Pannus Assistance Needed for Obstetric Ultrasound Studies: A Randomized Controlled Trial

NCT05764408

Protocol

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1. Introduction

1.1 Abstract

Pannus Assistance Needed for Obstetric Ultrasound Studies (PANOUS) is a single-center randomized controlled trial to determine whether pannus retractor adhesive use improves completion rates of sixteen prespecified fetal anatomy ultrasound components among pregnant patients with body mass index (BMI) ≥40 kg/m^2 and a pannus. One hundred fifty participants will be randomized in a 1:1 fashion to control (no retractor) or intervention (retractor) group during their midtrimester detailed anatomy ultrasound. The primary outcome will be completeness of the detailed ultrasound, measured by 16 prespecified views from the anatomic survey. The secondary outcomes include survey responses measuring participant and sonographer experience, completeness of all ultrasound views, detection of fetal anomalies, skin to amniotic cavity depth, duration of ultrasound exam, and an assessment of the incidence of adverse outcomes in both treatment groups.

1.2 Specific Aims

Primary Research Aim:

AIM 1: Determine whether pannus retractor adhesive use improves completion rates of sixteen prespecified fetal anatomy ultrasound components among pregnant patients with BMI ≥40 kg/m^2 and a pannus.

Secondary Research Aims:

AIM 2: Evaluate whether pannus retractor adhesive use improves sonographer pain perception during the fetal anatomy ultrasound evaluation of pregnant patients with obesity and a pannus.

AIM 3: Evaluate whether pannus retractor adhesive use improves patient satisfaction regarding fetal anatomy ultrasound image quality.

1.3 Purpose of the Protocol

The protocol describes the background, design and organization of the study. It represents a written agreement between study investigators. A similar version of this protocol is reviewed by the Institutional Review Board at the study site prior to recruitment.

2. Background

2.1 Introduction

Pregnancies complicated by obesity have an increased risk of multiple pregnancy complications including structural fetal anomalies [1-3]. Therefore, obesity in pregnancy (BMI ≥30 kg/m^2) is an indication for a detailed anatomic ultrasound examination [4]. Ultrasound is a critical tool for the detection of congenital anomalies; however, obesity makes ultrasound examinations technically challenging [5]. Specifically, the ability to detect structural fetal anomalies by ultrasound significantly decreases as maternal body mass index (BMI) increases [6]. The American College of Obstetricians and Gynecologists (ACOG) recommends that patients with obesity are counseled on the limitations of ultrasound to detect structural anomalies [7].

2.1.1 Obesity's Impact on Obstetric Ultrasound

Several studies have evaluated completion rates of ultrasound exams for patients with obesity, all showing a similar trend: patients with normal BMI achieve a complete ultrasound 58-79% of the time, while patients with BMI ≥40 kg/m^2 have complete ultrasounds just 10-56.2% of the time [8-11]. Other studies have focused on aspects of the ultrasound examination other than completion. Yaqub et al. demonstrated a statistically significant decrease in image quality scores with increasing BMI, Gupta et al. showed that the ultrasound examination took 8.9 minutes longer for patients with BMI of 40 or greater compared to normal BMI, and Hendler et al. found a linear correlation between increasing BMI and decreasing visualization of fetal heart and spine views [12-14].

It should also be noted that the presence of obesity does not only impact pregnant patients and their fetuses, but also sonographers. Additional pressure and manipulation are needed to accomplish ultrasounds when obesity is present, placing increased mechanical strain on sonographers. It has been documented that obstetric/gynecologic (OB/GYN) sonographers report pain during ultrasound exams 66-67% of the time [15, 16]. There is also significant risk for sustaining a work-related injury, reported in 48.15% of OB/GYN sonographers [16].

2.1.2 Previously Attempted Solutions

Numerous studies have evaluated techniques to improve visualization and completion of obstetric ultrasound for patients with obesity. The Sims technique uses unique patient and ultrasound probe positioning to decrease the distance from skin to amniotic cavity [17]. Others advocate for patient engagement with physical modifications like holding up their pannus to optimize ultrasound imaging [18]. Puissegur et al. graded ultrasound image quality when standard ultrasound settings were applied versus customized settings chosen by sonographers; they concluded that the quality of ultrasound images was improved when customized settings were allowed [19]. Other studies have tried adding an early ultrasound or delaying the timing of the midtrimester ultrasound for patients with obesity [20-23]. Despite these efforts, completion rates of anatomic surveys for patients with obesity remain lower than those for patients without obesity.

2.1.3 Conclusions from Pilot Study

We recently completed a pilot study investigating a novel approach for this issue, entitled Pannus Retraction for Ultrasound Evaluation of the Obese Gravida: A Pilot Study. Twenty prospective participants with a BMI of at least 40 kg/m^2 were enrolled to have a pannus retractor adhesive in place at the time of detailed anatomic ultrasound. This study confirmed that recruitment, enrollment, and intervention implementation are feasible for the same population and study setting that we intend to use for this randomized controlled trial. The pilot study was not adequately powered to assess differences in completion rates for ultrasounds with pannus retractor adhesive use. The noted completion rate was 38% in patients with a pannus and BMI ≥40 kg/m^2, compared to a retrospective completion rate of 23% for those with a BMI ≥40 kg/m^2 collected over 6 months prior to the trial.

2.2 Rationale for Clinical Trial

In summary, pregnant patients with obesity have more limited ultrasound exams when compared to patients with a normal BMI. Decreased ultrasound completion rates translate into significant maternal and neonatal risks as the ability to detect structural fetal anomalies by ultrasound significantly decreases as maternal BMI increases [6]. Despite the many strategies that have been attempted in effort to resolve this issue, fetal anatomic ultrasound examination remains negatively affected by obesity. This study seeks to test a novel approach to improve completion of the anatomic survey for pregnant patients with obesity, supported by recent pilot study completion.

3. Study Design

3.1 Research Questions

Question 1: Does the use of a pannus retractor adhesive increase the rate of detailed anatomic survey completion, defined by satisfactory visualization of sixteen prespecified fetal anatomy views, for participants with a pannus and body mass index greater than or equal to 40 kg/m^2?

Hypothesis 1: Pannus retractor adhesive use improves completion of sixteen prespecified fetal anatomy ultrasound components.

Question 2: Does the use of a pannus retractor adhesive improve sonographer pain during the fetal anatomy ultrasound evaluation of pregnant patients with a pannus and body mass index greater than or equal to 40 kg/m^2?

Hypothesis 2: Pannus retractor adhesive use improves sonographer-experienced pain during the fetal anatomy ultrasound.

Question 3: Does pannus retractor adhesive use improve patient satisfaction regarding fetal anatomy ultrasound image quality?

Hypothesis 3: Pannus retractor adhesive use improves patient satisfaction regarding fetal anatomy ultrasound image quality.

3.2 Design Summary

This is a pragmatic randomized controlled trial that will be conducted and reported in concordance with the Consolidated Standards of Reporting Trials guidelines [24]. One hundred fifty participants will be enrolled and randomized to the control group (no retractor) or intervention group (retractor) at a 1:1 ratio. The randomization sequence will be generated by the study statistician using a permuted block design. Investigators will be masked to the randomization sequence and variabler block sizes. Study participants, sonographers and attending physician will not be masked. The ultrasound examinations will be performed according to usual office protocols for a detailed anatomic ultrasound. Participants allocated to the intervention group will initially undergo pannus retractor adhesive placement with fetal evaluation below the pannus. Upon completion of this, the adhesive will be removed, and other transabdominal or transvaginal imaging will be performed as per routine. The adequacy of ultrasound visualization will be compared between the two groups. Sonographer and participant survey responses will be compared between the two groups.

3.3 Eligibility Criteria

3.3.1 Inclusion Criteria

Pregnant patients presenting for anatomy ultrasound with:

- Age of 16 or older
- English or Spanish language
- BMI of at least 40.0 kg/m^2 , calculated within 6 months of conception or at the first obstetric visit
- Pannus grade ≥1 (per the scale reported in 4.4 Baseline Procedures)

- Gestational age between 18 weeks 0 days to 23 weeks 6 days, confirmed by prior ultrasound assessment

3.3.2 Exclusion Criteria

- Patients who have already had a routinely timed anatomy ultrasound during the same pregnancy with Prisma Health Maternal-Fetal Medicine
- Patients with a known major fetal anomaly, confirmed by Prisma Health Maternal-Fetal Medicine
- Tape/adhesive allergy
- Multifetal gestation
- Intrauterine fetal demise

4. Study Procedures

4.1 Screening

Medical records of all potential participants scheduled for an anatomic ultrasound will be screened by trained research coordinators or study investigators. The research team will attempt to contact potential participants who satisfy inclusion and exclusion criteria to determine willingness to participate prior to the ultrasound appointment. If the research team is unable to reach potential participants prior to the ultrasound visit, they will be approached for study enrollment when they arrive in the office for their scheduled ultrasound visit. A screening log will be used to track all patients approached for the study. Once a potential participant arrives to the ultrasound office, full informed consent will be obtained. The presence of a pannus will be confirmed through visual assessment. Those who do not have a pannus will not randomized to a study arm. Those who meet the full set of inclusion and exclusion criteria will then be randomized to control or intervention arm. The graphics in Appendix A and B may be shown to potential participants as a component of the recruitment and consenting process.

4.2 Randomization and Masking

One hundred fifty participants will be randomized to the control group (no retractor) or intervention group (retractor) at a 1:1 ratio. The randomization sequence will be confidential and computer-generated by the study statistician using a permuted block design. Investigators will be masked to the randomization sequence and variable block sizes. Study participants, sonographers and attending physicians interpreting the ultrasound will not be masked.

4.3 Intervention Implementation

traxi® Panniculus Retractor (Laborie, Portsmouth, NH) is a disposable adhesive medical device designed for surgical patients with a BMI of at least 30kg/m^2. The adhesive retracts the pannus cephalad and exposes the lower abdomen. The device is similar to a large sticker or bandage, posing no more than minimal risk to participants. The adhesive will be applied to the abdomen immediately prior to a participant's scheduled ultrasound and will occur according to manufacturer instructions (see Appendix A). The adhesive's instructions for application are straightforward for study personnel and sonographers to follow without additional training needed. Sonographers will proceed with the ultrasound exam per usual protocol. Once the ultrasound exam has ended, the adhesive will be immediately removed and discarded.

4.4 Baseline Procedures

1. <u>0-15 weeks before scheduled ultrasound:</u> potential participants will be contacted to identify willingness to participate.
2. <u>Fifteen minutes prior to the ultrasound:</u> The participant will be taken to an exam room at the office. The study will be explained, and informed consent will be obtained. Baseline demographic and medical history will be collected from the participant's chart, including: weight/BMI at first obstetric visit during this pregnancy and in the 6 months leading up to

pregnancy, gestational age, parity, diabetic status, insurance status, smoking status, cesarean delivery history, and prior other abdominal surgical history. Race and ethnicity will be verbally collected from participants' self-report. Waist circumference will be recorded.

3. Ultrasound: The participant will be taken to the ultrasound exam room. The presence of a pannus will be confirmed. The grade of pannus will be evaluated in a reclined, supine position like what will be used for the ultrasound exam. It will be classified according to the following system described by Iglesias et al.: no pannus (grade 0), pannus remaining above the inguinal ligament (grade 1), overhanging pannus below the inguinal ligament but not surpassing the upper third of the thigh (grade 2), overhanging pannus located within the middle third of the thigh (grade 3), overhanging pannus within the lower third of the thigh (grade 4), overhanging pannus below the knee (grade 5) [25]. The presence of fetal cardiac activity will be confirmed with ultrasound. Once all eligibility criteria have been satisfied, randomization will occur. Using only the minimal amount of pressure to create the image, the shortest mid-sagittal distance will be measured from the skin to the amniotic cavity above and below the pannus.
    A. Intervention group: Research team members, with or without assistance from the sonographer, will apply the pannus retractor adhesive according to manufacturer's directions. This will be performed with the patient in supine position. The same ultrasound depth measurement will be repeated once the pannus has been retracted. The ultrasound will then proceed in usual fashion. The sonographer will be asked to attempt all views of the detailed anatomic survey before the adhesive is removed. If the sonographer thinks that additional views could be obtained with the adhesive removed using transabdominal or transvaginal imaging, this is acceptable based on the pragmatic design of this study. The start and end time for evaluation of fetal anatomy will be recorded, along with the length of time that is needed for retractor application.
    B. Control group: the detailed anatomic survey will proceed per normal protocol. Approaches may include transabdominal and transvaginal imaging. The start and end time for evaluation of fetal anatomy will be recorded.
4. Immediately after the ultrasound: The participant and sonographer will fill out surveys about their experience. These will be completed directly through REDCap, utilizing an electronic tablet for entry.
5. After the ultrasound: The ultrasound report will be completed by the Maternal-Fetal Medicine attending physician per normal protocol. The research team will subsequently review the report and abstract pertinent outcome data.

4.5 Study Visits / Follow-Up

Study participation will be completed when the participant's ultrasound visit concludes. No additional visits or study follow-up is planned.

4.5.1 Withdrawals

Participants who withdraw from the study after randomization will be excluded from further data collection. Outcomes ascertained up until the time of withdrawal will be reported in intent to treat fashion.

4.6 Outcome Measures

4.6.1 Primary Outcome

- Specific aim 1 will be assessed by comparing the proportion of patients with adequate visualization of sixteen prespecified fetal anatomy ultrasound components: brain (lateral ventricles, cerebellum, cavum), face, heart (four chamber view, right outflow tract, left outflow tract, three vessel view, three vessel trachea view), spine (cervical, thoracic, lumbar, sacrum, and spine shape will be summarized as one spine view), ventral wall, umbilical cord, stomach, left and right kidneys, and bladder.
    - A view is considered adequate if the interpretation from the ultrasound report is "normal/within normal limits," "present," "visualized," "seen," or an abnormality is visualized.
        - All individual portions of the spine views must be labeled as above for the overall spine visualization to be considered adequate.
        - For the "umbilical cord" field, "3 vessel cord" or a visualized abnormality such as "2 vessel cord" will be considered adequate visualization.
    - A view is considered inadequate if the interpretation is "limited views," "color only," "not seen," or "limited normal views."

4.6.2 Secondary Outcomes

- Sonographer experience
    - Specific Aim 2 will be assessed by comparing sonographer pain as reported on Question #1 on the Sonographer Survey (Appendix C).
    - Average Likert scale response will be compared between groups.
        - Responses to questions 1 and 2 will be interpreted with 1 signifying the best experience and 5 signifying the worst experience.
        - Responses to questions 3, 4, and 5 will be interpreted with 1 signifying the worst experience and 5 signifying the best experience.
- Participant experience
    - Specific Aim 3 will be assessed by comparing participant satisfaction with image quality as reported on Question #2 on the Participant Survey (Appendix D).
    - Average Likert scale responses will be compared between groups.
        - Responses will be interpreted with 1 signifying the worst experience and 5 signifying the best experience.
- The proportion of patients with adequate visualization of all anatomy views within the ultrasound report will be compared between groups, views including: calvarium/cranium,

intracranial anatomy, cavum, parenchyma, lateral ventricles, choroid plexus, cerebellum/vermis, cisterna magna, midline falx, cervical spine, thoracic spine, lumbar spine, sacral spine, spine shape/curvature, face, lips, neck, nuchal fold, nasal bone, palate, profile, orbits/eyes, mandible, maxilla, thoracic contour, lungs, four chamber view, cardiac activity, cardiac rhythm, cardiac situs, right outflow tract, left outflow tract, aortic arch, ductal arch, SVC, interventricular septum, cardiac axis, diaphragm, three vessel view, three vessel trachea view, IVC, crossing, ventral wall, cord insertion, situs, stomach, gallbladder, left kidney, right kidney, bladder, left humerus, right humerus, left forearm, right forearm, left hand, right hand, left femur, right femur, left lower leg, right lower leg, left foot, right foot, umbilical cord, genitalia

    - Adequacy of interpretation will be followed as described above under the primary outcome.
    - For the “genitalia” field, “male,” “female,” or “normal/within normal limits” will be considered adequate visualization.
- The proportion of participants with detected fetal anomalies will be compared between groups.
    - The ultrasound reports’ individual fields and summary will be reviewed to determine if a fetal anomaly was suspected or confirmed during the encounter. The name of the anomaly or anomalies will be recorded.
- Skin to amniotic cavity depth
- Duration of ultrasound exam
- Adverse events, compared between groups. The specific events we plan to report as an outcome include:
    - Skin irritation
    - Allergic reaction
    - Maternal intolerance of pannus retractor adhesive (intervention group only)
    - Fetal demise
    - Hospital admission immediately following the ultrasound examination

4.7 Reportable Adverse Events

This study does not pose more than minimal risk to participants. Investigators will monitor participants for any adverse event during participation, as defined by the U.S. Department of Health and Human Services Office for Human Research Protections 2007 guidance documents (45 CFR part 46). The above list of adverse events will be studied as an outcome, but any adverse event will be reported promptly to the IRB.

5. Statistical Considerations

5.1 Sample Size and Power

A retrospective review of detailed anatomic ultrasound examinations at our institution confirmed that ultrasound completion rates decrease with increasing BMI, consistent with literature review. Specifically, a subset of sixteen anatomy views were successfully visualized in 23% of patients with a BMI ≥40 kg/m^2. One hundred and thirty-two patients randomized in a 1:1 ratio provides 80% power to detect a two-fold improvement in the primary outcome assuming a baseline completion rate of 23% and a two-sided alpha of 0.05. To account for an attrition rate after initial enrollment of over 10%, this calculation will be inflated to a target sample size of 150 participants.

It is anticipated that some participants who meet study inclusion criteria by chart review will not have a pannus and therefore not meet full criteria for inclusion. Some patients may also be diagnosed with an intrauterine fetal demise on the day of the examination and would be excluded. Those who do not have a pannus and/or get diagnosed with an intrauterine fetal demise will give consent for the study but not be randomized or included for analysis. In the pilot study, 10% of participants who met BMI criteria did not have a pannus. We will inflate that to 20% and therefore plan to consent up to 180 participants to reach the 150 who meet criteria for randomization.

This sample size is not expected to be adequately powered for determination of a difference in fetal anomaly detection or for the other secondary outcomes.

5.2 Analysis Plan

We will compare the characteristics of participants between groups using descriptive statistics to examine the success of randomization. Outcome data analysis will follow the intention-to-treat principle. The primary outcome for Aim 1 (the completion rate of sixteen prespecified fetal anatomy ultrasound components) will be compared between the intervention group and the control group by two-proportion Z-test and risk ratio. The outcomes for Aims 2 (sonographer pain perception) and 3 (patient satisfaction) will be compared using Student's t-test and risk ratios. Affiliates at Clemson University will assist with data analysis.

5.3 Data Processing

Data will be collected from the electronic medical record, during the research visit prior to the ultrasound, from the ultrasound imaging and reporting software, and from surveys. All data fields will be directly entered into a password-protected REDCap database. This will occur at the point of contact with the study participant, other than data input for the ultrasound report. The report is completed at a variable timepoint after the participant encounter. Once it is complete, relevant fields will be entered into REDCap.

6. Study Administration

This study will take place within one department, Prisma Health – Upstate Maternal-Fetal Medicine. The study will take place at two office locations within this department:

Prisma Health Maternal-Fetal Medicine – Faris Rd
890 W Faris Rd #420, Greenville, SC 29605

Prisma Health Maternal-Fetal Medicine – Anderson
2000 E Greenville St #4600, Anderson, SC 29621

The following personnel will be participating with the described roles, from Prisma Health:

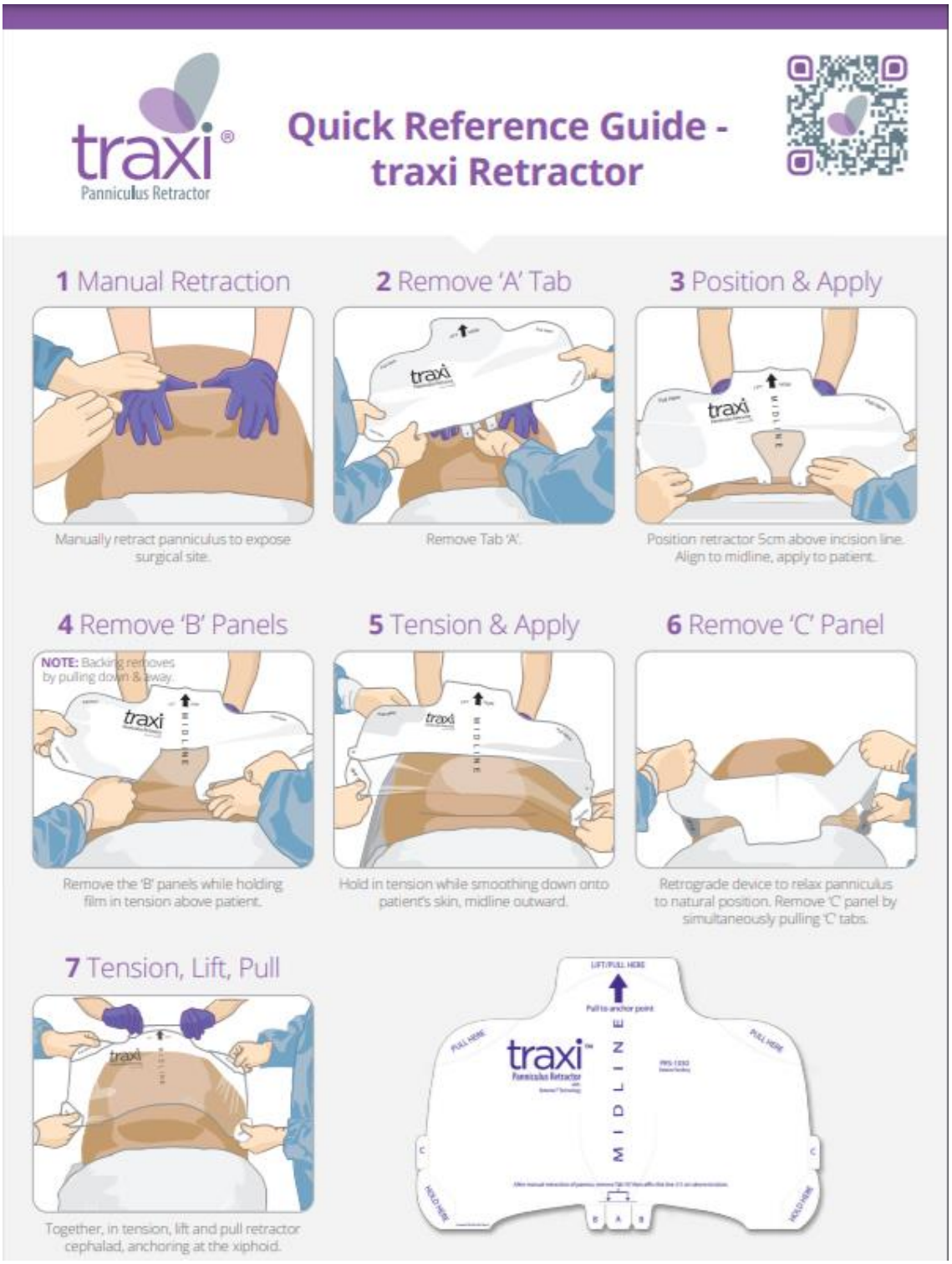
Daniel Pasko, MD	**Senior Investigator**
Melissa Wise, MD	**Principal Investigator**
Amy Crockett, MD	**Sub-investigator**
Andrew Lane, MD	**Sub-investigator/Medical Director – Ultrasound**
Laura Carlson, MD	**Sub-investigator**
Patti Parker, BSN, RN	**Sub-investigator/Manager of Clinical Trials Research**
Jessica Britt, PhD	**Sub-investigator/Biostatistician**
Alexis Kelly, BS	**Sub-investigator/Coordinator**
Emma Klipstein, BSN	**Sub-investigator/Coordinator**
Katelyn Pratt, MD	**Sub-investigator**
Alison Kimura, MD	**Sub-investigator**

The following personnel will be participating with the described role, from Clemson University:

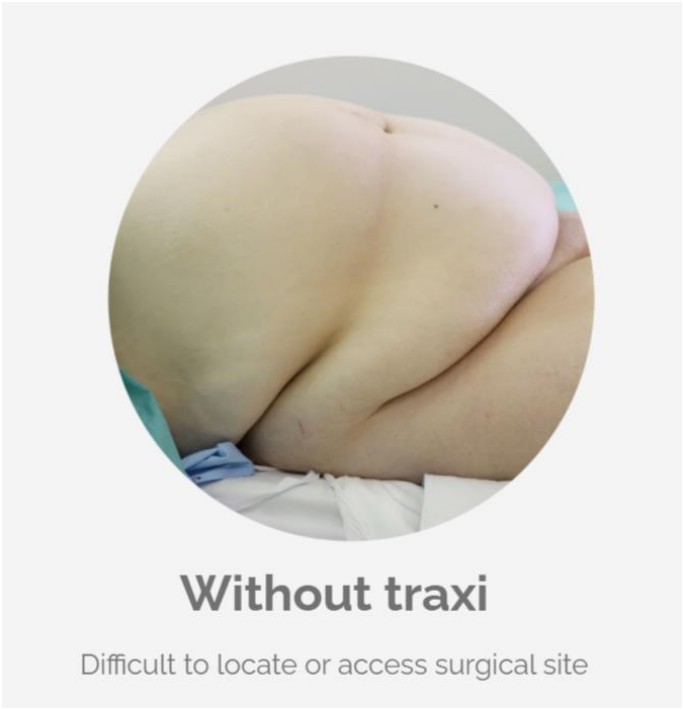
Lu Zhang, PhD	**Sub-investigator/Biostatistician**
Marvin Okom, MBBS	**Sub-investigator/Biostatistician**

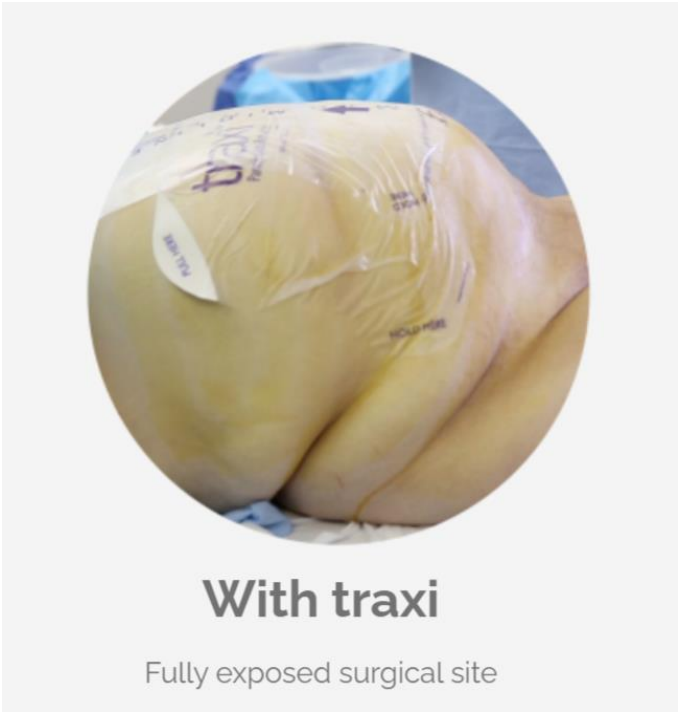
APPENDICES

A: Device Application Guide



B: Example of before and after application





C: Sonographer Survey

You are invited to participate in a survey on your experience with a pannus retractor adhesive used at time of ultrasound. This is a research project being conducted by Daniel Pasko, a physician at Prisma Health. Your participation in this study will require the completion of the attached survey. This should take approximately five minutes of your time. This survey involves minimal risk to you. The benefits, however, may impact society by helping increase knowledge.

You will not be contacted again in the future. You will not be paid for being in this study. Your survey answers will be maintained in REDCap database where data will be stored in a password protected electronic format. REDCap does not collect identifying information such as your name, email address, or IP address for this survey, though the ultrasound report that includes sonographer name will be collected from the patient participants. Your name would not be identified in any scientific publications or presentations.

We will be happy to answer any questions you have about this study. If you have further questions about this project or if you have a research-related problem you may contact me, Daniel Pasko at 864-455-1600. If you have any questions about your rights as a research participant, you may contact the IRB Administrator at 864-455-8997. The completion of this survey implies your consent to participate. Thank you!

Rate your level of agreement with the following statements by checking one box for each row:						
	Strongly disagree	**Disagree**	**Neither disagree nor agree**	**Agree**	**Strongly agree**	**Not Applicable**
1. I experienced pain in my arm, shoulder and/or wrist while performing this ultrasound						
2. The participant's body habitus affected my ability to complete the ultrasound						
3. I feel confident about the quality of ultrasound images obtained						
4. The use of a pannus retractor made the ultrasound easier to perform						
5. It was easy to apply the pannus retractor						
Comments						

D: Participant Survey

Rate your level of agreement with the following statements by checking one box for each row:						
	Strongly disagree	**Disagree**	**Neither disagree nor agree**	**Agree**	**Strongly agree**	**Not Applicable**
1. I felt comfortable during the ultrasound						
2. I am satisfied with the quality of ultrasound pictures I received						
3. I enjoyed the ultrasound experience today						
4. I would be willing to have future ultrasounds performed with the retractor adhesive in place						
Comments						

REFERENCES

1. Lashen, H., K. Fear, and D.W. Sturdee, *Obesity is associated with increased risk of first trimester and recurrent miscarriage: matched case-control study.* Hum Reprod, 2004. **19**(7): p. 1644-6.
2. Stothard, K.J., et al., *Maternal overweight and obesity and the risk of congenital anomalies: a systematic review and meta-analysis.* JAMA, 2009. **301**(6): p. 636-50.
3. Racusin, D., et al., *Obesity and the risk and detection of fetal malformations.* Semin Perinatol, 2012. **36**(3): p. 213-21.
4. *AIUM Practice Parameter for the Performance of Detailed Second- and Third-Trimester Diagnostic Obstetric Ultrasound Examinations.* J Ultrasound Med, 2019. **38**(12): p. 3093-3100.
5. Weichert, J. and D.R. Hartge, *Obstetrical sonography in obese women: a review.* J Clin Ultrasound, 2011. **39**(4): p. 209-16.
6. Dashe, J.S., D.D. McIntire, and D.M. Twickler, *Effect of maternal obesity on the ultrasound detection of anomalous fetuses.* Obstet Gynecol, 2009. **113**(5): p. 1001-1007.
7. Sagi-Dain, L., *Obesity in Pregnancy: ACOG Practice Bulletin, Number 230.* Obstet Gynecol, 2021. **138**(3): p. 489.
8. Dashe, J.S., D.D. McIntire, and D.M. Twickler, *Maternal obesity limits the ultrasound evaluation of fetal anatomy.* J Ultrasound Med, 2009. **28**(8): p. 1025-30.
9. Thornburg, L.L., et al., *Fetal anatomic evaluation in the overweight and obese gravida.* Ultrasound Obstet Gynecol, 2009. **33**(6): p. 670-5.
10. Pasko, D.N., et al., *Completion and Sensitivity of the Second-Trimester Fetal Anatomic Survey in Obese Gravidas.* J Ultrasound Med, 2016. **35**(11): p. 2449-2457.
11. Simmons, P.M., et al., *Accuracy and Completion Rate of the Fetal Anatomic Survey in the Super Obese Parturient.* J Ultrasound Med, 2021. **40**(10): p. 2047-2051.
12. Yaqub, M., et al., *The effect of maternal body mass index on fetal ultrasound image quality.* Am J Obstet Gynecol, 2021. **225**(2): p. 200-202.
13. Gupta, V.K., et al., *Detailed Fetal Anatomic Ultrasound Examination Duration and Association With Body Mass Index.* Obstet Gynecol, 2019. **134**(4): p. 774-780.
14. Hendler, I., et al., *The impact of maternal obesity on midtrimester sonographic visualization of fetal cardiac and craniospinal structures.* Int J Obes Relat Metab Disord, 2004. **28**(12): p. 1607-11.
15. Bagley, J.E.B., J.; Baldwin, J.; DiGiacinto, D.; Anderson, M.P., *On-the-Job Pain and Injury as Related to Adaptive Ergonomic Equipment in the Sonographer's Workplace and Area.* Journal of Diagnostic Medical Sonography, 2016. **33**(1): p. 15-21.
16. Hogan, A., *Pain Levels and Injuries by Sonographic Specialty: A Research Study.* Journal of Diagnostic Medical Sonography, 2021. **38**(1): p. 53-58.
17. Benacerraf, B.R., *A technical tip on scanning obese gravidae.* Ultrasound Obstet Gynecol, 2010. **35**(5): p. 615-6.
18. Maxwell, C. and P. Glanc, *Imaging and obesity: a perspective during pregnancy.* AJR Am J Roentgenol, 2011. **196**(2): p. 311-9.
19. Puissegur, A., et al., *Impact of ultrasound speed choice on the quality of the second-trimester fetal ultrasound examination in obese women.* Diagn Interv Imaging, 2021. **102**(2): p. 109-113.
20. Glanc, P., et al., *Should an Early Anatomy Ultrasound Scan Be Offered Routinely to Obese Pregnant Women?* J Obstet Gynaecol Can, 2018. **40**(10): p. 1288-1294.
21. Romary, L., et al., *The Role of Early Gestation Ultrasound in the Assessment of Fetal Anatomy in Maternal Obesity.* J Ultrasound Med, 2017. **36**(6): p. 1161-1168.
22. Gupta, S., et al., *Early second-trimester sonography to improve the fetal anatomic survey in obese patients.* J Ultrasound Med, 2014. **33**(9): p. 1579-83.

23. Khaikin, Y., et al., *Delay of Fetal Anatomy Ultrasound Assessment Based on Maternal Body Mass Index Does Not Reduce the Rate of Inadequate Visualization.* J Ultrasound Med, 2020. **39**(11): p. 2123-2130.
24. Dwan, K., et al., *CONSORT 2010 statement: extension to randomised crossover trials.* BMJ, 2019. **366**: p. l4378.
25. Iglesias, M., et al., *An anthropometric classification of body contour deformities after massive weight loss.* Ann Plast Surg, 2010. **65**(2): p. 129-34.