

Electrocoagulation versus gelatine-thrombin matrix sealant for haemostasis after laparoscopic surgery of ovarian endometriomas: a randomised control trial (abridged secondary publication)

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KEY MESSAGES

1. The use of haemostatic sealant after laparoscopic cystectomy for ovarian endometriomas achieved a greater increase in antral follicle count at 6 months, compared with bipolar coagulation.
2. FloSeal seems to provide greater ovarian protection. It is an alternative to bipolar coagulation for haemostasis during laparoscopic ovarian cystectomy for ovarian endometriomas, especially in those with fertility wish and

compromised ovarian reserve.

Hong Kong Med J 2022;28(Suppl 3):S43-4

HMRF project number: 04152656

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Introduction

Up to 44% of women with endometriosis have ovarian endometrioma.¹ Laparoscopic cystectomy, by the stripping method, is the most common technique. However, the procedure may reduce ovarian reserve, which may be further reduced when bipolar coagulation is used for haemostasis on the residual ovarian tissue.^{1,2} The concern on bipolar coagulation and its impact on ovarian reserve has led to the use of non-thermal haemostasis approaches such as suturing or topical haemostatic agents. FloSeal (Baxter Healthcare, Deerfield [IL], USA) is a haemostatic sealant. It could be an alternative to bipolar coagulation during ovarian surgery. We aimed to determine the post-surgical ovarian reserve in women who achieved haemostasis using FloSeal or bipolar coagulation after laparoscopic cystectomy for ovarian endometriomas.

Methods

The study was approved by the Joint Chinese University of Hong Kong – New Territories East Clinical Research Ethics Committee (CRE 2011.296-T). This was a patient-blinded, randomised controlled trial conducted at the Prince of Wales Hospital between February 2013 and December 2017. Women aged 18 to 40 years with unilateral or bilateral ovarian endometrioma (measuring 3 to 8 cm) and with no history of ovarian surgery or hormonal therapy who underwent laparoscopic ovarian cystectomy (by the stripping method) were invited to participate.

Participants were asked to return to the hospital on day 3±1 of the menstrual cycle preoperatively

and day 3±1 of her 1st, 3rd, and 6th menstrual cycles after laparoscopic ovarian cystectomy for measurement of levels of follicular-stimulating hormone (FSH) and anti-mullerian hormone (AMH) and for ultrasonographic scanning of the ovaries to determine the antral follicle count (AFC) of each ovary. FSH, AMH, and AFC are markers for ovarian reserve. Particularly, AFC reflects the impact of any surgical treatment on the operated ovary. Perioperative outcomes including the success of haemostasis, complications, postoperative recovery, and pain and satisfaction scores (assessed using the Chinese version of the validated Client Satisfaction Questionnaire-8) were also analysed.

According to the preliminary result of an earlier study,³ the postoperative AFC in bipolar diathermy group was reduced to ~27% of preoperative level, whereas the postoperative AFC in FloSeal group was reduced to ~57%, similar to the suture group. Thus, the sample size required for an alpha value of 0.05 and 80% power would be 42 cases in each group. Assuming that 10% of the patients were excluded owing to incomplete data or dropouts, 47 cases in each group were needed.

Results

A total of 94 patients were randomised to the FloSeal group (n=47) or the bipolar coagulation group (n=47). 38 patients in each group completed the 6-month follow-up. The two groups were comparable in terms of patient age, follow-up rate, operative details, and postoperative complications. The successful haemostasis rate was 95.7% in the FloSeal group and 97.9% in the bipolar coagulation

group. Histopathology examination confirmed endometrioma in all cases. The two groups were comparable in terms of postoperative outcomes and pain and satisfaction scores.

Repeated measures ANOVA revealed a significant time effect ($P < 0.001$) and significant group \times time interaction effect ($P = 0.028$) on the AFC of the affected ovary. In both groups, the mean AFC at 1st, 3rd, and 6th months were all higher (but not significantly) than that before surgery. The change of mean AFC of the affected ovaries was significantly higher in the FloSeal group than in the bipolar coagulation group ($P = 0.018$).

Repeated measures ANOVA revealed a significant time effect ($P < 0.001$) but no group effect ($P = 0.320$) or group \times time effect ($P = 0.563$) on the AMH level. In both groups, the mean AMH level at 1st, 3rd, and 6th months was lower (but not significantly) than that before surgery. The change of AMH levels between the two groups was not significant.

Repeated measures ANOVA revealed no significant time effect ($P = 0.740$), group effect ($P = 0.473$), or group \times time effect ($P = 0.052$) on the FSH level. The change in FSH level between 1st month and baseline was greater in the bipolar coagulation group than in the FloSeal group ($p = 0.041$).

Discussion

Ovarian endometrioma is a common gynaecological condition and its surgical treatment may impair future fertility.^{3,4} Our results suggested that applying haemostatic sealant after laparoscopic cystectomy for ovarian endometriomas achieved a greater increase in AFC at follow-up, compared with bipolar coagulation. The protective effect of FloSeal may be particularly important to patients with an already compromised ovarian reserve. Therefore, FloSeal is a viable alternative to bipolar coagulation in achieving haemostasis after laparoscopic cystectomy for endometrioma, particularly in women who wish to preserve fertility.²

There is no consensus on a single test or measurement that accurately reflects reserve of an operated ovary. In the present study, three common ovarian reserve markers were used: AFC, AMH, and FSH. AFC was the primary outcome measure as it reflects the ovarian reserve of each ovary, whereas AMH and FSH reflect the combined reserve of both ovaries. It is likely that normal function of the unoperated ovary may mask any adverse effect of the operation of the operated ovary. Therefore, AFC of the affected ovary is a more sensitive measurement. Not surprisingly, a significant difference between the two groups was noted in the change of AFC but not in other markers. The AFC was measured by a single

sonographer who was blinded to the treatment modality to reduce inter and intra-observer bias.

Conclusion

The improvement in AFC of the operated ovary was greater in the FloSeal group than in the bipolar coagulation group at 6-month post-operation. FloSeal is an alternative to bipolar coagulation for haemostasis after laparoscopic cystectomy for endometrioma, particularly for women who wish to preserve fertility.

Acknowledgements

We thank Dr Irene Cheung Mei Ling, Jennifer Tsang Sau Fung, Tse Lai Yiu, and Jason Leung Chi Shun for assistance in implementation of this study. We are grateful to all patients for their participation.

Funding

This study was supported by the Health and Medical Research Fund, Food and Health Bureau, Hong Kong SAR Government (#04152656). The full report is available from the Health and Medical Research Fund website (<https://rfs1.fhb.gov.hk/index.html>). The Hong Kong Obstetrical and Gynecological Trust Fund (#MD13951) was provided by the Hong Kong Obstetrical and Gynecological Society.

Disclosure

The results of this research have been previously published in:

1. Chung J, Law T, Chung C, Mak J, Sahota DS, Li TC. Impact of haemostatic sealant versus electrocoagulation on ovarian reserve after laparoscopic ovarian cystectomy of ovarian endometriomas: a randomised controlled trial. *BJOG* 2019;126:1267-75.

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