



Comparison of hemostatic sealants on ovarian reserve during laparoscopic ovarian cystectomy



Jun Hyeok Kang^{a,1}, Yong Seok Kim^a, San Hui Lee^{b,1}, Woo Young Kim^{a,*}

^a Department of Obstetrics & Gynecology, Kangbuk Samsung Hospital, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea

^b Department of Obstetrics & Gynecology, National Health Insurance Service Ilsan Hospital, Goyang, Republic of Korea

ARTICLE INFO

Article history:

Received 30 March 2015

Received in revised form 13 July 2015

Accepted 6 August 2015

Keywords:

Ovarian reserve
Ovarian cystectomy
Hemostatic sealant
Pathologic type
Serum AMH level

ABSTRACT

Objective: To determine whether different methods of hemostasis and pathologic subtypes would lead to significant differences regarding ovarian reserve after laparoscopic ovarian cystectomy.

Study design: Data were prospectively collected from 129 patients who underwent laparoscopic ovarian cystectomy with either a hemostatic sealant (FloSeal or TachoSil) or bipolar coagulation to achieve hemostasis. Serum anti-Müllerian hormone (AMH) levels as measured by enzyme immunoassay. Measurements were made preoperatively and at 3 months postsurgery in each group [bipolar coagulator group ($n = 43$), FloSeal group ($n = 46$), and TachoSil group ($n = 40$)].

Results: Age, BMI, parity, sociodemographic variables, and preoperative AMH levels were similar between the three groups of patients. At 3 months post-surgery, the AMH decline rate was significantly greater in the bipolar coagulation group compared with the two hemostatic sealant groups (41.2% [IQR, 16.7–52.4] vs. 15.4% [IQR, 5.2–41.9], respectively; $P = 0.003$). However, the AMH decline rates of the two hemostatic sealant groups (FloSeal and TachoSil) were not significantly different (15.4% [IQR, 7.8–44.6] vs. 15.9% [IQR, 0.7–41.1], $P = 0.962$). Also, subgroup analysis according to ovarian cyst type revealed no significant differences in the rate of serum AMH decline regardless of the hemostatic method (bipolar group, $P = 0.30$; FloSeal group, $P = 0.47$, and TachoSil group, $P = 0.79$).

Conclusion: The two hemostatic sealants (FloSeal and Tachosil) did not exhibit any significant differences regarding the preservation of ovarian reserve regardless of ovarian cyst type.

© 2015 Elsevier Ireland Ltd. All rights reserved.

Introduction

Laparoscopic ovarian cystectomy is the first-line treatment for benign ovarian tumors [1]. Although stripping the ovarian cyst wall is widely performed when treating ovarian tumors, previous studies have shown that the use of bipolar coagulation to control bleeding can cause considerable thermal damage to ovarian tissue [2–4]. Thus, the excessive use of bipolar coagulation for hemostasis is believed to injure normal ovarian follicles. For instance, some cases of premature ovarian failure have been reported after surgical management of bilateral ovarian endometriomas [5–7].

Several methods have been introduced to reduce damage to ovarian follicles, such as suture, plasma-jet vaporization, and

bipolar coagulation [8]. However, the efficacies of such methods remain somewhat controversial. We recently reported the ability of a topical hemostatic collagen, FloSeal[®] (Baxter, Zurich, Switzerland), to preserve ovarian reserve [9]. Although FloSeal is easy to handle for laparoscopic use, cases of granuloma formation after the use of FloSeal have been reported [10,11]. Therefore, it is necessary to remove all excess FloSeal by irrigation [11,12].

With the aim of identifying a safer alternative, here we investigated the suitability of TachoSil[®] (Nycomed Linz, Austria) for preserving ovarian reserve during laparoscopic ovarian cystectomy. TachoSil is an improved version of TachoComb[®] (Nycomed Linz) and TachoComb[®] H (Nycomed Linz) that is made with equine collagen, bovine thrombin, bovine aprotinin, and human fibrinogen. TachoSil works by mimicking the final steps of the natural blood clotting process, creating a fibrin clot at the surgical site to achieve hemostasis [13].

The objective of this study was to evaluate the ability of TachoSil to preserve ovarian reserve and to compare it with that of FloSeal. Specifically, we aimed to determine whether different pathologic subtypes and methods of hemostasis would lead to

* Corresponding author at: Department of Obstetrics & Gynecology, Kangbuk Samsung Hospital, Sungkyunkwan University School of Medicine, 29, Saemunan-ro, Jongno-gu, Seoul 110-746, Republic of Korea. Tel.: +82 2 2001 2001; fax: +82 2 2001 1102.

E-mail address: obgykim@gmail.com (W.Y. Kim).

¹ Both these authors contributed equally to this paper.

significant differences regarding ovarian reserve after laparoscopic ovarian cystectomy.

Materials and methods

After receiving approval from the Institutional Review Board (IRB) of Kangbuk Samsung Hospital (Seoul, Republic of Korea) and National Health Insurance Service Ilsan Hospital (Goyang, Republic of Korea), we conducted prospective, non-randomized study between December 2012 and June 2014 at two institutions (Kangbuk Samsung Hospital and National Health Insurance Service Ilsan Hospital). All subjects provided written informed consent before participation. A total of 129 patients who underwent laparoscopic ovarian cystectomy were included in the study. Inclusion criteria consisted of women aged 19–45 with regular menstrual periods (21–35 days), a maximal cyst diameter between 3 and 10 cm, and appropriate medical status for laparoscopic surgery (American Society of Anesthesiologists Physical Status classification 1 or 2). Exclusion criteria were evidence of any other endocrine disorder such as diabetes mellitus, thyroid dysfunction, hyperprolactinemia, or Cushing's syndrome; postmenopausal status; preoperative serum AMH < 1.0 ng/mL; pregnancy; or the use of any hormonal treatment in the three months before surgery [9].

Laparoscopic ovarian cystectomy was performed in the usual manner described in several texts. During laparoscopic procedure, after the entire cystic portion was separated from the ovarian cortex, a hemostatic sealant (FloSeal or TachoSil) or bipolar coagulation was applied for hemostasis. We employed a novel wet gauze technique in order to efficiently manipulate TachoSil. TachoSil sealant has two sides, a white collagen spongy side and a yellow side that is coated with fibrinogen and thrombin. Before delivering TachoSil into the intra-abdominal cavity, we applied a piece of wet gauze to the white section of the TachoSil. The gauze was cut to precisely fit the TachoSil. Then, we rolled up the yellow section of the TachoSil into the trocar and inserted the TachoSil into the intra-abdominal cavity through the single-umbilicus incision site. This technique prevents the TachoSil from being exfoliated during delivery into the intra-abdominal cavity and also avoids the crumbling of TachoSil due to contact with blood or fluid. We then carefully refolded the gauze-embedded TachoSil in the peritoneal space using atraumatic grasping forceps. After applying TachoSil to the bleeding site, we carefully removed only the gauze. In the hemostatic sealant group, the bleeding sites were covered with FloSeal or TachoSil while viewed directly with a laparoscopic applicator, followed by a 2-min wait time to allow the sealants to take action. The bleeding sites were then checked again by irrigation. In the bipolar coagulation group, hemostasis of the ovarian parenchyma was achieved with minimal electrical contact and limited coagulation to minimize ovary damage. No additional chemical or mechanical means of achieving hemostasis were used

in any of the groups. All operations in this study were performed by two experienced surgeons (Dr. W.Y. Kim and Dr. S.H. Lee) with comparable skill and experience in laparoscopic ovarian cystectomy.

The primary aim of the study was to evaluate whether TachoSil-mediated hemostasis achieves an equivalent effect to that of FloSeal-mediated hemostasis with respect to preserving ovarian reserve, as assessed by serum AMH levels. Serum AMH levels, which have been shown to accurately reflect ovarian reserve, were measured before operation and at 3 months postoperation in all patients. The decline rate of serum AMH level (%) was calculated as follows: $100 \times ([\text{preoperative AMH level} - \text{postoperative AMH level}] / \text{preoperative AMH level})$. We measured the serum AMH levels of all patients at 3 months postoperation since a previous study indicated that measurement at this time most accurately reflects the degree of recovery during folliculogenesis [1]. This protocol was approved by the Institutional Review Board of Kangbuk Samsung Hospital.

All statistical analyses were performed in SPSS 13.0 (SPSS Inc., Chicago, IL, USA). All analyses were performed according to the intention-to-treat principle. Qualitative data are presented as frequencies. For quantitative variables, it was first determined whether data were distributed normally. Data with normal and non-normal distributions are reported as medians (ranges). Baseline clinical characteristics and study outcomes were compared between the three groups using one-way ANOVA or the Kruskal–Wallis test for continuous variables and the χ^2 test for categorical variables, as appropriate. Student's *t*-test and the Mann–Whitney test were used to compare serum AMH levels before and after surgery within a group. All *P* values were two-sided and considered significant when *P* < 0.05.

Results

Patients were enrolled from December 2012 to June 2014. Of the 129 patients recruited for the study, 43 patients were in the bipolar coagulation group, 46 in the FloSeal group, and 40 in the TachoSil group. No significant differences were observed between any of the groups regarding patient baseline characteristics (Table 1). The mean patient age, BMI, maximum diameter of ovarian cysts, and lesion bilaterality were similar between the three groups. The preoperative AMH levels were also similar between the three groups (3.47 ng/mL [IQR, 2.47–5.54] in the bipolar coagulation group, 3.42 ng/mL [IQR, 2.61–6.14] in the FloSeal group, and 4.19 ng/mL [IQR, 2.46–6.47] in the TachoSil group; *P* = 0.840). However, as shown in Table 2, the serum AMH level decreased significantly more in the bipolar coagulation group compared with the hemostatic sealant groups. The rate of serum AMH decline was 41.2% [IQR, 16.7–52.4] in the bipolar coagulation group, whereas it was 15.4% [IQR, 5.2–41.9] in the hemostatic sealant groups (*P* = 0.003). No significant difference was observed

Table 1
Patient baseline characteristics.

	Bipolar coagulation group (<i>n</i> = 43)	FloSeal group (<i>n</i> = 46)	TachoSil group (<i>n</i> = 40)	<i>P</i>
Age (years)	30.9 ± 5.4	30.6 ± 5.8	30.4 ± 5.1	0.922
Body mass index (kg/m ²)	20.4 ± 2.7	20.9 ± 2.6	21.5 ± 2.9	0.213
Parity				0.908
Nulliparous	34 (79%)	38 (82%)	32 (80%)	
Parous	9 (21%)	8 (18%)	8 (20%)	
Maximum diameter of ovarian cyst (cm)	6.02 ± 1.57	5.93 ± 2.13	5.61 ± 1.80	0.487
Bilaterality of lesion	11 (25%)	6 (13%)	8 (20%)	0.503
Preoperative hemoglobin (mg/dL)	12.8 ± 1.04	12.9 ± 1.4	12.9 ± 0.78	0.953
Preoperative AMH level (ng/mL)	3.47 (2.47–5.54)	3.42 (2.61–6.14)	4.19 (2.46–6.47)	0.840

Note: Data are presented as mean ± standard deviation, median (interquartile ranges) or frequencies (percentages). AMH = anti-Mullerian hormone.

Download English Version:

<https://daneshyari.com/en/article/6173066>

Download Persian Version:

<https://daneshyari.com/article/6173066>

[Daneshyari.com](https://daneshyari.com)