A Quality Improvement Project to Prevent Spinal-Induced Hypotension

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A DNP Project Manuscript
Submitted in Partial Fulfillment of the Requirements for the
Doctor of Nursing Practice Degree

School of Nursing, University of Maryland at Baltimore
May 2023

Author Note

We have no known conflict of interest to disclose.

Abstract

Problem& Purpose: At an acute care teaching hospital in Washington D.C., adult patients undergoing elective surgery for total joint replacements are anesthetized via spinal anesthesia. This anesthetic provides adequate analgesia and decreased sensation at the surgical site, however, over 60% of patients experience spinal-induced hypotension. Hypotension can give rise to many complications such as anoxic brain injury, kidney injury, and delayed wound healing subsequently increasing hospital costs and length of stay. Despite multiple interventions used to mitigate this, its occurrence at this hospital was double the incidence found in published studies. The purpose of this Doctor of Nursing Practice quality improvement project was to implement and evaluate compliance with the evidence-based administration of ondansetron 4 milligrams intravenously five minutes prior to spinal anesthesia. **Methods:** A team of key stakeholders and change champions was mobilized to identify barriers and facilitators and foster implementation. Education was provided to all anesthesia providers to administer ondansetron 4 milligrams within five minutes prior to spinal anesthesia and document administration. Using the Compliance of Ondansetron Administration Tool, retrospective data were collected and analyzed weekly for all eligible patients. Run charts were created to examine for runs, shifts, and trends over the 14-week implementation period. **Results:** Results show that of 176 eligible patients, over 53% received ondansetron. Over 75% of patients who received ondansetron prior to spinal anesthesia did not experience spinal-induced hypotension. **Conclusions:** Findings suggest that the administration of ondansetron 4 milligrams within five minutes prior to spinal anesthesia is feasible and sustainable at the project site. Overall, this quality improvement project remarkably prevented the incidence of spinal-induced hypotension among patients at this hospital.

Keywords: ondansetron, hypotension, spinal, intrathecal, anesthesia

A Quality Improvement Project to Prevent Spinal-Induced Hypotension

At an acute care teaching hospital in Washington D.C., adult patients undergoing elective surgery for total joint replacements are anesthetized via spinal anesthesia. Although this method of anesthesia provides adequate analgesia and decreased sensation at the surgical site, an untoward complication is spinal-induced hypotension (SIH). SIH is a significant problem as persistent hypotension can lead to vital organ hypoperfusion. This leads to a cascade of more severe complications such as myocardial injury, acute renal failure, delirium, and stroke, subsequently increasing hospital costs and length of stay (Guarracino & Bertini, 2022). Despite multiple interventions used to mitigate SIH such as the administration of intravenous fluids, vasoactive drugs, and prompt supine repositioning after the spinal injection, SIH persists in up to 60% of orthopedic surgical patients in this acute-care teaching hospital. The incidence of SIH is nearly double the overall incidence in published studies, which is 33% (Tatikonda et al., 2019; Tubog et al., 2017).

Many contextual factors within the organization impact the problem of SIH (see Figure 1). Patients at this site have multiple comorbidities such as anemia, thyroid disorders, and hypertension, which can impact SIH incidence. Additionally, much of the patient population requiring joint replacements is elderly and prone to polypharmacy. Polypharmacy increases the risk of hypotension during anesthesia. Another root cause of this problem is the extra time that it takes to implement interventions before surgery, which can lead to slower operating room turnover. Lastly, with multiple providers providing spinal anesthetics, this can lead to a variety in medication selection and dosing, leading to hypotension in some patients more than others. The most important root cause is the lack of an evidence-based intervention used in this facility to mitigate SIH, such as the administration of prophylactic ondansetron prior to spinal anesthesia.

Therefore, the purpose of this quality improvement (QI) project was to implement and evaluate compliance with the administration of prophylactic intravenous (IV) ondansetron 4mg five minutes prior to spinal anesthesia to reduce the incidence of SIH in 100% of elective total joint replacement patients.

Ondansetron is a medication typically used to treat post-operative nausea and vomiting (PONV) however, it also blocks the Bezold-Jarisch Reflex (BJR) responsible for SIH. To further support this QI intervention, an integrative evidence review was completed and articles were evaluated using the Johns Hopkins Evidence Rating Scale (see Appendix A). Three studies were randomized controlled trials (RCTs) and two were systematic reviews and meta-analyses of randomized controlled trials. All studies assessed the efficacy of ondansetron in attenuating spinal-induced hypotension (SIH). Overall, the literature supports the administration of IV ondansetron in doses of 4 to 12 milligrams (mg) five minutes prior to spinal anesthetic injection to reduce the incidence of SIH.

Although the dosing of ondansetron varied throughout the studies, most studies found efficacy in doses of 4-8mg of ondansetron to reduce SIH. The setting for some RCTs took place in the operating room setting for elective general, urologic, and orthopedic surgery, while some included patients undergoing cesarean section. All patients had an American Society of Anesthesiology (ASA) Status score of I to III. The method of spinal anesthetic administration was also similar throughout the studies including standard ASA patient monitoring, administration of ondansetron five minutes prior to spinal anesthesia using Bupivacaine, and supine positioning after the injection. The impact of hypotension, bradycardia, and nausea/vomiting were also assessed among study participants.

Studies included in the evidence review found that the administration of ondansetron 4-8mg five minutes prior to spinal anesthetic administration reduced the incidence of hypotension with significant p-values ranging from 0.02 to 0.04 (Tatikonda et al., 2020; Medonca et al., 2021; Shah et al., 2016) There is sufficient and consistent high-quality evidence, seen in Table 1, to support the practice change in the administration of ondansetron 4mg five minutes prior to spinal anesthetic administration. For this project, the dose of ondansetron 4mg was selected due to its efficacy against SIH as seen in research, and its typical dosing for surgical PONV prophylaxis at this clinical site.

The Knowledge to Action Framework was utilized to guide the implementation of this QI project (see Figure 2). This framework adapted from Graham et al. (2006) utilizes two distinct components: a centered funnel of knowledge creation surrounded by the action cycle (Field et al., 2014). For this project, the funnel of knowledge was utilized to facilitate knowledge inquiry and synthesis of evidence supporting the administration of ondansetron prior to spinal anesthesia. The action cycle was utilized by mobilizing key stakeholders, assessing the culture of the site, planning the project, and implementing the project. Initially, SIH was identified at the site and the evidence to support a practice change was reviewed and synthesized. Potential barriers to implementation such as provider preference and compliance, were assessed at the site and discussed with key stakeholders. An implementation plan to translate evidence into practice was created utilizing the evidence and input from key stakeholders within the anesthesia department. After implementation, the framework was utilized to monitor the use of knowledge within the site, evaluate outcomes, and promote sustainability. Each of these steps was guided by the Knowledge to Action Framework.

Methods

A context assessment was conducted to evaluate the culture of the organization and its readiness for change. This organization was a large teaching hospital with three dedicated orthopedic operating rooms (ORs), and multiple anesthesia providers including Anesthesiologists, Anesthesiology Residents, Certified Registered Nurse Anesthetists (CRNAs), and Anesthesiology Assistants (AAs), each providing spinal anesthesia for the orthopedic surgery population. Given that multiple anesthesia providers demonstrated interest and were willing to advocate for this project, a comprehensive team was mobilized to support the practice change. The team consisted of a clinical project lead (PL), a faculty advisor, a clinical sponsor who was also the chief of anesthesiology, a clinical site representative (CSR), and multiple CRNA change champions.

The current process for spinal anesthesia prior to project implementation, illustrated in Figure 3, allowed for variation in many steps due to the provider's preference in fluid amount, local anesthetic concentration and dosing, and lastly positioning. The missing component in this process was an evidence-based intervention to prevent SIH, which includes ondansetron 4mg given prior to the spinal anesthetic. Figure 4 outlines the desired process used for this QI project. During implementation, anesthesia providers were expected to administer ondansetron 4mg five minutes prior to the spinal anesthetic, rather than at the end of the procedure, therefore reducing the risk of SIH. This required providers to prepare this medication prior to the case, administer the medication prior to the spinal, and document it while monitoring vital signs for SIH.

Project implementation occurred over 14 weeks, from September 5th to December 9th. Following the creation of a 14-week implementation plan, an educational PowerPoint presentation indicating intervention instructions for the QI project was disseminated to all anesthesia providers at the site. Each anesthesia provider for total joint replacement surgery was

encouraged to administer intravenous ondansetron 4mg five minutes prior to spinal anesthesia for all eligible patients. Eligible patients included all adult patients, aged 18 years or older, receiving elective total joint replacement surgery. Excluded patients included those who required general anesthesia or had an allergy or contraindication to receiving ondansetron. The administration of ondansetron was charted in the electronic anesthesia record.

Using the Expert Recommendations for Implementing Change (ERIC) study by Powell et al. (2015), specific implementation strategies and tactics were selected to achieve 100% compliance in the administration of ondansetron. Formal commitments were obtained from key stakeholders within the project site including the chief of anesthesiology, the chief nursing officer, and the director of acute pain services. For accountability and communication, change champions were available as resources to staff and assist with implementation via weekly emails and in-person discussions. Monthly formal meetings and weekly communication with the CSR were completed during the first few weeks of implementation. With the PL being onsite for the month of October, informal individual meetings were easily conducted and consistent feedback and support for the project was communicated. As compliance increased, weekly recognition emails were sent starting in week five. Additionally, visual reminders to administer ondansetron were placed on all spinal kits in stock and quick tip sheets were placed in all orthopedic operating rooms.

Structure goals included educating 100% of the anesthesia providers and placing reminder notices on each of the spinal kits in stock. Process goals included 100% compliance from anesthesia providers with the intervention and documentation in the electronic anesthesia record. For this process goal, multiple studies demonstrated a statistically significant reduction in hypotension with the administration of ondansetron 4mg, five minutes prior to spinal

administration. The main outcome goal was that SIH will be reduced for 100% of total joint replacement patients in an acute care teaching hospital, measured by anesthesia providers within the first 15 minutes post-injection by systolic blood pressure decrease by 20% of baseline. Multiple studies, including Shah et al. (2016), Tatikonda et al., (2020), and Medonca et al. (2021), used this specific measure to define SIH. Reliability and validity of the monitoring instruments used to measure SIH have been found as standard ASA monitors are used in every surgical healthcare setting for vital signs measurement. Furthermore, a detailed description of the measures and the measurement plan can be found in Tables 2 and 3, respectively. Measures were tracked by the PL via weekly electronic chart and anesthesia record reviews and documented using a data collection tool via Research Electronic Data Capture (REDap) software for data analysis and secure storage (see Appendix B).

Prior to the implementation of the project, multiple measures were taken to ensure that ethical standards would be upheld. Training and certifications, including the Collaborative Institutional Training Initiative (CITI) course on the protection of human subjects and the Health Insurance Portability and Accountability Act (HIPAA) training in human research, privacy, and security awareness, were completed by the PL. Additionally, the quality improvement project was reviewed and determined to be non-human subject's research by the Human Research Protections Office (HRPO) of the UMSON Institutional Review Board (IRB). Furthermore, approval for the QI project from the project site was obtained. Non-identifying project data was collected, coded, and analyzed solely by the PL using HIPAA privacy practices. A secure web software application, REDCap, was utilized to collect, survey, store, and analyze QI data. This application was accessed only by the PL in a private location using a password-protected computer to protect patient privacy.

Results

The structure goals for this project included educating 100% of anesthesia providers on the QI project and placing reminders on all spinal kits. Education occurred during week one of implementation. Initially, there was 17% education compliance due to the department's large number of anesthesia providers. The PL conducted daily informal discussions with anesthesia providers to improve this percentage. Additionally, during the first few weeks of implementation, spinal kits were out of stock limiting the ability of the PL to place visual reminders until week five. However, laminated quick tip sheets were placed in all orthopedic operating rooms, and reminders were placed on shelves of the anesthesia workroom where spinal kits were typically stocked.

From 178 retrospective chart reviews over 14 weeks, 138 patients were eligible. A total of 109 patients were included; 29 were excluded due to incomplete documentation or inaccurate dose timing. The process goal, 100% of total joint replacement patients to receive 4mg of ondansetron five minutes prior to spinal anesthesia, is demonstrated in Figure 5. Out of 109 patients, 53% of patients (N=58) received 4mg of ondansetron five minutes of spinal anesthesia. Weeks one through four indicated a decreasing compliance in ondansetron administration demonstrated by a downward run of multiple consecutive data points. Subsequently, week four specifically is an astronomical data point. Only three patients were included in the data this week and zero received ondansetron. This run can be attributed to the low education compliance among anesthesia providers during this time frame. With the addition of daily reminders and individual discussion, weeks five and six display an increase in compliance. Compliance continued to stay above the median during weeks seven through nine, with 100% compliance during week eight. This can be attributed to the PL being on-site daily during those weeks.

Weeks nine through 11 showed a slight decrease in compliance which could be attributed to the PL not being on-site daily to provide in-person reminders and recognition. After sending additional email reminders, compliance increased during week 12, achieving over 90% compliance in week 14.

Results for the outcome goal, to prevent SIH in 100% of patients receiving spinal anesthesia, can be found in Figure 6. During the first two weeks, 75 to 100% of patients receiving ondansetron did not experience SIH. During weeks three and four, this decreased, which can be attributed to the low compliance with ondansetron administration. Out of 13 patients, only two received the QI project intervention. Additionally, during week four, an astronomical data point was observed, the non-incidence of SIH was zero as no patients received ondansetron this week. During weeks five and six, 75 to 80% of patients did not experience SIH, which can be attributed to the increase in compliance and the PL being onsite. During week seven there was a decrease in the non-incidence of SIH, however, there was 70% compliance which was unexpected. This decrease can be attributed to patient characteristics predisposing them to hypotension and the addition of anesthetic medications such as propofol. Weeks eight through 11 show an increased non-incidence of SIH above the median, achieving 100% non-incidence in weeks 13 and 14. Overall, findings of this QI project suggest that the administration of ondansetron 4mg five minutes prior to spinal anesthesia, prevented spinal-induced hypotension in over 75% of total joint replacement patients at this site.

Discussion

A key finding from this QI project was the overall feasibility of the administration of IV ondansetron 4mg, five minutes prior to spinal anesthesia for total joint replacement patients. Additionally, this intervention helped decrease SIH in over 75% of patients. This is a significant

improvement from the months prior to implementation in which only about 40% of patients did not experience SIH. Provider compliance was initially low, however, for a total of nine weeks, the compliance percentage was above the median percentage indicating reception of change among anesthesia providers at the site. When provider compliance was above the median percentage, the non-incidence of SIH remained high. Continuous communication amongst the project team, provider education, utilization of change champions, and the frequent presence of the PL onsite contributed to the success of this QI project.

Results from this QI project align with current research. According to Medonca et al. (2021), the administration of ondansetron results in significantly lower rates of hypotension, especially in patients aged 60 years or older. Additionally, a meta-analysis by Tubog et al. found that the administration of intravenous ondansetron five minutes prior to spinal injection attenuates hypotension in obstetric and non-obstetric patient populations (2017). Although the effect of ondansetron has been studied more extensively in the obstetric population, the QI project shows its efficacy in total joint replacement surgical patients. On the contrary, some studies investigated ondansetron's effects on spinal-induced bradycardia, nausea, and the need for vasopressor support, however, this QI project did not (see Appendix A).

During the course of this project, several limitations to success were identified. A significant limitation of this project was the inability to capture vital signs for spinal anesthetics completed in the preoperative area. Over 20 charts were excluded from the QI project due to incomplete documentation. Having this information could have provided QI data for a much larger scale of patients. Another limitation was the initial low education compliance. With the project site being a teaching institution with over 80 anesthesia providers, accountability for reviewing the education was difficult to track. Having greater education compliance could have

positively impacted intervention compliance. Furthermore, the project site is comprised of anesthesia providers with different preferences for practice. With strong preferences, some providers were resistant to change also limiting project data. To mitigate this, anesthesia providers were provided education on the evidence-based intervention as well as quality improvement project data from the project to show ondansetron's efficacy in preventing SIH. Factors limiting internal validity could include the accuracy of provider documentation. For this project, there was no way to specifically track if items were charted in real-time or backdated without having strict observation for every anesthesia case involved in the QI project. To minimize this factor, providers were encouraged to be as accurate and as timely as possible with documentation. Charts, where documentation showed ondansetron administered outside of the five-minute window, were reflected in ondansetron administration compliance and/or process data, however, excluded from outcome data.

Conclusion

Overall, this quality improvement project demonstrated the feasibility of an evidence-based intervention in clinical practice. It also remarkably prevented the incidence of SIH among patients receiving elective total joint replacement surgery at this hospital. The information gained from this project is pivotal for spinal anesthesia, as many providers at the site were completely unaware of ondansetron's ability to prevent SIH. The insignificant cost of this intervention and the feasibility of change within the anesthesia workflow are great strengths for this QI project. In terms of cost, ondansetron is a medication typically given to nearly all patients requiring anesthesia. By this medication being low cost, readily available, and commonly given by anesthesia providers, sustaining this evidence-based intervention to prevent SIH is feasible and

favorable. Although the timing of ondansetron administration changes anesthesia workflow, evidence of this quality improvement project demonstrated that it is achievable.

Key stakeholders, change champions, and many anesthesia providers at the site continue to be supportive of this practice change. By using current evidence and data from the quality improvement project, anesthesia providers will continue to implement this intervention. Recently, there has been a shift from spinal anesthesia being completed in the OR to being completed in the preoperative area, decreasing turnover time for OR cases. Further QI projects, specifically focusing on data collection for spinal anesthesia in the preoperative area could provide useful data to strengthen the argument for this practice change. In order to promote the continuation of the practice change, visual reminders, and quick tip sheets will remain in operating rooms and anesthesia supply areas. Increasing awareness of QI data and its positive impact on the prevention of SIH among total joint replacement patients, by way of email and staff meetings, can influence anesthesia providers to adopt this change in everyday practice.

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Tables

Table 1

Evidence Synthesis

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	3 Double-Blind RCT's 2 Systematic Review & Meta-analysis of RCTs	A	Each study within the evidence review demonstrated level one evidence in the form of a randomized controlled trial or a systematic review and meta-analysis of randomized controlled trials assessing the efficacy of ondansetron given prior to spinal anesthesia in attenuating spinal induced hypotension (SIH). Although ondansetron was the drug of choice, dosing varied anywhere from 2mg up to 12mg. Most studies found efficacy in doses of 4-8mg of ondansetron. Most studies took place in the operating room setting for elective surgery, while some included patients undergoing cesarean section. Typical practices for spinal anesthetic administration were similar in each study including patient monitoring, the ondansetron dose timing, the intrathecal drug Bupivacaine varying in concentration and dose from 10 to 20mg, and the supine positioning after the injection. Statistical analysis was used to assess the impact of hypotension, bradycardia, and nausea/vomiting among study participants. All individual studies and systematic reviews found that the administration of ondansetron 4-8mg five minutes prior to spinal anesthetic administration significantly reduced the incidence of hypotension and the need for rescue vasopressor administration.
Level II · Quasi-experimental studies · Systematic review of a combination of RCTs and quasi-experimental studies, or quasi-experimental studies only, with or without meta-analysis			

Level II · Quasi-experimental studies · Systematic review of a combination of RCTs and quasi-experimental studies, or quasi-experimental studies only, with or without meta-analysis			
Level IV · Opinion of respected authorities and/or reports of nationally recognized expert committees/consensus panels based on scientific evidence			
Level V · Evidence obtained from literature reviews, quality improvement, program evaluation, financial evaluation, or case reports · Opinion of nationally recognized expert(s) based on experiential evidence			
Recommendations Based on Evidence Synthesis: There is sufficient and consistent high-quality evidence indicating the need for practice change in the administration of ondansetron four to eight milligrams five minutes prior to spinal anesthetic administration.			

Table 2

Measures Table

PLAN		
Measures		
Project Goals	**Measure Pre-Implementation**	**Measure During Implementation**
Structure Goal(s)		
1. 100% of anesthesia providers in an acute care teaching hospital will be educated on the use of prophylactic intravenous Ondansetron injection prior to spinal anesthetic injection for orthopedic surgical patients.	Anesthesia provider attendance counted for virtual education presence.	Anesthesia provider attendance counted for virtual education presence.
2. Reminder notices will be placed on all spinal kits as a hard stop for 100% of anesthesia providers to administer prophylactic ondansetron 4mg prior to spinal injection.	Notices placed and spinal kits assessed by anesthesia technicians.	Notices placed and spinal kits assessed by anesthesia technicians.
Process Goal(s)		
1. 100% of anesthesia providers in an acute care teaching hospital will be compliant with the administration of prophylactic intravenous ondansetron 4mg 5 minutes prior to spinal anesthetic injection for all eligible total joint replacement surgical patients.	**Numerator:** # of patients receiving intravenous ondansetron 4mg, five minutes prior to spinal anesthetic injection. **Denominator**: # of patients receiving a spinal anesthetic injection	**Numerator:** # of patients receiving intravenous ondansetron 4mg, five minutes prior to spinal anesthetic injection. **Denominator**: # of patients receiving a spinal anesthetic injection
2. 100% of anesthesia providers will document the administration of ondansetron in the electronic anesthesia record.	**Numerator:** # of ondansetron administrations documented in the electronic anesthesia record **Denominator**: # of ondansetron administrations	**Numerator**: # of ondansetron administrations documented in the electronic anesthesia record **Denominator**: # of ondansetron administrations
Outcome Goal		

1. Hypotension (SIH) will be reduced for 100% of total joint replacement patients in an acute care teaching hospital, measured by anesthesia providers within the first 15 minutes post injection by systolic blood pressure decrease by 20% of baseline.	**Numerator:** # of patients receiving spinal anesthesia sustaining a decrease in systolic blood pressure by 20% of baseline within the first 15 minutes of intrathecal injection. **Denominator**: # of patients receiving spinal anesthesia.	**Numerator**: # of patients receiving spinal anesthesia sustaining a decrease in systolic blood pressure by 20% of baseline within the first 15 minutes of intrathecal injection. **Denominator**: # of patients receiving spinal anesthesia.

Table 3

Measurement Plan Table

Measure	Measurement Plan
Structure Goal: 100% of anesthesia providers in an acute care teaching hospital will be educated on the use of prophylactic intravenous Ondansetron injection prior to spinal anesthetic injection for orthopedic surgical patients.	• PowerPoint Presentation (PPT) sent to the entire anesthesia department for review • Compliance tracked via sign-in sheet paper and goggle document • Weekly email reminders will be sent to the entire anesthesia department • Change champions available as a resource and coach for staff
Structure Goal: Reminder notices will be placed on all spinal kits as a hard stop for 100% of anesthesia providers to administer prophylactic ondansetron 4mg prior to spinal injection.	• Anesthesia technicians will be provided a bulletin to place in each anesthesia workroom • Each bulletin will provide instructions on placing reminders on each spinal kit when stocking. • Printed reminders will be provided to the anesthesia technicians in the workroom
Process Goal: 100% of anesthesia providers in an acute care teaching hospital will be compliant with the administration of prophylactic intravenous ondansetron 4mg 5 minutes prior to spinal anesthetic injection for all eligible total joint replacement surgical patients.	• Electronic charts will be reviewed for the documentation of ondansetron in the medication section • The time of administration and relation to the administration of spinal local anesthetic will be reviewed to determine compliance with the practice change • A comment will be placed in the comment section of spinal documentation indicating the administration of prophylactic ondansetron
Process Goal: 100% of anesthesia providers will document the administration of ondansetron in the electronic health record.	• Electronic charts will be reviewed for the documentation of ondansetron in the medication section • The time of administration and relation to the administration of spinal local anesthetic will be reviewed to determine compliance with the practice change

	• A comment will be placed in the comment section of spinal documentation indicating the administration of prophylactic ondansetron
Outcome Goal: Hypotension (SIH) will be reduced for 100% of total joint replacement patients in an acute care teaching hospital, measured by anesthesia providers within the first 15 minutes post injection by systolic blood pressure decrease by 20% of baseline.	• Anesthesia records in the EHR will be assessed for baseline blood pressure prior to the start of anesthesia. This blood pressure will be compared to a precalculated chart determining the threshold for SIH for that specific blood pressure. • Blood pressure readings will be measured every 3 minutes will for the duration of the time in the operating and assessed for SIH within the first 15 minutes after spinal injection. • An excel spreadsheet will be used to compile data • Vital signs data will be extracted from reports via the information technology department, if available.

Figures

Figure 1

Fishbone Diagram

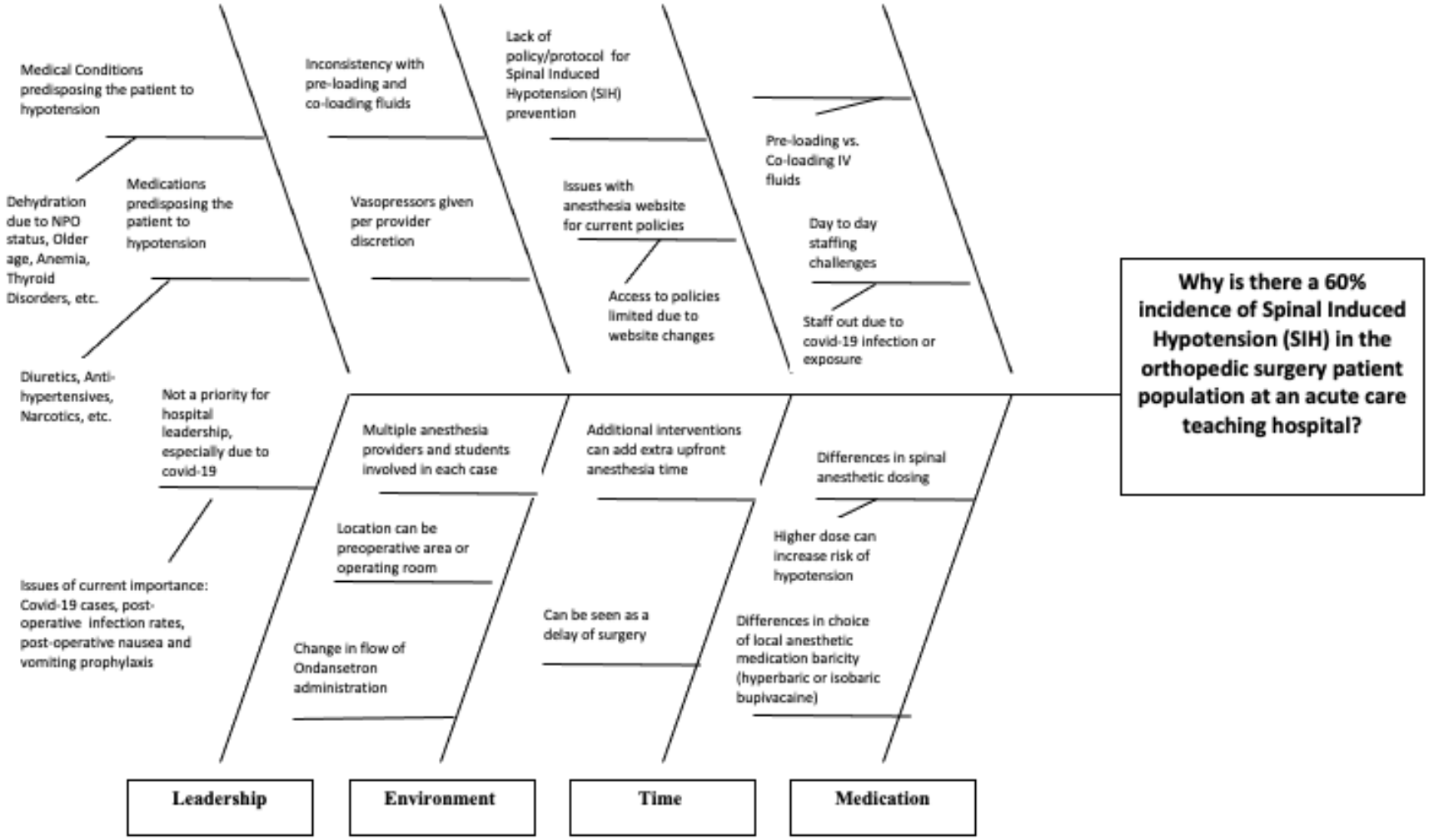


Figure 2

The Knowledge to Action Framework

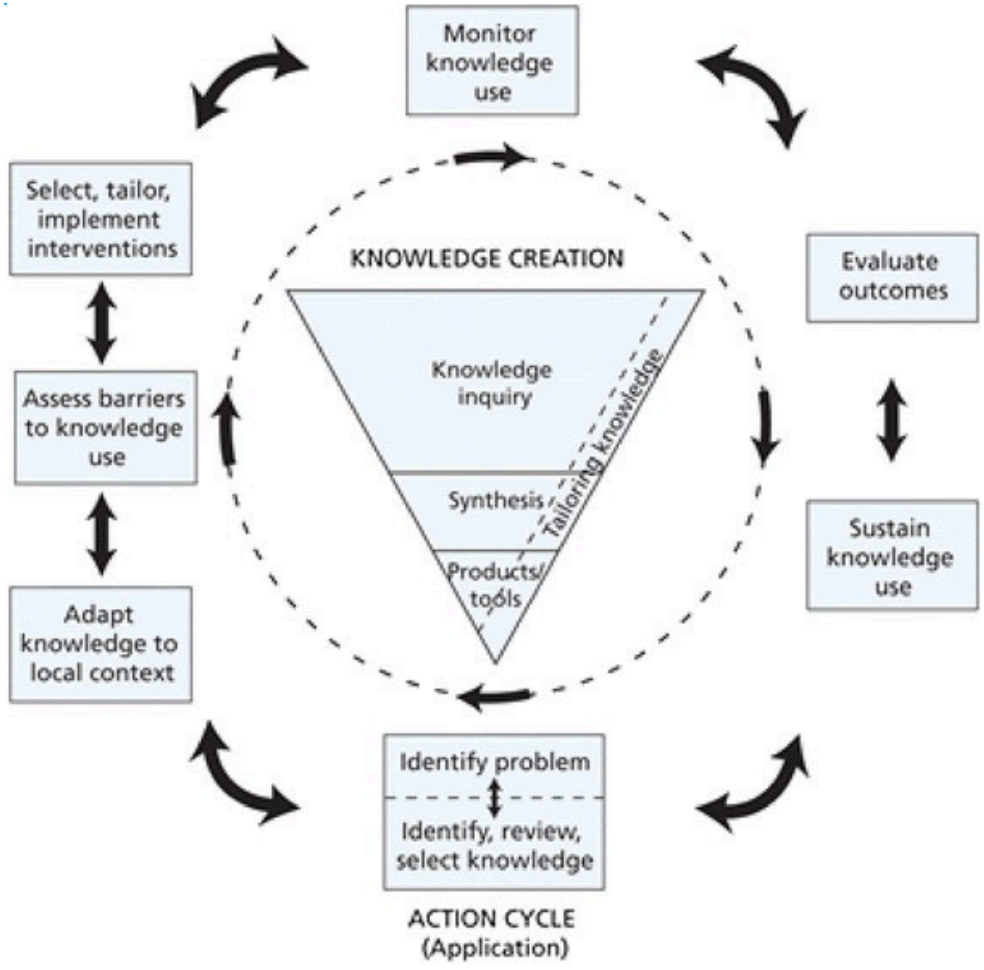
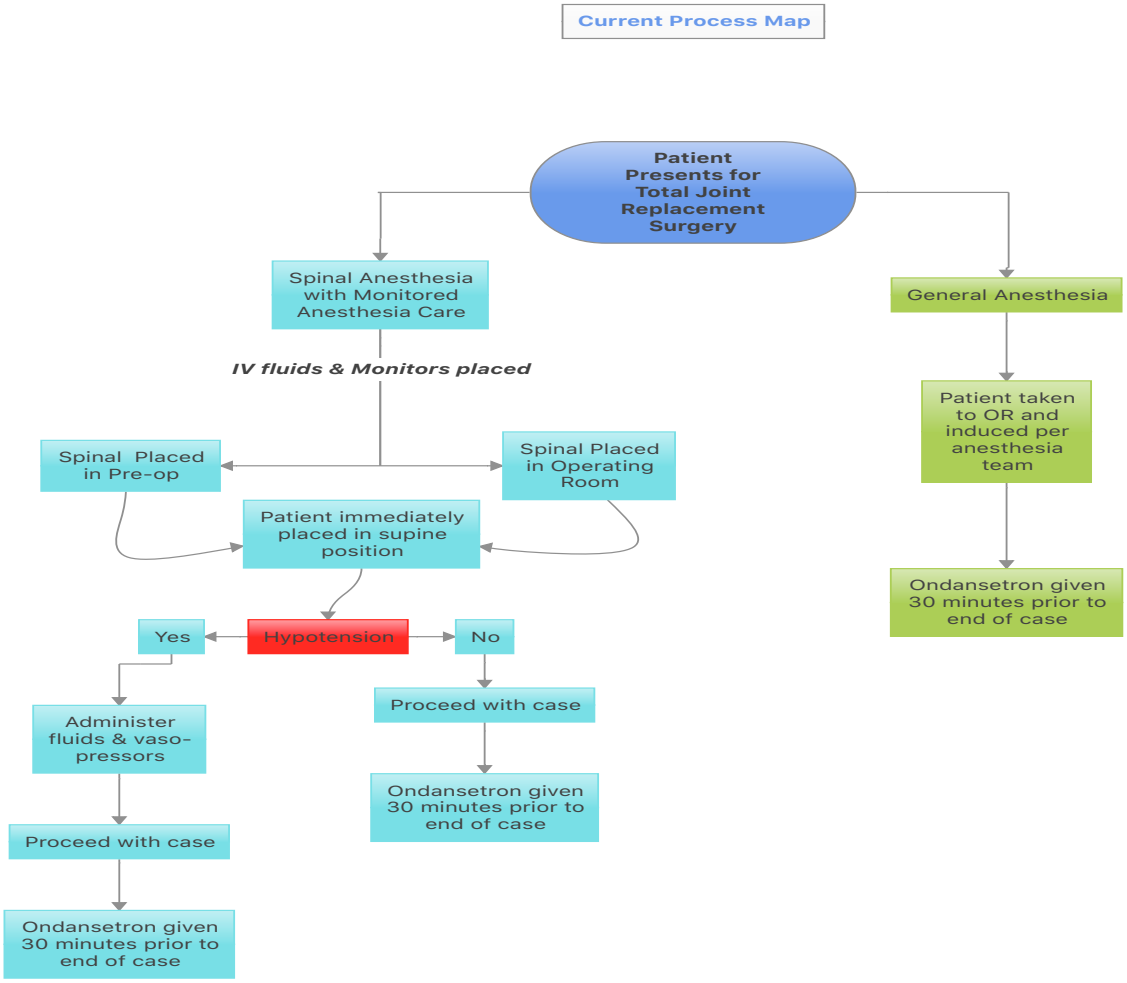


Figure 3

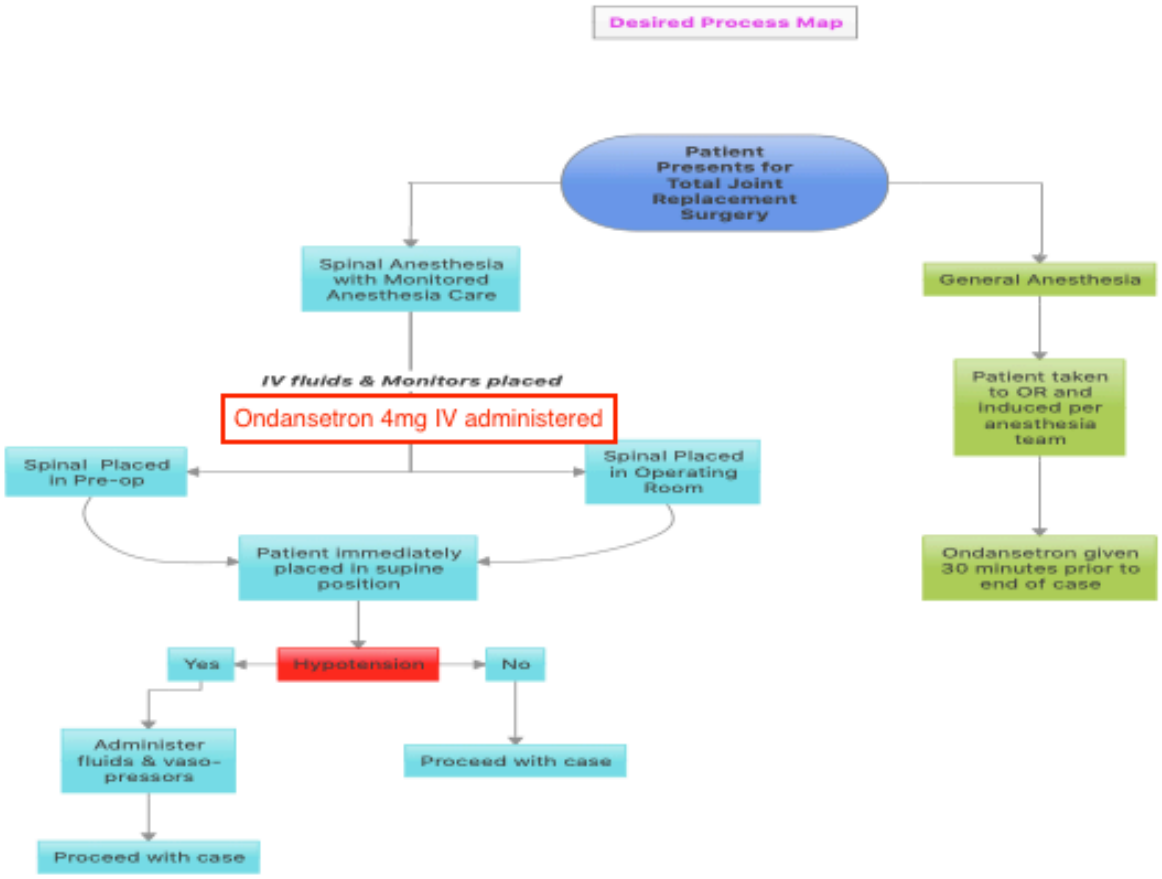
Current Process Map



Key: Green= General Anesthesia, Teal= Spinal Anesthesia, Red=Complications, Arrows= next step of process

Figure 4

Desired Process Map



Key: Green= General Anesthesia, Teal= Spinal Anesthesia, Red=Complications, Arrows= next step of process

Figure 5

Run Chart: Compliance of Ondansetron Administration

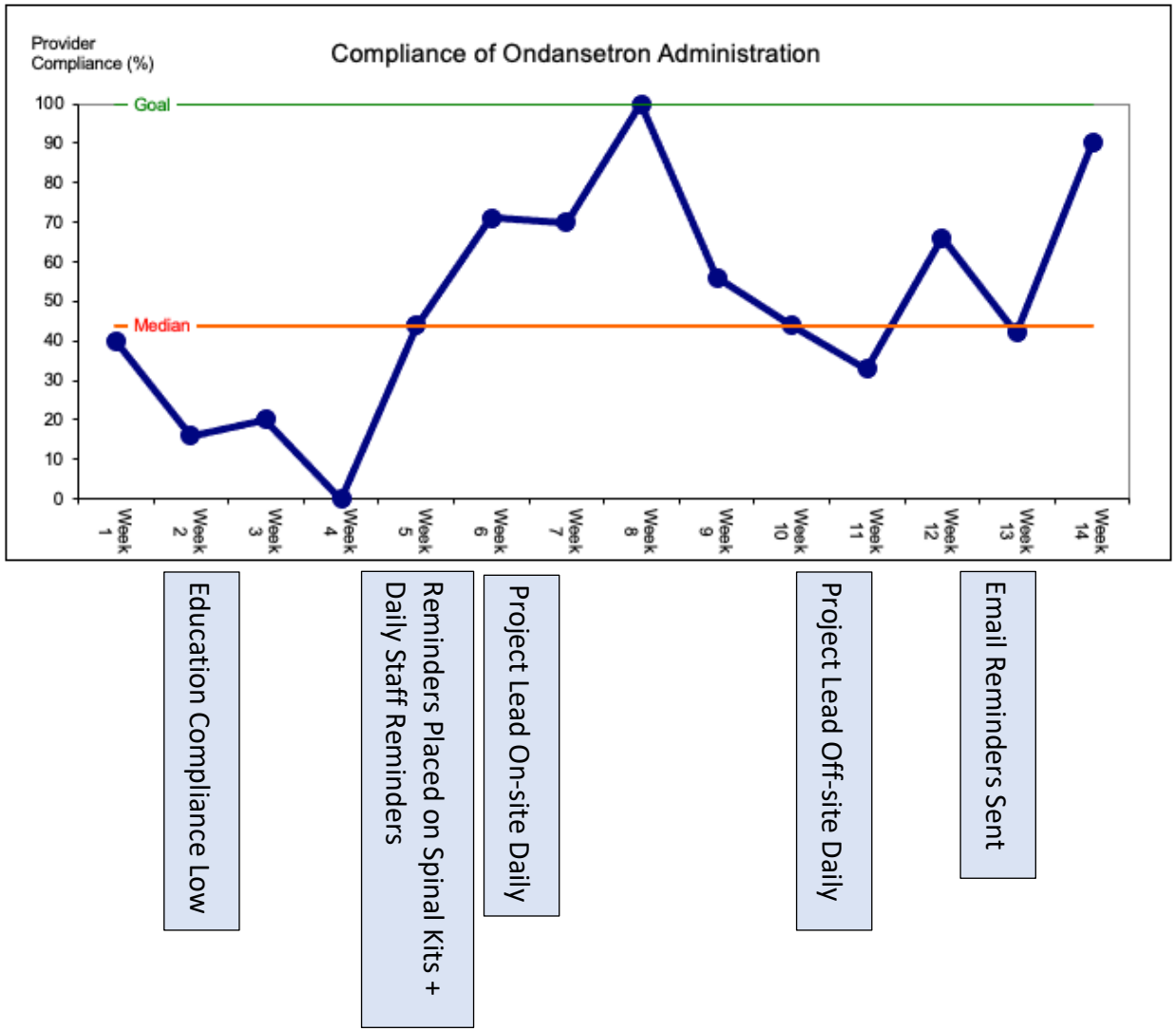
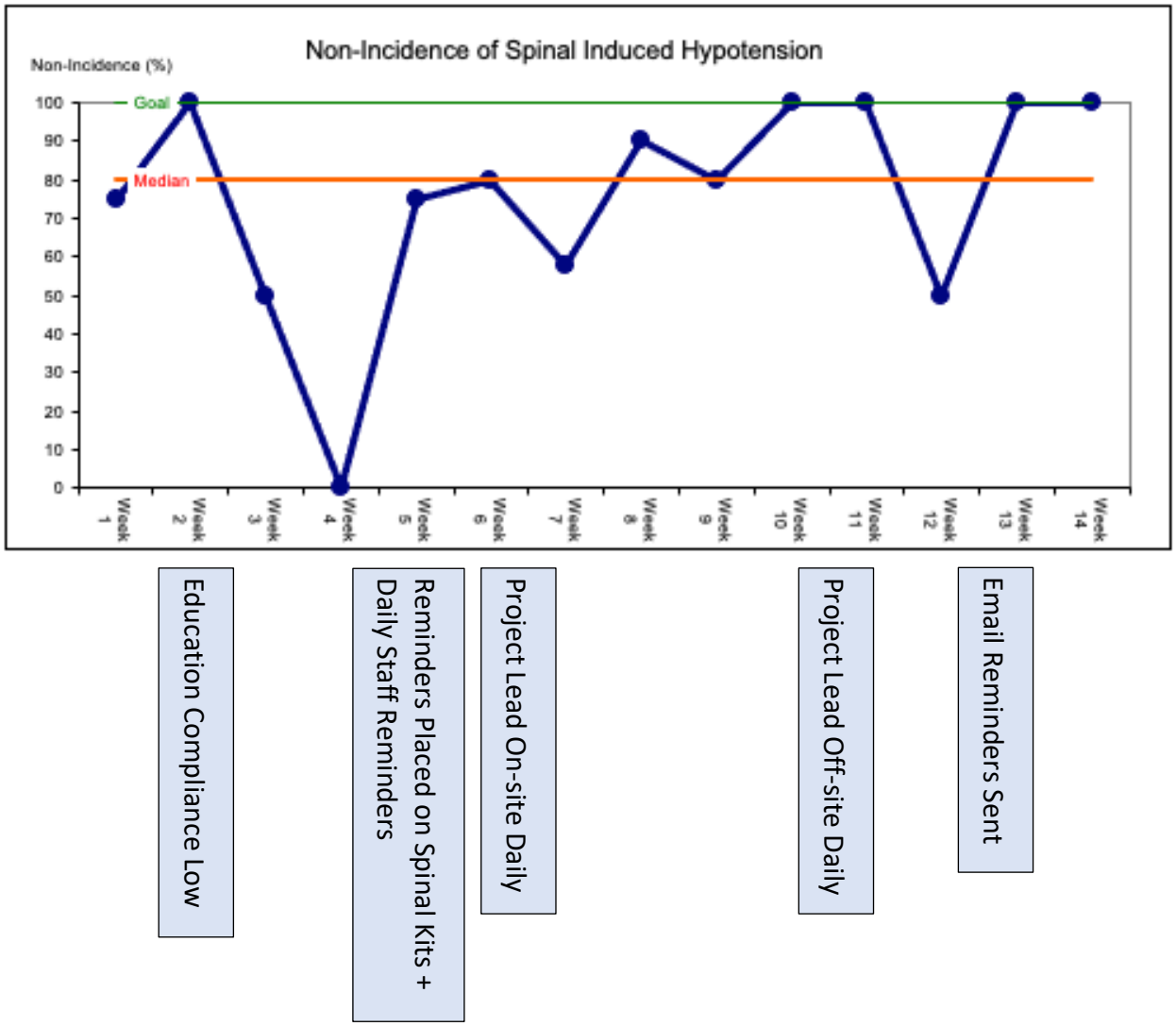


Figure 6

Run Chart: Non-Incidence of Spinal-Induced Hypotension



Appendix A

Evidence Review Table

Citation #1	Shah, S., Naqvi, S., & Abbas, M. (2016). Efficacy of prophylactic intravenous administration of ondansetron for prevention of spinal induced hypotension in elderly patients. *Anaesthesia, Pain & Intensive Care, 20*(1), 17-20. Retrieved from http://survey.hshsl.umaryland.edu/?url=https://search-ebscohost-com.proxy-hs.researchport.umd.edu/login.aspx?direct=true&db=asn&AN=117428978&site=eds-live
Level and Quality	I-A
Purpose/Hypothesis	The purpose of this research study was to determine the effectiveness of the prophylactic administration of ondansetron for the prevention of spinal anesthesia induced hypotension in the elderly patient population.
Type of Evidence Research Design	**Research:** Double blind Randomized Controlled Trial
Sample	**Sampling Technique:** Non-probability. Random numbers table for study groups. **Eligible Participants:** Patients presenting for elective surgery with American Society of Anesthesiology (ASA) status of I to III, aged 50-80 years. **Setting:** Main operating room of Combined Military Hospital Rawalpindi **Exclusion Criteria:** Contraindication to spinal anesthesia, allergy to local anesthetics, ischemic heart disease, short stature, morbidly obese, and/or failed spinal block **Eligible:** Not specified **Accepted:** 100 **Control Group:** 50 **Intervention Group:** 50 **Power analysis:** The sample size was determined to include 100 patents based on power analysis from two previous studies. **Group Homogeneity:** Participants were homogenous in terms of characteristics such as age and weight and tested using mean, standard deviation, and independent T-test.
Intervention	**Control Protocol (Group B):** Each patent received a placebo injection of normal saline five minutes prior to spinal administration. **Intervention Protocol (Group A):** Each patient received an intravenous injection of ondansetron 8 milligrams (mg) five minutes prior to spinal administration. **Intervention fidelity:** Written informed consent was obtained from each patient. A staff nurse, unrelated to the surgical case, prepared the drugs for both groups. The anesthetist administering the drugs was kept blinded. Each patient in the intervention group was administered ondansetron 8mg, while the control group received normal saline both five minutes prior to the subarachnoid block. Blood pressure and heart rate were monitored and each patient was placed in the supine position immediately after spinal administration of 15mg of 0.75% bupivacaine.

Primary Outcome/Measures	**Dependent Variable:** Spinal induced hypotension (SIH) was defined as a drop in systolic blood pressure (SBP) greater than 20 % of the baseline reading or less than 90 mmHg. Bradycardia was defined as a heart rate less than 60 beats per minute. **Measurement:** Standard monitors were applied prior to the procedure including continuous heart rate monitoring and blood pressure measured every three minutes for a total of 21 minutes. Frequency of bradycardia and hypotension were expressed in percentage and compared using chi square test with a significant p - value < 0.05. No information for reliability or validity of measuring tools was indicated.
Results/Conclusion	**Statistical Results:** IBM SPSS version 20 was used to analyze study data including gender and frequency of bradycardia and hypotension. These were each expressed in percentages and compared using chi square test. Hypotension was present in 23 patients (46%) in the intervention group and in 34 (68%) patients in the control group showing a statistically significant higher incidence of hypotension in the control group with a p value of 0.026. **Conclusions:** The researchers concluded that the administration of 8mg of ondansetron prior to spinal anesthesia significantly reduced the incidence of hypotension.
Citation #2	Medonca, F., Crepaldi Junior, L., Gersanti, R., & de Araujo, K. Effect of ondansetron on spinal anesthesia-induced hypotension in non-obstetric surgeries: A randomised, double-blind and placebo-controlled trial. (2021). *Brazilian Journal of Anesthesiology, 71*(3), 233-240. https://doi.org/10.1016/j.bjane.2020.12.028
Level and Quality	I-A
Purpose/Hypothesis	The purpose of this research study was to compare the effect of the administration of ondansetron and placebo before a spinal anesthetic on the incidence of SIH in the non-obstetric surgical patient population.
Type of Evidence Research Design	**Research:** Double-blind Randomized Placebo-controlled Trial
Sample	**Sampling Technique:** Non-probability. Computer generated random sequencing for study groups. **Eligible Participants**: Patients scheduled for urgent or elective surgery requiring spinal anesthesia, 18 years or older, and ASA status I to III **Setting:** The operating room of a hospital in Brazil **Exclusion Criteria:** Drug hypersensitivity, use of clonidine during the spinal anesthesia, patients on anticoagulants, atrioventricular block or cardiac arrhythmias, heart failure, kidney disease, liver diseases, localized infection or any contraindication to spinal anesthesia **# Eligible:** 188 **# Accepted:** 144 patients **Control Group:** 72 patients **Intervention Group:** 72 patients

	Power analysis: A power analysis determined that 70 patients per group (a total of 140) would be required to give the trial 90% power to detect a treatment difference. **Group Homogeneity:** Study groups were comparable in terms of baseline clinical characteristics and demographics.
Intervention	**Control Group:** Each patient received a placebo injection five minutes prior to spinal administration. **Intervention Group:** Each patient received an intravenous dose of ondansetron 8mg five minutes prior to spinal injection **Intervention Fidelity:** Anesthesiologists, surgeons, and operating room staff were all blinded to the study. Syringes were de-identified and made identical in terms of viscosity, volume, color, and odor. These syringes were prepared by an independent investigator, not involved in the patient's surgery, and sent directly to the operating room right before administration. All patient received standard monitoring. Patients in the intervention group received intravenous ondansetron 8mg while patients in the control group received intravenous distilled water, 5 minutes prior to spinal injection of hyperbaric bupivacaine, 15mg or more. All patients were placed in the supine position after the injection.
Primary Outcome/Measures	**Dependent Variable:** Hypotension was defined as SBP below 80% of baseline or below 90mmHg. Bradycardia was defined as a heart rate less than 50 beats per minute. **Measurement:** Using standard ASA monitors, baseline systolic blood pressure and heart rate values were recorded, additionally values were recorded after anxiolysis administration and every 5 minutes after. The difference between the highest and lowest systolic blood pressure and heart rate (was calculated and identified. No information for reliability or validity of measuring tools was indicated.
Results/Conclusion	**Statistical Results:** Normality was assessed using the Shapiro-Wilk test, while between-group differences were examined using Chi-square. Continuous variables were compared using unpaired t-tests. Additionally, a logistic regression model and linear mixed-effects model were used. For the ondansetron group, hypotension was present in 20 patients (27.8%) and in the placebo group, hypotension was present in 36 patients (50%) (OR = 0.38; 95% CI 0.19 to 0.77; $p = 0.007$). Additionally, fewer patients in the intervention group required ephedrine administration compared to the placebo group (13.9% [10 of 72 patients] vs. 27.8% [20 of 72 patients]; OR = 0.42; 95% CI 0.18 to 0.98; $p = 0.04$). **Conclusion:** The administration of ondansetron resulted in significantly lower rates of hypotension, especially in patients aged 60 years or older and less use of ephedrine.
Citation #3	Tatikonda, C., Rajappa, G., Rath, P., Abbas, M., Madhapura, V., & Gopal, N. (2019). Effect of intravenous ondansetron on spinal anesthesia-induced hypotension and bradycardia: A randomized controlled double-blinded study. *Anesthesia Essays and Researches*,13(2), 340-346. https://dx.doi.org/10.4103/aer.AER_22_19
Level and Quality	I-A

Purpose/Hypothesis	The purpose of this study was to compare the efficacy of ondansetron versus a placebo in reducing the incidence of SIH, nausea, vomiting, and shivering.
Type of Evidence Research Design	**Research:** Double-Blind Randomized Controlled Trial
Sample	**Sampling Technique:** Non-probability; Convenience. Computer generated random numbers for study groups. **Participants:** Patients ages 20 to 60 years, presenting for elective gynecologic, orthopedic, and general surgical procedures with an ASA Class of I and II. **Setting:** Tertiary care teaching hospital, Operating room **Exclusion Criteria:** Patients with allergy to ondansetron, spinal anesthesia contraindication, hypertension, coronary artery disease, parturient, autonomic neuropathy, patients taking selective serotonin reuptake inhibitors. **Accepted:** 140 patients **Control Group:** 70 patients **Intervention Group:** 70 patients **Power analysis:** The sample size of 68 per group was determined based on the power analysis. **Group Homogeneity:** Both groups were homogenous in terms of demographics, ASA, and clinical status.
Intervention	**Control:** Each patient received 2mL of normal saline prior to the spinal administration. **Intervention:** Each patient received 4mg ondansetron prior to the spinal administration. **Intervention Fidelity:** Study drugs were labeled by an anesthesiologist not involved in the study. Patients were monitored by another anesthesiologist. Both the patient and primary anesthesiologist were blinded to the study. The intervention group received intravenous ondansetron 4mg, while the control group received intravenous normal saline both 5 minutes prior to spinal anesthesia which included 15mg of 0.5% hyperbaric bupivacaine. Blood pressure and heart rate was recorded for every patient using standard monitors. All patients were placed supine after the spinal injection.
Primary Outcome/Measures	**Dependent Variable:** Hypotension was defined as a 20% change from the baseline mean arterial pressure (MAP). **Measurement:** The dependent variable was measured by using standard ASA monitors. Hemodynamic parameters such as heart rate, blood pressure, electrocardiograph, and oxygen saturation, were measured prior to spinal anesthetic and every three minutes for a total of 30 minutes. No information for reliability or validity of measuring tools was indicated.
Results/Conclusion	**Statistical Results:** Descriptive and inferential statistics were used including two-tailed independent t-tests for significance in study parameters on a continuous scale and Chi-square/Fischer's exact test for significance on a categorical scale. In the intervention group, 19 (27%) patients required ephedrine, while in the control group 33 (47%) patients required ephedrine after the spinal administration ($p=0.029$). **Conclusions:** The study concludes that the prophylactic administration of ondansetron 4mg reduces the requirement for ephedrine in patient undergoing spinal anesthesia.

Citation #4	Gao, L., Zheng, G., Han, J., Wang, Y., & Zheng, J. (2015). Effects of prophylactic ondansetron on spinal anesthesia-induced hypotension: A meta-analysis. *International Journal of Obstetric Anesthesia, 24,* 335-343. http://dx.doi.org/10.1016/j.ijoa.2015.08.012
Level and Quality	I-B
Purpose/Hypothesis	This meta-analysis was conducted with the purpose of identifying the effects of prophylactic ondansetron on hemodynamics following spinal anesthetic administration.
Type of Evidence Research Design	Research: Meta-analysis
Sample	**Sample:** Records were identified using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) method. Multiple databases such as Medline, Embase, and the Cochrane Library databases were used and searched using medical subject headings such as spinal anesthesia, intrathecal anesthesia, subarachnoid anesthesia, ondansetron, hypotension, and blood pressure. **Inclusion:** Randomized controlled trials published in full-text English studying the effects of ondansetron on hemodynamic changes associated with spinal anesthesia. **Eligible Articles:** 44 **Accepted Articles:** 10 **Total Subjects:** 863 **Participants:** Patients presenting for orthopedic, urologic, or gynecologic surgery, parturients presenting for cesarean section, all ages 16 to 70, and ASA status I and II. **Group Homogeneity:** Homogeneity between study groups was assessed indicating a low risk of bias shown in Figure 2.
Intervention	**Control Group:** These patients received a placebo five minutes prior to spinal administration. **Intervention Group:** These patients received intravenous ondansetron 4-12mg, depending on the study, five minutes prior to spinal injection **Intervention Fidelity:** The quality of included studies was independently assessed by two reviewers and evaluated using the five-point Oxford scale, and multiple domains of the Cochrane Collaboration. Specific intervention fidelity for each study was not discussed. Each study included an intervention group which administered 4-12mg of ondansetron 5 minutes prior to spinal anesthesia, while the control groups received a placebo. The spinal anesthesia drug given ranged from 10 to 20mg of bupivacaine.
Primary Outcome/Measures	**Dependent Variable:** The dependent variable was hypotension which was determined by individual authors' definitions in *Table 1* such as a SBP less than 80-90 mmHg, a diastolic blood pressure less than 60 mmHg, a SBP less than 75-80% of baseline, a SBP decrease greater than 20% from baseline, and lastly a MAP less than 80 or decrease greater than 20% from baseline. Secondary outcomes were also measured, which included bradycardia, nausea, vomiting, and vasopressor use. **Measurement:** Outcomes were analyzed by using relative risk (RR) with 95% confidence intervals (CI).

Results/Conclusion	**Statistical Results:** Results were based on the random effects meta-analysis model, pooled weighted RRs, and mean difference with 95% CI, calculated using Mantel-Haenszel and Inverse Variance statistical methods. The RR of spinal anesthesia-induced hypotension after ondansetron administration was 0.53 (95% CI 0.32 to 0.86) in obstetric patients and 0.16 (95% CI 0.05 to 0.51) in non-obstetric patients indicating that there was a reduced incidence when compared to the control groups. The research also showed that the administration of ondansetron also reduced the incidence of bradycardia, nausea and vomiting after spinal anesthesia with RRs of 0.27 (95% CI 0.16 to 0.47), 0.24 (95% CI 0.14 to 0.42) and 0.48 (95% CI 0.08 to 3.08). Additionally, vasopressor requirements were reduced when ondansetron was administered prior to spinal administration. **Conclusions:** This review concluded that the prophylactic administration of ondansetron reduces the incidence of hypotension and vasopressor use after spinal anesthesia in both obstetric and non-obstetric patients.
Citation #5	Tubog, T., Kane, T., & Pugh, M. (2017). Effects of ondansetron on attenuating spinal induced hypotension and bradycardia in obstetric and non-obstetric subjects: A systematic review and meta-analysis. *AANA Journal, 85*(2), 113-122. Retrieved from http://survey.hshsl.umaryland.edu/?url=https://search-ebscohost-com.proxy-hs.researchport.umd.edu/login.aspx?direct=true&db=rzh&AN=122287353&site=eds-live
Level and Quality	I-B
Purpose/Hypothesis	The purpose of this systematic review and meta-analysis of randomized controlled trials was to determine the efficacy of prophylactic intravenous ondansetron in reducing the incidence of SIH and bradycardia in obstetric and non-obstetric patients.
Type of Evidence Research Design	**Research:** Systematic Review and Meta-Analysis of Randomized Controlled Trials
Sample	**Sample:** Records were identified using the PRISMA method. Multiple databases such as PubMed, Google Scholar, and CINAHL were used and searched using medical subject headings such as ondansetron, hypotension, spinal-induced hypotension, maternal hypotension, bradycardia, and spinal anesthesia. **Inclusion:** Full-text, English, randomized controlled trials assessing efficacy of ondansetron in attenuating SIH **Eligible Articles:** 17 **Accepted Articles:** 13 **Total Subjects:** 1,225 **Participants:** ASA class I and II presenting for cesarean or elective surgery requiring spinal anesthesia. **Group Homogeneity:** Patient demographics were homogenous across 9 of the 17 studies for cesarean and 4 studies for non-obstetric surgery. Statistical heterogeneity was present among the 13 studies within this article. A subgroup analysis was performed subgroup consisting of obstetric surgery, non-obstetric surgery, and the dosing of ondansetron, indicating high heterogeneity
Intervention	**Control Group:** These patients received a placebo. **Intervention Group:** These patients received a dose of ondansetron (2-12mg), depending on the study, five minutes prior to spinal injection.

	Intervention Fidelity: Study validity was assessed using the Cochrane Handbook for Systematic Reviews. Information from each study was obtained including patient demographics, ASA classification, definitions of hypotension and bradycardia, ondansetron dosing, local anesthetic dosing, and rescue drug administration and dosing. Patients in the intervention group were given intravenous ondansetron 2-12mg, but mostly 4-8mg, 5 minutes prior to spinal injection. Patients in the control group were given a placebo. Each patient received bupivacaine 0.5-0.75% as the spinal anesthetic with varying doses from 10-20mg.
Primary Outcome/Measures	**Dependent Variable:** Variable definitions of hypotension among studies including a drop in SBP by 75-80% of baseline, or a SBP less than 80-90 mmHg, or both. Some studies used a MAP decrease greater than 20% from baseline to define hypotension. **Measurement**: Each study included standard monitors used to measure hemodynamics in specific time intervals after the spinal injection. Hypotension and bradycardia were summarized using a risk ratio (RR) with a 95% confidence interval (CI) ensuring reliability of results.
Results/Conclusion	**Statistical Results:** For meta-analysis, Review Manager software was used. The effects of ondansetron on the incidence of SIH and bradycardia was calculating using pooled RR with a 95% confidence interval and results reported as a mean difference. The I^2 statistic was used to assess variation among studies. The administration of intravenous ondansetron prior to spinal anesthesia reduced the incidence of hypotension in both the all-procedure analysis group (RR: 0.64, CI: 0.45-0.90) and also the cesarean delivery group (RR: 0.63, CI: 0,45-0.88). Additionally, the administration of ondansetron reduced the risk for bradycardia (RR: 0.31, CI: 0.19-0.50) **Conclusions:** This systematic review and meta-analysis shows that the administration of intravenous ondansetron five minutes prior to spinal injection attenuates hypotension in obstetric and non-obstetric patient populations.

Appendix B

REDCap Data Collection Tool

Appendix B: Compliance of Ondansetron Administration Tool

Please complete the survey below.

Thank you!

1)	Patient Code	_____
2)	Anesthesia Provider	◯ MDA ◯ CRNA ◯ AA ◯ Resident
3)	Was ondansetron (zofran) 4mg administered five minutes prior to spinal anesthesia?	◯ Yes ◯ No
4)	Did the patient experience hypotension (20% decrease in SBP from baseline) within 15 minutes of spinal anesthesia?	◯ Yes ◯ No