36 weeks age of gestation.<sup>[11]</sup> Cost of urgent care was calculated as seen in Table 3. Cost of NSD is estimated at Php 40,000.00 and cost of CS delivery at Php 70,000.00 based on institution's standards. Looking at high-risk patients who underwent FTS and were given ASA, five out of seven patients

**Table 1: Preeclampsia status versus first trimester screening and initiation of aspirin therapy**

First trimester screening	ASA status		Total	Chi-square test <i>P</i>
	(+) ASA	(-) ASA		
High risk				
PE status				
(+) PE	2	0	2	No test (all patients on ASA)
(-) PE	5	0	5	
Total	7	0	7	
Low risk				
PE status				
(+) PE	0	0	0	No test (all patients not on ASA)
(-) PE	0	26	26	
Total	0	26	26	
Total				
PE status				
(+) PE	2	0	2	0.04 (S)
(-) PE	5	26	31	
Total	7	26	33	

PE: Preeclampsia, S: Significant

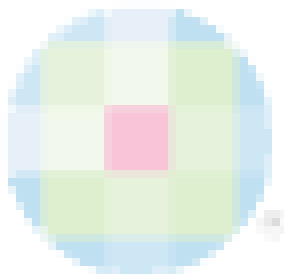
**Table 2: Estimated cost for first trimester screening, aspirin therapy, urgent care of preeclampsia, and cost of delivery**

	Clinical Assessment	Cost of Screening	Result of FTS	ASA Status	Cost of Aspirin Treatment	PE Status	Timing of PE	Cost of Urgent Care	Delivery	Cost of Delivery	Total Cost	Count
First Approach	High Risk for PE	9,405.00	High Risk for PE	(+) ASA	588.00	(+) PE	Early PE	79,687.02	CS	70,000.00	159,680.02	2
	High Risk for PE	9,405.00	High Risk for PE	(+) ASA	588.00	(+) PE	Late PE	63,587.02	CS	70,000.00	143,580.02	0
	High Risk for PE	9,405.00	High Risk for PE	(+) ASA	588.00	(-) PE	No PE	0	CS	70,000.00	79,993.00	5
	High Risk for PE	9,405.00	Low Risk for PE	(-) ASA	0	(+) PE	Early PE	79,687.02	CS	70,000.00	159,092.02	0
	High Risk for PE	9,405.00	Low Risk for PE	(-) ASA	0	(+) PE	Late PE	63,587.02	CS	70,000.00	142,992.02	0
	High Risk for PE	9,405.00	Low Risk for PE	(-) ASA	0	(-) PE	No PE	0	CS	70,000.00	79,405.00	21
	High Risk for PE	9,405.00	High Risk for PE	(+) ASA	588.00	(+) PE	Early PE	79,687.02	NSD	40,000.00	129,680.02	0
	High Risk for PE	9,405.00	High Risk for PE	(+) ASA	588.00	(+) PE	Late PE	63,587.02	NSD	40,000.00	113,580.02	0
	High Risk for PE	9,405.00	High Risk for PE	(+) ASA	588.00	(-) PE	No PE	0	NSD	40,000.00	49,993.00	0
	High Risk for PE	9,405.00	Low Risk for PE	(-) ASA	0	(+) PE	Early PE	79,687.02	NSD	40,000.00	129,092.02	0
	High Risk for PE	9,405.00	Low Risk for PE	(-) ASA	0	(+) PE	Late PE	63,587.02	NSD	40,000.00	112,992.02	0
	High Risk for PE	9,405.00	Low Risk for PE	(-) ASA	0	(-) PE	No PE	0	NSD	40,000.00	49,405.00	5
												33
Second Approach	High Risk for PE	0	0	(+) ASA	588.00	(+) PE	Early PE	79,687.02	CS	70,000.00	150,275.02	0
	High Risk for PE	0	0	(+) ASA	588.00	(+) PE	Late PE	63,587.02	CS	70,000.00	134,175.02	0
	High Risk for PE	0	0	(+) ASA	588.00	(-) PE	No PE	0	CS	70,000.00	70,588.00	0
	High Risk for PE	0	0	(-) ASA	0	(+) PE	Early PE	79,687.02	CS	70,000.00	149,687.02	24
	High Risk for PE	0	0	(-) ASA	0	(+) PE	Late PE	63,587.02	CS	70,000.00	133,587.02	67
	High Risk for PE	0	0	(-) ASA	0	(-) PE	No PE	0	CS	70,000.00	70,000.00	390
	High Risk for PE	0	0	(+) ASA	588.00	(+) PE	Early PE	79,687.02	NSD	40,000.00	120,275.02	0
	High Risk for PE	0	0	(+) ASA	588.00	(+) PE	Late PE	63,587.02	NSD	40,000.00	104,175.02	0
	High Risk for PE	0	0	(+) ASA	588.00	(-) PE	No PE	0	NSD	40,000.00	40,588.00	0
	High Risk for PE	0	0	(-) ASA	0	(+) PE	Early PE	79,687.02	NSD	40,000.00	119,687.02	0
	High Risk for PE	0	0	(-) ASA	0	(+) PE	Late PE	63,587.02	NSD	40,000.00	103,587.02	5
	High Risk for PE	0	0	(-) ASA	0	(-) PE	No PE	0	NSD	40,000.00	40,000.00	214
												700

PE: Preeclampsia, FTS: First trimester screening, NSD: Normal spontaneous delivery, CS: Cesarean section

**Table 3: Cost of urgent care of preeclampsia**

Item	Item number	Price	Total
First trimester screening for preeclampsia+aspirin initiation			
First trimester screening for preeclampsia	1	9405	9405
Aspirin initiation at 12 weeks age to 36 weeks (1 tablet×168 days)	168	3.5	588
Total expense for first trimester screening for preeclampsia+aspirin initiation			9993
Urgent care of early preeclampsia			
Service			
Private room	4	3150	12,600
Intensive maternal unit	2	5500	11,000
CTG tracing for 24 h	2	5000	10,000
Patient monitoring for 24 h	2	5000	10,000
IV insertion	2	750	1500
Medications			
Betamethasone 5 mg/2 mg/amp (12 mg/IM×2 doses)	4	1166.40	4665.60
Syringe 5 cc for administration of betamethasone	2	12.48	24.96
Magnesium sulfate 5 g/20 ml (4 g loading dose+25 g for 24 h)	6	60.3	361.8
D5W 500 ml	1	370	370
D5W 1000 ml	1	250	250
Macroset	1	279	279
Syringe 10 cc for administration of magnesium sulphate	3	15.94	47.82
Hydralazine 20 mg/amp (max dose 20 mg/IV)	1	267.8	267.8
Syringe 3 cc for administration of hydralazine	4	9.24	36.96
Nicardipine 10 mg/amp (max dose 10 mg/h)	12	1375	16,500
D5W 250 ml	5	175	875
Soluset	1	266	266
Syringe 10 cc for administration of nicardipine	12	15.94	191.28
Nifedipine 10 mg/tab (max dose 20 mg every 6 h)	8	45.35	362.8
Methyldopa 250 mg/tab (max dose 3 g/day)	12	29.75	357
Diagnostics			
Biophysical profile scoring+Doppler velocimetry	1	3630	3630
Complete blood count with platelet count	1	547	547
Urinalysis	1	412	412
AST	1	755	755
ALT	1	888	888
LDH	1	645	645
Creatinine	1	565	565
Uric acid	1	515	515
BUN	1	480	480
24 h urine protein	1	1194	1194
Total expense of urgent care of early preeclampsia			79,587.02
Urgent care of late preeclampsia			
Service			
Private room	4	3150	12,600
Intensive maternal unit	1	5500	5000
CTG tracing for 24 h	1	5000	5000
Patient monitoring for 24 h	1	5000	5000
IV insertion	2	750	1500
Medications			
Betamethasone 5 mg/2 mg/amp (12 mg/IM×2 doses)	4	1166.40	4665.60
Syringe 5 cc for administration of betamethasone	2	12.48	24.96
Magnesium sulfate 5 g/20 ml (4 g loading dose+25 g for 24 h)	6	60.3	361.8
D5W 500 ml	1	370	370
D5W 1000 ml	1	250	250
Macroset	1	279	279
Syringe 10 cc for administration of magnesium sulfate	3	15.94	47.82
Hydralazine 20 mg/amp (max dose 20 mg/IV)	1	267.8	267.8



Contd...

**Table 3: Contd...**

Item	Item number	Price	Total
Syringe 3 cc for administration of hydralazine	4	9.24	36.96
Nicardipine 10 mg/amp (max dose 10 mg/h)	12	1375	16,500
D5W 250 ml	5	175	875
Soluset	1	266	266
Syringe 10 cc for administration of nicardipine	12	15.94	191.28
Nifedipine 10 mg/tab (max dose 20 mg every 6 h)	8	45.35	362.8
Methyldopa 250 mg/tab (max dose 3 g/day)	12	29.75	357
<b>Diagnostics</b>			
Biophysical profile scoring+Doppler velocimetry	1	3630	3630
Complete blood count with platelet count	1	547	547
Urinalysis	1	412	412
AST	1	755	755
ALT	1	888	888
LDH	1	645	645
Creatinine	1	565	565
Uric acid	1	515	515
BUN	1	480	480
24 h urine protein	1	1194	1194
Total expense of urgent care of late preeclampsia			63,587.02

ALT: Alanine aminotransaminase, AST: Aspartate transaminase, LDH: Lactate dehydrogenase, CTG: Cardiotocography, BUN: Blood urea nitrogen

did not develop PE. These patients have an estimated expense of P79,993.00 since all had CS delivery. This could further go down to P49,993.00, if NSD but there were no patients for this category in the study. For the two patients who developed early PE, the cost was estimated to reach P159,680.00. A patient who was high risk on clinical assessment but did not undergo FTS, not put on ASA, and develop early PE is estimated to spend P149,687.02 (if CS) or P119,687.02 (if NSD). These are 1.87 times more (if CS) or 2.4 times more (if NSD) than those spent by patients who did not develop PE given ASA treatment [Table 2].

Cost-effectiveness analysis revealed that the cost of FTS of P9,405.00 for screening and ASA therapy of P588.00 for prophylaxis, resulted to medical cost averted of P79,687.02, and P63,587.02 for urgent care of early PE and late PE, respectively. The calculated net cost savings for preventing early PE and late PE were P69,694.02 and P53,594.02, respectively. The approach of investing in FTS and ASA therapy was noted to be cost saving, hence, reported as net cost savings rather than cost-effectiveness ratio<sup>[12]</sup> [Table 4].

## Discussion

In our analysis of the cost-effectiveness of the two approaches described in the study for preventing PE, FTS and initiation of low-dose ASA as prophylaxis was the dominant approach. It was associated with a 71.4% prevention rate of PE and the least cost. Preventing PE will give the patient a net savings of P69,694.02 and P53,594.02 for urgent care of early PE and late PE, respectively. The initial investment of P9,405.00 for

FTS and additional of P588.00 for ASA prophylaxis is a minimal price compared to the cost of developing PE.

This is the first cost-effectiveness analysis on the use of FTS and ASA prophylaxis in the Philippines. Results revealed significant cost savings similar to the cost-effectiveness studies published. Ortved *et al.* evaluated the cost-effectiveness of FTS program coupled with initiation of low-dose aspirin as prophylaxis for the prevention of PE in Canada. The study revealed that the preventive model would save the health-care system over C\$140 million in 10 years. The report of Liu *et al.* mentioned in the study of Ortved *et al.* emphasized on the incremental costs of PE to be substantially increased by intrapartum care, maternal transfer, CS, and neonatal care.<sup>[2]</sup>

The screening, prevention, and subsequent management of PE are subject to observer error, test accuracy, and clinical manifestation of PE per patient.<sup>[11]</sup> The FMF first-trimester multimarker screening algorithm, applied in this institution's FTS, is found to significantly reduce the incidence of early PE by 90%. Furthermore, the ASPRE trial, which used this screening tool, coupled with the initiation of low-dose ASA therapy for the prevention of PE, revealed a significant reduction of early PE by 82%, and late PE by 62%.<sup>[1,2,11]</sup> In an unpublished study done in the Philippines by Martin and Gonzaga in 2019, the FTS was validated as a predictive tool for PE with high accuracy of 91.87% and 88.62% at a false-positive rate of 8% and 7%, those women who are high risk of developing both early and late PE, respectively (Martin M, Gonzaga Z, 2018, unpublished).

**Table 4: Cost-effectiveness analysis calculation**

Formula	Value
Cost of intervention	First trimester screening: P9,405 Aspirin therapy: P588 Total: P9,993
Cost averted	Urgent care of early preeclampsia: P79,687.02 Urgent care of late preeclampsia: P63,587.02
Net costs (negative value means cost-savings)	Net cost-saving when early preeclampsia is averted: P69,694.02 Net cost saving when early preeclampsia is averted: P53,594.02

ASA has been studied to be one of the most effective therapeutic options for preventing PE. Initiation of ASA therapy for high-risk women before 16 weeks age of gestation has shown to reduce the development of PE and its subsequent complications.<sup>[2]</sup> The use of low-dose aspirin as a therapeutic agent for preventing PE has gone through multiple studies that challenge its safety and efficacy. Despite the variable outcomes of the numerous trials, a meta-analysis done on the randomized trials proved to show that ASA is most beneficial when initiated < 16 weeks age of gestation, resulting in 50% reduction (relative risk [RR], 0.47 [95% confidence interval [CI], 0.34–0.65]) of developing PE in any age of gestation, 90% reduction (RR, 0.11 95% CI, 0.04–0.33) of developing PE at < 34 weeks age of gestation. In a study done by Park *et al.*, the combination of early screening for PE using clinical and biochemical markers, and initiation of ASA as therapeutic intervention has proven to reduce the prevalence of PE by 90%. The study also showed reduced number of required deliveries below 37-week age of gestation due to PE.<sup>[4]</sup> The ASPRE trial supports this conclusion with its own findings which showed that administration of low-dose aspirin (150 mg/tablet) after screening between 11 and 13-week age of gestation, reduced the rate of early-PE (<32 weeks) by an estimate of 90%, and reduced preterm PE by about 60%. Administration of ASA, however, did not prevent the development of PE for patients beyond 37-week age of gestation.<sup>[5,11]</sup>

## Conclusion

There is a significant rate of PE prevention and cost savings from implementation of FTS and initiation of low-dose ASA. This cost-effectiveness analysis can guide in decision-making for the screening and prevention of the disease. Based on this study, it is recommended that patients undergo clinical risk assessment, then FTS to accurately and timely screen the risk of developing PE to initiate ASA therapy.

## Limitation of study

The scope of the study is limited to screening, prevention, and urgent care of PE. The costs of outpatient maternal care including antihypertensive medications and antenatal fetal well-being studies were not included in

the cost analysis. Doctors' professional fees and indirect costs during the course of admission were not included as well. The cost of adverse outcomes of PE on future maternal health, fetal development, and neonatal care is also beyond the scope of the study.

## Recommendations

The study opened opportunities that can bridge the knowledge gap on addressing the socioeconomic burden of PE. This cost-effectiveness study can serve as a pilot study that may be replicated in a multicenter research, accounting for socioeconomic diversity. A cost-benefit analysis (CBA) may also be undertaken using a wider population that includes the pediatric group. This shall take into consideration other benefits derived from the intervention such as costs averted from the prevention of lost productivity and long-term maternal and neonatal health consequences. Results of a CBA can be used to guide future public health policymaking and implementation.

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## Conflicts of interest

There are no conflicts of interest.

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