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Improving Maternal Outcomes through Labetalol Algorithm Utilization for
Hypertensive Disorders of Pregnancy

Doctor of Nursing Practice Project Presented to the
Faculty of Graduate Studies
University of Missouri – St. Louis

In Partial Fulfillment of the Requirements
for the Degree of Doctor of Nursing Practice
by Hailee Taylor, DNP

DNP Committee Chair: Alicia Hutchings, PhD, RN, CNE
DNP Committee Member: Maryann Bozzette, PhD
DNP Committee Member: Heather Decker, RN, MSN, MHA

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Abstract

Hypertensive disorders of pregnancy can have negative effects on both mothers and neonates and are a major contributor to the increasing morbidity and mortality affecting women pregnant women in the United States. Treatment algorithms are available for treatment of hypertensive disorders of pregnancy when treatment criteria are met. With proper use of these algorithms, healthcare personnel can decrease the mortality and morbidity rates, which will increase patient safety and decrease healthcare spending. This research project focused on implementing The American College of Obstetricians and Gynecologists' (ACOG) Labetalol treatment algorithm to treat patients diagnosed with severe preeclampsia. Prior to implementation, data was collected from November 1, 2018 through January 31, 2019 and compared to data that was collected after implementation, March 1, 2019 through May 31, 2019. Although compliance with algorithm utilization decreased post implementation, the data proves that with proper use, the Labetalol algorithm improves maternal blood pressures and maternal outcomes.

Improving Maternal Outcomes through Labetalol Algorithm Utilization for Hypertensive Disorders of Pregnancy

Hypertensive disorders of pregnancy continue to be a key contributor to mortality and morbidity in pregnant women in the United States. According to Collier & Martin (2018), 7.4% of the 800 pregnancy related deaths that occur each year are hypertension related. Not only do these disorders affect the pregnant female, but they can have a negative effect on the neonate as well; leading to preterm delivery, fetal growth restriction, and perinatal mortality. In 1993, hypertensive disorders affected approximately 500 per 10,000 delivery hospitalizations compared to 900 per 10,000 in 2014 (CDC, 2018). Prompt treatment of hypertensive disorders of pregnancy with a recommended hypertensive medication use can decrease mortality and morbidity significantly if implemented appropriately (ACOG, 2013).

Hypertensive disorders of pregnancy are separated into four different classifications: chronic hypertension, gestational hypertension, preeclampsia and eclampsia, chronic hypertension plus superimposed preeclampsia. Chronic hypertension is defined as a systolic blood pressure (SBP) of greater than 140 or a diastolic blood pressure (DBP) greater than 90 that occurs prior to pregnancy or before 20 weeks gestation (American Congress of Obstetricians and Gynecologists [ACOG], 2017). Gestational hypertension is defined as a SBP

greater than 140 or a DBP greater than 90 that occurs after 20 weeks gestation with no detection of proteinuria or other systemic signs/symptoms (ACOG, 2017). Preeclampsia is defined as a SBP greater than 140 or a DBP of 90 with the presence of proteinuria with or without systemic signs/symptoms; or the presentation of systemic signs/symptoms/lab abnormalities in the absence of proteinuria (ACOG, 2017). Chronic hypertension plus superimposed preeclampsia is defined as the presence of chronic hypertension in addition to the development of proteinuria or systemic signs/symptoms/lab abnormalities (See Appendix A). Signs/symptoms of severe features of preeclampsia include: Two severe blood pressure values obtained 15-60 minutes apart ($SBP \geq 160$ or $DBP \geq 110$), persistent oliguria $<500\text{mL}/24$ hours, progressive renal insufficiency, unremitting headache/visual disturbances, pulmonary edema, epigastric or right upper quadrant (RUQ) pain, liver function tests (LFTs) $> 2x$ the normal value, platelets $< 100,000$, and the development of HELLP (hemolysis, elevated liver enzymes, and low platelet counts) syndrome (ACOG, 2017). HELLP syndrome is a life-threatening emergency.

Early detection of hypertensive disorders of pregnancy and appropriate management can improve outcomes for both the pregnant female and the neonate. Missed opportunities for recommended care contribute to the morbidity and mortality. ACOG (2018) provides recommendations for diagnostic criteria, treatment implications, medications (such as Labetalol), and monitoring. These

recommendations are available for adoption and use in healthcare settings throughout the United States and have proven to improve maternal and fetal outcomes; however, many facilities lack an evidence-based maternal safety bundle. The purpose of this project is to describe the care of pregnant women with preeclampsia following the establishment of a protocol for use of the Labetalol Algorithm.

The aims of this project were to establish baseline data on the number of diagnosed preeclamptic patients that required treatment and how quickly treatment was implemented; disseminate this data to physicians; and implement a Labetalol Algorithm for treatment to improve maternal outcomes. On completion, this project answered the following PICOT questions: In pregnant women aged 18-45 at a Midwestern, suburban hospital,

1. What is the rate of the Labetalol Algorithm use by physicians when criteria are met for preeclampsia?
2. When criteria are met, how quickly was treatment initiated?
3. When criteria are met for severe preeclampsia and treatment is initiated, what is the rate of maternal blood pressure (BP) improvement (return to patient baseline) pre and post algorithm?

4. What is the rate of unplanned cesarean section when diagnosis of preeclampsia is met before the Labetalol Algorithm was implemented compared to after?

Review of Literature

Using truncation from October 1, 2010 to October 31, 2018, a literature search was conducted using the following databases: CINAHL, Consumer Health Complete, eBook Clinical Collection, MEDLINE, and Cochrane. The terms used to conduct the search were “ACOG guidelines for hypertensive disorders of pregnancy,” and “labetalol.” The search resulted 57 articles. After reviewing the titles of the articles, 17 articles were chosen for abstract review based on relevance to current pharmacological treatment recommendations. After further review of these articles, five were excluded that only contained data on neonatal outcomes during hypertensive emergencies in intrapartum patients.

The percentage of pregnancies affected by hypertensive disorders ranged from 2.3% to 15% and are becoming more prevalent leading to an increased rate of maternal mortality and morbidity (Anderson & Schmella, 2017; Arukumarlan & Lighthouse, 2013; Cairns et al., 2016; Delgado De Pasquale, Velarde, Reyes, & De La Ossa, 2014; Kelley, 2012; Vadhera & Simon, 2014). In the United States, hypertensive disorders of pregnancy led to the death of 256 women in a three-year time span, whereas eclampsia contributes to an estimated 50,000 deaths each year

worldwide (Kelley, 2012). Between the years 1990-2015 in the United States, maternal mortality rose by as much as 27% (Collier & Martin, 2018).

ACOG's report titled *Hypertension in Pregnancy* (2013) asserts that for every maternal death due to hypertension that there is nearly 50-100 "near misses" that result in serious health consequences for the mother which contributes to the increasing costs of healthcare. Preeclampsia has the potential to affect multiple organ systems leaving the woman susceptible to multiple morbidities including: disseminated intravascular coagulation and respiratory, cardiovascular, cerebrovascular, liver, kidney, uterine, and neurologic complications (Anderson et al., 2013; Kelley, 2012). Kilpatrick et al. (2016) compared morbidity rates between women with acute severe intrapartum hypertension (2252 women) and women without severe hypertension (93,560 women). This retrospective cohort study found that severe maternal morbidities were more frequent in women with severe hypertension (8.8%) as opposed to the control group (2.3%). However, morbidities were present in only 8.6% of severe hypertensive women that received treatment as opposed to 9.5% of the women who didn't receive treatment (Kilpatrick et al., 2016).

Risk factors for the development of hypertensive disorders of pregnancy include: type 1 diabetes, gestational diabetes, other endocrine disorders, chronic hypertension, kidney disease, connective tissue disease, multiple gestation, molar

pregnancy, pre-pregnancy obesity, increased SBP in early pregnancy, extremes of reproductive age, and a personal or family history of preeclampsia (Kelley, 2012). In a cross-sectional study by Omani-Samani et al. (2017), the rate of preeclampsia was higher in women who had a significant weight gain during their pregnancy compared to women who gained an appropriate amount of weight. In this study, the women with preeclampsia also showed higher rates of preterm birth, cesarean section, and low birth weight infants.

In the past, there has been a lack of data on the safety and efficacy of hypertensive drugs when used during pregnancy. This has contributed to the large variations in practice guidelines globally. However, in recent years the diagnosis and treatment of these disorders has been modified by ACOG (Vadhera & Simon, 2014). Clark et al.'s report (2014) showed a significant reduction in morbidity when order sets and protocols were implemented in facilities. Amro, Moussa, Ashmini, & Sibai (2016) recommend a step-wise approach when diagnosing and treating hypertensive disorders or pregnancy. Like Delgado De Pasquale et al. (2014), Amro et al. (2016) recommend maxing out the use of one medication prior to the use of a second antihypertensive. One prospective, randomized, controlled trial utilized the Hydralazine and Labetalol protocols that were identical to the example protocol provided in the Maternal Safety Bundle provided by ACOG. A total of 261 participants were included in the study (Hydralazine group: n=131 and Labetalol group: n=130). Prior to utilization of

the algorithm, the initial SBP, DBP, and Mean Arterial Pressure (MAP) for the Hydralazine group were as follows: 170 mmHg, 108 mmHg, and 128 mmHg. After the protocol was implemented, their readings saw improvements: 144 mmHg (SBP), 91 mmHg (DBP), and 109 mmHg (MAP). The same held true for the Labetalol group. The results prior to treatment were 172 mmHg (SBP), 107 mmHg (DBP), and 129 mmHg (MAP). After treatment, the values improved to 144 mmHg (SBP), 92 mmHg (DBP), and 109 mmHg (MAP). This study concluded that Hydralazine or Labetalol has efficacy in controlling hypertensive crises; however, the study concluded that there was persistent hypertension with the use of Hydralazine (4.6%) compared to Labetalol (1.5%) (Delgado De Pasquale et al., 2014). In the report *Hypertension in Pregnancy* by ACOG (2013), it discusses that a Cochrane systematic review was conducted and that there was no significant difference between the safety and efficacy of Labetalol and Hydralazine. ACOG (2013) encourages the use of the drug that the physician and facility is most familiar and comfortable with. For this project, the drug of choice will be Labetalol due to familiarity and facility preference.

A cohort study by Xie et al. (2013) concluded that there has been an increase use in antihypertensive drugs in pregnancy. According to the survey conducted by Cairns et al. (2016), Labetalol was the most used antihypertensive (91% of physicians). When compared to physicians, midwives stated that they had a lower threshold for reducing antihypertensive medications than physicians.

This study concluded that there is lack of consistency present in the management of hypertensive patients. This may be the result of lack of evidence or guidance. ACOG (2013) points out that there have been major advances in the knowledge surrounding hypertensive disorders of pregnancy as well as new evidence that can guide therapies and management. However, these new advancements have not made their way into clinical practices yet. This is where the importance of adopting and implementing treatment algorithms is crucial in the management of these patients.

Treatment Recommendations

Prompt triage and assessment of pregnant women presenting with hypertension is crucial for earlier diagnosis and treatment. A full of review of systems should be performed to evaluate for cardiovascular symptoms (chest pain), neurological symptoms (headache or visual disturbances), consciousness, and difficulty breathing (Vadhera & Simon, 2014). When triaging a hypertensive patient, baseline labs must be ordered and include: complete blood count (CBC) with differential and platelet count, comprehensive metabolic panel (CMP), urinalysis (UA), and a protein/creatinine ratio (ACOG, 2017; Kelley, 2012; Vadhera & Simon, 2014). If end organ involvement is detected, pharmacologic treatment and continuous monitoring is warranted. If the fetus is at a viable gestation (>23 weeks), continuous fetal monitoring is recommended (ACOG,

2017; Vadhera & Simon, 2014). When using the ACOG suggested Labetalol algorithm, maternal blood pressure and pulse should be measured at least every 10 minutes until stable (ACOG, 2017; Vadhera & Simon, 2014). Once stable, blood pressure should be monitored according to ACOG recommendations (see Appendix D) (ACOG, 2017). If a diagnosis of severe preeclampsia is made and pharmacologic treatment has been initiated, depending on gestation, consult should be made to anesthesiology and maternal fetal medicine (Vadhera & Simon, 2014). Once diagnosis has been made, the objectives of treatment are the prevention of seizures (eclampsia), tight blood pressure control, and the plan for delivery (Peres, Mariana, & Cairrao, 2018). Maternal indications for delivery include: “recurrent severe hypertension, recurrent symptoms of preeclampsia, progressive renal insufficiency, persistent thrombocytopenia of HELLP syndrome, pulmonary edema, eclampsia, suspected abruptio placentae, or progressive labor or rupture of membranes” (ACOG, 2013, p.39). Transfer to a tertiary care center may be necessary for services for the mother and neonate.

For this Quality Improvement (QI) project, a Plan-Do-Study-Act (PDSA) framework was used to implement change. A PDSA is a four-stage cycle approach that aids in the adaptation of changes. The first stage includes the identification of the change followed by the testing of the change in the “do” phase. The third stage identifies if the change was successful followed by making necessary modifications in the fourth stage. PDSA approaches have demonstrated

significant improvements in the care patients receive and their outcomes (Taylor et al., 2013).

Methods

Design

A descriptive study design was for this quality improvement project. A quality improvement process using the Plan-Do-Study-Act (PDSA) cycle was used to implement the Labetalol Algorithm.

Setting

An inpatient women's services unit at an organizationally owned hospital in a suburb of a metropolitan area that is home to over three million people. This unit employs more than 40 staff nurses and a team of more than 15 house obstetricians. While not employed by the hospital, more than 30 private physicians have practice rights to perform services at this setting. This unit is open 24 hours a day and 365 days a year. Delivery services are offered to pregnant patients who have completed at least the 32nd week of gestation. Women who present to this unit who are less than 32 weeks gestation and are in stable condition are transferred to a tertiary care center. This unit performs approximately 75 deliveries per month and did 828 deliveries last year.

Sample

A convenience sample of antepartum, intrapartum, or postpartum patients whom are at least 32 weeks gestation or greater was used. The study period was March 1st through May 31st. Inclusion criteria included pregnant females between the ages of 18-45 who are greater than 32 weeks of gestation with a known or newly diagnosed hypertensive disorder of pregnancy. Exclusion criteria included non-pregnant females, pregnant females below the age of 18 and above the age of 45, and pregnant females less than 32 weeks gestation that require transfer to a tertiary care center.

Approval Process

This project was approved by the Assistant Nurse Manager and Manager at Progress West Hospital in the Women's Services department at the beginning of Semester 2018. The Labetalol algorithm was approved for use by the house Obstetrician at Progress West as well as the Chief Medical Officer of the department in October 2018. It was submitted to the University of Missouri-St. Louis (UMSL) College of Nursing doctoral committee and UMSL graduate school for approval. In addition, UMSL Institutional Review Board (IRB) approval was obtained.

The benefits of this project included: standardization of evidence-based care for hypertensive patients; decreased rates of eclampsia with prompt

treatment; and increased awareness of treatment and management of hypertensive disorders by all healthcare personnel.

Data Collection

Prior to implementation of the Labetalol algorithm, data was collected via a retrospective chart review from November 1st 2018 through January 31st, 2019 to determine the current treatment of hypertensive antepartum females using the data collection tool (Appendix E). The chart review contained data extracted from the medical record that contained: weeks of gestation, vital signs, time from diagnosis to treatment, medication and dose administered, and method of delivery of the fetus. After implementation of the Labetalol algorithm, retrospective chart review occurred once a week from March 1, 2019 to May 31, 2019 to allow for statistical analysis of pre and post intervention data and dissemination of results.

Data collected was de-identified and coded. Charts reviewed prior to the new protocol were labeled “B” for baseline beginning with B1. Charts reviewed following implementation of the Labetalol algorithm were labeled “A” beginning with A1. All data was stored on a password protected computer and encrypted USB flash drive. This information was deleted after completion of the project in July 2019.

Procedure

A team of key stakeholders which included the principal investigator, nursing management, House Obstetrical Physician, Manager of Quality and Education, and the Chief Medical Officer was formed October 2018. The team reviewed the Anthem Blue Cross and Blue Shield Manual to Quality-In-Sights: Hospital Incentive Program (Q-HIP) which provides a report of this facilities performance along with data on best practice measures. For this unit's report, it was noted that an algorithm for monitoring and treating severe preeclampsia/eclampsia was non-existent. The Labetalol Algorithm provided by ACOG (see Appendix C) was adopted in March 2019 after project proposal approval and was implemented into clinical practice.

Prior to implementation, the algorithm was presented to the lead house obstetrician and the Chief Medical Officer of the unit for dissemination to the attending physicians. An email was sent to the attending physicians discussing the algorithm and the terms of the project. The contents of the email will contain the algorithm, the implementation date, and the importance of their participation. An email was also sent out to the nursing staff with the algorithm attached. A flyer was placed in the employee bathroom to notify the employees that the project was taking place and to have them check their emails for details.

Results

From November 1, 2018 to January 31, 2019, there were 11 patients diagnosed with a hypertensive disorder of pregnancy. Of these 11 patients, four ($n=4$, 36.36%) met criteria for severe preeclampsia requiring treatment due to blood pressure recordings. Two ($n=2$, 50%) patients were treated using the recommended ACOG Labetalol algorithm driven by private physician orders, and two ($n=2$, 50%) of these patients were treated using other orders given by their attending. Three ($n=3$, 75%) of the patients that received treatment delivered vaginally, while the other ($n=1$, 25%) delivered by repeat cesarean section (Appendix A).

The two patients who were treated with the recommended algorithm, saw a decrease in both systolic and diastolic blood pressure. The average decrease in systolic and diastolic blood pressure was 19 mmHg and 6.5 mmHg respectively (Appendix B). The timing of blood pressure recordings to the onset of treatment for these two patients was an average of 37.5 minutes (Appendix C). The two patients who were treated with other orders that didn't follow the Labetalol algorithm had an average increase in systolic blood pressure of 3 mmHg, and an average decrease in diastolic blood pressure of 2 mmHg (Appendix B). The average timing of treatment initiation was 49.5 minutes (Appendix C).

From March 1, 2019 to May 31, 2019, after algorithm implementation, there were 11 patients that were diagnosed with a hypertensive disorder of pregnancy. Of these 11 patients, three ($n=3$, 27.27%) met criteria for severe preeclampsia requiring treatment due to blood pressure recordings. One ($n=1$, 9.09%) patient never met criteria, but orders following the algorithm were placed in case blood pressures became severe. One ($n=1$, 33.33%) patient was treated with the recommended ACOG Labetalol algorithm driven by nursing personnel, house obstetrician, and attending physician; and two patients ($n=2$, 66.66%) were treated with other orders given by their attending. Of the three patients that received treatment, one ($n=1$, 33.33%) patient delivered vaginally, while the other two ($n=2$, 66.66%) delivered by primary cesarean section (Appendix D). The one patient who received treatment following the Labetalol algorithm saw a decrease in systolic blood pressure of 22 mmHg, and a decrease in diastolic blood pressure of 18 mmHg (Appendix E). The timing from blood pressure recording to the onset of treatment was 30 minutes (Appendix F). The two patients who received treatment using orders other than the Labetalol algorithm saw an average decrease in systolic blood pressure of 8.5 mmHg and saw an average increase in diastolic blood pressure of 7 mmHg (Appendix E). One of these patients was admitted to the Intensive Care Unit with a diagnosis of pulmonary edema; a known complication of severe preeclampsia. The average timing from blood pressure

recordings to the onset of treatment for patients that weren't treated using the algorithm was 62 minutes (Appendix F).

Discussion

When criteria were met for the diagnosis and treatment of preeclampsia, the rate of Labetalol algorithm use by physicians prior to implementation of algorithm introduction to the unit was 50% (Appendix G). After algorithm implementation on the unit, the rate of use by physicians was 33% (Appendix H). The choice of algorithm use is ultimately up to the attending physician, regardless of nursing and house obstetrician recommendations.

Prior to implementation, the average time of onset of treatment was 43.5 minutes. After the implementation, the average time for onset of treatment was 51.3 minutes. The physician should be contacted if one severe blood pressure is obtained (≥ 160 mmHg systolic or ≥ 110 mmHg diastolic). If severe blood pressure persists for more than 15 minutes or two severe pressures are obtained within 15 minutes, treatment should be initiated. Because of the variation in treatment guidelines and the potential to obtain non-consecutive severe blood pressure reading at various times, treatment initiation times will vary.

When criteria were met for treatment of severe preeclampsia prior to algorithm implementation, the average rate of maternal systolic blood pressure improvement was 8.75 mmHg. However, an average increase of 4 mmHg was

seen in the diastolic blood pressure. After the implementation period, the average rate of maternal systolic and diastolic blood pressure improvement was 12.3 mmHg and 3.7 mmHg, respectively. It is important to note that although this project's algorithm was not implemented at this facility prior to March 2019, some attending physicians still used the algorithm to treat their patients prior to this date. It is also important to note that after the implementation period, not all physicians used the algorithm to treat their patients. This skewed the results.

Before algorithm implementation, the number of diagnosed preeclamptic patients that delivered by unplanned cesarean section was 0. Three of these patients delivered vaginally (previous successful vaginal deliveries) and one patient delivered by repeat cesarean section. After algorithm implementation, two patients delivered by unplanned cesarean section, and one patient delivered vaginally. Of these three patients, the two patients who delivered by unplanned cesarean section were not treated with the algorithm. The one patient who was treated using the algorithm had a vaginal delivery. One patient who didn't receive appropriate treatment was admitted to Intensive Care Unit with a diagnosis of Pulmonary Edema.

Conclusion

When the Labetalol algorithm was followed during this project (both pre and post implementation period), there was a greater improvement in blood

pressure measurements compared to the patients who were treated with individual physician orders. The pre and post implementation data in this project doesn't give an accurate representation of how effective the algorithm is due to noncompliance from physicians. Some attending physicians also used the algorithm under their own volition prior to unit wide implementation which also affected the retrospective chart review. Post implementation data demonstrated that when healthcare personnel don't use the Labetalol algorithm, the potential for unplanned cesarean sections occur more frequently, as well as maternal complications, such as ICU admissions.

This project should be completed again with education for both nursing personnel and physicians prior to implementation. Data should also be collected for longer periods of time due to the small sample size at this facility. It is critical for healthcare personnel to understand the importance of adopting and following algorithms and protocols in order to increase patient safety. There is a need for further education for all healthcare personnel regarding hypertensive disorders of pregnancy, diagnostic criteria, monitoring of these patients, and treatment using recommended protocols. As mentioned earlier, Clark et al.'s report (2014) showed a significant reduction in morbidity when order sets and protocols were implemented in facilities. Nursing staff play an integral role in the assessment and treatment of hypertensive patients during pregnancy. Once they assess the patient and determine that treatment is warranted, it is their responsibility to

contact the physician, report critical values, and recommend evidence-based treatment. ACOG is an organization that is dedicated to the improvement of women's health and encourages obstetricians to implement best practice. The Labetalol algorithm is recommended by ACOG for the treatment of preeclamptic patients.

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Appendix A

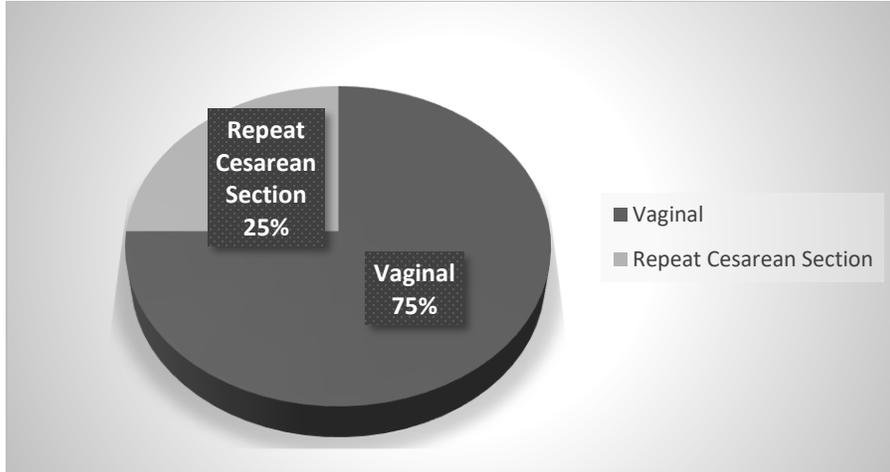


Figure 1. Method of Delivery Pre-Implementation.

Appendix B

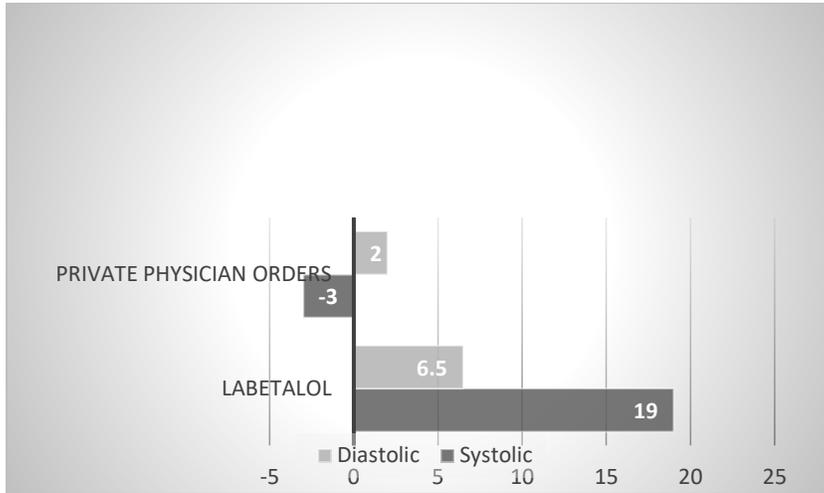


Figure 2. Average Effect on Blood Pressure Pre-Implementation.

Appendix C

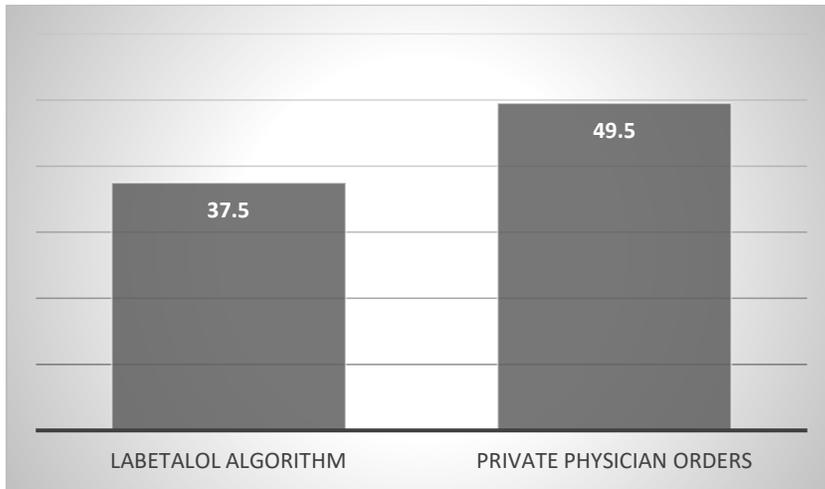


Figure 3. Timing of Onset of Treatment Pre-Implementation (minutes).

Appendix D

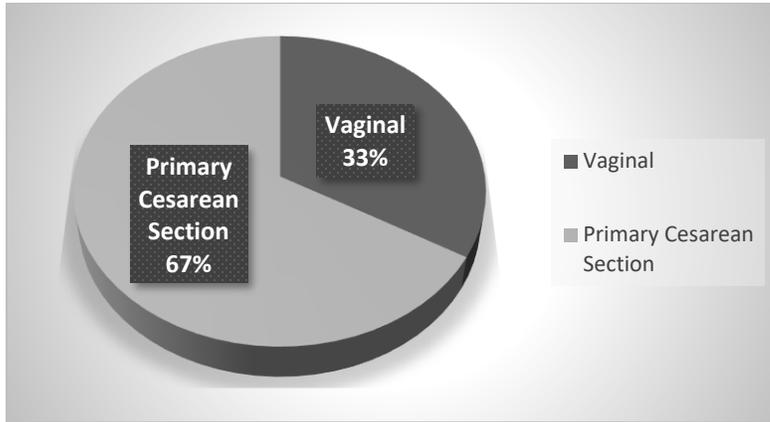


Figure 4. Method of Delivery Post-Implementation.

Appendix E



Figure 5. Average Effect on Blood Pressure Post-Implementation.

Appendix F

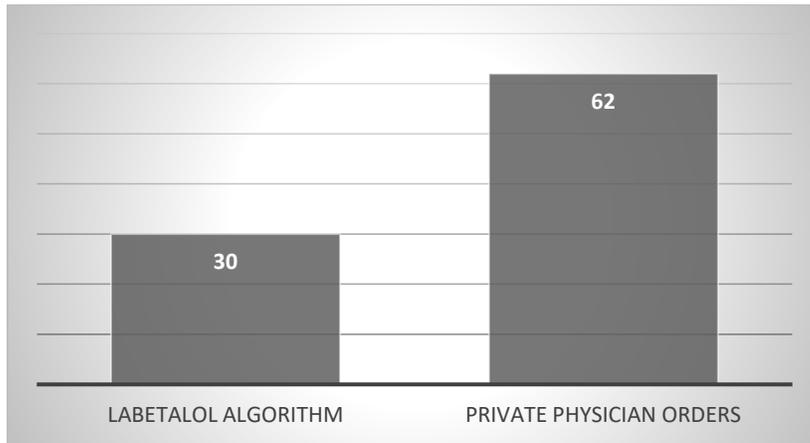


Figure 6. Timing of onset of Treatment Post-Implementation (minutes).

Appendix G

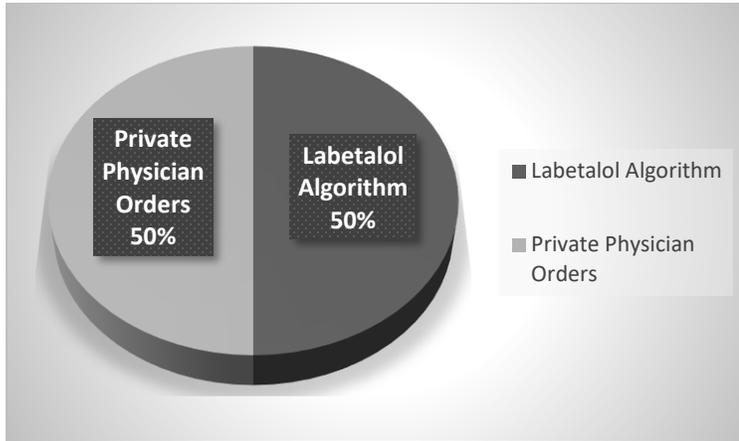


Figure 7. Rate of Labetalol Algorithm use Pre-Implementation.

Appendix H

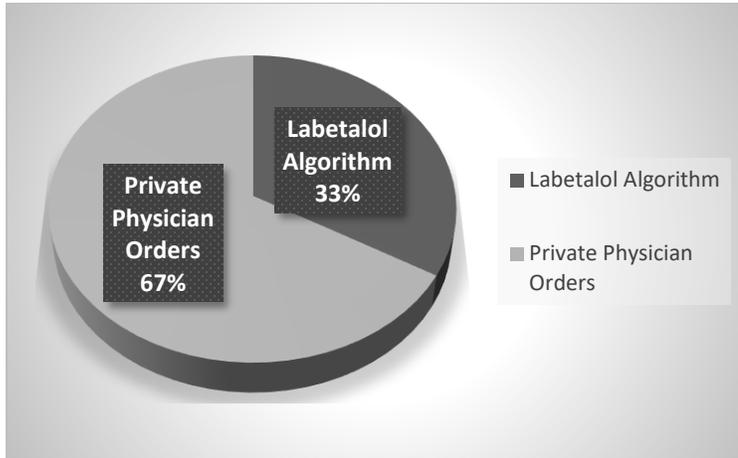


Figure 8. Rate of Labetalol Algorithm use Post-Implementation.