European Journal of Obstetrics & Gynecology and Reproductive Biology 179 (2014) 141–146

Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.elsevier.com/locate/ejogrb

Reproducibility of three-dimensional gel installation sonohysterography in the assessment and classification of intrauterine abnormalities

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ARTICLE INFO

Article history:
Received 23 January 2014
Received in revised form 2 May 2014
Accepted 9 May 2014

Keywords:
Saline or gel infusion
Sonohysterography
Three dimensional
Reproducibility
Intrauterine abnormalities

ABSTRACT

Objective: Purpose of this study is to determine the interobserver and intraobserver variability of 3D GIS in the assessment of intrauterine abnormalities.
Study design: Forty five 3D volumes were randomly selected from a larger prospective cohort study that studied the diagnostic accuracy of 3D GIS in addition to 2D GIS. To study interobserver agreement volumes were reviewed by two independent examiners. One examiner reviewed these samples twice with an interval of 1 month in a random order. Interobserver and intraobserver agreement were tested with Cohen's kappa coefficient and shown in Bland and Altman plots. Quality of the 3D volumes was evaluated.
Results: Cohen's kappa for interobserver variability for type of abnormalities (none, polyp, fibroid, other) was 0.64 and for presence of a fibroid (fibroid yes/no) 0.77. Agreement on type of fibroid was 0.59. Intraobserver agreement was almost perfect for type of abnormality (Cohen's kappa of 1.0) and good for fibroid diameter. Quality of the 3D volumes was poor in 11 out of 45 cases. Reproducibility increased when poor quality images were excluded.
Conclusion: Substantial interobserver and intraobserver agreement for 3D GIS in the diagnoses of intrauterine abnormalities was found. 3D GIS interobserver and intraobserver agreement are good for fibroid diameter and moderate for volume and protrusion.

Introduction

Intracavitary pathology (polyps, submucous fibroids) is expected in more than 40% of the women who are referred by the general practitioner for abnormal uterine bleeding [1]. Other associated symptoms are dysmenorrhoea, infertility or miscarriage [2,3]. Sonohysterography is a procedure in which fluid (saline or gel) is instilled transcervically into the uterine cavity to provide enhanced visualisation of the endometrial lining during transvaginal ultrasound examination. Both saline infusion sonohysterography (SIS) and GIS are simple, safe, well tolerated and accurate techniques in the assessment of intra-uterine abnormalities [4,5]. Three-dimensional SIS enhances visualisation of the uterine cavity and is highly accurate in the diagnosis of uterine abnormalities [6] and can provide an alternative to hysteroscopy in the diagnostic workup of abnormal uterine bleeding instead of hysteroscopy [7]. The advantage of 3D SIS (over 2D SIS) lies in the fact that it provides very accurate information about diameter and extent of sub mucous protrusion of fibroids into the uterine cavity [8–10]. Mavrelos et al. [9] reported that in particular these parameters (diameter and protrusion) are of significant influence on completeness of resection. The latter suggests that 3D provides useful information for the clinical practice.

Although much has been written on the accuracy of 3D SIS, little is known about its reproducibility. Without good reproducibility, even a highly accurate test cannot be of use in general practice. Dueholm et al. [11] reported intermediate agreement for the interobserver agreement on conventional transvaginal sonography for detecting/excluding uterine cavity abnormalities. To the best of our knowledge, only three studies [6,8,12] reported about 3D SIS

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http://dx.doi.org/10.1016/j.ejogrb.2014.05.010
0301-2115/

reproducibility and none on the reproducibility of 3D GIS. Our objective is to evaluate the interobserver and intraobserver agreement of 3D gel installation sonohysterography (GIS) in the diagnosis for intracavitary abnormalities, its classification and diameter, volume and percentage of protrusion into the uterine cavity of submucous fibroids. Main outcome is identification of an abnormality and type of abnormality.

Materials and method

Data collection, storage and sample selection

We used stored 3D volume datasets generated from a larger prospective cohort study assessing the diagnostic accuracy of 3D GIS in addition to 2D GIS [13]. Women with abnormal uterine bleeding, dysmenorrhoea, recurrent miscarriage, infertility or suspicion of an intrauterine abnormality on regular ultrasound received a 2D GIS ($n = 855$). 3D GIS volumes ($n = 203$) were obtained when an intracavitary abnormality was suspected at 2D GIS. A random sample of 45 3D volumes was taken by an independent statistician unfamiliar with the content of the volumes, patients, sonographic or hysteroscopic results. 3D volumes were reviewed independently by two examiners between January and March 2012 (MvdV, LLN).

Generation of 3D volumes

A 3D volume was generated by an automatic sweep of the mechanical transducer (trans vaginal transducer 5–8 MHz), with the ultrasound probe in the midsagittal plane and the uterus within the scan sector. The sweeps were taken by experienced and sufficiently trained sonographers in a daily practice in the VU medical centre, Amsterdam, the Netherlands. The volumes were stored digitally (mvl file) on a personal computer. SonoView Pro – 1.5 VOCAL software and 3D XI viewer (Samsung Medison) were used for analysing 3D volumes.

Evaluation of the stored 3D volumes

For interobserver agreement 3D volumes were reviewed by two independent examiners (residents), familiar (after training) with the interpretation of 3D ultrasound. Both were blinded for the 2D GIS and hysteroscopy findings. For intraobserver agreement, 25 of these volumes were randomly reviewed twice by the same observer. A minimum of one month between the two measurements was set. Volumes were reviewed in a different random order. Both observers were blinded for patient characteristics, symptoms, 2D GIS, hysteroscopic or histological outcomes.

Image quality evaluation

Each image was scored for its quality of visualisation and possibility to analyse. Quality was scored on a Lickert scale from 1–5, 1 representing very poor quality and 5 representing almost perfect image quality. Quality depended on contrast, sharpness and brightness of the image, air bubbles and other artefacts, distension and total visualisation in case of an intrauterine abnormality. Each category (contrast, sharpness, etc.) was weighted and could render a point.

Cavity evaluation

A normal cavity was defined as an undistorted outline of the endometrium. The following details of the intrauterine abnormalities were recorded: origin, diameter and protrusion into the uterine cavity. Smooth margined echogenic masses with a homogenous texture were described as polyps, while structures of mixed echogenicity disrupting the endometrial continuity were described as submucous fibroids [14]. This resulted in 4 categories of abnormality: 'none', 'fibroid', 'polyp' or 'other', the latter consisting of abnormalities that could not be categorised as previously mentioned. Presumed intrauterine fibroids were classified into subtypes (type 0, 1, 2) according to the degree of protrusion into the uterine cavity (type 0 100% intracavitary, type 1 > 50% protrusion into the cavity, type 2 < 50% protrusion into the cavity) [10].

Evaluation of fibroid protrusion

A standardised method was used for the measurement of fibroid protrusion as previously reported by Lee et al. [8] (see Fig. 1). Measurement started with the multiplanar display (software: XI viewer, Samsung Medison, Hoofddorp, the Netherlands). Fibroids located anteriorly, posteriorly or fundally were analysed in the longitudinal or sagittal plane. Lateral fibroids were analysed in the coronal or transversal plane. First the fibroid was localised, by taking the frame with the largest diameter. Then the *z*-axis was rotated until the *y*-axis was perpendicular to the fibroid. When in good position, the *y*-axis was rotated. While rotating the *y*-axis, the fibroid protrusion ratio (part intracavitary and part myometral) should not change. When the ratio was not changing, a line was drawn were the fibroid entered the endometrial–myometrial junction. A section of the fibroid protruding into the cavity (A) and a part confined to the myometrium (B) were both measured. Protrusion into the cavity was calculated using $(A/(A + B) \times 100)$.

Evaluation of fibroid volume

Volumes of the fibroids were calculated using XI VOCAL manual contour mode (software: XI viewer) according to a standardized protocol. The main contour axis was positioned in the centre of the fibroid. In the reference plane, both poles were set at the boundaries of the fibroid. The manual contour mode was applied to outline the shape of the whole fibroid in 5 different sections. The contour was redefined if necessary. A volume was then automatically calculated. We also calculated fibroid volumes using the formula $1/6 \times \mathrm{pi} \times d^3$ and plotted them with the measured ones using VOCAL to show agreement.

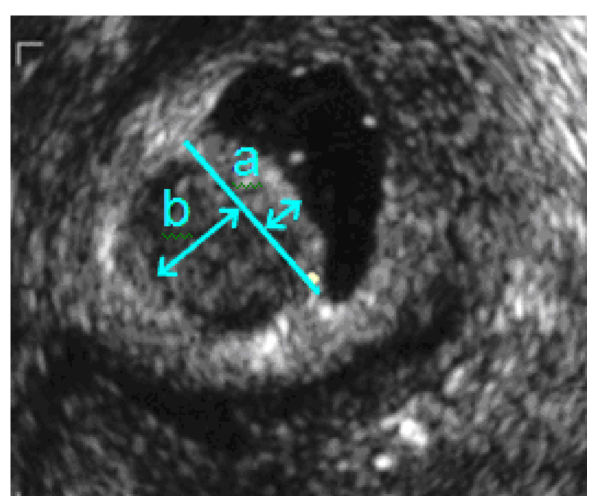

Fig. 1. Measuring protrusion in a submucous fibroid in coronal plane (picture taken during gel installation sonohysterography). A. Protrusion into the cavity, B. part of the fibroid in the myometrium. Fibroid protrusion into the cavity is calculated using $(A/(A + B) \times 100)$.