Preventing Spinal Induced Hypotension in the Obstetric Population

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Abstract

Problem & Purpose: At a Baltimore, Maryland hospital 50% of parturients undergoing elective cesarean sections experienced spinal induced hypotension. Spinal induced hypotension has maternal and fetal adverse effects. Despite performing a substantial percentage of cesarean sections each year, the facility lacked a standardized protocol to prevent this complication. The purpose of this Doctor of Nursing Practice Quality Improvement Project was to achieve 100% compliance with administration of 4mg ondansetron five minutes prior to spinal anesthesia, in parturients undergoing elective cesarean sections, to reduce the incidence of spinal induce hypotension. **Methods:** Key stakeholders and change champions were mobilized. Anesthesia providers were educated and provided current literature supporting prophylactic administration of ondansetron, prior to spinal anesthesia, decreases the incidence of spinal induced hypotension. Each patient deemed eligible received 4mg ondansetron five minutes prior to spinal administration. Data was collected via chart audits over 15 weeks. **Results:** A total of 48 patients were included in the project data. 35 patients received 4mg ondansetron prior to spinal anesthesia, achieving an overall compliance rate of 73%. Of these 35 patients, 74% did not experience spinal induced hypotension. **Conclusions:** The project proved feasible at the project site. Dissemination of evidence-based practice, on compliance with the initiative and incidence rates of spinal induced hypotension, increased buy-in from anesthesia providers to produce practice change. Findings align with current literature demonstrating ondansetron's effectiveness in reducing the incidence of spinal induced hypotension. Results were disseminated at the 2023 Maryland Association of Nurse Anesthetists Spring Webinar and the 2023 University of Maryland School of Nursing Doctor of Nursing Practice Poster Day.

Key Words: spinal induced hypotension, cesarean section, prevention of hypotension, obstetrics

Preventing Spinal Induced Hypotension in the Obstetric Population

Hypotension occurs in up to 80% of obstetric patients following administration of spinal anesthetic (Bhiwal et al., 2021). Spinal induced hypotension (SIH) has both maternal and fetal adverse effects. In the mother, hypotension may cause nausea, vomiting, dizziness, decreased level of consciousness, bradycardia, and in rare cases cardiovascular collapse (Bhiwal et al., 2021). Fetal adverse effects include reduced uteroplacental blood flow, impaired oxygenation, and acidosis, which may lead to fetal demise (Bhiwal et al., 2021). These adverse effects can be avoided, and patient outcomes improved with prevention of SIH.

At a hospital in Baltimore, Maryland more than 50% of parturients undergoing elective cesarean sections experienced SIH. Despite performing a substantial percentage of cesarean sections each year, the facility lacked a standardized protocol to prevent this common complication. Without a protocol in place, interventions to prevent SIH were provider dependent, widely variable, and often undocumented. While some anesthesia providers pre-loaded crystalloid solutions, others co-loaded. Many providers prophylactically administered phenylephrine, either as a continuous infusion or in bolus doses. Few providers administered ondansetron prior to spinal anesthetic to prevent SIH despite evidence demonstrating efficacy in preventing this complication.

There are many factors which contribute to the incidence of SIH in patients undergoing elective cesarean sections (see Figure 1). Physiologic factors include a decrease in cardiac output, blood pressure (BP), and heart rate (HR) directly related to aortocaval compression, activation of the Bezold-Jarisch Response (BJR), and sympathectomy (Bhiwal et al., 2021). Researchers have concluded that ondansetron, a 5-hydroxytryptamine (5HT3) receptor agonist, inhibits this response (Bhiwal et al., 2021). Through development of a root cause analysis, a

comprehensive literature review, and collaboration with the clinical site, administration of 4mg ondansetron five minutes prior to spinal anesthesia was identified as a feasible evidence-based intervention to implement at the site. This Doctor of Nursing Practice (DNP) Quality Improvement (QI) project aimed to implement and monitor compliance of prophylactic administration of ondansetron to decrease SIH in patients undergoing elective cesarean sections.

An extensive literature review was conducted to explore the effectiveness of ondansetron in preventing SIH in patients undergoing elective cesarean sections. Five Level 1 studies with an overall A quality rating were included. Level I designations were assigned to these double-blinded, randomized controlled trials utilizing the Johns Hopkins Nursing Evidence-Based Practice Levels of Evidence Guidelines (Dang et al., 2022). A strong indication for practice change was evident, and in support of administrating prophylactic ondansetron to decrease SIH in patients undergoing elective cesarean sections by preventing activation of the BJR. For a detailed description of these studies, design, and results see Appendix A.

Abdalrahman et al., (2021) defined hypotension as a drop in BP >30% of baseline, and demonstrated hypotension was significantly lower in the group of parturients who received ondansetron (69%) than the control group (95%). Sharma et al., (2020) defined hypotension as a decrease in systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) >20% of baseline, and similarly found the incidence of SIH was significantly lower in the intervention group (30%), receiving ondansetron, than the control group (70%). Devkota et al., (2021) defined hypotension and treated patients with vasopressors at SBP <90mmHg, DBP <60mmHg, or MAP<60 and found the incidence of hypotension requiring vasopressor treatment was higher in the control group (43%) than the intervention group (17%), who received 4mg of ondansetron prior to spinal administration. Sahbana et al., (2018) defined

hypotension as a decrease of SBP ≥20% from baseline or a SBP <80mmHg and found vasopressor requirements were significantly lower in the intervention group, receiving 4mg of ondansetron prior to spinal administration (30%), than the control group (58%). Additionally, researchers found ondansetron decreased fluctuations in HR. Bhiwal et al., (2021), similarly defined hypotension as a fall in SBP >20% of baseline, but uniquely compared administration of two different doses of ondansetron in reducing SIH. Significantly higher intraoperative hypotension occurred in the control group (58%), than intervention group A (31%), who received 4mg of ondansetron, and intervention group B (16%), who received 8mg of ondansetron.

All five randomized controlled trials concluded administration of 4mg ondansetron five minutes prior to spinal administration reduced the occurrence of SIH in patients undergoing cesarean sections (Abdalrahman et al., 2021; Bhiwal et al., 2021; Devkota et al., 2021; Sahbana et al., 2018; Sharma et al., 2020). Overall, a strong indication for practice change was evident as, the recommendations were consistent and compelling. A detailed evidence synthesis is included in Table 1.

The Knowledge-to-Action (KTA) Framework was selected to guide this DNP QI project (see Figure 2). The framework is designed to deliver knowledge and substantial evidence-based interventions. Instilling a strong foundation of knowledge at the clinical site paved the way for successful implementation and goal attainment. The framework has two distinct components, knowledge creation and the action cycle (Crockett, 2017). During the knowledge creation component, evidence of high level and quality was utilized to instill knowledge within the anesthesia department, foster confidence, and generate buy-in of the initiative. During the action cycle, the interventions were adapted to local context to foster knowledge and achieve desired

outcomes. Assessing the effectiveness of the action cycle provided feedback for the knowledge creation component to improve knowledge and implementation (Crockett, 2017). Ongoing assessment of facilitators and barriers helped to tailor and meet desired outcomes, which was essential when utilizing the KTA framework.

Methods

The project was implemented over a 15-week period in a 12-bed obstetric unit, where Certified Registered Nurse Anesthetists (CRNAs) and Anesthesiologists provided care for the low and high-risk obstetric population. Mobilization, assessment of the clinical site, and planning occurred between January and May 2022. Appropriate key stakeholders were mobilized to ensure successful implementation of the project. Planning and implementation considered feedback of all team members, aiding in substantial buy-in from the site.

Structure, process, and outcome goals were identified for this project (see Table 2). Structure goals included educating anesthesia providers on SIH and the efficiency of ondansetron in reducing the complication, posting visual aids to remind providers to prophylactically administer ondansetron, and posting quick response (QR) codes to provide easily accessible current education on the topic. An educational presentation on reducing SIH in the obstetric population occurred in August 2022. The project lead presented information on SIH at the global and site level, detailed strategies for prevention utilized within the facility, and strategies for prevention guided by evidence. The project timeline was detailed and planned interventions were discussed. QR codes linking providers to facts about ondansetron's effectiveness in mitigating SIH were posted in the anesthesia lounge, block rooms, supply rooms, and other high traffic areas. Visual reminders were posted on the block carts, in the block rooms, and on all anesthesia carts to trigger prophylactic administration of ondansetron. See Table 3 for site specific implementation

strategies and tactics. The process goals aimed for 100% of eligible patients to receive 4mg ondansetron five minutes prior to spinal administration.

Eligible patients included all parturients scheduled for an elective cesarean section, receiving spinal anesthesia, with an American Society of Anesthesiology class II designation. Emergent cesarean sections and parturients with an allergy or contraindication to ondansetron were excluded. In some cases, providers chose to prophylactically administer a vasopressor prior to the onset of SIH. Since it was unable to determine whether SIH was prevented by prophylactic administration of ondansetron or administration of the vasopressor, these cases were excluded from the project. Current and desired process maps are illustrated in Figures 3 and 4, respectively. Altering the workflow among anesthesia providers was the largest obstacle and required effective dissemination of current evidence. An effective and motivated project team ,and change champions were essential to overcome this obstacle. Lastly, the outcome goal aimed for a 100% reduction in the incidence of SIH in parturients undergoing elective caesarean sections.

Structure, process, and outcome goals were assessed weekly by the project lead to determine compliance with the initiative and incidence of SIH. Data was collected via chart audits and analyzed weekly during the implementation phase. For all eligible patients' data collected included: time of administration of 4mg ondansetron, time of spinal anesthetic administration, incidence of SBP <90mmHg, administration of vasopressors, and anesthesia provider in attendance. See data collection tool in Appendix B. Once accuracy and completeness were ensured, data was recorded in Research Electronic Data Capture (REDcap) to allow for ongoing analysis. Analysis of the data and run charts generated quantitative data and descriptive

statistics, allowing for a quantitative assessment of compliance with the DNP QI project and incidence of SIH. Final analysis of data and trends was conducted in December 2022.

The data collection process ensured Health Insurance Portability and Accountability Act (HIPAA) requirements were maintained. Primarily, data was collected from paper charting utilized by the anesthesia department. Patient records reviewed in the electronic medical record (EMR) were viewed on a password protected computer, on a secure network. In addition, all patient data was de-identified. The minimum required protected health information was accessed and collected during chart audits. All data was recorded in REDCap, a secure data management tool, on a secure network. These actions ensured HIPAA requirements were maintained and data was collected ethically. This DNP QI project was submitted to the University of Maryland, Baltimore Human Research Protection Office (HRPO) and to the International Review Board (IRB) Office at the project site. HPRO and site IRB approval was granted.

Results

Over the 15-week implementation period a total of 53 scheduled elective cesarean sections were deemed eligible to participate in the DNP QI project. Five cases were excluded from the project data due to prophylactic administration of vasopressors. Overall, an upward trajectory toward the process and outcome goals of the project occurred over the course of the implementation period. There was 100% compliance with the DNP QI project during weeks five, seven, eight, and 15 (see Figure 5). Astronomically low data points occurred in weeks six and nine, reported as a 0% compliance rate. This was due to the anesthesia provider's failure to administer ondansetron prophylactically. To facilitate adoption of the evidence-based intervention, additional modifications to implementation strategies were made after discussions with key stakeholders and change champions during week nine. Compliance improved over the

remainder of the implementation period due to biweekly project updates displayed in the anesthesia lounge and increased presence of the project lead on site, educating anesthesia providers and spreading awareness about the DNP QI project.

Ultimately, data from 48 elective cesarean sections was included in the project. The implementation period was divided into weeks one through nine, and weeks ten through 15. This was due to the previously mentioned project modifications that occurred during week nine. Following these mid-implementation period interventions, an upward trend in both compliance and absence of SIH was evident. Compliance increased from an average of 69%, over the first nine weeks, to an average of 75% over the last six weeks. Absence of SIH increased from an average of 37% over the first nine weeks of the implementation period, to an average of 70% over the last six weeks, see Figure 6. All 10 patients who did not receive 4mg ondansetron five minutes prior to spinal anesthesia experienced SIH, for an incidence rate of 100%. Results were disseminated at the 2023 Maryland Association of Nurse Anesthetists Spring Webinar and the 2023 University of Maryland School of Nursing DNP Poster Day.

Barriers in compliance were experienced despite counseling and presentation of current evidence-based practice recommendations. Noncompliance occurred in the form of prophylactic administration vasopressors, administration of a vasopressor when SBP>90mmHg, and failure to administer ondansetron five minutes prior to spinal anesthesia. Altering the workflow among anesthesia providers was the largest obstacle and required effective dissemination of current evidence. An effective and motivated project team and change champions were essential to overcome this obstacle.

Discussion

Implementation of an evidence-based protocol requiring prophylactic administration of ondansetron was feasible at the site and helped decrease the incidence of SIH, improving patient outcomes. This project further supports the efficacy of ondansetron in preventing SIH. In the final stage of the implementation period the absence of SIH at the project site increased to 70% from the pre-implementation 50% in patents receiving spinal anesthesia for elective cesarean sections. The literature review demonstrated a mean average of 65% absence of SIH when ondansetron was administered five minutes prior to spinal anesthesia in parturients. The results of this project align with current literature, further proving the efficacy of prophylactic administration of ondansetron in decreasing the incidence of SIH. Since the ondansetron is readily available at the project site and administration in this population is standard practice, the only change to practice is time of ondansetron administration. Therefore, the improvement in patient outcomes comes at no additional cost.

The data analysis also revealed an unexpected finding. All patients who did not receive prophylactic ondansetron experienced SIH. This unexpected finding during data analysis increased buy-in and compliance with the initiative among anesthesia providers. While the results of the DNP QI project revealed a 100% incidence of SIH when ondansetron was not administered prophylactically, this was not the case in the current evidence. The documented literature review showed an average of 65% incidence of SIH when ondansetron was not administered prophylactically. This variance is likely due to the smaller sample size of this QI project.

The validity of this project was possibly challenged by the utilization of paper anesthesia charting at the project site. Paper charting can be less accurate than utilization of electronic

anesthesia charting methods (Kadry et al., 2012). Providers may have also incorrectly documented the time of administration of ondansetron and the time of spinal administration. The importance of accurate charting was stressed to the anesthesia providers during the education session and throughout the implementation period. However, human error, whether during charting or the data collection process, could have potentially challenge the validity of the project.

Conclusions

Presentation of current evidence-based practice helped spread awareness about SIH and decreased the incidence of SIH. Dissemination of evidence-based practice and periodic updates including compliance rates with the initiative and incidence rates of SIH proved feasibility of the project and increased buy-in from anesthesia providers to produce practice change. Additionally, findings align with current literature demonstrating ondansetron's effectiveness in reducing the incidence of spinal induced hypotension. The DNP QI project increased administration of 4mg ondansetron five minutes prior to spinal administration in parturients undergoing elective caesarean sections, updating the method utilized to decrease the incidence of SIH to align with current literature. Prophylactic administration of ondansetron improves patient outcomes and possibly lowers healthcare costs by decreasing the added expense of the treatment of adverse effects directly related to SIH in parturients.

It is important to build on this new momentum, aligning practice with current evidence at the project site. QR codes linking providers to current evidence on the effectiveness of ondansetron in mitigating SIH and visual aids reminding providers to prophylactically administer ondansetron will remain in place. The project sponsor, clinical site representative, and change champions are committed to the continuation of this new protocol at the project site. Future QI

projects can be implemented in other hospitals and populations, receiving spinal anesthetic, to influence practice change and reduce the incidence of SIH. The hope is this DNP QI project will influence more anesthesia providers to administer 4mg ondansetron five minutes prior to spinal anesthesia to decrease SIH and improve patient outcomes.

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Table 1

Evidence Synthesis Table: Preventing Spinal Induced Hypotension

Category (Level Type)	Total Number of Sources/Level	Overall Quality Rating	Synthesis of Findings
Level 1 - Experimental study · Randomized Controlled Trial (RCT) · Systematic review of RCTs with or without meta-analysis	5 Double-Blind, RCTs	A	All five of the randomized controlled trials included in the evidence review conclude administering 4mg ondansetron five minutes prior to spinal administration reduces the occurrence of spinal induced hypotension in patients undergoing cesarean sections. Abdalrahman et al, (2021) defined hypotension as a drop in blood pressure (BP) >30% of baseline, and demonstrated hypotension was significantly lower in the group of parturients who received ondansetron (69%) than the control group (95%). Sharma et al., (2020) defined hypotension as a decrease in systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) >20% of baseline, and similarly found the incidence of SIH was significantly lower in the intervention group (30%), receiving ondansetron, than in the control group (70%). Devkota et al., (2021) defined hypotension and treated patients with vasopressors at SBP <90mmHg or DBP <60mmHg or MA P<60 and found the incidence of hypotension requiring vasopressor treatment was higher in the control group (43%) than the intervention group (17%), who received 4mg of ondansetron prior to spinal administration. Sahbana et al., (2018) defined hypotension as a decrease of SBP $\geq$20% from baseline or a SBP <80mmHg and found the need for vasopressor administration was significantly lower in the intervention group, receiving 4mg of ondansetron prior to spinal administration (30%), than the control group (58%). Additionally, this study found ondansetron decreased fluctuations in HR. Bhiwal et al., (2021), similarly defined hypotension as a fall in systolic blood pressure SBP >20% of baseline, but uniquely compared administration of two different doses of ondansetron in reducing SIH. Comparison revealed significantly higher intraoperative hypotension in the control group (58%), than in interventional group A (31%), who had received 4mg of ondansetron, and interventional group B (16%), who had received 8mg of ondansetron.
Recommendations Based on Evidence Synthesis: The evidence presented is of high level and quality. Results are consistent and compelling. There is a strong indication for practice change. The literature supports administration of 4mg intravenous ondansetron five minutes prior to administering spinal anesthesia to prevent spinal induced hypotension in patients undergoing elective cesarean section.			

Table 2

DNP Quality Improvement Project Goals

Structure Goals
Present education to anesthesia providers on SIH and efficacy of ondansetron in reducing the complication
Visual aids posted in operating rooms and supply areas to remind providers to prophylactically administer ondansetron
QR codes posted in high traffic areas to provide easily accessible information on the topic
Documentation of method utilized to prevent SIH will be charted in the anesthesia record
Process Goals
100% of elective cesarean sections will receive 4mg ondansetron 5 minutes prior to spinal administration
Method utilized to minimize risk of SIH documented in anesthesia record 100% of the time
Outcome Goal
A 100% reduction in incidence of SIH in patients receiving elective cesarean sections.

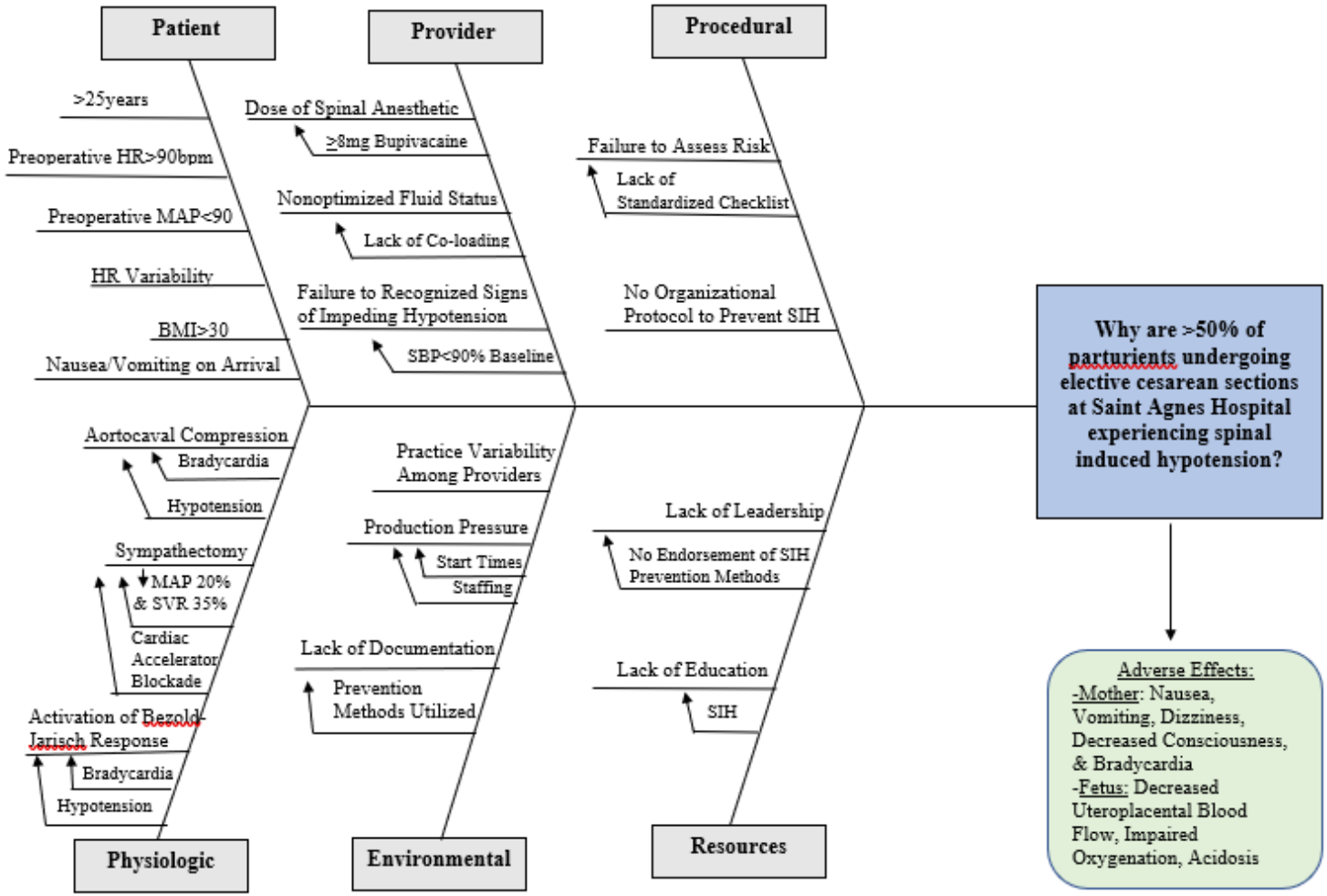
Table 3

Site Specific Implementation Strategies and Tactics

Strategy	Tactical Approach	Rationale	Monitoring
Accountability			
Obtain Formal Commitments	A doctoral project team, including key stakeholders and change champions was mobilized early in January. These include the project lead, project faculty advisor, clinical site representative, site sponsor, and six change champions.	The team will offer advice and collaborate with the project lead, assist in implementation, and help generate buy-in staff. Within the organization the team is key to push the initiative forward and gain buy-in from team members who may be resistant to changing their current practice.	Ongoing evaluation of the project, with the doctoral project team is imperative to identify areas needing improvement or reveal when further education is necessary to ensure successful implementation.
Collaboration, Communication & Changes in Structure			
Meetings	Meetings with the clinical site representative will occur biweekly.	Frequent communication with the clinical site representative throughout the entire course of the project is essential to ensure project goals are met.	Meetings and ongoing communication with the clinical site representative will be documented, and feedback will be incorporated to improve the project.
Data			
Provide Data Reports	Biweekly reports detailing compliance with the initiative and current spinal induced hypotension rates will be posted in the anesthesia lounge.	Updating staff of ongoing compliance and success of the initiative will strengthen project as it progresses through the implementation phase.	Run charts are expected to show an increase in compliance overtime and decreased rates of spinal induced hypotension.
Education			
Develop Educational Materials	A PowerPoint presentation, quick response codes, and visual reminders will be developed and provided to staff. Quick response codes will be posted in the anesthesia lounge, while visual reminders will be posted in perioperative locations.	A PowerPoint presentation will occur at a mandatory staff meeting, introducing the anesthesia staff to the project. QR codes will link providers to current evidence on ondansetron's effectiveness in mitigating SIH and visual reminders will increase awareness of the project and generate more buy-in.	Feedback will be garnered from anesthesia staff biweekly to identify ways to strengthen the initiative, increase compliance, and identify where further education is required to ensure successful implementation of the project.

Figure 1

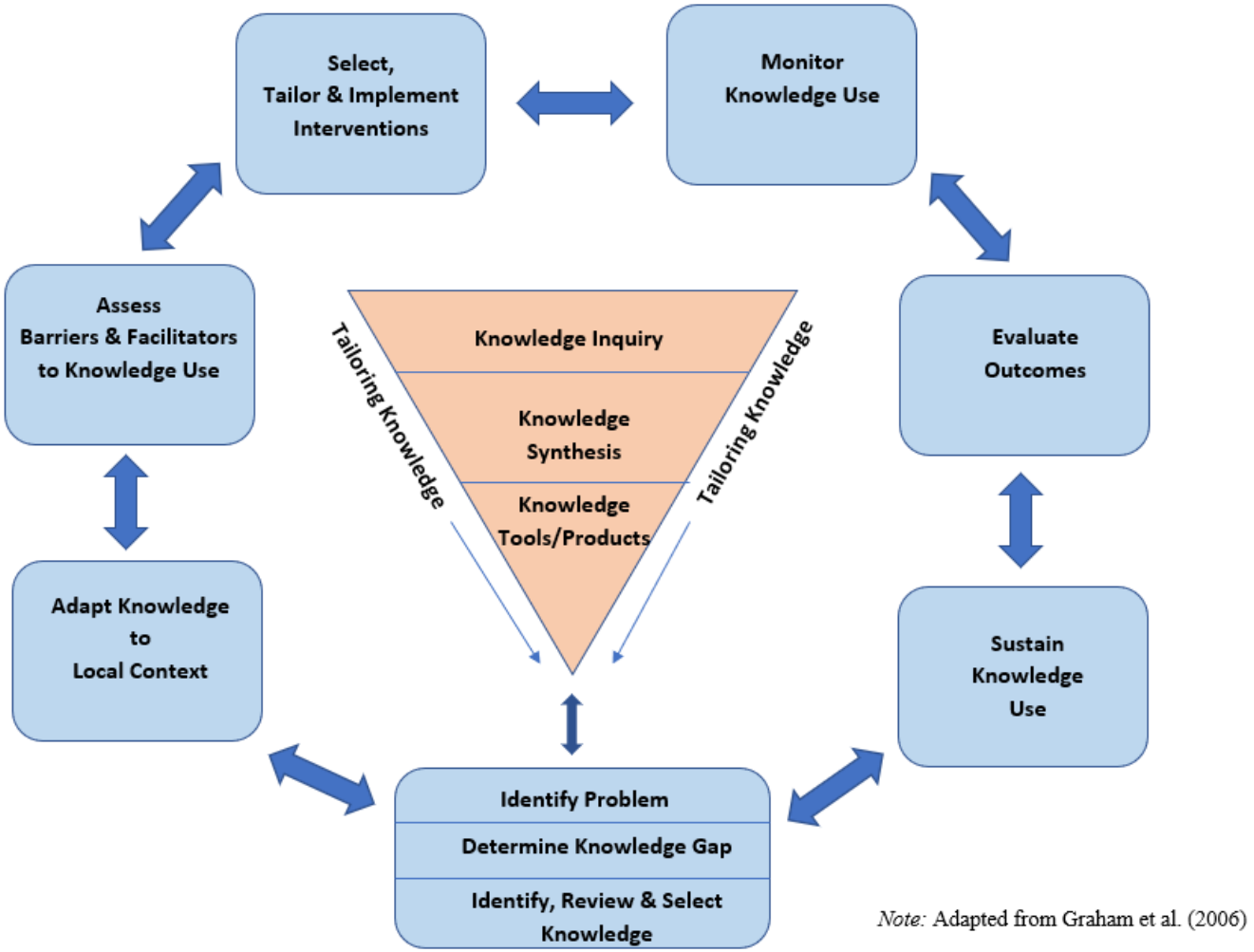
Fishbone Diagram: Root Cause Analysis of Spinal Induced Hypotension



Note. bpm, beats per minute; MAP, mean arterial pressure; HR, heart rate; BMI, body mass index; SBP, systolic blood pressure; SIH, spinal induced hypotension; SVR, systemic vascular resistance.

Figure 2

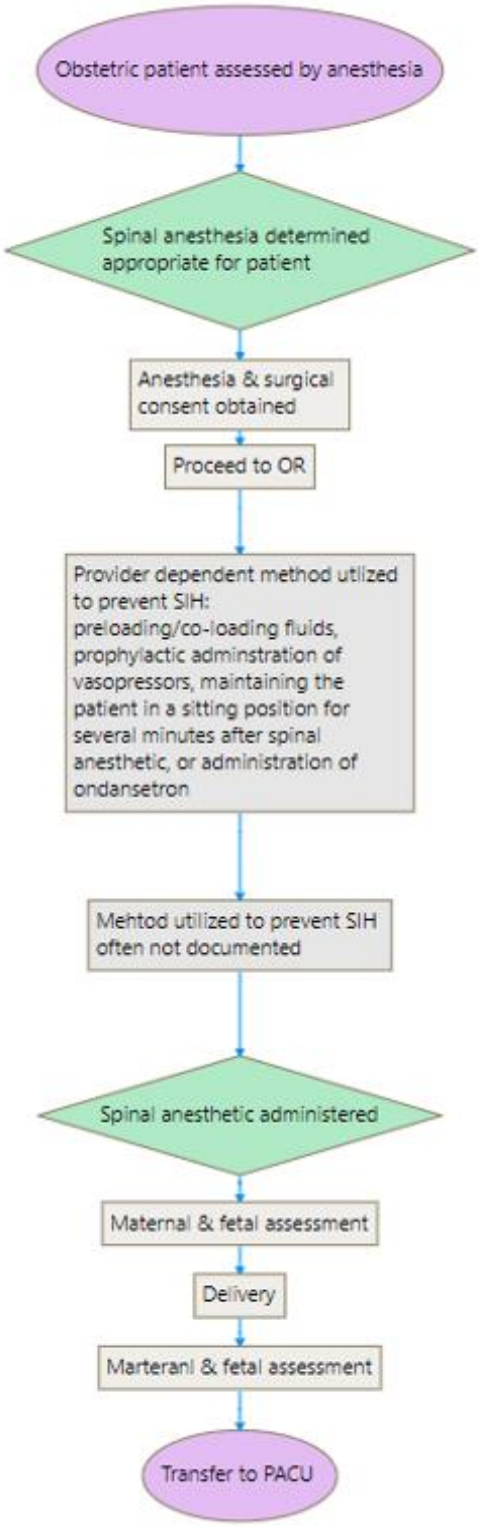
Knowledge-to-Action Framework



Note: Adapted from Graham et al. (2006)

Figure 3

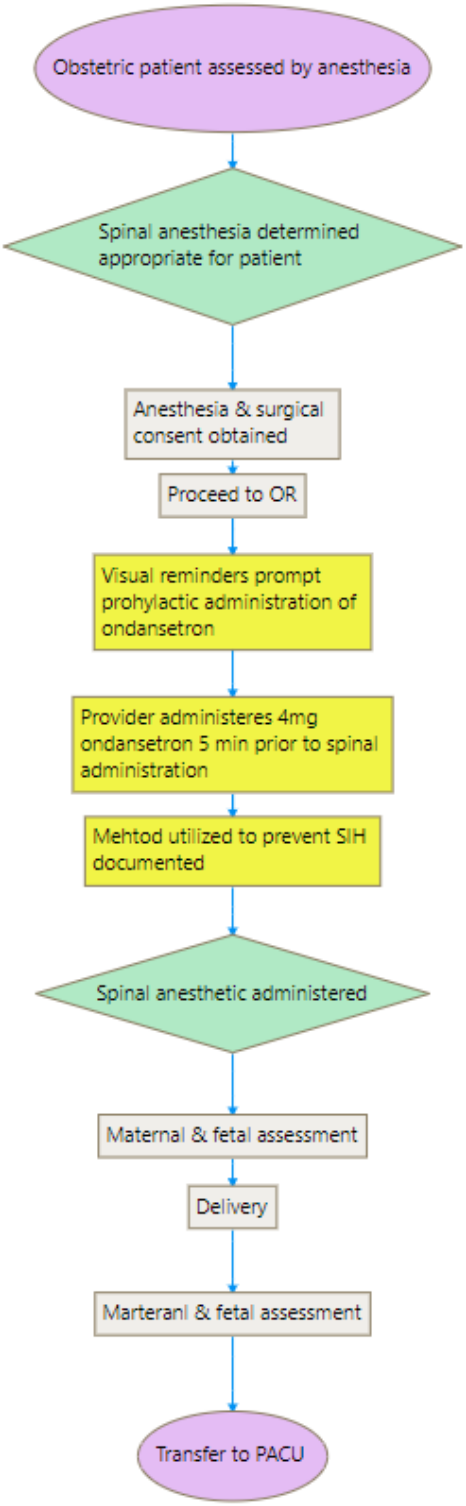
Current Process Map: Preventing Spinal Induced Hypotension in the Obstetric Population



Key: Oval- start or end of process; Rectangle- step in process; Triangle- decision point

Figure 4

Desired Process Map: Preventing Spinal Induced Hypotension in the Obstetric Population



Key: Oval- start or end of process; Rectangle- step in process;
Triangle- decision point; Yellow rectangles- desired steps in process

Figure 5

Run Chart: Process Goal

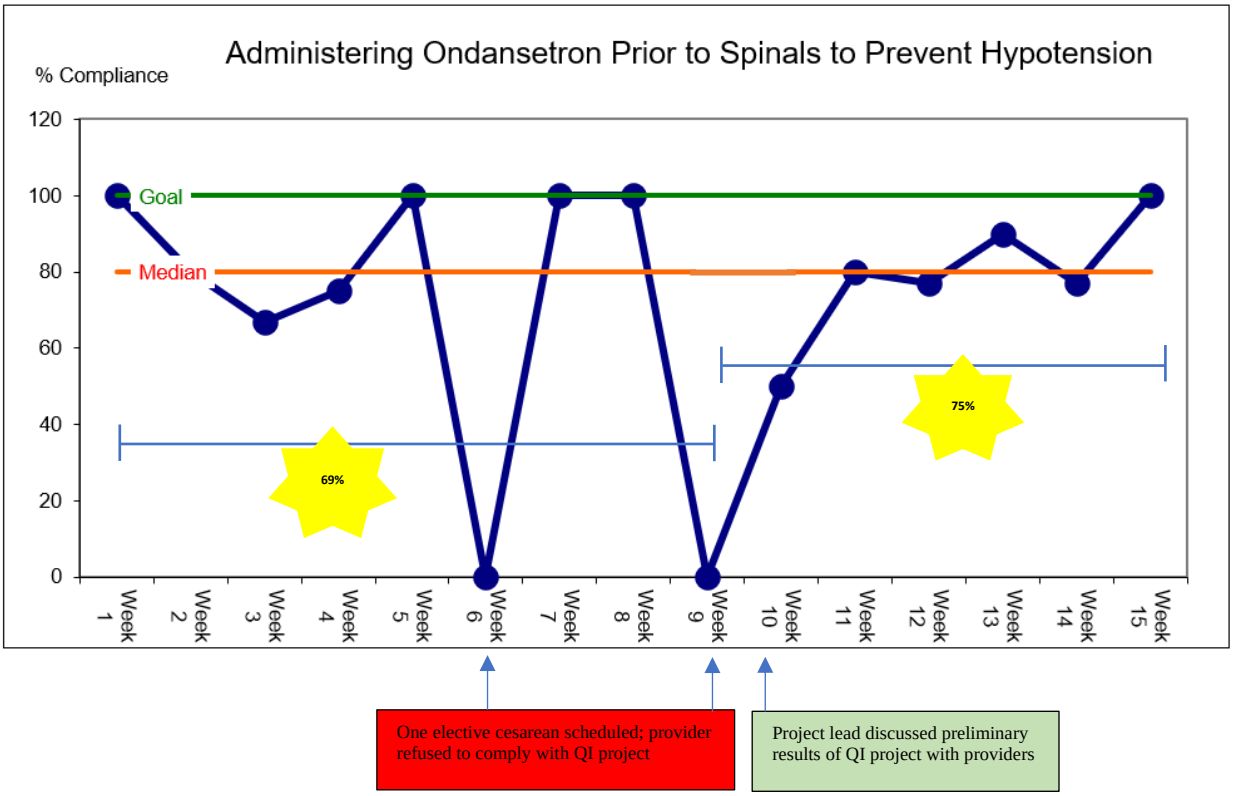
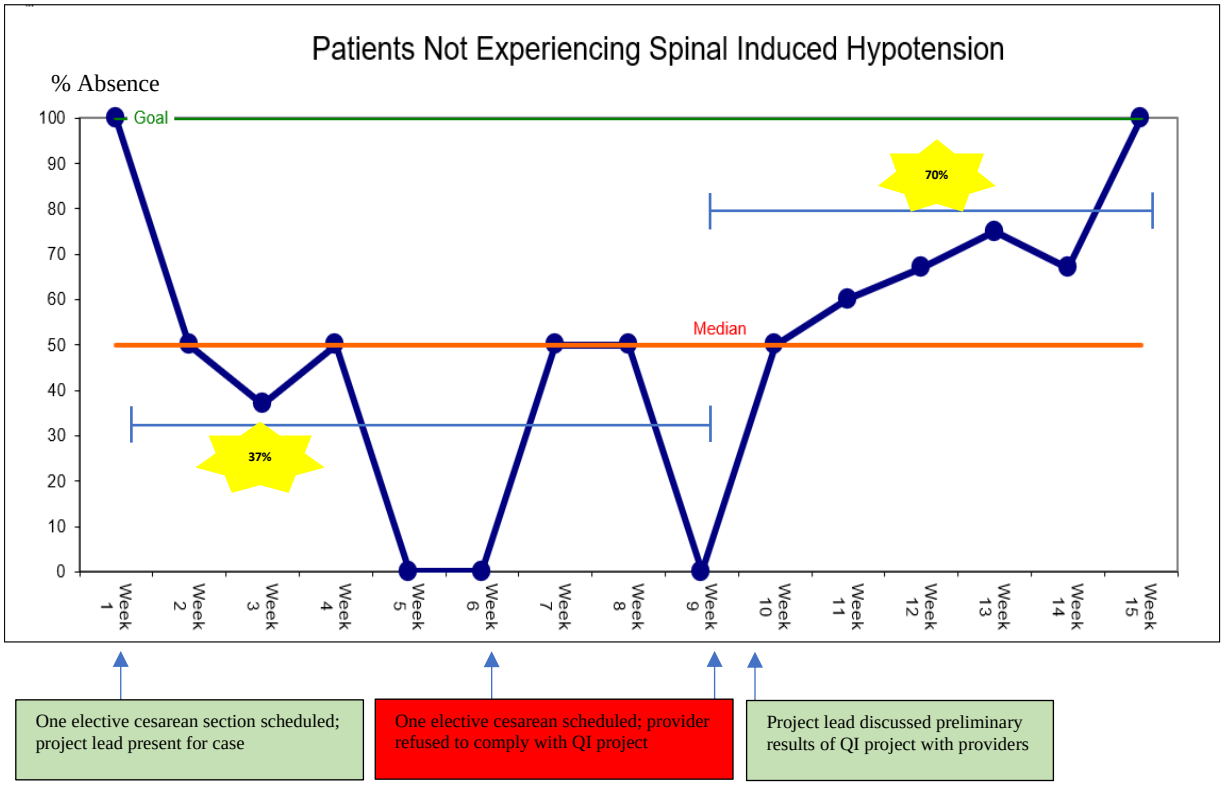


Figure 6

Run Chart: Outcome Goal



Appendix A

Integrative Evidence Review: Preventing Spinal Induced Hypotension

Abdalrahman, M. A., Abbas, H. M., & Salman, I. A. (2021). Effect of ondansetron on blood pressure during elective cesarean section under spinal anesthesia at Baghdad teaching hospital. *Al-Rafidain Journal of Medical Sciences, 1*, 36-41. https://ajms.iq/index.php/ALRAFIDAIN/article/view/25					**Level and Quality I-B**
Purpose/ Hypothesis	**Type of Evidence Research Design**	**Sample – Population, Size, Setting**	**Intervention/Procedures**	**Primary Outcome/Measures**	**Results/Conclusions**
The purpose of this study was to evaluate the effect of ondansetron to prevent spinal induced hypotension in patients undergoing elective cesarean section.	Prospective, double-blind, randomized controlled trial	**Sampling Technique:** Convenience **Setting:** Obstetric operating room - Academic medical center, Iraq **Eligible Participants:** Age 18-45 years, American Society of Anesthesiologists Classification (ASA) II, 50-100kg undergoing elective cesarean section under spinal anesthesia. **Excluded:** Patients with a contraindication to spinal anesthetic or ondansetron, cardiovascular disease or risk factors, use of selective serotonin reuptake inhibitors or antimigraine medications, patients with placenta accrete or prepartum hemorrhage. **Accepted:** 87 **Control:** 42 **Intervention:**45 **Power Analysis:** No power analysis conducted. Limited sample size. **Group Homogeneity:** Intervention/Control homogeneous based on p values in Table 1, comparing demographics of the two groups.	**Control Protocol:** 3mL 0.9% normal saline administered 5 minutes prior to subarachnoid block. **Intervention Protocol:** 6mg (3mL) ondansetron administered 5 minutes prior to subarachnoid block. **Intervention Fidelity:** After informed consent was obtained the participant was transported to the operating room. After obtaining baseline vital signs a blinded anesthesiologist slowly administered the randomly preselected treatment intravenously, either 3mL 0.9% normal saline or 6mg(3mL) ondansetron, 5 minutes prior to subarachnoid block. 3mL 0.5% hyperbaric bupivacaine was administered via a 25G spinal needle at the L3-L4 or L4-L5 interspace in the sitting position. Mean atrial blood pressure (MAP), heart rate (HR), and vasopressor use were documented at baseline and then in 3-minute intervals up to 45 minutes.	**Dependent Variable:** Hypotension was defined as a drop in BP >30% of baseline. **DV Measure:** The dependent variable was measured by documentation of MAP, HR, and vasopressor use at baseline and then in 3-minute intervals up to 45 minutes. No reliability data reported.	**Statistical Results**: Categorical data was analyzed using a Chi square test. Independent sample t-tests were utilized to compare between two means. The incidence of spinal induced hypotension was significantly lower in the intervention group (69%) than the control group (95%) (p=0.001). **Conclusions:** The research concluded 6mg ondansetron administered 5 minutes prior to spinal anesthetic decreased the incidence of hypotension, decreased intraoperative nausea and vomiting, and decreased need for vasopressors in parturients undergoing cesarean section.

Bhiwal, A. K., Chauhan, K., Choudhary, S., Bhatt, H., & Gupta, S. (2021). Intravenous ondansetron to prevent hypotension during cesarean section under spinal anaesthesia. *Journal of Obstetric Anaestheisa and Critical Care, 11*(1), 15-19. doi: 10.4103/joacc.JOACC_61_20					**Level and Quality I-A**
Purpose/ Hypothesis	**Type of Evidence Research Design**	**Sample – Population, Size, Setting**	**Intervention/Procedures**	**Primary Outcome/Measures**	**Results/Conclusions**
The purpose of this study was to evaluate the effectiveness of two different doses of ondansetron, 4mg and 8mg, administered prophylactically to prevent spinal induced hypotension in patients undergoing cesarean section.	Prospective, double-blind, randomized controlled trial	**Sampling Technique:** Convenience **Setting:** Obstetric operating room – Academic medical center, India **Eligible Participants:** Age 18-40 years, ASA I & II undergoing elective cesarean section under spinal anesthesia. **Excluded:** Patients with a history of allergy to ondansetron or local anesthetics, obesity, pregnancy induced hypertension, or any other comorbid conditions. **Accepted:** 150 **Control:** 50 **Intervention A:** 50; 2/50 participants excluded due to inadequate anesthesia after spinal administration **Intervention B:** 50 **Power Analysis:** 150 subjects required, 50 in each group required to meet 80% Beta, 0.05 Alpha, with confidence level 95% - Power Analysis Met **Group Homogeneity:** Intervention/Control homogeneous based on p values in Table 1, comparing demographics, obstetric data, and neonatal outcomes of the groups.	**Control Protocol:** 10mL 0.9% normal saline administered 5 minutes prior to subarachnoid block. **Intervention A Protocol:** 4mg ondansetron in 0.9% normal saline, for a total of 10mL, administered 5 minutes prior to subarachnoid block. **Intervention B Protocol:** 8mg ondansetron in 0.9% normal saline, for a total of 10mL, administered 5 minutes prior to subarachnoid block. **Intervention Fidelity**: Selected participants underwent preanesthetic evaluation the day prior to surgery. Placebo or ondansetron was administered 5 minutes prior to subarachnoid block. 2mL 0.5% hyperbaric bupivacaine was administered with a 25G Quincke spinal needle in the left lateral position at L3-L4. HR, blood pressure (BP), and oxygen saturation were documented at time of spinal block, at 2-minute intervals for 20 minutes, and then at 5-minute intervals for 30 minutes or until end of surgical procedure.	**Dependent Variable (DV):** Hypotension was defined as a fall in systolic blood pressure (SBP) >20% of baseline **DV Measure:** The dependent variable was measured by assessing BP at time of spinal block, at 2-minute intervals for 20 minutes, and then at 5-minute intervals for 30 minutes or until end of surgical procedure. No reliability data reported.	**Statistical Results:** Demographic data and hemodynamic variables were compared by analysis of variance (ANOVA) test. A Chi-square test was used to analyzed adverse effects. Comparison revealed significantly higher intraoperative hypotension in the control group (58%), than in interventional group A (31%), and interventional group B (16%) ($p<0.01$). **Conclusions:** The researchers concluded that intravenous ondansetron administered 5 minutes prior to spinal anesthetic decreases incidence of spinal induced hypotension and vasopressor requirements in patients undergoing cesarean section under spinal anesthetic, with 8mg ondansetron further decreasing vasopressor requirements.

Devkota, K., Adhikari, K., & Pradhan, B. (2021). Effect of intravenous ondansetron for prevention of spinal anaesthesia induced hypotension during caesarean section. *Journal of College of Medical Sciences, 17*(4), 289-297. doi:10.3126/jcmsn.v17i4.41651					**Level and Quality I-A**
Purpose/ Hypothesis	**Type of Evidence Research Design**	**Sample – Population, Size, Setting**	**Intervention/Procedures**	**Primary Outcome/Measures**	**Results/Conclusions**
The purpose of this study was to determine the effect of intravenous ondansetron in preventing spinal induced hypotension during elective cesarean sections.	Prospective, double-blind, randomized controlled trial	**Sampling Technique:** Convenience **Setting:** Obstetric operating room – Academic medical center, Nepal **Eligible Participants**: ASA II, singleton parturients undergoing elective cesarean section under spinal anesthesia **Excluded:** Patients with known contraindications to spinal anesthesia, allergy to ondansetron, and any comorbid condition. **Accepted:** 135 **Control:** 65 **Intervention**: 65 **Power Analysis:** Required sample size was calculated using a formula demonstrated effective by Sahoo et al. A minimum of 58 participants in each group was required – Power Analysis Met **Group Homogeneity:** Intervention/Control homogeneous based on p values in Table 1, comparing demographics and baseline values of the two groups.	**Control Protocol:** 10mL of 0.9% normal saline administered 5 minutes prior to subarachnoid block. **Intervention Protocol:** 4mg ondansetron in 0.9% normal saline, for a total of 10mL, administered 5 minutes prior to subarachnoid block. **Intervention Fidelity:** Preanesthetic evaluation was conducted the day before surgery and informed consent was obtained. After baseline vital signs were obtained, a blinded anesthesiologist administered either placebo or 4mg ondansetron over 10 seconds, 5 minutes prior to spinal anesthetic. 2.2mL 0.5% hyperbaric bupivacaine was administer via a Quincke spinal needle at the L3-L4 or L4-L5 interspace in the sitting position. The patient was then positioned supine with a 15-degree left tilt. HR, BP, and oxygen saturation were documented at the time of spinal administration and in 3-minute intervals following, up to 30 minutes.	**Dependent Variable:** Hypotension was defined and treated with vasopressors at SBP<90mmHg or diastolic blood pressure (DBP) <60mmHg or mean arterial pressure (MAP) <60. **DV Measure:** The dependent variable was measured by assessing BP at the time of spinal administration and in 3-minute intervals following up to 30 minutes. No reliability data reported.	**Statistical Results:** T-test and Chi-squared test were used to analyze the data. The incidence of hypotension requiring vasopressor treatment was higher in the control group (43%) than the intervention group (17%) (p=0.002). **Conclusions:** The research concluded 4mg ondansetron administered 5 minutes prior to spinal anesthetic decreased the incidence of hypotension in parturients undergoing cesarean section.

Shabana, A. A., Elkholy, N. I., Mohamed, A. M., & Hamid, M. I. A. (2018). Effect of ondansetron on hypotension and bradycardia associated with spinal anesthesia during cesarean section. *Menoufia Medical Journal*, *31*(1), 12. doi: 10.4103/1110-2098.234215					**Level and Quality I-A**
Purpose/ Hypothesis	**Type of Evidence Research Design**	**Sample – Population, Size, Setting**	**Intervention/Procedures**	**Primary Outcome/Measures**	**Results/Conclusions**
The purpose of this study was to evaluate the efficacy of ondansetron in reducing nausea, vomiting, bradycardia, and hypotension in patients undergoing spinal anesthesia for elective cesarean section.	Prospective, double-blind, randomized controlled trial	**Sampling Technique:** Convenience **Setting:** Obstetric operating room – Academic medical center, Egypt **Eligible Participants**: Age 18-45 years, ASA I & II, full-term parturients undergoing elective cesarean section under spinal anesthesia. **Excluded:** Patients with a hypersensitivity to ondansetron, contraindication for spinal anesthesia, pre-eclampsia, history of nausea and/or vomiting within 24 hours before induction, cardiovascular disease, use of selective serotonin reuptake inhibitors or antimigraine medication, and patient refusal. **Accepted:** 100 **Control:** 50 **Intervention:** 50 **Power Analysis:** 82 subjects required to meet 90% power with a significance level of 2.5%. **Group Homogeneity:** Intervention/Control homogeneous based on p values in Table 1 and Figure 1, comparing baseline vital signs of the groups.	**Control Protocol:** 10mL 0.9% normal saline administered 5 minutes prior to subarachnoid block. **Intervention Protocol:** 4mg Ondansetron in 0.9% normal saline, for a total of 10mL, administered 5 minutes prior to subarachnoid block. **Intervention Fidelity:** During preanesthetic evaluation participants were randomized into two groups. Baseline vitals were obtained, and patients received either the placebo or ondansetron intravenously, 5 minutes prior to prior to spinal administration. 2mL 0.5% hyperbaric bupivacaine was administered via a 25G spinal needle in the L3-L4 or L4-L5 interspace in the sitting position. The patient was then positioned supine with a 15-degree left tilt. BP, HR, and pulse oximetry were documented before spinal anesthetic administration, then again immediately after, and then in 10-minute intervals until surgery completion.	**Dependent Variable:** Hypotension was defined as a decrease of SBP $\geq$20% from baseline or a SBP <80mmHg. **DV Measure:** BP, HR, and pulse oximetry were documented before spinal anesthetic administration, then again immediately after, and then in 10-minute intervals until surgery completion. No reliability data reported.	**Statistical Results:** Quantitative data was compared using a t-test for independent sample. Categorical data was compared using a Chi-square test, with Fisher's exact P test utilized for expected frequency less than 5. The need for vasopressor administration was significantly lower in the intervention group (30%) than the control group (58%) (p=0.005). **Conclusions:** The researchers concluded 4mg ondansetron administered 5 minutes prior to spinal administration significantly decreased hypotension, HR fluctuations, and vasopressor requirements in patients undergoing elective cesarean section.

Sharma, S. N., & Maravi, G. S. (2020). Effect of ondansetron in prevention of hypotension in elective lower segment cesarean section under spinal anesthesia: A randomized, double-blind study. *International Journal Of Scientific Study*, *7*(11), 89-98. http://galaxyjeevandhara.com/index.php/ijss/article/view/1744					**Level and Quality I-B**
Purpose/ Hypothesis	**Type of Evidence Research Design**	**Sample – Population, Size, Setting**	**Intervention/Procedures**	**Primary Outcome/Measures**	**Results/Conclusions**
The purpose of this study was to evaluate the effect of ondansetron on hemodynamic response during elective cesarean section.	Prospective, double-blind, randomized controlled trial	**Sampling Technique:** Convenience **Setting:** Obstetric operating room - Academic medical center, India **Eligible Participants:** Hemodynamically stable patients weighing 50-90kg, height 140-180cm undergoing elective cesarean section under spinal anesthesia **Excluded:** Patients with preexisting cardiovascular disease, liver dysfunction, renal dysfunction, pre-eclampsia, convulsion, and bleeding disorders. **Accepted:** 60 **Control**: 30 **Intervention:** 30 **Power Analysis:** No power analysis mentioned. **Group Homogeneity:** Intervention/Control homogeneous based on p values in Table 8, Table 9, and Graph 6, comparing demographics and baseline values of the two groups.	**Control Protocol:** 10mL 0.9% normal saline administered over 1 minute, 5 minutes prior to subarachnoid block. **Intervention Protocol**: 4mg Ondansetron in 0.9% normal saline, for a total of 10mL, administered over 1 minute, 5 minutes prior to subarachnoid block. **Intervention Fidelity:** Following preanesthetic evaluation participants were randomly assigned to one of the two groups via lottery method. Baseline vitals were obtained, and patients received either placebo or ondansetron intravenously over 1 minute, 5 minutes prior to prior to spinal administration. 2.2mL 0.5% hyperbaric bupivacaine was administered via a 23G Quincke spinal needle in the L3-L4 interspace in the left lateral position. After anesthetic administration patients were immediately placed supine. BP and HR were documented at baseline and in 3-minute intervals util delivery of fetus, and then in 5-minute intervals until surgery completion.	**Dependent Variable:** Hypotension was defined a decrease in SBP, DBP, and MAP >20% of baseline. **DV Measure**: BP and HR were documented at baseline and in 3-minute intervals until delivery of fetus, and then in 5-minute intervals until surgery completion. No reliability data reported.	**Statistical Results:** Chi-squared test was used to test for statistical differences between the two groups. T-test was used to test the mean differences between groups, and paired t-test was applied to test for changes in each parameter over the intraoperative period. The incidence of spinal induced hypotension was significantly lower in the intervention group (30%) than the control group (70%) (p=0.002). **Conclusions:** The researchers concluded 4mg of ondansetron administered 5 minutes prior to spinal anesthetic prevents an initial fall in blood pressure following administration of spinal anesthesia.

Appendix B

Data Collection Tool: Spinal Induced Hypotension

SIH Data Collection Tool

Record ID

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Patient Code

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Ondansetron Administered Five Minutes Prior to Spinal Anesthetic?

◯ Yes
◯ No

SBP< 90mmHg Intraoperatively?

◯ Yes
◯ No

Clinical Notes or Observations

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