Hysterosalpingography with a balloon catheter versus a metal cannula: a prospective, randomized, blinded comparative study

I.Tur-Kaspa1,2, D.S.Seidman1, D.Soriano1, I.Greenberg2, J.Dor1 and D.Bider1

1IVF Unit, Department of Obstetrics and Gynecology and 2Department of Radiology, Sheba Medical Center, Tel Aviv University, Tel Hashomer 52621, Israel

To whom correspondence should be addressed

A prospective, randomized, blinded study was conducted to compare the use of a balloon catheter for performing hysterosalpingography (HSG) with the use of a traditional metal cannula. Sixty-one consecutive women who underwent HSG for evaluation of infertility were prospectively randomized to undergo the procedure with either a metal cannula (n = 31) or the balloon catheter (n = 30). The HSG procedure was identical in both groups. HSG using the balloon catheter, compared to the metal cannula, required significantly less fluoroscopic time (57.4 ± 17.6 versus 75.6 ± 40.5 s), smaller amounts of contrast medium (7.8 ± 3.9 versus 20.1 ± 15.8 ml), produced less pain (3.8 ± 2.0 versus 5.6 ± 2; on a scale of 1–10), and was easier for the physician to perform (8.8 ± 1.1 versus 6.4 ± 1.9; on a scale of 1–10) (P < 0.01). Eight patients (13%) were diagnosed as having proximal tubal occlusion. It was possible to offer an immediate transcervical tubal catheterization for further diagnosis and treatment of the occlusion only to the five patients with this condition from the balloon catheter group. We conclude that the balloon catheter is superior to the traditional metal cannula for performing HSG. Furthermore, if proximal tubal occlusion is diagnosed, an immediate selective salpingography and transcervical tubal catheterization can be performed without the need to replace the cannula or to reschedule the patient.

Key words: Fallopian tube/infertility/interventional procedure/proximal tubal occlusion/tubal catheterization

Introduction

Hysterosalpingography (HSG) is an important diagnostic procedure in the investigation of infertility. HSG should be performed with minimal radiation exposure and causing minimal pain and discomfort to the patient. In order to achieve these goals, and to provide maximal technical ease in performing the procedure, disposable balloon catheters have been introduced to replace the traditional acorn-tipped metal cannulas (Austin et al., 1984; Sholkiff, 1987; Varpula, 1989).

New cervical balloon catheters were introduced as a platform for transcervical tubal catheterization (TTC) for the diagnosis and treatment of proximal tubal occlusion (PTO) (Confino et al., 1990; Thurmond and Rosch, 1990; Tur-Kaspa et al., 1995; Golan and Tur-Kaspa, 1996; Lang and Dunaway, 1996). Since PTO is diagnosed in ~10–20% of HSGs (Novy et al., 1988; Thurmond and Rosch, 1990) it was important to investigate whether the new cervical catheter can also be used for regular HSG. This would enable the physician performing the procedure to perform TTC immediately for PTO without the need to replace the HSG cannula. A prospective, consecutive, randomized, blinded study was conducted to compare the use of a balloon catheter versus the traditional metal cannula for HSG.

Materials and methods

Sixty-one consecutive women who underwent HSG for the evaluation of infertility were prospectively randomized to undergo the procedure with either a metal cannula (n = 31) or the HSG balloon catheter (n = 30) (Bard Reproduction Systems, Galway, Ireland) (Figure 1). The HSG procedure was identical in both groups except for the specific use of the catheter or the cannula. The procedure began with a bimanual gynaecological examination and a speculum was introduced into the vagina. After the cervix was cleaned with an antiseptic solution, the anterior lip was grasped with a single-toothed tenaculum. Thereafter, the catheter or the cannula, prefilled with water-soluble radio-opaque contrast dye (Urovist 60% (amidotrizoic acid), BRACCO, Milan, Italy), was introduced into the cervical canal. The metal cannula was wedged into the cervical os and was rigidly attached to the arms of the tenaculum forceps. Alternatively, the double-balloon HSG catheter was inserted into the cervical canal. The upper balloon was inflated with 3 ml of air and wedged at the level of the internal cervical os (which seals the uterine cavity), and the caudal balloon was then inflated with 7 ml of air to seal the cervix and to provide stability.

The contrast medium was then injected into the uterus until visualization of the uterine cavity and Fallopian tubes. More medium was then injected in order to fill both Fallopian tubes and to demonstrate bilateral spillage. Fluoroscopic time was measured automatically in seconds. The recorded volume of contrast dye used did not include the amount required to fill the cannula (2.3 ml) or the catheter (2.0 ml).

To assess the degree of pain that the patient experienced during the procedure we used a rating scale with 10 categories, 1 denoting no pain at all and 10 denoting very severe pain (Varpula, 1989). The patients were familiarized with the scale prior to the procedure. To standardize patients’ results, and to avoid falsely high pain ratings due to the grasping of the anterior lip of the cervix by the tenaculum or to peritoneal pain due to leakage of the contrast agent from the Fallopian tubes into the peritoneal cavity, we took the following measures. The patients were allowed a 1–2 min waiting period until they had no complaints, and no pain sensation, beside the discomfort of the speculum inside the vagina. Then the catheter or cannula was
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Table I. Comparison hysterosalpingograms performed with the metal cannula or with the balloon catheter

<table>
<thead>
<tr>
<th></th>
<th>Metal cannula</th>
<th>Balloon catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>31</td>
<td>30</td>
</tr>
<tr>
<td>Age (years)</td>
<td>32 ± 6.2</td>
<td>33 ± 6.5</td>
</tr>
<tr>
<td>Gravidity</td>
<td>1.6 ± 2.2</td>
<td>1.5 ± 1.9</td>
</tr>
<tr>
<td>Parity</td>
<td>0.9 ± 1.5</td>
<td>0.4 ± 0.9</td>
</tr>
<tr>
<td>Years of infertility</td>
<td>2.1 ± 1.2</td>
<td>1.9 ± 1.6</td>
</tr>
<tr>
<td>Fluoroscopic time (s)</td>
<td>75.6 ± 40.5</td>
<td>57.4 ± 17.6*</td>
</tr>
<tr>
<td>Volume of contrast material used (ml)</td>
<td>20.1 ± 15.8</td>
<td>7.8 ± 3.9*</td>
</tr>
<tr>
<td>Patient’s pain</td>
<td>5.6 ± 2</td>
<td>3.8 ± 2*</td>
</tr>
<tr>
<td>Physician’s ease</td>
<td>6.4 ± 1.9</td>
<td>8.8 ± 1.1*</td>
</tr>
<tr>
<td>No. of patients with distal tubal occlusion</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>No. of patients with PTO</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>No. of proximal occluded Fallopian tubes</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>No. of Fallopian tubes recanalized immediately with TTC</td>
<td>N/A</td>
<td>6</td>
</tr>
</tbody>
</table>

*P < 0.01.
PTO = proximal tubal occlusion, TTC = transcervical tubal catheterization.

Discussion

This study demonstrates that the use of a balloon catheter for HSG offers several significant advantages over the traditional metal cannula. Significantly less fluoroscopic time and a smaller amount of contrast agent are required. The use of a balloon catheter ensures a good seal at the level of the internal os and/or the cervix. Thus, it prevents any reflux of contrast medium back into the vagina and allows higher pressures to be reached within the uterus. This results in faster visualization of the uterine cavity and bilateral tubal filling. Once imaging was achieved, the quality of the uterine and tubal imaging was similar in the two groups.

Furthermore, the balloon catheter caused significantly less pain to the patient and it was easier for the physicians to perform the procedure. HSG involves discomfort or pain to most patients. The pain intensity can be substantially reduced by using a smaller amount of contrast agent and by eliminating the tension applied by the fixation of the cannula to the cervix (in order to seal the cervix). There are several balloon catheters currently on the market (Cook; Conceptus; etc.) which probably offer similar advantages.

To our knowledge, this is the first prospective, consecutive, randomized, blinded study which compares the use of a balloon catheter with a metal cannula for HSG as well as for possible TTC. Varpula (1989) designed a prospective and randomized study for HSG only. However, he used a paediatric Foley catheter as the balloon catheter (the inflation of the balloon is in the distal cervical canal and not in the proximal part) and he excluded from the final analysis 36.2% (29/80) of his patients because of tubal occlusion or technical difficulties during the HSG. We excluded no patients. Moreover, we feel that technical difficulties in sealing the cervix while using the cannula may partly explain the larger amount of contrast agent used. Tubal occlusion, on the other hand, may explain differences in the level of patients’ complaints.

This work describes an additional advantage of the use of balloon catheters for HSG. Unilateral or bilateral PTO is a common disorder, diagnosed in about 10–20% of HSG procedures (Novy et al., 1988; Thurmond and Rosch, 1990) (13% in
this study, Table I). If PTO is diagnosed, the new cervical balloon catheters, recently introduced, can serve as a platform for TTC which is currently recommended for further diagnosis and treatment (Confino et al., 1990; Thurmond and Rosch, 1990; Meyerovitz, 1991; Tur-Kaspa et al., 1995; Gleicher and Karande, 1996; Golan and Tur-Kaspa, 1996; Lang and Dunaway, 1996). One can immediately and easily continue to perform selective salpingography and tubal catheterization with no need to replace the cannula or to reschedule the patient.

The balloon catheters have the disadvantage of being more expensive than their metal counterparts. However, the preferred use of disposable catheters, the saving in contrast agents and fluoroscopic time, the significant reduction in patients’ pain and the avoidance of rescheduling some patients for TTC, may justify the use of balloon catheters for HSG.

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References

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