PROTOCOL TITLE: The use of P6 Acupressure for the Reduction of Intraoperative and Postoperative Nausea and Vomiting in Women undergoing Cesarean Delivery: a Randomized Trial

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STUDY SUMMARY:

Investigational Agent(s) (Drugs or Devices)	N/A
IND / IDE / HDE #	N/A
Indicate Special Population(s)	☐ Children ☐ Children who are Wards of the State ☐ Adults Unable to Consent ☐ Cognitively Impaired Adults ☐ Neonates of Uncertain Viability ☒ Pregnant Women ☐ Prisoners (or other Detained/Paroled Individuals) ☐ Students/Employees
Sample Size	200
Funding Source	Department of Anesthesiology
Indicate the type of consent to be obtained	☒ Written ☐ Verbal/Waiver of Documentation of Informed Consent ☐ Waiver of HIPAA Authorization ☐ Waiver/Alteration of Consent Process
Site	☐ Lead Site (For a Multiple Site Research Study) ☐ Data Coordinating Center (DCC)
Research Related Radiation Exposure	☐ Yes ☒ No
DSMB / DMC / IDMC	☐ Yes ☒ No

OBJECTIVES:
The purpose of this study is to evaluate if the addition of P6 pressure point stimulation as opposed to sham-point stimulation will decrease intraoperative and postoperative

nausea and vomiting (IONV and PONV) for patients undergoing non-emergent cesarean delivery. We hypothesize that the addition of stimulation of the P6 pressure point to our institutional current standard of care (phenylephrine infusion, intravenous fluid bolus, and as needed intraoperative ondansetron) will decrease the occurrence of intraoperative emesis.

BACKGROUND:

Intraoperative and postoperative nausea and vomiting (IONV and PONV) are very common among parturients undergoing cesarean delivery with neuraxial anesthesia, with an incidence up to 80% without intervention.[1] IONV and PONV are thought to be reduced with the use of prophylactic phenylephrine infusion post spinal anesthesia, however, a recent Cochrane review noted only low-quality evidence to support this hyopthesis.[2] IONV may decrease maternal satisfaction, increase the risk of aspiration, and impair surgical conditions.[3] IONV during cesarean delivery is multifactorial, secondary to hypotension, visceral stimulation from uterine/peritoneal manipulation, physiologic changes of pregnancy, and neuraxial opioids.

Although the mechanism is unknown, there are multiple studies demonstrating that stimulation of the P6 acupressure point decreases PONV in a variety of surgical procedures.[4,5] Stimulation of the P6 acupressure point for antepartum patients has also been demonstrated to improve nausea.[6]

There is mixed data on stimulation of the P6 pressure point alone preventing IONV during cesarean delivery.[7,8] Studies have demonstrated inferiority of stimulation of the P6 acupressure point alone compared to ondansetron during cesarean delivery.[9] However, there are no studies that evaluate if P6 stimulation in addition to ondansetron decreases IONV during cesarean delivery. Benefits of P6 stimulation include simplicity, quick onset of action (~2-3 min of pressure), minimal adverse events, no drug-drug interactions, low cost, and lack of transfer to the fetus through placenta and breast milk. An evaluation of the efficacy of P6 acupressure stimulation in addition to the current standard of care (phenylephrine infusion, intravenous fluid bolus, and ondansetron) is warranted.

STUDY ENDPOINTS:

Primary Endpoint: Presence of emesis *during* scheduled cesarean delivery.

Secondary Endpoints: Presence of emesis *after* scheduled cesarean delivery, presence of nausea *during* scheduled cesarean delivery, presence of nausea *after* scheduled cesarean delivery, number of additional antiemetic rescue medications given intraoperatively and postoperatively, maternal satisfaction with IONV/PONV management.

STUDY INTERVENTION(S) / INVESTIGATIONAL AGENT(S):
The P6 pressure point is 2 inches proximal to the flexor retinaculum, between the flexor carpi radialis and palmaras longus.

A non-coated ferrite 0.09-inch by 0.2-inch diameter magnet with a small protrusion with an adhesive sticker will be used for P6 acupressure point stimulation bilaterally. The magnets used are the same magnets used in clinical practice by Northwestern Medicine Osher Center for Integrative Medicine (150 E Huron St UNIT 1100, Chicago, IL 60611).

The sham pressure point used will be more distal to the P6 acupressure point, which has been used in other studies comparing the effectiveness of acupressure to sham point.[10]

PROCEDURES INVOLVED:
Prospective, double-blinded, sham controlled, randomized clinical trial.

After signing the informed consent form, study subjects will be randomized to P6 acupressure group (P6) vs sham point group (Sham control). Randomization will occur by randomly selecting a single envelope from a mixed pile of 1:1 P6 vs sham group sealed envelopes (total 200, 100 designating P6 group, 100 designating sham group, will decrease by 1 envelope after every patient enrollment). Each study subject will be assigned a study number. An envelope containing two pressure point magnets, two adhesive stickers, and diagram showing where to place the magnet will be opened by the research team member. The magnets will be placed on the patient by a research team member. The study subject will be in one (1) of two (2) groups:

- P6 group: the pressure point will be stimulated by the presence of the magnet when positioned properly on the P6 acupressure point. Additional pressure may be applied as desired by the study subject but is not necessary for P6 stimulation.
- Sham group: the sham pressure point (distal to the P6 acupressure point) will not provide any benefit.

The study subject will then be taken to the operating room where a spinal anesthetic will be administered according to current standard of practice. Maternal hypotension will be defined by systolic blood pressure less than 100mmHg *or* mean arterial pressure less than 65mmHg *or* mean arterial pressure less than 20% of the baseline mean arterial pressure (baseline blood pressure will be considered the value in mmHg obtained by the nursing staff in the preoperative area). Maternal hypotension will be treated with phenylephrine, ephedrine and/or intravenous fluid boluses as per our current standard of care.

A surgical anesthetic level check will be completed per our current standard of care. If the anesthesia level is noted to be above T2, the magnets and adhesive will be removed and the patient will be excluded from the study.

Ondansetron 8mg IV and dexamethasone 8mg IV will be given after delivery per our current institutional standard of care (Northwestern University Enhanced Recovery after Cesarean) or prior to delivery on an as needed basis. Additional antiemetic medications will be given as needed by the anesthesia provider. Patients will not be denied additional antiemetic medications when participating in the study. All medications will be documented in EPIC. If the patient experiences IONV, the “nausea” or “vomiting” icons will be documented in their electronic anesthesia record (EPIC).

There will be routine postoperative orders placed by the anesthesia team in the post-anesthesia care unit (PACU). These orders include antiemetic medications, which can be administered by the PACU nursing staff as needed. Routine postoperative orders, including antiemetic medications as needed, will be placed by the OB team on admission to postpartum per our institution’s current standard of care. Medications will be administered and documented by the nursing staff in standard fashion, and this data will be collected by the study personnel. Patients can provide additional pressure point stimulation as needed throughout their postoperative course, for up to 72 hours or until discharge, whichever comes first. The patients can contact a research team member by phone if a magnet is lost or moved, and the team member will help replace the magnet(s) in the appropriate location.

The patient will be instructed to remove the magnets 48 hours postoperatively or upon discharge, whichever occurs first. Data collection will terminate at this point. Removing the magnets involves only removal of the adhesive stickers. The magnets can be disposed in the trash or patients may keep the magnets if desired. Patients will then complete a 5-minute survey to record their incidence and experience of nausea. This survey includes a validated PONV intensity and visual analog scale.[11,12]

Standard of care is not altered in this study. All participants will receive the same level of care if they choose to participate in the study, regardless of which study group they are in.

SHARING RESULTS WITH PARTICIPANTS

Results will not be shared with participants.

STUDY TIMELINES

For research team:

- IRB approval is expected to take 4 weeks.
- Patient enrollment and data collection will likely occur for 3-6 months (assuming there are approximately 5 scheduled caesarean deliveries per day Monday-Friday and 2 scheduled caesarean deliveries on Saturday and Sunday). Data collection ends when 200 patients are enrolled in the study
- Data analysis occurs after 50 and 150 participants or in the event of an adverse event related to a magnet

- Statistical analysis will occur after data collection and will take 1 month
- Manuscript production and editing will occur over the following 2 months

For patients:
At admission:

- Informed consent obtained
- Demographics obtained including: age, weight, height, BMI, race/ethnicity, parity, number of prior caesarean deliveries
- Patient randomized into P6 or sham group
- Magnets placed by research team member using enclosed diagram
- Spinal anesthesia administered in standard fashion with accompanying phenylephrine infusion, rate documented in EPIC
- Patient can apply additional pressure to magnets as needed intraoperatively
- Nausea and vomiting icons utilized by in-room anesthesia provider
- The following protocol will be followed for intraoperative nausea/vomiting and all medications will be documented appropriately in EPIC:
    - If nausea begins prior to delivery:
        - With the first complaint of nausea, phenylephrine or ephedrine can be administered to treat hypotension, and intravenous fluids will be given as a bolus
        - With the 2nd complaint of nausea, or at the onset of emesis, encourage use of additional pressure on magnets
    - After delivery:
        - Administer 8mg Ondansetron and 8mg Dexamethasone
        - If continued IONV, encourage use of additional pressure on magnets
        - If continued IONV, consider the following medications: IV Fentanyl, Prochlorperazine, Propofol, Diphenhydramine
- Additional rescue medications administered as needed after delivery and documented in EPIC

PACU/floor:

- Patient can apply additional pressure to magnets as needed postoperatively
- Rescue medications administered as needed and documented in EPIC by nursing staff

At 48 hours post-delivery or discharge, whichever is first:

- Magnets removed by patient by removing adhesive
- Survey given to patient by anesthesia provider

INCLUSION AND EXCLUSION CRITERIA

Inclusion: age ≥18 years of age, English-speaking, pregnant patients presenting for scheduled cesarean delivery of a full-term fetus (>37 weeks' gestation), patients scheduled as ERAC, parturients undergoing spinal anesthesia.

Exclusion: patients requiring emergent delivery, fetal demise, patients with adhesive allergy/sensitivity,patients with allergy/sensitivity to nickel, patients with inability to consent, patients with known abnormal placentation, patients with pacemakers/defibrillators, patients with positive COVID-19 tests.

VULNERABLE POPULATIONS

This study includes pregnant patients. See attached HRP-412.

PARTICIPANT POPULATION(S)

Accrual Number:	Category/Group: (Adults/Children Special/Vulnerable Populations)	Consented: Maximum Number to be Consented or Reviewed/Collected/Screened	Enrolled: Number to Complete the Study or Needed to Address the Research Question
Local	200 HRP 412	200	200
Study-wide			
Total:	200	200	200

RECRUITMENT METHODS

Anesthesia providers will be educated on the project, the consent process, and will remain blinded to P6/sham pressure point during the education process. A study team member will be available at all times to answer questions during the education process.

Potential study subjects will first be identified on the Labor and Delivery board as being both a scheduled cesarean delivery and part of ERAC. Potential study subjects will not be approached by a research team member until there is a documented negative result of their COVID-19 test. Given COVID-19, we will attempt to minimize the number of people entering the subjects' room. Subjects that meet inclusion criteria will be approached after the anesthesia evaluation/consent by a study team member. The study team member will: ask potential participants to sign the informed consent form; answer all subjects' questions; and place the magnets on all subjects.

COMPENSATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

Study subjects will not be compensated for their participation in this study. As noted above, they can keep their magnets at study completion if desired.

WITHDRAWAL OF PARTICIPANTS

A subject can request withdrawal from the study at any time. The study subject can self-terminate their study involvement by magnet removal, an event which will be addressed by our post-intervention survey. Surveys will be evaluated regularly to address any questions/concerns found on the post-intervention survey, and the subject will be contacted if follow-up is required/requested. A research team member will contact the PI by secured email to inform her about the event leading to early study termination. If the subject requests, all data collected will not be used.

RISKS TO PARTICIPANTS

Due to COVID19, we will attempt to minimize the number of people entering patients' rooms.

The magnets may cause mild discomfort at the pressure point site. The magnets will not puncture skin. There are no known systemic risks to patients with short-term stimulation of the P6 pressure point.

The main risk in study participation is skin irritation from adhesive that holds the magnets in place. Subjects with known adhesive sensitivity/allergy will be excluded from participation.

The magnets are ferrite magnets, composed of ceramic and iron, which are the same magnet components used intraoperatively for deactivating defibrillators that Northwestern currently uses in operating rooms with electrocautery. The magnets could theoretically cause the patient to be at an increased rate of burns related to the electrocautery used during the operation, however, this risk is minimal to none. There are zero case reports of hand/wrist jewelry-related burns during any surgical procedures using electrocautery. A study involving metal microdermal implants in pigs with electrocautery did not show any evidence of tissue damage[13]. A grounding pad will be placed on the patient, as per the current standard of care, decreasing the risk of electrical current conducting through the magnet. The magnets will be a great distance away from the site where electrocautery will be used. The magnets could also uncommonly cause contact dermatitis, redness of skin, skin breakdown, and possible temporary discoloration of the skin.

Study subjects will be excluded from the study with immediate magnet removal prior to incision if a sensory dermatomal level higher than T2 to sharp tactile sensation is observed. This measure will be taken to prevent any potential burn injury from occurring without the patient having completely intact thermal nociception. The study subject will also be excluded from the study with immediate magnet removal in the event general anesthesia is required at any point during their operative course. The subject can verbalize to the anesthesia provider if she is experiencing discomfort at the site of the

magnets during the operation, and the magnets will be immediately removed by the anesthesia provider.

There will be no known risk to the fetus from magnet use. These magnets are frequently used for pregnancy-related nausea for patients in all trimesters.

If the study subject experiences any magnet discomfort, it will be immediately removed by the in-room provider.

POTENTIAL BENEFITS TO PARTICIPANTS

Study subjects utilizing the magnets may experience a reduction in IONV and PONV and have increased satisfaction. Subjects with the magnets over the P6 point will experience a benefit only while the magnets are in place (intraoperatively and up to ~48h post operatively or upon discharge).

Subjects with the magnets over the sham point will likely not experience a benefit.

DATA MANAGEMENT AND CONFIDENTIALITY

This sample size was determined by assuming there is a baseline rate of 33% intraoperative vomiting and that there will be a relative decrease of approximately 50% in the group that receives acupressure during cesarean delivery[14]. Using a two-sided Fisher's Exact Test, with a significance level of 0.05, it was determined each group should contain 98 participants to achieve 80.01% power to detect a difference between the group proportions of 0.18. The proportion in the P6 group is assumed to be 0.15 under the null hypothesis and 0.33 under the sham group. The proportion in sham group is 0.15. Each group was rounded up to 100 participations for a total sample size of 200.

The hypothesis will be analyzed using a two-sided two-tailed independent sample t-test with a significance level of 0.05. The primary and secondary outcomes will be analyzed by two-tailed independent sample t-test or Chi-square test. All of the above information will be entered into clinicaltrials.gov prior to enrollment of the first research subject and within 1 year of study completion.

All participants will be assigned a participant study number. A single password-protected document will link the participant name to their participant number. This document will be kept in a password-protected computer in a locked office in of the Section of Obstetrical Anesthesiology suite in Prentice Women's Hospital. The survey data and the signed consent form, will be stored in REDcap, a secure web application specifically geared for data capture and research studies. Only study team members listed in the eIRB will have access to the REDcap files and study data. De-identified data will also be password protected on a Department of Anesthesiology dedicated computer.

- After the data set has been reviewed by the PI it will be deidentified.

- The deidentified data set will be kept in NM password protected computer located on the 10th floor Arkes Pavilion (Anesthesiology Administrative Office). Access of the data is controlled by the PI. The deidentified data set will be sent to Rush University statistician Robert McCarthy PharmD for complete statistical analysis. The data will be sent via Northwestern University encrypted email after IRB approval and completion and execution of a one-way data use agreement (Northwestern University to Rush University).

Only study ID numbers will be used to identify participants during data analysis. Data, including final analysis, will be stored on the departmental computer until study completion. Electronic and paper data will be destroyed 5 years after study completion using current standards.

PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS

A data safety monitoring board consisting of a Department of Anesthesiology attending physician, a statistician, and study research personnel will regularly review the data collected to evaluate participants' safety. Adverse event data and study withdraw data will be reviewed using the both medical record and surveys and stored in password-protected adverse event/withdrawal form. It will be reviewed after 50 and 150 subjects have completed the study or if one of the study subject experiences symptoms concerning for an intra-operative burn from the magnet(s). If the follow-up surveys reveal concerns for frequent adhesive intolerance or frequent magnet removal prior to study end, the study will be halted for an investigation.

If any study subject request removal of the magnets due to pain or symptoms concerning for a burn intraoperatively, the magnets will be immediately removed by the anesthesia provider with subsequent physician evaluation of the site. This information will be relayed to the PI via secure email.

These magnets are considered safe for use and are frequently used by the acupuncturists at Northwestern Medicine Osher Center for Integrative Medicine. Adhesive intolerance is the most likely complication (redness, irritation, pruritus, and rash) and removal the adhesive should resolve symptoms with no long-term consequences. Subjects will be instructed during the consent to immediately remove the magnets/adhesive if they experience any discomfort. The follow-up survey will include a question specifically asking if the magnets were removed early and the circumstances leading up to removal.

Participants are at risk for loss of confidentiality, however, there will be strict measures

to prevent such an occurrence. Refer to the section “DATA MANAGEMENT AND CONFIDENTIALITY” (above) for a detailed description.

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS
Research subjects will have limited interactions with study team members, unless the patient requests further information, given COVID19 and to minimize disruption. The patient will discuss the research study with an anesthesia team member who will obtain written informed consent after pre-anesthesia evaluation and consent per our current standard of care. All further questions and follow-up will be conducted by phone by a research team member. Participants will complete a short survey (requiring less than 5 minutes) prior to discharge or at approximately 48 hours post-operatively if that time frame falls between 7am and 6pm. Patients outside this time frame will be contacted the following morning to not disrupt their lives/sleep.

ECONOMIC BURDEN TO PARTICIPANTS
Participants are responsible for all costs of their care; however, these costs are the same costs they would incur if not participating in the study.

CONSENT PROCESS
Consent will occur in the preoperative area or in the patient’s private room, prior to transport to the operating room on the Labor and Delivery Unit, 8th floor, at Prentice Women’s Hospital. Written informed consent will be obtained from all study participants by the in-room anesthesia provider with a study team research member available for additional questions. There will be no waiting period. Consent document HRP-502 will be followed. Anesthesia providers will spend greater than 5 minutes discussing the study with each subject and should plan for an additional 5 minutes for any patient questions regarding the study or consent document. If the subject has further questions, a research team member will provide any additional information prior to transportation to the operative room. The subject will be notified that there is no conflict of interest between any research team member and the protocol, nor will any research team member receive financial compensation. Participants will be notified that study participation will not affect their medical care costs.

NON-ENGLISH SPEAKING PARTICIPANTS
Only English-speaking participants will only be enrolled.

PROTECTED HEALTH INFORMATION (PHI AND HIPAA)
This study involves the use of Protected Personal Health Information. HIPAA Authorization will be obtained from all participants. PHI collected will include only the following:

- Names

- Dates and Age: Including birth date, admission date, and discharge date
- Telephone numbers
- Medical Record Numbers
- Email address

QUALIFICATIONS TO CONDUCT RESEARCH AND RESOURCES AVAILABLE

Northwestern's section of Obstetrical Anesthesiology provides obstetric care to approximately 4,000 patients per year undergoing caesarian delivery. The principal investigator (Feyce M. Peralta, MD, MS) is an Associate Professor in the obstetrical anesthesiology section who regularly supervises fellows, residents, and CRNAs providing care to patients on labor and delivery. An obstetric anesthesia fellow (Stephanie Woodward, MD) will have ample time for data collection and evaluation during the course of the study. The section of Obstetrical Anesthesiology has a dedicated group of clinical research nurses and study coordinator who assist with recruitment and follow-up of patients in clinical anesthesiology trials. All study team members have CITI training.

Northwestern's Integrative Medicine Acupuncturists were used to educate anesthesia providers on acupressure. These acupuncture providers maintain certification and regularly see patients in clinic to treat a variety of diseases/symptoms, including nausea/emesis. This study will utilize the same type of magnets used in their clinical practice.

REFRENCES

1. Balki M, Carvalho JC. Intraoperative nausea and vomiting during cesarean section under regional anesthesia. Int J Obstet Anesth. 2005 Jul;14(3):230-41. doi: 10.1016/j.ijoa.2004.12.004. PMID: 15935649.
2. Chooi C, Cox JJ, Lumb RS, Middleton P, Chemali M, Emmett RS, Simmons SW, Cyna AM. Techniques for preventing hypotension during spinal anaesthesia for caesarean section. Cochrane Database of Systematic Reviews 2020, Issue 7. Art. No.: CD002251. DOI: 10.1002/14651858.CD002251.pub4. PMID: 28976555.
3. Ho CM, Tsai HJ, Chan KH, Tsai SK. P6 acupressure does not prevent emesis during spinal anesthesia for cesarean delivery. *Anesth Analg*. 2006;102(3):900-903. doi:10.1213/01.ane.0000195553.82409.00. PMID: 16492848.
4. Albooghobeish M, Mohtadi A, Saidkhani V, et al. Comparison Between Effects of Acupuncture and Metoclopramide on Postoperative Nausea and Vomiting after Gynaecological Laparoscopy: A Randomized Controlled Trial. *Anesth Pain Med*. 2017;7(5):e12876. Published 2017 Aug 22. doi:10.5812/aapm.12876. PMID: 29696109.
5. Lee A, Fan LT. Stimulation of the wrist acupuncture point P6 for preventing postoperative nausea and vomiting. *Cochrane Database Syst Rev*. 2009;(2):CD003281. Published 2009 Apr 15. doi:10.1002/14651858.CD003281.pub3. PMID: 19370583.

6. Matthews A, Haas DM, O'Mathúna DP, Dowswell T. Interventions for nausea and vomiting in early pregnancy. *Cochrane Database Syst Rev*. 2015;2015(9):CD007575. Published 2015 Sep 8. doi:10.1002/14651858.CD007575.pub4. PMID: 26348534.
7. Allen TK, Habib AS. P6 stimulation for the prevention of nausea and vomiting associated with cesarean delivery under neuraxial anesthesia: a systematic review of randomized controlled trials. *Anesth Analg*. 2008;107(4):1308-1312. doi:10.1213/ane.0b013e31816d1864. PMID: 18806045.
8. Habib AS, Itchon-Ramos N, Phillips-Bute BG, Gan TJ; Duke Women's Anesthesia (DWA) Research Group. Transcutaneous acupoint electrical stimulation with the ReliefBand for the prevention of nausea and vomiting during and after cesarean delivery under spinal anesthesia. *Anesth Analg*. 2006;102(2):581-584. doi:10.1213/01.ane.0000189217.19600.5c. PMID: 16428565.
9. El-Deeb AM, Ahmady MS. Effect of acupuncture on nausea and/or vomiting during and after cesarean section in comparison with ondansetron. *J Anesth*. 2011;25(5):698-703. doi:10.1007/s00540-011-1198-0. PMID: 21761206.
10. Tan JY, Suen LK, Wang T, Molassiotis A. Sham Acupressure Controls Used in Randomized Controlled Trials: A Systematic Review and Critique. PLoS One. 2015;10(7):e0132989. Published 2015 Jul 15. doi:10.1371/journal.pone.0132989. PMID: 26177378.
11. Wengritzky R, Mettho T, Myles PS, Burke J, Kakos A. Development and validation of a postoperative nausea and vomiting intensity scale, *British Journal of Anaesth*. 2010; 104(2): 158-166, https://doi.org/10.1093/bja/aep370. PMID: 20037151.
12. Boogaerts JG, Vanacker E, Seidel L, Albert A, Bardiau FM. Assessment of postoperative nausea using a visual analogue scale. Acta Anaesthesiol Scand. 2000 Apr;44(4):470-4. doi: 10.1034/j.1399-6576.2000.440420.x. PMID: 10757584.
13. Sheldon RR, Loughren MJ, Marenco CW, Winters JR, Bingham JR, Martin MJ, Eckert MJ, Burney RO. Microdermal Implants Show No Effect on Surrounding Tissue During Surgery With Electrocautery. J Surg Res. 2019 Sep;241:72-77. doi: 10.1016/j.jss.2019.03.039. Epub 2019 Apr 19. PMID: 31009888.
14. A DM, A K. Effect of acupressure on post-operative nausea and vomiting in cesarean section: a randomised controlled trial. J Clin Diagn Res. 2013 Oct;7(10):2247-9. doi: 10.7860/JCDR/2013/5702.3485. Epub 2013 Oct 5. Erratum in: J Clin Diagn Res. 2015 Jul;9(7):ZZ03. PMID: 24298488.