Salpingectomy versus neosalpingostomy in women with hydrosalpinx: a prospective cohort study with long-term follow-up

li yan¹, Chenfeng Zhu², Guiling Liang¹, chuqing he¹, liang yan¹, xiaoya zhao¹, Xiaoqing He¹, Yiqin Zhang¹, Ben Mol³, Jian Zhang¹, and Judith Huirne⁴

¹International Peace Maternity and Child Health Hospital, School of Medicine, Shanghai Jiao Tong University

² International Peace Maternity and Child Health Hospital, School of Medicine, Shanghai Jiao Tong University

³Monash University Medical Centre

⁴Amsterdam Reproduction and Development Research institute, Amsterdam University Medical Centre, location AMC and VUmc

March 30, 2022

Abstract

Objective: To compare postoperative reproductive outcomes between salpingectomy and neosalpingostomy for bilateral severe hydrosalpinges. Design: Single center, prospective cohort study. Setting: A hospital affiliated to a medical college in China. Population: Women aged 20 to 45 years old, diagnosed with bilateral hydrosalpinges and scheduled for surgery were initial eligibility criteria. Women with previous tubal surgery or tubal pregnancy, no fertility intention, or no confirmation of severe bilateral hydrosalpinges during surgery were excluded. Methods: Bilateral salpingectomy or neosalpingostomy was performed based on a shared decision approach. Main outcome measures: The primary outcome was the cumulative livebirth rate. Secondary outcomes included time to first live birth, biochemical pregnancy, clinical miscarriage, ectopic pregnancy, mode of conception, and gestational age at delivery. Results: A total of 113 women were involved in the analysis. When the result of In Vitro Fertilization (IVF) in the neosalpingostomy group was incorporated, salpingectomy resulted in a higher cumulative livebirth rate (85.3% vs 76.0%, hazard ratio of the whole survival curve = 2.18, 95% CI 1.37 - 3.45), a lower risk of ectopic pregnancy (1.8% vs 20.7%, risk ratio = 0.07, 95% CI 0.01 - 0.57), and a shorter time to live birth than neosalpingostomy. 16/58 (27.6%) women in the neosalpingostomy group had a live birth via natural conception, compared to 0/55 (0.0%) in the salpingectomy group. Conclusions:Salpingectomy for bilateral severe hydrosalpinges resulted in a higher cumulative livebirth rate and a lower risk of ectopic pregnancy. However, neosalpingostomy can offer certain option for women to conceive naturally without IVF treatment.

Introduction

Hydrosalpinges is a severe form of tubal disease, referred to as a fluid-filled distention of the fallopian tube in the presence of a distal tubal occlusion. It accounts for 10-30% of tubal diseases, which forms 25-35% of female subfertility.¹⁻³

Hydrosalpinges may be diagnosed with hysterosalpingography, laparoscopy or ultrasonography.^{4, 5} The presence of a hydrosalpinges has a negative effect on pregnancy rate in women who undergo In Vitro Fertilization (IVF),⁶ however, the exact mechanism has not been fully confirmed. It is hypothesized that the leakage of fluid into the uterine cavity may disturb the receptivity of the endometrium, alternatively the fluid may also be embryotoxicy, for example lipophilic factors are reported to be detrimental to embryo development.^{7, 8} In the last decades, IVF has become more and more implemented in women with bilateral hydrosalpinges. Salpingectomy before IVF is assumed to increase clinical pregnancy rates.^{3, 9, 10} However, in the cases of bilateral disease, a bilateral salpingectomy results in permanent sterility while a neosalpingostomy is a tuba-sparing surgery that provides the option of future natural conception for more than one cycle. As for women who would like to preserve their fallopian tubes and the ability for natural conception, a salpingostomy could be performed to restore the anatomy.

Previous studies reported a pooled livebirth rate of 25% (95% CI: 22 - 28%) through natural conception after neosalpingostomy and ongoing pregnancy rate of 55.8% (24/43) via one IVF/ICSI (Intra-Cytoplasmic Sperm Injection) treatment cycle (including embryo-transfer of cryopreserved embryos) after salpingectomy.^{11, 12}Intrauterine pregnancy rates after neosalpingostomy for mild hydrosalpinges range from 58% to 77% and for severe disease from 0% to 22%.¹³ The variation can be explained by variations in the indicators for severity of hydrosalpinges, variations in outcomes' definition and variations in the follow-up.

None of the previous studies compared the cumulative livebirth rate between salpingectomy and neosalpingostomy, also prognostic factors to select women who will benefit from salpingectomy or neosalpingostomy are lacking. To compare long term reproductive outcomes between salpingectomy and neosalpingostomy, we performed a prospective cohort study in women with subfertility with bilateral severe hydrosalpinges.

Methods

Study Design

We performed a single-center prospective cohort study in the International Peace Maternity and Child Health Hospital affiliated to School of Medicine, Shanghai Jiao Tong University, Shanghai, China. This study was approved by the Ethics Committee of the International Peace Maternity and Child Health Hospital in Shanghai, China (GKLW201534). All patients provided informed consent, and all data have been anonymized.

Participants

We included women aged 20 to 45 years old, diagnosed with tubal subfertility with bilateral hydrosalpinges at hysterosalpingography, and scheduled for surgery between tubal pregnancy, or those without fertility intention were excluded. Women were not eligible if the condition of the tubes was not confirmed to reach a severe degree according to the intraoperative evaluation. Thus, only women with confirmed bilateral severe hydrosalpinges were enrolled.

Participants consented to the planned surgery after extensive counseling concerning the pros and cons of two types of surgery preoperatively. Ultimately, the choice for treatment was based on a shared decision approach. If patients did not want to accept the chance of ectopic pregnancy (EP) and were willing to undergo IVF, a salpingectomy was advised. Neosalpingostomy was suggested if one had a strong desire to conserve the fallopian tube or was unwilling to accept postoperative IVF treatment. In all other cases it was up to the patient to decide what type of treatment they preferred.

After registration of baseline characteristics, including demographic characteristics (age and birthplace), reproductive history (parity, miscarriage, abortion), known gynecological disorders (polycystic ovary syndrome [PCOS]),¹⁴ and semen quality of male partners according to the Hull & Rutherford (H&R) classification of infertility,¹⁵ women were followed up on an annual basis until July 2020 for the occurrence of live birth.

Interventions

Preoperative hysterosalpingography (HSG) and an intraoperative tubal scoring system at laparoscopy were used to evaluate the severity of bilateral tubal lesions. Hydrosalpinx was diagnosed when a dilated, convoluted tubular structure was seen during HSG and a lack of diffusion of contrast medium into the abdomen (Figure S1).^{16, 17}The H&R classification (2002) was used to assign subfertile women into three categories based on the severity of pelvic findings at laparoscopy or laparotomy.¹⁵ According to H&R classification, severe was rated in the cases of bilateral severe tubal damage, extensive tubal fibrosis, tubal distension > 1.5 cm, abnormal

mucosal appearance, bilateral occlusion, and extensive dense adhesions (Table S1). All scores were evaluated by two experienced gynecologists during the operation independently. If there was any disagreement, another independent chief physician made an assessment based on the stored video after the surgery.

All women underwent surgery within 3 to 7 days after menstruation. Surgical procedures were performed using a 7mm hysteroscope (Shen Da) and 30-degree 10mm laparoscope (Stryker, American). In both groups, women received general endotracheal anesthesia in lithotomy and Trendelenburg position. Artificial pneumoperitoneum and surgery approaches of laparoscope and hysteroscope were established according to a routine protocol, followed by a detailed examination of the uterus, ovaries, pelvis and detailed evaluation of hydrosalpinges as described above.

Salpingectomy

After dissection of adhesions if presence, the mesosalpinx was cut, using an ultrasonic scalpel, just below the fallopian tube in order to prevent injury of the blood supply to the ipsilateral ovary. After dissection, the fallopian tube was resected close to the interstitial part (Figure S2-A).

Neosalpingostomy

The first step was the injection of methylene blue-saline solution via the hysteroscope. By laparoscopy, a cross-cut was made, using cold scissors, at the thinnest part of the blind-ending fallopian tube, and gently extended up to 1.5 cm in order to form 4 fimbrial flaps. The mucosa was evertedly sutured to the serosal layer with a 4-0 braided absorbable suture and diluted methylene blue was injected in order to access the tubal patency. During the surgical procedure, we tried to be as gentle as possible and continuously flushed wounds with saline in order to reduce unnecessary damage to fallopian tubes (Figure S2-B).

In addition to salpingectomy and neosalpingostomy, co-interventions were allowed including adhesiolysis, cystectomy of ovarian cyst or Mullerian duct cysts, myomectomy, coagulation of endometriosis and resection of endometrial polyps.

A video of the procedure was recorded and stored. Per-operative findings were registered instantly after the surgery, including the presence of Fitz-Hugh-Curtis Syndrome (FHCS),¹⁸ leiomyoma, benign ovarian cyst (including mature cystic teratomas, epithelial (serous or mucinous) cystadenoma, Mullerian duct cyst, endometriosis (staged by revised-AFS classification of endometriosis),¹⁹adenomyoma, and endometrial polyps. All intra- or postoperative complications were registered.

Outcomes and Measures

The primary outcome was cumulative livebirth rate, defined as the birth rate of the first living neonate during the follow-up. Secondary outcome measures were time to first live birth, which was from the date of the first tubal surgery to the date of the first delivery of a live neonate; biochemical pregnancy, defined as a positive pregnancy test or serum HCG-level greater than 5 IU/L; clinical miscarriage, defined as a spontaneous pregnancy loss occurs after a confirmed intrauterine pregnancy (by ultrasound or by histology); ectopic pregnancy, defined as an embryo implanted outside the uterine cavity; and mode of conception, including natural conception or IVF. In case of live birth, we reported gestational age at delivery. Cumulative livebirth rate by natural conception was also calculated in the neosalpingostomy group.

Sample size calculation

We calculated sample-size by two independent proportions. Using the estimated livebirth rate of 25% with neosalpingostomy and 53% with salpingectomy based on previous literature, and assuming an alpha level of 0.05 for two-sided test, we calculated that a sample of 88 cases who underwent therapy would result in 80% power (1:1 ratio). The sample size was increased to 110 (two groups of 55) to allow for a 20% rate of loss to follow-up over the long time period.

Statistical Analysis

All data were analyzed by IBM SPSS Version 21.0 (IBM, Armonk, NY, USA), and the survival package in R was used for drawing plots of survival analysis. Continuous variables were compared using Student t-test and Mann-Whitney's U test for normally and non-normally distributed data, respectively. Categorical variables were analyzed using the Pearson chi-squared ($\chi 2$) or Fisher exact probability test. The Kaplan-Meier method was used to compute cumulative livebirth rate curves (1-survival function) between the two groups, and the differences were compared using a log-rank test. The date of entry for each patient was the date of surgery. The last day of analysis was the date of the first delivery or the last follow-up visit in women who remained non-livebirth. Women who had no event at the end of the analysis were recorded censoring data. We processed a Cox proportional hazards regression model with potential variables in an enter fashion to identify predictors of successful live birth. The magnitude of statistical significance was expressed with adjusted hazard ratios (AHR) and 95% confidence intervals (CI). Two-tailed P-values < 0.05 were considered statistically significant.

Initial analysis was by intention-to-treat (ITT). We also performed a per-protocol (PP) analysis in which we ruled out 8 patients who had additional bilateral salpingectomy for recurrent hydrosalpinges or for EP.

Results

Participants

During the study period, we screened 312 women, of which 199 did not meet our selection criteria and were excluded; 34 women had previous tubal surgery, 16 had previous EP, 17 had no fertility intention and in 132 women severity could not be confirmed during surgery. In total 113 women were followed up until July 2020 for the occurrence of live birth, 19 women were lost to follow-up; 8 in the salpingectomy group (4 at 2^{nd} year, 3 at 3^{rd} year, 1 at 4^{th} year) and 11 in the neosalpingostomy group (2 at 1^{st} year, 5 at 2^{nd} year, 3 at 3^{rd} year, 1 at 4^{th} year) (Figure 1).

Among 113 women involved, 55 in the salpingectomy group and 58 in the neosalpingostomy group were included in the ITT analysis, eventually 78 women had a live birth (16 through natural conception and 62 through IVF). In the neosalpingostomy group, 15 women had additional salpingectomy for recurrent hydrosalpinges or for EP, among whom 8 had additional bilateral salpingectomy and were ruled out in the PP analysis.

Baseline Characteristics

The groups were comparable regarding age, birth place, previous miscarriage, previous abortion, PCOS, and semen analysis (Table 1). Operative findings including Fitz-Hugh-Curtis Syndrome (FHCS), leiomyoma, benign ovarian cyst, Mullerian duct cyst, endometriosis, adenomyoma, and endometrial polyps were also comparable between the two groups (Table S2). There were no conversions to laparotomy or any complications such as bladder or bowel injuries.

Follow up

All patients were followed up yearly until July 2020 for the occurrence of live birth. The median period of follow-up was 27 months, with the shortest of 10.35 months and the longest up to 182 months. In the salpingectomy group, 55 women underwent IVF, of which 50 within 12 months. In the neosalpingostomy group, 25 women underwent IVF, of which 4 within 12 months.

Reproductive outcomes

In total, 113 women were included in the ITT analysis, 42 out of 55 women in the salpingectomy group conceived successfully after IVF treatment, and 21 out of 58 women had a live birth after the initial intended neosalpingostomy without any additional surgery (12 conceived naturally, and 9 through IVF). In the neosalpingostomy group, 15 women had additional salpingectomy (7 unilateral, and 8 bilateral) for recurrent hydrosalpinges (confirmed by HSG) or for ectopic pregnancy. These 15 women had live births successfully (4 conceived naturally, and 11 through IVF).

According to the ITT analyses, the cumulative livebirth rate was significantly higher in salpingectomy group than in the neosalpingostomy group (85.3% vs 76.0%, hazard ratio of the whole survival curve = 2.18, 95% CI 1.37 - 3.45). Compared to neosalpingostomy, the mean time to first live birth in salpingectomy group was shorter (19 [14,27] vs 36 [17,76] months, P = 0.001) and the risk of an ectopic pregnancy was lower (1.8% vs 20.7%, risk ratio = 0.07, 95% CI 0.01 - 0.57). All observed miscarriages were early clinical pregnancy losses (before gestational age of 12 weeks). No statistically significant differences regarding biochemical pregnancy rate and the overall livebirth rate were higher in the salpingectomy group, similar results were obtained in both groups in PP analysis. This can be explained by the fact that 8 women with additional bilateral salpingectomy, excluded in PP analysis, all had live births successfully after IVF treatment (Table 2, Table S3).

With the Kaplan-Meier analysis, the cumulative livebirth rate in salpingectomy group reached a plateau at 85.30% from the 7th year onwards, while in the neosalpingostomy group, five women had a live birth through IVF after 7 years of follow-up, of which three received additional bilateral salpingectomy (Figure 2-A). In neosalpingostomy group, 27.6% (16/58) of women had the first live birth through natural conception (12/58 conceived naturally without additional surgery), compared with 0% (0/55) in the salpingostomy group, and the mean time to live birth in this group was 23 [15,44] months. The trend of cumulative livebirth rate through natural conception in neosalpingostomy group is shown in Figure 2-B.

Subgroup analysis

Stratified by age

The cumulative livebirth rate stratified by age between the groups was shown in Figure 2. In women aged 20 - 33 years old, the cumulative livebirth rate of the salpingectomy group was significantly higher than the neosalpingostomy group (Figure 2-C, pj0.001), while in women aged 34 - 45 years old, the difference did not reach statistical significance (Figure 2-D, p = 0.373).

Cox proportional hazards analysis

After adjustment for confounding factors including age, previous abortion history, benign ovarian cyst, management and endometriosis, cox proportional hazards analysis revealed that the patients' age from 20 to 33 years old (AHR = 2.24, 95% CI 1.13 - 4.44), the history of previous abortion (AHR = 1.7, 95% CI 1.05 - 2.82), salpingectomy (AHR = 2.04, 95% CI 1.24 - 3.34), and a combined myomectomy for concurrent leiomyoma (AHR = 2.55, 95% CI 1.22 - 5.33) were positively correlated to live birth (Table S4).

Discussion

Our study demonstrates that in subfertile women with confirmed bilateral severe hydrosalpinges, salpingectomy compared to neosalpingostomy resulted in higher cumulative livebirth rate, shorter time to first live birth and lower risk of EP, when also the result of additional IVF in both groups are taken into account. There were no natural conceptions after salpingectomy, while neosalpingostomy resulted in a 20.7% (12/58) cumulative natural conception rates leading to live birth without any additional surgical interventions. This may be relevant for women in the higher age group, since IVF is not always an option. In the age group between 34 and 45 years we could not find statistically significant differences between two groups. However, our sample size for this subgroup may not have been sufficient. Future studies are needed to confirm this.

Comparison to other literature

The livebirth rate through natural conception in our neosalpingostomy group of 27.6%, this is in line with previous publications that reported ranges between 20% to 26%.^{11, 20-23} The number of the overall cumulative livebirth rate in our neosalpingostomy group of 76% is promising; however, this includes also the results of additional second surgeries and IVF treatments. These data are in line with the 72% (2369/3254) intra-uterine pregnancies in women with tubo-peritoneal subfertility after salpingo-ovariolysis and terminal salpingoneostomy in a very large retrospective study.²⁴ The overall cumulative livebirth rate of 85.3% after salpingectomy in our study is higher than the reported ongoing pregnancies of 55.8% (24/43).¹² Our higher

livebirth rates could be due to the very long follow-up period up to 15 years. In the neosalpingostomy group, 12/58 (20.7%) women had an EP, this is higher than the reported 10% in a systematic review¹¹ but is in line with the outcomes of two prospective cohort studies with respectively 17 and 18%.^{25, 26} In general, higher EP rates were found to be associated with positive history of pelvic inflammatory disease (PID), a bilateral procedure, perihepatic adhesions, and increasing severity of tubal damage.^{25, 27} Our study included women with bilateral severe hydrosalpinges, which may increase our EP rate to some extent, however, we could not assess the effect of potential risk factors due to the limitation of the small sample size. These prognostic factors may play a role in the patient selection for neosalpinostomy. In the salpingectomy group, the EP rate is similar to 2.13% in our study to 1.72% in Strandell A's study.²⁸

Strength and Limitations

As far as we are aware of is this the first study comparing the cumulative livebirth rate of women with bilateral severe hydrosalpinges between salpingectomy and neosalpingostomy. Well defined in- and exclusion criteria and consecutive inclusion of women reduced the risk on selection bias and reduced the effect of potential confounders. Given our strict selection criteria, caution needs to be taken by generalizing our data to other populations. The strength of our study is that we registered the fertility outcome during a very long follow-up period in a structured way. Another strength is that the severity of tubal lesions was scored by two surgeons using validated scoring systems and we included only women with severe hydrosalpinges based on this classification, excluding any confounding factors due to differences in severity score. Attention was paid to prevent any damage of the fallopian tubes or blood supply to the ovaries. It is unclear whether the carefully performed surgery by our skilled chief physicians played a role. Additionally, we also used cox regression analyses to adjust for potential confounders.

However, our study had also some limitations. First, we did not obtain the ethical approval number at the onset of our study for the reason that our hospital had not set up the Ethics Committee at that time, and we made a supplementary application and obtained the ethical approval later when it was established. Second, due to the fact that type of surgery was based on the shared medical decision-making approach, the risk on selection bias is inevitable, although this was limited when we only included women with confirmed severe bilateral hydrosalpinges during surgery, this was in line with that no major differences in baseline characteristics were found between the two groups. In the long follow-up period, the number of cases lost to follow-up was limited. The primary outcome could be assessed in 47(84%) in the salpingectomy and 47(81%) in the neosalpingostomy group. Future studies of sufficient sample size should be carried out to confirm our data and discover more predictors for successful live birth.

Clinical implications

Our study is in favor of bilateral salpingectomy compared to neosalpingostomy in women with laparoscopic confirmed severe bilateral hydrosalpinges given the higher cumulative livebirth rates and shorter time to live birth and lower chance of EP. However, after this sterilizing surgery women can only become pregnant after IVF therapy. All women should be counseled concerning the alternatives, they need to know that they have approximately a 21% chance on a live birth by natural conception without any additional second surgery. This counseling is very important in particular in women who do not wish to undergo IVF or have a high risk on morbidity during IVF for example advanced age. This should be weighed against a longer period to achieve a live birth and a higher risk on EP. Sufficient surgical skills are obligatory to perform a proper neosalpingostomy. Therefore, every team should have specialized surgeons or should refer the patient in case of intended neosalpingostomy.

Conclusions

Salpingectomy for tubal subfertility with confirmed bilateral severe hydrosalpinges results in higher cumulative livebirth rates and decreases the risk of EP. However, neosalpingostomy is the only option to achieve a live birth by natural conception that should be discussed with patients preoperatively.

Abbreviation

IVF: In Vitro Fertilization

EP: Ectopic Pregnancy

ITT: Intention-to-treat

PP: Per-protocol

Disclosure of interest

We declare that we have no financial and personal relationships with other people or organizations that can inappropriately influence our work, there is no professional or other personal interest of any nature or kind in any product, service and/or company that could be construed as influencing the position presented in, or the review of, the manuscript entitled.

Authors' contributions

Jian Zhang and Ben W. Mol conceived and designed this study; Jian Zhang, JAF Hurine and Ben W. Mol contributed to the manuscript editing and language editing; Li Yan was responsible for the data analysis and manuscript writing; Chenfeng Zhu, Guiling Liang, Chuqing He, Yan Liang, Xiaoya Zhao, Xiaoqing He and Yiqin Zhang contributed to the data collection. The final version of manuscript has been approved by all authors.

Details of ethics approval

All patients provided informed consent, and all data have been anonymized. This study was approved by the Ethics Committee of the International Peace Maternity and Child Health Hospital in Shanghai, China (approval date 2 August 2016, GKLW201534).

Funding

This work was supported by National Key Research and Development Program (grant number 2018YFC1002102) and the Shanghai Municipal Key Clinical Specialty, Shanghai, China (shslczdzk01802).

Acknowledgements

We appreciated all the participants in this study and all the staff at International Peace Maternal and Child Health Hospital for their precise data recording.

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Figure legends

Figure 1. Flow chart

Figure 2. Kaplan–Meier analysis and log-rank test for the cumulative live birth rate. 2-A. Compared cumulative live birth rate between neosalpingostomy and salpingectomy, there was a statistically significant difference between the groups ($\chi 2=11.514$, Pi0.01); 2-B. Compared cumulative live birth rate through natural conception between neosalpingostomy and salpingectomy, no live birth through natural conception happened in salpingectomy group; 2-C. In patients between 20 and 33 years old, the cumulative live birth rate was significantly higher in salpingectomy group than salpingostomy group ($\chi 2=11.551$, Pi0.001); 2-D. In patients between 34 and 45 years old, there was no statistically significant difference between two groups ($\chi 2=0.793$, P=0.373).

Supporting information

Additional supporting information may be found in the online version of this article:

Figure S1. Images on HSG

The arrows refer to dilated, convoluted tubular structures with lack of diffusion of contrast medium into the abdomen.

Figure S2. Methods of the surgery

S2-A. Method of salpingectomy, we cut the mesosalpinx just below the fallopian tube using an ultrasonic device in order to prevent injury of the blood supply to the ipsilateral ovary, and resected the fallopian tube close to the interstitial part;

S2-B. Method of neosalpingostomy, we made a cross cut at the thinnest part of the blind ending fallopian tube, gently extended up to 1.5cm in order to form 4 fimbrial flaps, and sutured the mucosa to the serosal layer.

 Table S1. Hull and Rutherford classification for tubal pelvic damage

Table S2. Surgical outcomes

Table S3. Supplemental details of comparision of reproductive outcomes between salpingectomy group and neosalpingostomy group

Table S4. Cox proportional hazards analysis

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