Research Project Title

Assessing gestational age in first trimester pregnancies: A comparison of a new handheld wireless transabdominal ultrasound to a portable transabdominal ultrasound.

Research Question

This research project is designed to determine the equivalence of a handheld wireless (Clarius C3) transabdominal ultrasound to the current portable ultrasound with transabdominal and transvaginal capabilities (Zonare ZS3) when used to date first trimester pregnancies.

Background

There have been several new recommendations in the SOGC encouraging the provision of first trimester pregnancy ultrasound.
In the June 2018 SOGC Clinical Practice Guideline No 360-Induced Abortion: Surgical Abortion and Second Trimester Medical Methods, the authors write, “Ultrasound should be performed prior to induced abortion to confirm gestational age and aid in operative planning (Strong recommendation. Level of evidence: Low)”. In the SOGC Clinical Practice Guidelines on Medical Abortion published in 2016, they recommend that “women with significant risk factors, signs, or symptoms of ectopic pregnancy should have a pretreatment ultrasound before medical abortion”, but they does not require it to be performed. In patients who receive medical abortion (Mifepristone 200 mg orally followed by misoprostol 800 mcg buccally 24 to 48 hours) under 9 weeks’ gestation, the product monograph states that “ultrasound shall be performed before medical abortion”. It is the current standard at the sites that perform medical abortion in Manitoba (Women’s Hospital, Winnipeg Health Clinic Portage and Brandon Hospital) that an ultrasound is performed prior to medical abortion to confirm an intrauterine pregnancy. In March 2019, the SOGC developed a Clinical Practice Guideline on the Use of First Trimester Ultrasound. They recommended the following: “First trimester ultrasound is recommended to date a pregnancy (ideally at 7 to 12 weeks).”

The cost of wireless portable ultrasounds that connect with a tablet computer or smart phone has made it more accessible for the average obstetrician/gynecologist going into practice. Canadian residents training in Obstetrics and Gynecology are now required to complete a month of training in ultrasound in their PGY1 year. If an inexpensive handheld ultrasound machine can be used to appropriately date a first trimester pregnancy, it would allow for the average obstetrician/gynecologist to appropriately date a pregnancy, regardless of their location. This would be highly valued in locations where ultrasound access by radiologists is not easily accessible.

In the SOGC practice guidelines Determination of Gestational Age (GA) by Ultrasound published February 2014, a mean sac diameter (MSD) is first used to date pregnancy using a transvaginal ultrasound when it is 2-3 mm or 32 to 33 days. The growth of the MSD is approximately 1 mm per day. Mean sac diameter becomes less reliable when it exceeds 14 mm or an embryo can be identified. A yolk sac or embryo seen inside the gestational sac in an intrauterine location provides confirmation that the pregnancy is definitely in the uterus. This makes an ectopic pregnancy extremely unlikely. The yolk sac usually becomes visible between 5 to 6 weeks GA. The embryo is usually seen after 6 weeks' GA. Crown rump length provides the most accurate estimate of gestational age when the embryo is clearly seen and it is reported to be accurate within 3-8 days. The SOGC recommend that crown rump length be used up to 84 mm in size (approximately 12 weeks and 4 days with Hadlock criteria), and the biparietal diameter be used for measurements greater than 84 mm. These criteria will be used to determine gestational age for the study.

Objective:

The objective of this study is to assess equivalency of the transabdominal Clarius handheld wifi C3 ultrasound (which uses Bluetooth to locate the ipad Mini 5 and then uses wifi direct to show the images) to the current standard of care in Women's Hospital outpatient department the portable Zonare ZS3 in patients presenting in the first trimester of pregnancy.

Research Design and Methodology

This is a prospective clinical study in which first trimester participants who are presenting to discuss termination of pregnancy, will consent to have an additional transabdominal ultrasound with the Clarius C3 immediately prior to their standard ultrasound which is performed to date their pregnancy. Participants who are presenting for medical abortion have been prescreened to be estimated to be less than 9 weeks GA. Participants who are being seen prior to surgical abortion will have been screened by nurses based on their last menstrual period or estimated time of conception to estimate their gestational age. Potential participants estimated to be less than 13 weeks GA, will be approached to see if they are interested in participating in the study before they are seen by their health care provider. The name, date of approach, and reason for decline of potential participants who refuse to participate will be documented. If agreeable, the participant will complete consent with a study nurse or medical student for the additional ultrasound.
Participants will then receive the 2 ultrasounds by the same health care provider with the Clarius C3 ultrasound first, then the standard care ultrasound. Occasionally, there may be a different provider doing the Clarius C3 ultrasound when the patient consents.

Participants will receive standard care for medical or surgical abortion. The following information will be documented from their chart:
Height and weight, age, Obstetrical history (Gravida, para, number cesareans, ectopic pregnancies, spontaneous abortions, therapeutic abortions). If they do not have a

documented intrauterine pregnancy, the standard questions to rule out possibility of ectopic pregnancy will be determined, and any positive answers will be documented in the chart. Anyone without a documented intrauterine pregnancy (no gestational sac or a gestational sac with no definite crown rump length or yolk sac) will be followed until a final outcome is determined or they are lost to follow up. When the patient has a pregnancy of unknown location (no evidence of a pregnancy inside or outside of the uterus, their data will not be used to compare the two ultrasounds but future outcome will be recorded.
The final outcome of their pregnancy and any complications will be determined within the next 6 weeks with the following potential outcomes:
completed medical abortion, completed surgical abortion (possibily following failed medical abortion), lost to follow up, continuing pregnancy, or ectopic pregnancy.

If a participant is determined to be over 13 weeks GA, they will receive a dating ultrasound with the Clarius C3 ultrasound using biparietal diameter as appropriate but it will not be included in the final study measurements.

For each participant, ultrasound reports and data from the “Research Participant Data Collection Form” will have a unique code and all information stored on a password-protected SPSS document on a locked desktop computer in the Research Office WS021 which is locked.

Sample Size

Sample size was estimated based on a one sided McNemar’s test, 15% clinically significant difference (estimating 60% of subjects would allow a transabdominal ultrasound to see a gestational sac and a yolk sac with the Zonare ZS3 and 45% with the Clarius C3) at a power of .8 and alpha value of 0.05. This would require 131 participants to be recruited for the study.

Statistical Analysis

McNemar’s test would be used to determine the ability of the transabdominal ultrasounds to measure the presence or absence of an intrauterine pregnancy.
A paired t-test would be used to compare gestational sac measurements or crown rump lengths between the two ultrasound machines.

Inclusion Criteria

1. Presenting requesting medical or surgical abortion
2. Estimated to be under 13 weeks gestational age based on last menstrual period or time of conception, or nurses best estimate.
3. Able to provide informed consent with adult supervision of a minor or with an interpreter present

Exclusion Criteria

1. Unable to provide informed consent

Timeline
We anticipate data collection to occur over a 9-month period.

Budget
Data collection by the participating physicians will be on a volunteer basis. A medical student volunteer will not be paid for the procedure. Physicians who perform ultrasound for medical and surgical abortion will be reimbursed by Manitoba Health for their procedure with no additional funding for participation in the study. The study nurses involved in recruiting, consenting and collecting data will be paid by the Department of Obstetrics and Gynecology.

Conflict of interest
There is no conflict of interest identified in this study.

Discussion of Ethics
Informed consent
Potential participants will be identified by nursing or physician. A volunteer medical student or research nurse will approach the patient to request consent.

Potential Benefits and Harms
The additional ultrasound may be associated with minimal physical discomfort due to pressure on their bladder. There is minimal risk to a developing pregnancy due to ultrasound. Participants will be chosen among patients requesting termination of pregnancy.

Alternative Procedures
The patient may choose to receive usual care and not receive a second ultrasound.

Protection of privacy and harm reduction
- Participation is strictly voluntary
- All personal information contained on the consent forms will be kept in a locked cabinet in the Research Office WS021 which itself is locked. These paper records will be destroyed via shredding at the end of the study.
- Ultrasound images obtained from patients will be initially stored on Clarius cloud using anonymized data and printed out to be placed in the study chart
- Information gathered from patient charts, and ultrasound image reports will be identified by a unique code and stored on a password-protected SPSS Document stored on a locked Desktop computer in the locked Research Office WS021. These files will be destroyed using the permanent deletion function on the computer if no further secondary research is planned within seven years.

Dissemination of information

Final results will be presented locally and also at a national or international forum. The data may be used to design future studies with regard to performing ultrasound in remote locations in Manitoba or Nunavut.

References

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