Effectiveness, safety, and acceptability of post-placental insertion of GyneFix postpartum intrauterine device among women undergoing cesarean section: A multicenter prospective cohort study in China

Yan Che[1], Gui-Fang Hou[2], Hong-Ping Zhang[3], Heng Yang[4], Shu-Juan Lin[5], Tao Gan[6], Wei-hua Yang[7], Chun-Hui Shi[8], Wei-Juan Ren[9], Ying-Qin Xu[10], Bao-Ming Yin[11], Ting-ting Chen[12], Yujie Gan[13], Yuan Zhang[14], Yan Zhang[15], and Li-Nan Chen[1]

[1]NHC Key Lab of Reproduction Regulation, Shanghai Institute for Biomedical and Pharmaceutical Technologies
[2]The Second People's Hospital of Huadu District, Guangzhou
[3]Wenzhou People's Hospital
[4]Shenzhen Luohu Maternal and Child Health Hospital
[5]Jiangmen Maternity and Child Healthcare Hospital
[6]Jun'an Hospital, Shunde Hospital of Guangzhou University of Chinese Medicine
[7]University of Chinese Academy of Sciences Shenzhen Hospital (Guangming)
[8]Affiliation not available
[9]Yangzhou Maternal and Child Health Hospital
[10]Laizhou Maternity and Child Healthcare Hospital
[11]Zhuhai Center for Maternal and Child Health Care (Zhuhai Women and Children's Hospital)
[12]The First People's Hospital of Longwan District, Wenzhou
[13]Boai Hospital of Zhongshan
[14]Yangjiang Maternal and Child Health Hospital
[15]1. NHC Key Lab. of Reproduction Regulation(Shanghai Institute of Planned Parenthood Research), School of Public Health, Fudan University

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Abstract

Objective To assess the effectiveness, safety, and acceptability of post-placental insertion of GyneFix postpartum intrauterine device (PPIUD) in women undergoing cesarean section (C-section). Design Prospective cohort study. Setting Fourteen hospitals in four provinces of China. Population and sample Women who underwent C-section and consented to the post-placental insertion of GyneFix PPIUD. We enrolled 470 participants, and 400 completed the 12-month follow-up. Methods Participants were interviewed in the wards after delivery and followed up at 42 days, and months 3, 6, and 12 after delivery. Main outcome measures Pregnancy, PPIUD expulsion, serious adverse events, and continuation of PPIUD. Results Nine pregnancies were detected during the first year after GytneFix PPIUD insertion, 7 were due to device expulsion and 2 occurred with PPIUD in situ. The Pearl Indices (PI; pregnancy per 100 women-years) for overall 1-year pregnancy rate and pregnancies with IUD in situ were 2.32 (95% CI: 1.06–4.40) and 0.51 (95% CI: 0.06–1.86), respectively. The 1-year expulsion PI was 8.25 (95% CI: 5.63–11.63). The expulsion PI was significantly higher in the first 6 months (12.78, 95% CI: 8.42–18.60) than the second 6 months (2.82, 95% CI: 0.92–6.58). The cumulative 1-year continuation rate was 86.56% (95% CI: 83.32–89.79). We did not identify

any patient with insertion failure, uterine perforation, pelvic infection, or excess bleeding due to GyneFix PPIUD insertion. Conclusions Post-placental insertion of GyneFix PPIUD is effective, safe, and acceptable for women undergoing C-section. An ultrasound scan during the first 6 months after PPIUD insertion is recommended to identify any unrecognized expulsions.

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