

## Research Article

## The Efficacy of Monoplant<sup>®</sup> and Indoplant<sup>®</sup> as Contraceptive Methods: A Comparative Study

### *Efektivitas Susuk Monoplant<sup>®</sup> dan Indoplant<sup>®</sup> sebagai Kontrasepsi: Sebuah Studi Komparative*

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#### Abstract

**Objective:** To determine the effectiveness, safety, and time of insertion between Monoplant<sup>®</sup> with Indoplant<sup>®</sup> to prevent pregnancy.

**Methods:** Data were collected from November 2015 until May 2016 in Raden Saleh Clinic. A total of 153 patients met the inclusion and exclusion criteria for the study and were divided into 77 patients who received Monoplant<sup>®</sup> and 76 patients received Indoplant<sup>®</sup>. The study period was 6 months.

**Results:** The data obtained showed no significant difference in the effectiveness of both contraceptive methods. In addition, side effects such as menstrual disorders and weight gain did not differ significantly in those study groups. However, the time of insertion between Monoplant<sup>®</sup> and Indoplant<sup>®</sup> was significantly different (162.91 + 197.04 + 49.81 seconds versus 44.96 seconds,  $p < 0.001$ ). For complications such as skin irritation, inflammation, there are no differences between Monoplant<sup>®</sup> (0.0%) and Indoplant<sup>®</sup> users (0.0%).

**Conclusion:** There are no significant differences in efficacy and side effects using Monoplant<sup>®</sup> and Indoplant<sup>®</sup> during the 6-month follow-up. However, the insertion time of Monoplant<sup>®</sup> is shorter compared to Indoplant<sup>®</sup>s. Monoplant<sup>®</sup> can be considered for use as contraception with the effectiveness and side effects are almost the same, but with shorter time of insertion compared to Indoplant<sup>®</sup>.

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**Keywords:** contraception, implant, indoplant<sup>®</sup>, monoplant<sup>®</sup>

#### Abstrak

**Tujuan:** Untuk mengetahui efektivitas, keamanan penggunaan, dan waktu penyisipan antara Monoplant<sup>®</sup> dibandingkan dengan Indoplant<sup>®</sup> untuk mencegah kehamilan.

**Metode:** Pengambilan data dilakukan sejak November 2015 hingga Mei 2016 di Klinik Raden Saleh. Sebanyak 153 pasien memenuhi kriteria inklusi dan eksklusi penelitian dan dibagi menjadi 77 pasien yang menerima susuk Monoplant<sup>®</sup> dan 76 pasien menerima susuk Indoplant<sup>®</sup>. Penelitian dilakukan secara kohort prospektif hingga observasi selama 6 bulan.

**Hasil:** Data yang didapat menunjukkan tidak terdapat perbedaan bermakna pada efektivitas yaitu kejadian hamil pada penggunaan Monoplant<sup>®</sup> dan Indoplant<sup>®</sup>. Selain itu, efek samping seperti gangguan haid dan kenaikan berat badan tidak berbeda bermakna pada kedua kelompok penelitian. Namun, waktu penyisipan antara Monoplant<sup>®</sup> dan penyisipan Indoplant<sup>®</sup> (162,91 + 49,81 detik vs 197,04 + 44,96 detik,  $p < 0,001$ ) berbeda secara bermakna. Untuk komplikasi seperti iritasi kulit, peradangan, tidak terdapat perbedaan komplikasi pada saat penyisipan Monoplant<sup>®</sup> (0,0%), dan Indoplant<sup>®</sup> (0,0%).

**Kesimpulan:** Tidak terdapat perbedaan bermakna pada efektivitas serta efek samping pada penggunaan Monoplant<sup>®</sup> dan Indoplant<sup>®</sup> selama 6 bulan follow-up. Namun, waktu penyisipan lebih singkat untuk penggunaan Monoplant<sup>®</sup> dibandingkan Indoplant<sup>®</sup>. Dapat dipertimbangkan untuk menggunakan Monoplant<sup>®</sup> sebagai implan untuk kontrasepsi dengan efektivitas dan efek samping yang hampir sama, namun waktu penyisipan yang lebih singkat dibanding Indoplant<sup>®</sup>.

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**Kata kunci:** indoplant<sup>®</sup>, kontrasepsi, monoplant<sup>®</sup>, susuk

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#### INTRODUCTION

Every contraceptive method has advantages and disadvantages. The advantages of implant are high effectiveness, long-term usage, convenient usage, minimal maintenance, quickly returned after releasing the implant, minimal metabolic effects, and relatively low cost. Limitations of the implant are menstrual disorders, requiring surgical proce-

dures for insertion and removal, and no providing of protection against sexually transmitted infections. The side effects are the main reason that women stop using implants. The side effects include irregular or prolonged bleeding, headaches, mood swings, weight gain, depression or anxiety, acne, abdominal discomfort, and pain in the area of insertion.<sup>1-8</sup>

Indoplant® has already been marketed in Indonesia since 2005 and gets good response among family planning users in Indonesia. Indoplant®, consisted of two rods, is reported to have an effective and safe contraceptive based on research.<sup>9</sup> Monoplant® is a contraceptive implant containing the same hormonal content as Norplant® but have different packaging because it consists only one rod. Monoplant® is expected to be one of the more desirable contraceptive method because the packaging is simpler which is expected easier insertion and removal. Therefore, it is needed to study further about comparison of the effectiveness and safety of new contraceptive implant that consists of one rod, which is Monoplant®, with Indoplant®.

From the background, it can be formulated whether there are differences in effectiveness, safety, and the time of insertion between Monoplant® compared with Indoplant®. This study aims to determine the effectiveness, safety, and time of insertion between Monoplant® with Indoplant® to prevent pregnancy.

## METHODS

A double-blind randomized clinical trial was used. The affordable population were implant acceptors in Family Planning Clinic, RSUPN Dr. Cipto Mangunkusumo from August 1<sup>st</sup>, 2015 until August 31<sup>st</sup>, 2018. Inclusion criteria of this study were reproductive age women between 20 and 35 years, healthy, not in a pregnant, had active sexual

intercourse, not used hormonal contraception within 6 months, explained and signed informed consent, were willing to do repetitive visits, and were only using implant as a contraceptive during the three years period of study. Exclusion criteria were having a family history of any type of cancer, abnormal uterine bleeding, cardiovascular problem, mental disorders, tuberculosis, frequent headaches, history of liver disease or active liver disease, using drugs that induce liver enzymes, having high blood pressure, and severe hirsutism.

Data were collected using consecutive sampling. If the corresponding patients were available, they would be recruited as a research subject. Processing and data analysis were performed using the software "SPSS for Windows" version 20.0.

## RESULTS

After the data were collected prospectively in Obstetrics and Gynecology clinic, RSCM, we obtained 153 subjects with 77 subjects of Monoplant® and 76 subjects of Indoplant®. At 1-month follow-up, there were three subjects that is loss-to-follow-up and 16 subjects had not yet reached the period of 1 month during the study period. At 3-month follow-up, there were two subjects who dropped out of the study because they developed intolerable side effects including drastic weight gain and continuous spotting. At 6-month follow-up, there were four subjects that can be assessed when writing this report. Characteristics of the subjects are presented in Table 1.

**Table 1.** Characteristics of the Subjects

Characteristics		Monoplant® (n=77)	Indoplant® (n=76)
Age	18-19 years old	0 (0.0)	1 (1.3)
	20-24 years old	15 (19.5)	15 (19.7)
	25-29 years old	22 (28.6)	26 (34.2)
	30-34 years old	35 (45.5)	28 (36.8)
	35-40 years old	5 (6.5)	6 (7.9)
Weight (kg)		58.78 ± 11.59	56.99 ± 12.52
Height (cm)		155.31 ± 6.42	154.93 ± 5.25
BMI (kg/m <sup>2</sup> )		24.37 ± 4.57	23.70 ± 4.74

Characteristics		Monoplant® (n=77)	Indoplant® (n=76)
Blood pressure (mmHg)	Systolic	115.06 ± 12.51	116.47 ± 14.45
	Diastolic	75.90 ± 9.43	75.64 ± 10.71
Parity	P0	2 (2.6)	0 (0.0)
	P1	21 (27.3)	25 (32.9)
	P2	34 (44.2)	30 (39.5)
	P3	15 (19.5)	20 (26.3)
	P4	3 (3.9)	0 (0.0)
	> P4	2 (2.6)	1 (1.3)
Length of menstruation	< 3 days	0 (0.7)	1 (1.3)
	3-7 days	73 (94.8)	72 (94.7)
	> 7 days	4 (5.2)	3 (3.9)
Lactation	No	40 (51.9)	36 (47.4)
	Yes	37 (48.1)	40 (52.9)
Last contraceptive method	Pill	14 (18.2)	13 (17.1)
	Implant	6 (7.8)	12 (15.8)
	Injection	34 (44.2)	30 (39.5)
	IUD	3 (3.9)	2 (2.6)
	Condom/diaphragma	0 (0.0)	2 (2.6)
	Withdrawal	0 (0.0)	0 (0.0)
	Lactational amenorrhea method (LAM)	3 (3.9)	2 (2.6)
	Never	17 (22.1)	15 (19.7)

Normal distribution of data presented in mean ± standard deviations; abnormal distribution data presented in median (minimum - maximum); categorical data are presented in the amount (percentage).

From these results, the most common of last contraceptive method used by both groups as

much as 34 subjects (44.2 %).

The effectiveness of a contraception assessed through the ability to prevent pregnancy. In both groups of the study, the subjects assessed as pregnant or suspected pregnant. The result of the analysis are shown in Table 2.

**Table 2.** Comparison of Effectiveness between Monoplant® and Indoplant®

Follow-up	Research group	N	Pregnant or suspected pregnant		p value
			Yes	No	
1 month	Monoplant®	69	0 (0.0)	69 (100.0)	-*
	Indoplant®	68	0 (0.0)	68 (100.0)	
3 months	Monoplant®	32	0 (0.0)	32 (100.0)	-*
	Indoplant®	30	0 (0.0)	30 (100.0)	
6 months	Monoplant®	1	0 (0.0)	1 (100.0)	-*
	Indoplant®	3	0 (0.0)	3 (100.0)	

\* Chi-Square test can not be conducted because the result of variable dependent is only 1 category

Weight of the subjects were assessed at the beginning of the implant insertion, 1 month, 3 months, and 6 months follow-up. The number of subjects who reached 1-month follow-up was 35 subjects for Monoplant® and 37 subjects for Indoplant®. Both group had increments in body weight, ie 0.85 kg for Monoplant® and 0.5 kg to Indoplant®. For the 3-month follow-up, insertion of 1 and 3 months of Monoplant®, there were increments of 0.27 kg and 0.57 kg from initial body weight. After the insertion of 1 month and 3 months of Indoplant®, weight tended to be stable. In four subjects who had reached the 6-month follow-up, one Monoplant® subject gained 0.5 kg since the use of the implant and stable 3 months onward. For three Indoplant® subjects, two of which gained 2 kg and 1 subjects gained 1 kg. It should be noted that there was one Monoplant® subject who dropped our study because she gained 11 kg in one month. The average weight gained in 3000 acceptors in China that used Norplant® was 2.5 kg.<sup>11</sup> Within three years of usage of LNG implant, the mean weight changed as much as 0.6 to 0.8 kg, of which 49.6 and 52.2% women in the study had gain 1 kg or more, while 29.5 and 29.7% decreased body of 1 kg or more.<sup>12</sup>

At the time of follow-up, menstrual disorders of both groups of the study were assessed. The result of the analysis is shown in Table 3.

Insertion time between Monoplant® and Indoplant® were assessed. The insertion time for Monoplant® and Indoplant® is 162.91 ± 49.81 seconds and 197.04 ± 44.96 seconds consecutively. This difference is significant based on statistical test (p value <0.001). At the time of insertion, complications were also assessed. The results showed no complications such as skin irritation, infection, inflammation, or anaphylactic reaction in Monoplant® (0.0%) and Indoplant® (0.0%).

### DISCUSSION

Table 2 suggested that there was no contraceptive failure at Monoplant® group (0.0%) and Indoplant® (0.0%). Thus, it can be concluded that there is no difference in effectiveness between Indoplant® and Monoplant®. Another studies showed that there were two Indoplant® subjects (0.7%) who experienced pregnancy during 36 months<sup>9</sup> and no pregnancy found in 30 Monoplant® subjects at 6 months follow-up.<sup>10</sup>

**Table 3.** Comparison of Menstrual Disorders in Monoplant® and Indoplant®

Follow-up	Characteristics		Monoplant®	Indoplant®	p value
1 month	Dismenorrhea	Yes	6 (8.7)	24 (2.9)	0.274
		No	63 (91.3)	30 (97.1)	
	Menstruation	Amenorrhea	26 (37.7)	27 (39.7)	0.931
		Shorter than usual	9 (13.0)	8 (11.8)	
		Normal/usual	21 (30.4)	18 (26.5)	
3 months	Dismenorrhea	Yes	1 (3.1)	0 (0.0)	1.000 <sup>a</sup>
		No	31 (96.9)	30 (100.0)	
	Menstruation	Amenorrhea	9 (28.1)	10 (33.3)	0.937 <sup>b</sup>
		Shorter than usual	3 (9.4)	3 (10.0)	
		Normal/usual	8 (25.0)	8 (26.7)	
6 months	Dismenorrhea	Yes	0 (0.0)	0 (0.0)	.*
		No	1 (100.0)	3 (100.0)	
	Menstruation	Amenorrhea	1 (100.0)	1 (33.3)	1.000
		Shorter than usual	0 (0.0)	0 (0.0)	
		Normal/usual	0 (0.0)	2 (66.6)	
	Longer than usual	0 (0.0)	0 (0.0)		

<sup>a</sup>T-dependent test, <sup>b</sup>Fisher test, <sup>\*</sup>Chi-Square test can not be conducted because the result of variable dependent is only 1 category

There were no differences in menstrual disorders between Monoplant<sup>®</sup> and Indoplant<sup>®</sup> at 1, 3, and 6 months follow-up. In addition, there was one subject using Monoplant<sup>®</sup> who dropped out due to excessive spotting. In both groups, there were increased percentage of subjects with longer menstrual duration. This is contrast with a study conducted by Affandi B<sup>9</sup> in Indonesia which compared Norplant<sup>®</sup> and Indoplant<sup>®</sup>. It is reported that were an increment in the percentage of subjects with shorter periods than usual from the beginning, 12, 24, and 36 months follow-up. This may occur due to differences in measurement time in our study, where the follow-up were conducted at 1, 3, and 6 months, while Affandi B<sup>9</sup> are at 12, 24, and 36 months.

### CONCLUSION

Both implant have the same effectiveness, safety, no differences in weight gain and menstrual disorders during 1, 3, and 6 months follow-up. However, the insertion of Monoplant<sup>®</sup> are faster than Indoplant<sup>®</sup>. Monoplant<sup>®</sup> can be used as a contraceptive method with the same effectiveness and safety as Indoplant<sup>®</sup>, yet with shorter insertion time.

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