COMPARATIVE STUDY OF THE IUB™ SCU300A INTRAUTERINE DEVICE VS. TCU380A COPPER IUD

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INTRODUCTION

We present a post marketing clinical study comparing between a novel spherical copper intra-uterine device, the IUB™ SCu300A ("IUB™", OCON Medical Ltd., Modi'in, Israel) and the TCu380A copper IUD ("IUD"), with regards to performance and quality of life (QoL) aspects. This report summarizes the twelve-month follow-up interim results of the study, which is designed to end after a twenty-four month follow-up.

STUDY DESIGN & METHODOLOGY

The study is a prospective single blind, two arms controlled study. A total of 367 subjects aged 18-45 (mean = 33) were enrolled throughout Romania and Bulgaria, randomized, and underwent insertion of either the study device, IUB™ SCu300A (n = 245; 66.3%), or the TCu380A T-shaped copper IUD (n = 122; 33.7%). Study Endpoints were as follows:

Efficacy Endpoint: One-year pregnancy rate

Safety Endpoints: One-year Expulsion rate, Malposition rate and Perforation rate.

Quality of Life (QoL) Endpoints: Menorrhagia and Dysmenorrhea

Menorrhagia parameters:

Bleeding period; measured in days

Bleeding intensity; measured in no. of tampons/pads used per day

Dysmenorrhea parameters:

Pain and cramps; measured on a 1-10 scale (10 being most painful)

General description of menstruation; 1-10 scale (10 indicating highest discomfort)

RESULTS

- No statistically significant differences were observed between the study arms regarding age, height, weight, BMI, marital status, uterus and ovaries measurements, parity and prior contraceptive use.
- No perforations or malpositions were detected in either of the groups.

RESULTS (CONTINUED)

Pregnancy rate:

Device used	no._of_pregnancies / total no._of_women (%)	95% CI	Pearl Index
IUB	4/245 (1.63 %)	0.45 % ; 4.13 %	1.1
IUD	1/122 (0.82 %)	0.02 % ; 4.48 %	0.8

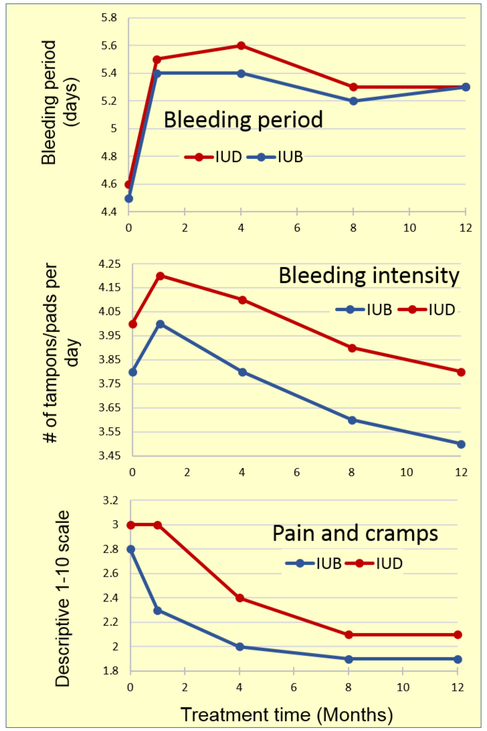
Pregnancy rates, their respective two-sided 95% exact binomial confidence interval (CI), and Pearl Index calculations for each study arm are shown. According to data, **both devices exhibit comparable efficacy**.

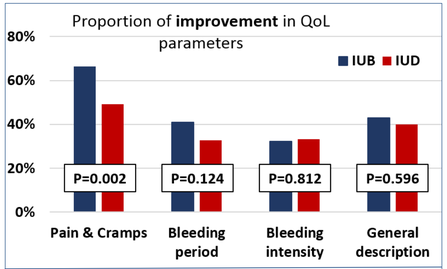
Expulsion rates:

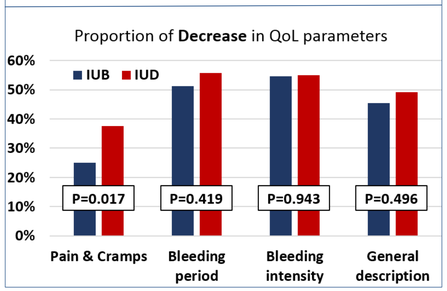
Recruitment Period	Treatment group	% expulsions / #_of_women	95% CI
1st	IUB	13.79 % (8/58)	6.15 % ; 25.38 %
	IUD	3.57 % (1/28)	0.09 % ; 18.35 %
2nd	IUB	4.81 % (9/187)	2.22 % ; 8.94 %
	IUD	0.00 % (0/94)	0.00 % ; 3.85 %

Expulsion rates and their respective two-sided 95% exact binomial confidence interval (CI) are shown for both devices. Expulsion rates were relatively high for IUB for the first 86 participants (two upper rows). Thus, recruitment was halted for 45 days during which investigators were further trained regarding the insertion technique. The rest of the participants were then recruited. The two lower rows show that **following proper insertion of the device expulsion rates for the two study arms are comparable**.

Quality of Life parameters:







Left: average QoL parameters as reported by participating women at 1, 4, 8, and 12 months following device insertion. **Above**: proportions of improvement or dissatisfaction for each parameter after one year.

SUMMARY

This study is the first large-scale comparative study of the IUB SCu300A device.

IUB SCu300A ("IUB") was found to have **comparable efficacy** to the long-standing TCu380A IUD ("IUD"), with a Pearl index of 1.1, while maintaining all safety parameters. Importantly, Expulsion rate decreased dramatically after proper training on insertion technique.

Regarding **Quality of Life** ("QoL") parameters, there is a statistically significant advantage for the IUB treatment vs. IUD in the Pain and Cramps parameter. This was shown under different approaches and definitions. However, Bleeding period, Bleeding intensity and Description of menstruation are quite similar for both devices, with a slight tendency of advantage (yet not statistically significant) for IUB.

Additional one-year follow up will allow a more substantial analysis in which observed trends are expected to become more definitive. Further studies are planned.