Title:

Lipiodol flush under ultrasound-guidance in Australia

Short title:

Pregnancy following Lipiodol flush with HyCoSy

Authorship:

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Abstract

Background:

Lipiodol tubal flushing is offered to select subfertile women primarily to confirm tubal patency and to increase pregnancy rates.

Aims:

To investigate the safety of HyCoSy using Lipiodol flush (through frequency of adverse events and mean recalled pain score) and secondarily to quantify pregnancy rates.

Materials and Methods:

Retrospective observational Phase 1 study of subfertile women in three centres across Australia between June 2017 to June 2019. Cases were identified from medical records, and women telephoned to assess adverse outcomes, procedure tolerability and confirm pregnancy outcomes within 6 months from procedure.

Results:

A total of 325 cases were identified. 14 were excluded due to incomplete or abandoned procedure 32 were lost to follow-up, leaving 279 for analysis. Fourteen women (5% overall) experienced mild vasovagal reactions, with one case of infection and no reports of anaphylaxis or allergy. There were 141 conceptions reported (51%) within 6 months after Lipiodol flush, and an ongoing pregnancy in 43% (119) of women. For women with ongoing pregnancies, 55% (78/119) conceived spontaneously, and 45% (63/119) via ART. Mean recalled pain score was 5.7 (SD 3.2; range 0-10) at a single site.

Conclusions:

This Phase 1 study has indicated that Lipiodol flush using HyCoSy may be a safe and efficacious alternative to HSG in the workup for infertility. The low adverse effect profile observed in this study coupled with a substantial ongoing pregnancy rate indicate that further investigation of Lipiodol under HyCoSy is warranted.

Introduction:

Infertility, the inability to conceive after 1 year of unprotected intercourse¹, affects between 8-12% of couples worldwide¹. The assessment of tubal patency under imaging is a necessary step in the investigation and treatment of infertility². This can occur under radiologic guidance, referred to as hysterosalpingography (HSG), or under ultrasound guidance called hysterosalpingo contrast sonography (HyCoSy). Although a diagnostic procedure, several studies have shown improved pregnancy rates directly following HSG and HyCoSy, suggesting a therapeutic effect^{1,3,4}. In order to ascertain tubal patency and uterine cavity shape, contrast media is injected via the cervix. The contrast media typically used is iodinated water (WSCM) however oil soluble contrast media (OSCM) such as Lipiodol has been used historically. Due to concerns regarding cost, allergic reactions, rare but clinically significant adverse events such as oil embolus as well as ease of imaging, OSCM fell out of favour and was replaced by WSCM⁵⁻⁷. More recently, the use of OSCM in HSG has been shown to be associated with increased conception compared with WSCM^{3,4,8} sparking a renewed interest in its use and safety profile, particularly in the outpatient setting.

The most commonly used OSCM is Lipiodol, which is comprised of ethyl esters of fatty acids of poppy seed oil combined with iodine⁵. Prior to fluoroscopic imaging, when only static x-ray images were obtained, the potential for intravasation of oil based media resulting in allergic reactions, anaphylaxis, pulmonary or cerebral embolus or long-term lipogranuloma formation was a significant concern and resulted in several reports of death⁸. Whilst no deaths have been reported since the introduction of fluoroscopic imaging in 1967, the use of WSCM was preferred in HSG as the lower viscosity of water based media allowed for more rapid visualization of tubal patency leading to decreased radiation dose⁹. Given the nature of HyCoSy (real-time sonography) time limitation is less relevant as radiation is avoided and the use of OSCM is more acceptable. Currently however, there is no existing literature reporting on OSCM under USS guided flush with regard to safety or fertility impact.

HyCoSy with OSCM is important to investigate as HyCoSy is emerging as the first-line diagnostic test for determining tubal patency given it eliminates radiation exposure, is quicker, more economic¹⁰ and tolerable when compared to HSG⁴. Importantly, it is as accurate as HSG in terms of establishing tubal patency^{8,9}. Additional benefits of HyCoSy include the three dimensional and ultrasonographic imaging of the intrauterine cavity allowing better detection of endometrial polyps, submucosal fibroids, as well as antral follicle counts, hydrosalpinges and abnormal ovaries¹⁰.

This Phase 1 retrospective observational study is the first step in investigating the use of Lipiodol in HyCoSy as both a therapeutic and diagnostic investigation for the assessment of infertility. As such we aimed to assess the safety and tolerability of HyCoSy using Lipiodol flush by quantifying rates of expected adverse events referenced in the literature for fluoroscopic Lipiodol HSG including vasovagal reactions, infections, allergic reactions or anaphylaxis as well as pain score to ascertain overall procedure tolerability. Secondly we aimed to quantify pregnancy rates (spontaneous conception or assisted reproductive technology) within 6 months following the procedure.

Materials and Methods

This was a retrospective observational study with the primary outcome being the safety and tolerability of Lipiodol flush. This study was approved by the St John of God Health Care (SJGHC) Human Research Ethics Committee, approval number 1319.

Medical records were audited to identify cases and women were telephoned to confirm participation consent, gynaecological history, the occurrence of adverse events (vasovagal reactions, infection, allergic reaction or anaphylaxis), perceived discomfort (numerical rating scale with 0-1 categorised as “no pain” and 7-10 “severe pain”). as well as subsequent pregnancy within 6 months of procedure.

The participants were women with unexplained subfertility or endometriosis referred for Lipiodol tubal flush via ultrasound guidance in Western Australia, South Australia and Victoria between 1 October 2016 and 1 June 2019. All participants were required to have first undergone hysterosalpingography with water-based contrast to confirm tubal patency. Women were excluded if they had bilateral fallopian tubal occlusion, the cervix was inaccessible for

cannulation or the procedure was abandoned due to venous intravasation (as was the case for 2 women).

Lipiodol flush was performed between days 5-10 of the menstrual cycle. Women were required to produce a negative pregnancy test beforehand and to undergo a transvaginal ultrasound examination to exclude any significant pelvic pathology. All women were instructed to have standard dosing of analgesics (paracetamol 1 g and/or ibuprofen 400 mg) prior to the procedure. The cervix was cannulated via speculum examination in lithotomy positioning, with a balloon catheter (Rocket HSG, Rocket Medical, Watford, England), and balloon inflated within the endometrial cavity. Under ultrasound guidance, warmed (37 degree water bath) Lipiodol was hand injected with contrast visualised distending the endometrial cavity and each fallopian tube. At all three sites this procedure was carried out by a subspecialist radiologist or obstetrician with simultaneous sonographer scanning. This procedure occurred only with Lipiodol, with the tubal patency being assessed at a prior procedure (within the same visit in some instances) with HyCoSy or HSG using water based contrast media such as ExemFoam. Similar to Johnson (2004)⁵ 10mL of Lipiodol was instilled, and peritoneal spill of contrast was demonstrated.

Data were analysed using SPSS version 24 (IBM, Armonk, NY, USA), with descriptive statistics reported.

Results

325 women with subfertility were referred for Lipiodol tubal flush during the study period (188 to O+G Adelaide in South Australia, 86 to Western Ultrasound for Women in Western Australia and 51 to Monash Ultrasound for Women in Victoria). 14 were excluded as the procedure was abandoned or incomplete; 2 (0.6%) had venous intravasation during HyCoSy using WSCM before starting the Lipiodol flush, the cervix was unable to be cannulated in one case and nine women had other pathology identified on preceding flush with WSCM; 7 had an endometrial polyp, 1 had a submusocal fibroid and 1 had hydrosalpinx. 311 women underwent Lipiodol flush, 279 were analysed as two participants declined to participate in follow-up and 30 were lost-to-follow-up (Figure 1).

Median age was 35 years (range 24-47; SD 5.85) and the median duration of unprotected intercourse at the time of Lipiodol flush was 26 months (range 4-94, IQR 12). 49% of the

women were nulligravidae, 81% were nulliparous and the remaining 19% were multiparous (Table 1).

Overall 14 women (5%) recalled mild vasovagal reactions and infection occurred in 1 woman. Importantly, there were no reported allergic or anaphylactic reactions. Recalled pain score was only recorded at one site (Western Ultrasound for Women); mean recalled pain score was 5.3 (SD 3.2), with a high variability of 0-10.

In terms of subsequent pregnancy, there was a 51% (141/279) conception rate, with two women conceiving twice within the six-month follow up time period. In the six-month follow up period, 20 miscarriages (14% miscarriage rate) and 2 ectopic pregnancies (1.4%) were reported. There were 119 (43% of women) ongoing pregnancies at 6 months (138 singleton, 5 dichorionic twin pregnancies and 2 monochorionic twin pregnancies). Of the total conceptions, 78 were conceived spontaneously, and 63 conceptions occurred after artificial reproductive technology (ART) (Table 2).

Discussion:

Our study supports the prospect of Lipiodol flush under ultrasound being a safe and effective alternative to HSG. No serious side effects were reported and 96% of procedures were successfully completed, with the majority of cases that were excluded being due to findings in the preceding HyCoSy with WSCM and one abandoned due to inability to cannulate the cervical canal (nulliparous woman).

There was substantial variability in pain scores, however women consistently described it as a short intense cramping pain during the inflation of the balloon catheter and initial injection of contrast. This supports the theory of pain resulting from expansion of the uterine cavity and tubal spasm¹². However, of note a limitation of our study was that it recorded recalled pain scores retrospectively. Given the Lipiodol HyCoSy was conducted by different operators in different centres adherence to the outlined methodology may have been variable. Dreyer et al reported approximately 40% (81/199) of women in the oil arm rated their pain >5 on the Visual Analogue Scale and women in this group experienced higher ongoing pregnancy rates when compared to the ≤5 group (49.4% vs 28.8%)¹³. This suggests that the generation of pressure against an obstruction and subsequent flushing may contribute to pain and it may be a prognostic indicator following Lipiodol flush.

Notably, we did not observe any instances of granuloma formation or Lipiodol intravasation which are commonly cited risks resulting in reluctance from clinicians for its widespread use. Intravasation in this context implies contrast flow into the draining lymphatic or myometrial vessels with subsequent draining into the pelvic veins¹⁴. Wang et al (2018) reported an incidence of 13% under 4D HyCoSy imaging where intravasation can be identified as either cloud-like diffuse hyperechogenicity within the myometrium or cord net-like hyperechogenicity around the uterus extending into surrounding tissue without specific direction with venous plexus intravasation¹⁵. These prevalence figures reference WSCM specifically however intravasation appears to occur more frequently with OSCM¹⁵. Intravasation with WSCM can lead to complications such as fever, infection and pain but when it occurs with OSCM there is added risk of cerebral or pulmonary oil embolism. There are several published case reports where this has occurred; in 1990, there was a case of contrast intravasation and cerebral embolism in Israel leading to coma¹⁶. In 1991, OSCM intravasation led to pulmonary oedema and shock in a 25 year old patient in Japan¹⁷.

Several factors built into our procedure protocol were intended to mitigate the risk of intravasation. Firstly, we required women to have undergone initial HSG with water-based contrast allowing practitioners to ensure tubal patency and identify intravasation with a safer contrast, before Lipiodol flush. Two women had Lipiodol flush cancelled as intravasation was noted with WSCM immediately prior. Additionally, women underwent Lipiodol flush between day 5-10 of their menstrual cycle. Wang et al reported that endometrial thickness and days after menstruation were significantly associated with venous intravasation ($P < 0.05$) with lowest incidence in days 5-7 after menstrual cycle¹⁵.

So et al (2017) reported that 25% of women develop transient subclinical hypothyroidism following Lipiodol HSG, compared with 10% of women following WSCM HSG¹⁹. Monitoring thyroid function post-Lipiodol may be warranted in order to optimise fertility and ensure safety during subsequent pregnancy. We have added pre and post Lipiodol flush thyroid function tests and assessment of urine excreted iodine to our routine practice protocol and are collating results for a follow up study.

With regard to fertility effect, the rate of ongoing pregnancy at six months following Lipiodol flush (43%) was similar to that reported in larger trials under HSG, such as the H2Oil trial

(39.7% in oil group vs 29.1% in water group)¹³, FLUSH study (48% pregnancy rate in women with endometriosis, 33.3% in women with unexplained subfertility)⁵ and Court et al (44.7% clinical pregnancy rate)¹¹. As we did not compare to a control group, a limitation of this study is that pregnancy rates cannot be statistically compared to that of HSG or WSCM HyCoSy.

However literature supports a higher fertility rate when using OSCM compared to either no intervention or tubal flushing with WSCM. A 2018 network meta-analysis assessing 14 randomised control trials showed that tubal flushing with OSCM resulted in more clinical pregnancies within 6 months and subsequent live births, compared to tubal flushing with WSCM (OR 1.67; 95% CI 1.38-2.03) and compared to no intervention (OR 2.28; 95% CI 1.50-3.47)³. Systematic analysis of four RCTs with a total population of 293 women comparing flushing with both WSCM and OSCM to tubal flushing with WSCM alone found significantly more women who underwent both flushes had ongoing pregnancy at 6 months compared to those with WSCM alone (OR 1.69; 95% CI 1.02, 2.81)²³⁻²⁶.

Of note, all these studies assess the efficacy of OSCM under fluoroscopic guidance. To our knowledge, there are no reports of pregnancy rates after OSCM flush under ultrasound guidance.

The precise mode of action of Lipiodol remains unclear. One theory is that endometrial bathing results in an upregulation of uterine natural killer cells which are likely to be important in implantation receptivity. This may explain the apparent increased benefit of Lipiodol in women with endometriosis and is consistent with the observation by Court et al where Lipiodol bathed the uterus without entering the fallopian tube and still resulted in fertility improvement^{5,11}. This theory has been used to assess whether Lipiodol improves the efficacy of IVF procedures in 70 participants in the IVF LUBE study, with lower rates of IVF pregnancy found in the Lipiodol group (36% vs 49% IVF; $p=0.43$)²⁷. In our study, six of the twenty women who conceived did so following ART. Larger randomised studies assessing the fertility enhancing effect of Lipiodol flush on women undergoing subsequent ART are necessary.

The H2Oil study contends that the increased fertility effect lasting over many cycles may indicate a tubal flushing effect resulting in a removal of debris from the fallopian tube^{11,13}. In our study, all pregnancies were reported in the first 4 months post procedure, a similar time

frame to that reported in the current literature. This may support the benefit of flushing as opposed to the endometrial effect as only three of the twenty women who conceived did so in the first month.

This Phase 1 study has indicated that Lipiodol flush using HyCoSy may be a safe and efficacious alternative to HSG in the workup for infertility. The low adverse effect profile observed in this study coupled with a substantial ongoing pregnancy rate indicate that further investigation of Lipiodol under HyCoSy is warranted. There is a need for high quality randomized control trials to determine if Lipiodol flush under HyCoSy is of fertility benefit when compared to either no treatment or HSG and if it can safely be performed in the outpatient setting.

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Table 1: Patient characteristics

Characteristics	
Median age	35.4 years (24-47)
Mean length of subfertility	26 months (4-94 months)
Primigravidas	49%
Multigravidas	51%
Multiparous	19%

Table 2: Outcomes

Primary Outcomes		Secondary Outcomes	
Vasovagal reactions	14 (5%)	Conception	141 (51%)
Infection	1 (0.003%)	Ongoing pregnancy at 6 months	119 (43%)
Allergic reactions	0	Spontaneous conception	78
Anaphylaxis	0	Conception via ART	63
Mean recalled pain score/10	5.3 (SD 3.2, range 0-10)		

Figure 1: Patient follow up

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