TRANS-VAGINAL ULTRASOUND FOR PREDICTION OF UTERINE SCAR DEHISCENCE IN LATE THIRD TRIMESTER

Protocol of thesis
Submitted for partial fulfillment of the Master Degree in Obstetrics and Gynecology

BY

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INTRODUCTION

The cesarean delivery rate has continued to increase over the past several years ***(Martin et al, 2002)***. The literature has suggested potential catastrophic events, including uterine rupture and fetal death, resulting from labor with a previous cesarean delivery ***(Chauhan et aL, 2003)***.

Three layers of the lower uterine segment (LUS) can be identified on ultrasound: the chorioamniotic membrane with decidualized endometrium; the middle muscular layer; and the uterovesical peritoneal reflection juxtaposed with muscularis and mucosa of the bladder ***(Michaels et al, 1988)***.

For women with previous caesarean section, the prevalence of uterine rupture reported was in the region of 1%, including 0.5% asymptomatic ruptures ***(Hofmeyr et al 2005)***

A number of methods have been used to evaluate the lower uterine segment after cesarean delivery. Hysterography of uterine scar, ***(Baker, 1955)*** pelvic examination,***(Meehan et al, 1972)*** amniography,***(Caterini***

et al 1972) and x-ray pelvimetry ***(Thubisi et al 1993)*** have not been proved to be useful for estimation of the risk of uterine rupture; however, several reports have suggested that transabdominal ultrasonography may detect a defective uterus after previous caesarean delivery***(Michaels et al, 1988, Rozenberg et al, 1996, Fukuda et al 1991).***

To assess the risk of uterine rupture in a subsequent pregnancy, researchers have used ultrasonography in the evaluation of the uterine scar in the second ***(Sambaziotis et al, 2004)*** and third trimesters***(Michaels et al, 1988, Rozenberg et al, 1996, Asakura et al, 2000)*** as well as the postpartum period ***(Koutsougeras et al, 2003).*** It has generally been found that the thicker the uterine scar the lower the rate of complications ***(Sambaziotis et al, 2004***, ***Michaels et al, 1988, Rozenberg et al, 1996, Asakura et al, 2000)***. One may postulate that a thicker scar is stronger, and thus performs better, than a thinner one. Whether thickness of the uterine scar varies with the technique used at the time of hysterotomy closure is an unexplored question.

Rozenberg et al, 1999 reported a relationship between third trimester sonographically measured thickness of the lower uterine segment and the safety of a trial of

labor in women with previous cesarean deliveries and the risk of uterine rupture or dehiscence (the separation of the muscular layer with an intact serosa).

Trans-vaginal ultrasonography could therefore be considered the standard diagnostic procedure that can predict accurately intrapartum uterine rupture in women with previous cesarean delivery. Results of a previous study emphasized the importance of measuring the uterine scar in the late second trimester in women with previous cesarean delivery ***(Gotoh et al, 2000)***.

AIM OF THE WORK:

To correlate measurements of lower uterine segment thickness by trans-vaginal ultrasound in late third trimester, and uterine scar dehiscence aiming to find a cutoff value below which the incidence of uterine scar dehiscence increases.

PATIENT AND METHOD

This study will be conducted in Ain Shams University Maternity Hospital. The study will include 300 pregnant patients admitted to our University Hospital between 36 - 40 weeks gestation with history of previous caesarian sections admitted at our hospital planning for elective cesarean delivery.

After obtaining informed consent, ultrasonographic measurements of the lower uterine segment will be performed using a 6.0 MHz vaginal probe （SONOACE × 4, MEDISON, Deutschland GmbH Elbestrasse ） within 20 minutes of voiding.

The lower uterine segment will be defined as the portion of the anterior uterine wall directly adjacent to the overlying bladder. When observed with a vaginal probe, three distinct layers can be distinguished in the lower uterine segment. The outermost layer is directly outside the muscular layer and adjacent to the bladder above. The second layer is the muscular layer. The third layer is located directly inside and under the muscular layer and contains the decidual layer of the endometrium. Only the muscle layer will be measured at its thinnest portion. The measurements

will be repeated three times through three different sagittal planes and a mean will be obtained ***(Asakura et al, 2000)***.

The sonographers will be limited to three experienced physicians.

During the cesarean section we will determine the actual state of the uterine scar and we will record our findings in scales and eventually compare these findings to the ultrasonographic findings to determine the usefulness of ultrasound in detection of the uterine scar status.

Uterine dehiscence was defined as a separation of the muscular layer with an intact serosa. The separation of the muscular layer was evaluated both by inspection and palpation. The mere thinning of the uterine wall without separation of the muscular layer was not regarded as dehiscence ***(Asakura et al, 2000).***

Sample Size

EPI info version 6 was used for calculation of sample size, Power of the test 80%, with confidence interval 95% and α –error (type 1 error) 5%, type of sample will be systematic random sample.

Statistical Analysis:

Statistical analysis will be performed. For each group, we will describe continuous-scale demographic variables by calculating 5 characteristics (minimum, 25^{th} quartile, median, 75^{th} quartile and maximum). For these variables, we will verify initial-state group comparability by analysis of the variance (independent-groups Student t-test). In order to analyze the distribution of ordinal and nominal demographic variables in the groups, we will use Pearson X^2 test.

Data will be expressed as mean ± SD. The Receiver operating characteristic curve will be used to find the upper limit and cut-off value for various measurements of the lower uterine segment, Sensitivity, specificity, positive, and negative predictive values will be calculated. Student's t test was used for between-group comparisons of demographic and clinical data. Statistical analyses will be performed using SPSS for Windows release 15.0 (SPSS Inc., Chicago, Ill., USA). A p value < 0.05 is considered significant.

ETHICAL AND LEGAL ASPECTS

1. Good Clinical Practice (GCP)

The procedures set out in this study protocol, pertaining to the conduct, evaluation and documentation of this study, are designed to ensure that the investigators abide by the principles of good clinical practice and the ethical principles laid down in the current revision of the Declaration of Helsinki.

2. Delegation of Investigator Responsibilities

The investigator will ensure that all persons assisting with the study are adequately informed about the protocol, any amendments to the protocol, the study variants, and their information collection-related duties and functions.

3. Patient Information and Informed Consent

Before being admitted to the clinical study, the patient must consent to participate after the nature, scope, and possible consequences of the clinical study have been explained in a form understandable to her. An informed consent document, in Arabic language, contains all locally required elements and specifies who informed the patient [Form 1]. After reading the informed consent document, the

patient must give consent in writing. The patient's consent must be confirmed at the time of consent by the personally dated signature of the patient and by the personally dated signature of the person conducting the informed consent discussions.

If the patient is unable to read, oral presentation and explanation of the written informed consent form and information to be supplied to patients must take place in the presence of an impartial witness [Form 2]. Consent must be confirmed at the time of consent orally and by the personally dated signature of the patient or by a local legally recognized alternative (e.g., the patient's thumbprint or mark). The witness and the person conducting the informed consent discussions must also sign and personally date the consent document. The original signed consent document will be retained by the investigator. The investigator will not undertake any measures specifically required only for the clinical study until valid consent has been obtained.

4. Confidentiality

Only the patient number and patient initials will be recorded in the Master Sheet, and if the patients name appears on any other document, it must be kept in privacy

by the investigators. The investigator will maintain a personal patient identification list (patient numbers with the corresponding patient names) to enable records to be identified.

5. Protocol Approval

Before the beginning of the study and in accordance with the local regulation followed, the protocol and all corresponding documents will be declared for Ethical and Research approval by the Council of OB/GYN Department, Ain Shams University.

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