



SAFETY, EFFICACY AND QUALITY OF LIFE OF THE IUB™ SCu300A INTRAUTERINE DEVICE, EARLY COMPARATIVE RESULTS

July 6, 2015

Objective: To evaluate the initial safety, efficacy and quality of life of the IUB™ SCu300A, a spherical copper intrauterine device (IUD) compared to a T-shaped copper IUD, the TCU380A.

Study Design: A total of 362 women, 240 using the IUB™ SCu300A and 122 using a TCU380A, were randomized into two study arms. The present report provides interim results up to the four month visit.

Results: Dysmenorrhea and menorrhagia were reduced in the IUB™ group with a marked trend of improvement in all measured parameters. Efficacy was comparable and expulsion rates were found comparable following investigator training on IUB™ insertion. No perforations were observed.

Conclusion: Early data demonstrates improved overall quality of life benefit with the IUB™ SCu300A compared to the TCU380A while maintaining comparable efficacy. It has also been established that proper IUB™ insertion significantly reduces expulsion rates.

Introduction

The purpose of this report is to summarize the interim results of the PMS study. The present report presents the data analyses of the subjects who were followed for four months after enrollment into the study. The objective of the study was to confirm the safety and to verify the performance of the IUB™ SCu300A copper intrauterine device (OCON Medical Ltd., Modiin, Israel).

Materials and Methods

The study is a prospective, randomized, single blind, two arms, controlled, multi-center study. A total of 362 subjects aged 18-45 (mean=33) were enrolled in 12 centers throughout Romania and Bulgaria, randomized and underwent insertion of the study device at the time of the database lock. No major protocol deviation is known. Of the total number of subjects enrolled n=240 (66.3%) were assigned the IUB™ SCu300A and n=122 (33.7%) were assigned a TCU380A T-shaped copper IUD (both shown above). Recruitment initiated in June 2014 and was separated into two sequential segments, the first including n=88 subjects followed by a 45 day pause, and the second including n=274 subjects. No statistically significant differences were observed between the study arms regarding age, height, weight, BMI, marital status, prior pregnancies and prior contraceptive use.



Results

A total of three pregnancies in the IUB™ arm and one in the TCU380A arm were recorded, reflecting a pregnancy rate of 1.25% & 0.83% (95%CI 0.26%;3.61% & 0.02%;4.52%) respectively. Investigator training on avoidance of insertion tube withdrawal before IUB™ deployment was conducted prior to enrollment of the second segment (IUB™ n=185) leading to a significantly lower expulsion rate of 2.7% in that segment compared to 14.5% in the first segment (IUB™ n=55; p=0.002). The difference between the second segment rate and the TCU380A expulsion rate of 0.8% was insignificant (p=0.41). No perforations were recorded in either arm. Measured blood markers related to blood loss were found comparable at both follow-up visits. Scoring was conducted on a 1-10 scale, a lower figure indicating improvement, figures are mean.

Bleeding, pain and cramping parameters were found to be overall superior in the IUB™ arm with a trend of improvement into the four month visit. Pain and cramping scores were statistically significant with 2.3 & 2.9 (p=0.002) at the one month follow-up and 1.9 & 2.4 (p=0.010) at the four month follow-up for the IUB™ and TCU380A respectively (figure 1). Graphical renderings of days of menstruation (figure 2), bleeding amount (figure 3) and menstruation description (figure 4) demonstrate overall superiority of the IUB™ compared to the TCU300A (p>0.05).

Subject satisfaction was higher in the IUB™ arm both at one month (2.4 vs. 2.8; p=0.127) and at four months (2.1 vs. 2.5; p=0.107). At four months user recommendation to an acquaintance scoring were higher in the IUB™ arm (2.4 vs. 2.8; p=0.127).

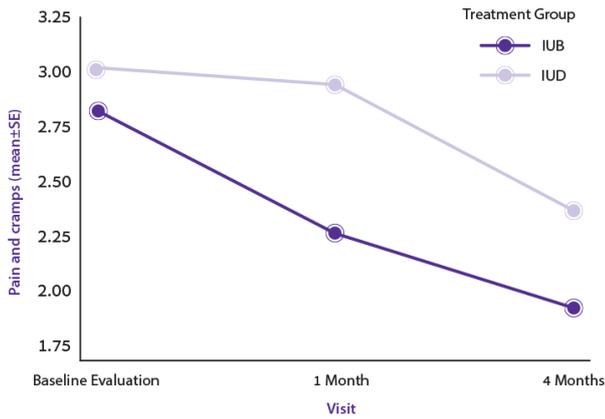


Figure 1: pain and cramping scores

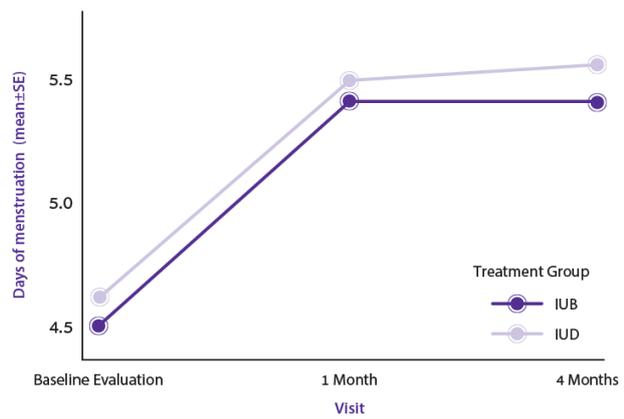


Figure 2: days of menstruation

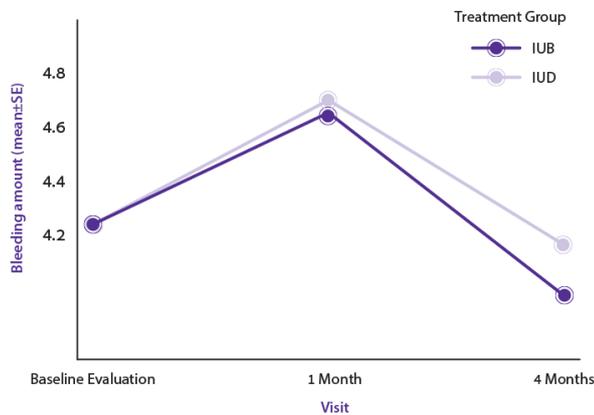


Figure 3: bleeding amount scores

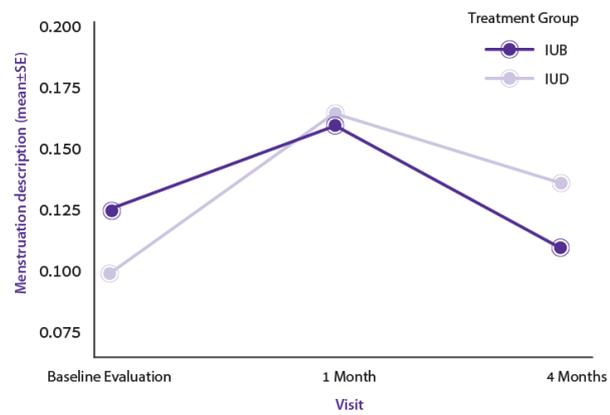


Figure 4: menstruation description scores

Discussion

The initial few months of any IUD use are usually related to negative user quality of life experiences. The presented early data nevertheless demonstrates overall improved user quality of life parameters such as bleeding, pain and cramping compared to the TCu380A with comparable efficacy rates. Higher IUB™ expulsion rates were observed in the initial study segment. These rates were significantly lower in the second segment following investigator training on proper insertion technique of the IUB™ in which pull-back of the insertion tube prior to deployment was to be avoided. This suggests the existence of a learning curve which may further lend to a decrease in expulsion rates once experience is gained. The recent addition of larger and stiffer IUB™ variants to better fit uterine physiologies can be expected to further reduce expulsion rates. Nevertheless, the second segment expulsion rate of 2.7% is lower than the 6%-10.2% published rates^{1,2}. While these rates are accumulative over a longer period, expulsions occur more frequently during the first few months.

Conclusion

This interim report presents early four month follow-up data. Notwithstanding the short span of time the IUB™ SCu300A shows superior quality of life characteristics and comparable safety performance. Comparable efficacy was shown and expulsion rates were also found comparable following IUB™ insertion training. One year follow-up data from the present study will allow a more substantial analysis, maintenance of observed trends can be expected to become statistically significant at that time. Further studies are planned.

¹Aoun et al. Effects of age, parity, and device type on complications and discontinuation of intrauterine devices. *Obstetrics & Gynecology* (123;3) 2014, 585-592

²Madden et al. Association of age and parity with Intrauterine device expulsion. *Obstetrics & Gynecology* (124;4) 2014, 718-726