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Original Article

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ABSTRACT

Introduction: Tubal flushing effect is a published phenomena of hysterosalpingography in connection with tubal patency test. The aim of the study was to evaluate the flushing effect of the outpatient method: selective chromoperturbation via office hysteroscopy (OHSC-SPT), and compare it to that of HSG.

Materials and methods: Sixty infertile patients receiving OHSC-SPT (mean [SD] age: 34.1 [3.2] years) and 163 receiving HSG (32.7 [4.7] years) took part in the study. As part of the infertility work-up, diagnostic office hysteroscopy was performed to evaluate the uterine cavity. Patients with at least one patent tube had a 12-month follow-up, during which their obstetrical events, including successful conception of pregnancy after a sterile period, were recorded. The between-groups comparison was quantified by calculating a pregnancy proportion ratio.

Results: Out of the 60 OHSC-SPT subjects, both tubes were blocked in 24 cases, and at least one of the tubes was patent in 36 cases. Out of these 36 cases, 7 (19.4%) spontaneous pregnancies were conceived; in three (8.3%) cases, pregnancy was conceived after intrauterine insemination (IUI) performed on male indication. The number of pregnancies observed in the HSG group (163 examined subjects) was 37 (32 spontaneous, 5 IUI-assisted) out of 153 followed-up subjects (24.4%). The pregnancy proportion ratio estimate was 1.15 (90% CI: 0.70–1.90; $p = 0.671$).

Conclusions: The novel method of OHSC-SPT has a tubal flushing effect that is non-inferior to that observed with HSG.

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1. Introduction

The incidence of tubal dysfunction as a cause of infertility has increased lately. Prior surgical interventions and infections are often found in the medical history, as well as endometriosis, the incidence of which is also on the rise [1]. For evaluating tubal patency, a variety of methods are used worldwide, including hysterosalpingography (HSG), saline infusion sonography (SIS), and laparoscopy (LSC) [2]. A common feature of these methods is the injection of a fluid through the tubes and the detection of its flow. In cases where the tubes are only blocked by a moderate amount of detritus or a loose “plug”, there is a chance for the tubes to be reopened by the injected fluid. Referred to as the tubal flushing effect, this phenomenon has been described in relation to hysterosalpingography using oil-soluble contrast media [3]. After performing the examination for the evaluation of tubal patency in patients with an

infertile period in their recent history, spontaneous pregnancies were observed more often than expected.

The tubal flushing effect may also manifest itself upon selective perturbation via office hysteroscopy for the assessment of tubal patency [4]. Compared to other, non-selective procedures (HSG, SIS, LSC) [5], the selective nature of the method may lead to a more prominent effect and result in Selective Tubal Reopening (eSTeR).

In this study, obstetrical outcomes of patients who underwent selective perturbation via office hysteroscopy were monitored. By quantifying the frequency of subsequent pregnancy, the effects of the novel method were compared to those of hysterosalpingography.

2. Materials and methods

Between January 2013 and May 2014, selective perturbation via office hysteroscopy (OHSC-SPT) was performed on patients as part of their infertility workup. Infertility was defined as one year (six months over 35 years of age) of unprotected intercourse without conceiving pregnancy. In all cases partners examination was performed. All OHSC-SPT examinations were carried out in an

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Table 1

	OHSC-SPT group	HSG group
Initially examined (n)	60	163
At least one patent tube (n)	36	153
Age (years; mean [SD])	33.1 [3.26]	32.7 [4.72]
Pregnancies within 12 months (n [%])	10 [27.8]	37 [24.2]

outpatient setting at the Department of Obstetrics and Gynecology, University of Debrecen Clinical Center, Hungary. Written informed consent was obtained from patients. The procedure was performed between the 5th and 10th postmenstrual days to ensure optimum visibility conditions. No anesthesia was used [6]. During Office Hysteroscopy guided selective chromopertubation (OHSC-SPT) evaluation of uterine cavity performed, followed by evaluating tubal patency using transparent plastic catheter. Method previously described and compared to the gold-standard laparoscopic procedure [4]. Patients with negative hysteroscopic findings and with at least one patent tube were enrolled for follow-up. Pregnancies verified by sonography were recorded over the 12 months following the examination. The end point was defined as clinical pregnancy, detection of a viable embryo by sonography, and quantified as the proportion of subjects reaching a positive end point.

A reference group was comprised of patients who underwent HSG in Kenézy Hospital, Debrecen, Hungary, in the same period and on the same indication, using water-soluble contrast media. Inclusion and evaluation criteria and procedures were identical to those for the OHSC-SPT group. The end point was the same as in OHSC-SPT group, clinical pregnancy detected by sonography. Pregnancy rates of both groups were compared.

The follow-up groups were described using appropriate summary statistics and compared in terms of positive end point frequency by estimating the proportion ratio with a 90% confidence interval (CI) and Fisher's exact p-value. Equivalence was defined as the inclusion of the CI within the range 0.70–1.43.

3. Results

Hysteroscopic examination was performed on 60 patients; HSG was performed on 163 patients. The number of subjects qualifying for follow-up in each group, their demographic characteristics, and outcomes are summarized in Table 1. Patients were similar in terms of age. Out of the 10 pregnancies in the OHSC-SPT group, seven were conceived spontaneously, and three required intrauterine insemination (IUI) without stimulation, due to the presence of a male indication, while the 37 pregnancies in the HSG group were composed of 32 spontaneous and 5 IUI-assisted conceptions. The pregnancy proportion ratio (OHSC-SPT versus HSG) was estimated to be 1.15 (90% CI: 0.70–1.90; $p = 0.671$), satisfying the equivalence criterion at the low end but exceeding the range at the high end. Pregnancies conceived during the follow-up period resulted in seven spontaneous deliveries and three cesarean sections in the OHSC-SPT group.

4. Discussion

Evaluating tubal patency is cornerstone of infertility work-up in identifying the optimum therapeutic approach [2]. As a side-effect of patency tests, tubal flushing has been described as a therapeutic impact [3]. Due to this effect, a rise in spontaneous conception can be observed after the diagnostic procedure. The emerging use of OHSC-SPT has created a need to find out about the extent to which this beneficial side-effect exists with this new method of tubal tests.

A tubal flushing effect associated with OHSC-SPT was observed on our sample of patients with a history of infertility. The extent of the effect was comparable with that seen in a parallel sample of HSG recipients, with the non-inferiority criterion satisfied, and an indication that a potential existence of superiority in terms of frequency of subsequent pregnancy cannot be ruled out.

Because the patient groups were not randomized but convenience sampled from two different health care provider institutes, the issue of selection bias arises. The university department where OHSC-SPT took place is part of one of four medical universities in Hungary, with a service area comprised mostly of the city of Debrecen and its surrounding county areas, inhabited by about 133,000 females aged 15–49 [7]. The hospital hosting the HSG arm of the study is also located in Debrecen, serves the same geographic area, and provides a similar obstetrics and gynecology service profile complete from pre-pregnancy to post-partum care. The two providers are freely selectable based on patients' individual preference; the choice is typically down to personal doctor-patient relations. The infertility workup protocols are required by nationwide guideline regulations to be identical, and include a gynecological examination, ultrasound study, andrological evaluation of the partner, and tubal patency assessment. In summary, there is no obvious systematic difference between the source populations at the two study sites to stand as a strong candidate to introduce selection bias. However, the findings of this first-exploration research should be corroborated by more substantial evidence from a randomized study before final conclusions can be made.

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