The role of other imaging modalities in evaluating the tubal patency

Sir,
I anxiously read the recently published an article in your journal entitled “Imaging techniques for assessment of tubal status” and I found it as a very well-structured article, which reviewed the evidence about the imaging modalities for evaluation of the tubal patency. They finally focused and confirmed on the hysterosalpingo-contrast-sonography (HyCoSy) as a new and potentially useful and reliable imaging in these patients. Although they attempted to review all applied imaging technique, they missed some valuable and practical, which we would like to talk about them in this letter.

A newly considered imaging which every day is declared its value in assessing the pelvic organs especially uterus is magnetic resonance imaging (MRI). MRI-hysterosalpingography (MR-HSG) in addition to conventional MRI (with or without contrast) is effectively used in diagnosing the tubal and uterus cause of infertilities. MR-HSG was firstly used for a 32-year-old woman with a history of iodine-induced hypothyroidism, which conventional HSG was contraindicated for her. On that time, MR-HSG was recommended for patients with contraindication for conventional HSG. The method of MR-HSG was simply and briefly described in the following sentence derived from Ma et al.: “A balloon catheter was placed into the uterine cavity, and then flash 3D coronal scanning by MRI was performed with the uterine injection of a diluted mixture of gadolinium-based contrast (1:100), and data were reconstructed after digital subtraction scan.”

There are many benefits in MR-HSG, which stated in the previous reports; (1) Nonionizing radiation is used in scanning, it is so important when consider that the target population of this workup is in fertility age, (2) it is not operator dependent versus sonography, (3) evaluating the other causes of infertility and assessing the adjacent organs, (4) selective tubal catheterization is possible during the procedure, (5) excellent resolution and multiplanar imaging, (6) evaluating distal tubal pathology and possible peritubal adhesions.

However, there is some limitation for this modality; (1) An experienced reader and radiologist is needed for interpreting the pictures, (2) there are some contraindications for MR-HSG including general MRI contraindication such as hepatic and renal insufficiency, intolerance to gadolinium-based contrast, severe claustrophobia, and metal device in body, e.g. cardiac pacemakers, cochlear implants. Furthermore, MR-HSG is an expensive and time lasting procedure which is the other limitations. (3) Dislocating the catheter due to unavoidable motion and higher failure rate, (4) felling discomfort during the contrast injection up to 21%.

Thirty minutes is the maximum time, which take by MR-HSG that is acceptable for nonemergency patients such as infertile women. Furthermore, MR-HSG can be hybrid with conventional radiography for more accurate diagnosis of the anatomical defects.

On the other hand, other multi-sectional imaging which can provide more anatomic information is virtual HSG with multidetector computed tomography (CT) technique. Due to high dose of radiation, this modality is not preferred for simple and noncomplicated cases but sometimes “virtual HSG with multidetector CT may provide a diagnostic advantage in complex cases.”

Finally, MR-HSG or even multidetector CT scanning can be helpful in infertile patients with normal HyCoSy doubtful for tubal and peritubal lesions.

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Sir,

Re: Suresh K, Chandrashekara S. Sample size estimation and power analysis for clinical research studies. J Hum Reprod Sci 2012;5:7‑13.

Although informative and useful Suresh and Chandrashekara’s article on sample size estimation and power analysis contains a serious error (Suresh and Chandrashekara, 2012). In the section titled “sample size estimation with two means” they state the minimum required sample size for detecting a mean difference between two groups is:

\[ N = \frac{Z_{\alpha/2} + Z_{1-\beta}}{\sigma^2} \cdot r \cdot n_1 + (1-r) \cdot n_2 \]

Where
- \( \alpha \) is the false positive rate
- \( \beta \) is the false negative rate
- \( N \) is the sample size required to detect an inter‑group mean difference of \( d \) with specified \( \alpha \) and power of \( 1-\beta \)
- \( \sigma^2 \) is the variance in each group (both groups having the same variance)
- \( r \) is the ratio of size (\( n_1 \) and \( n_2 \)) of the two groups, that is, \( r = \frac{n_1}{n_2} \)
- \( Z \) is the standard normal distribution deviate, note this is the absolute of the z‑score, as in (Suresh and Chandrashekara, 2012) Tables 2 and 3.

The formula as stated cannot be correct as relabeling of the two groups results in different values of \( N \).

Example:

If \( n_1 = 100 \) and \( n_2 = 200 \) then \( r = 1/2 \) and \( (1/2 + 1/2) = 1 \).

Swapping the two groups around:

Then \( n_1 = 200 \) and \( n_2 = 100 \) then \( r = 2 \) and \( (2 + 1/2) = 2.5 \).

The \( N \) calculated for the first case is twice that of the second; they should be identical.

In fact, the formula given is the formula for \( n_2 \), which I prove thus.

In the ‘Sample Size estimation with two means’ case, the z‑score of the test statistic \( d \) is related to the required false positive rate and power by

\[ d = Z \cdot \frac{\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}}{\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}} \cdot \frac{\sigma_1^2 + \sigma_2^2}{2} \]

Where the standard error of \( d \) is

\[ \text{stdErr}(d) = \sqrt{\frac{1}{n_1} + \frac{1}{n_2}} \cdot \frac{\sigma_1^2 + \sigma_2^2}{2} \]

Substituting the expression for stdErr \((d)\) into the first equation and rearranging gives:

\[ n = \frac{Z_{\alpha/2} + Z_{1-\beta}}{\text{stdErr}(d)} \cdot \frac{1}{r} \cdot n_1 + (1-r) \cdot n_2 \]

The formula for \( N \) is then

\[ N = n + \text{stdErr}(d) \cdot (1-r) \cdot n_2 \]

With the new formula group labels can be swapped without changing the value calculate for \( N \).

The original erroneous formula could result in studies seriously underestimating their required sample size. For instance, the required sample size (as calculated by the current formula) is half that truly required, given equal numbers in the two groups. I therefore draw this error to your attention. The illustrative