Inter-Operator Reproducibility of Pulmonary Vein Isolation Guided by the Ablation Index

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ABSTRACT

Background. Atrial fibrillation (AF) ablation outcome is still operator dependent. Ablation Index (AI) is a new lesion quality marker that has demonstrated to allow acute durable pulmonary vein (PV) isolation followed by a high single-procedure arrhythmia-free survival.
Objectives. This prospective, multi-center study was designed to evaluate the inter-operator reproducibility of acute PV isolation guided by the AI.
Methods. A total of 490 consecutive patients with paroxysmal (80.4%) and persistent AF underwent first time PV encircling and were divided in four study groups according to operator preference in choosing the ablation catheter (a contact force (ST) or contact force sourrounding flow (STSF) catheter) and the AI setting (330 at posterior and 450 at anterior wall or 380 at posterior and 500 at anterior wall). Radiofrequency was delivered targeting interlesion distance ≤ 6 mm.
Results. Procedure (ST330 129±44 min, ST380 144±44 min, STSF330 120±72 min, STSF380 125±73 min, $p<0.001$) and fluoroscopy time (ST330 542±285 s, ST380 540±416 s, STSF330 257±356 s, STSF380 379±454 s, $p<0.001$) significantly differed among the four study groups, whereas the rate of first-pass PV isolation (ST330 90±16 %, ST380 87±19 %, STSF330 90±17 %, STSF380 91±15 %, $p=0.585$) was similar. The difference in the rate of first pass isolation was not statistical different ($p=0.06$) among the 12 operators that performed at least 15 procedures.
Conclusions. Ablation protocol respecting strict criteria for contiguity and quality lesion results in high and comparable rate of acute PV isolation among operators performing ablation with different catheters, AI settings, procedure and fluoroscopy times.

CONDENSED ABSTRACT

This prospective, multi-center study was designed to evaluate the inter-operator reproducibility of acute pulmonary vein (PV) isolation guided by the AI in 490 patients with paroxysmal and persistent atrial fibrillation. Patients were divided in four study groups according to operator preference in choosing the ablation catheter (a contact force or contact force sourrounding flow catheter) and the AI setting (330 at posterior wall and 450 at anterior wall or AI 380 at posterior wall and 500 at anterior wall). Radiofrequency was delivered targeting interlesion distance ≤ 6 mm. Procedure and fluoroscopy time significantly differed among the four study groups, whereas the rate of first-pass PV isolation was similar. We conclude that an ablation protocol respecting strict criteria for contiguity and quality lesion results in high and comparable rate of acute PV isolation among operator performing ablation with different catheters, AI settings, procedure and fluoroscopy times.

KEY WORDS
Atrial fibrillation, catheter ablation, reproducibility, ablation index

ABBREVIATIONS
AF= atrial fibrillation
AI= ablation index
PV= pulmonary vein
ST= ThermoCool SmartTouch catheter
STSF= ThermoCool SmartTouch Surround Flow catheter

INTRODUCTION

Catheter ablation is a well established therapy in the management of patients with atrial fibrillation (AF) after failure of a pharmacological trial or as first-line therapy (1,2). However the wide range of success and complication rates among the several operator and centers justify the recommendation that ablation should be performed by an electrophysiologist who has received appropriate training and who perform the procedure in an experienced centre (2). To overcome these limitations and simplify the ablation procedure, several one-shot techniques have been developed (3-6). When ablation is performed with a point-by-point approach, the operator dependent outcome (7) still remains a limitation of the procedure. Recently, the use of a new lesion quality marker, the Ablation Index (AI) (Biosense-Webster, Diamond Bar, California) has demonstrated to allow acute durable pulmonary vein (PV) isolation followed by a high single-procedure arrhythmia-free survival (8-10). This prospective, multi-center study was designed to evaluate the inter-operator reproducibility of acute PV isolation guided by the AI.

METHODS

The Ablation Index Registry (AIR) (ClinicalTrials.gov Identifier: NCT03277976) is a prospective, multi-center, research study designed to evaluate the acute achievement of PV isolation with ThermoCool SmartTouch (ST) (Biosense-Webster, Diamond Bar, California) or ThermoCool SmartTouch SF (STSF) (Biosense-Webster, Diamond Bar, California) catheter using the AI Module. Enrollment started in November 2017 and ended in July 2018. The study was approved by local Ethics Committees and complied with the Declaration of Helsinki guidelines. Written informed consent was obtained from all patients.

Study population. We enrolled patients with paroxysmal or persistent AF who underwent their first AF ablation. Exclusion criteria were: 1) age < 18; 2) permanent AF (AF was the sole rhythm for the last 12 months); 3) AF secondary to a transient or correctable

abnormality, including electrolyte imbalance, trauma, recent surgery, infection, toxic ingestion, and endocrinopathy; 4) intra-atrial thrombus, tumor, or other abnormality precluding catheter insertion; 5) left ventricular ejection fraction < 35%; 6) women of childbearing potential who are or might be pregnant; 7) hematological contraindications to ionizing radiation exposure; 8) presence of complex congenital heart disease, and cardiac surgery within 1 month from enrollment.

Study protocol. This registry compared different clinical practices. Each operator performed AF catheter ablation using its own ablation technique as concerning the ablation catheter (ST or STSF) and the AI setting (380 posterior-500 anterior and 330 posterior-450 anterior). Therefore the study population was divided in 4 groups: ST 330-450, ST 380-500, STSF 330-450, and STSF 380-500. No randomization was required neither any deviation from the clinical practice of each center and operator.

End points. Given that the rate of PV isolation with a standard wide antral circumferential ablation technique (first pass isolation) is about 70% (8,11), we wanted to test if one of two catheters or one of two AI settings could increase the first pass isolation rate of at least 10% (from 70% to 80%, 95% CI 75-85%). Patients were divided in 4 groups and enrollment stopped when at least 80 patients were enrolled in each group. The primary end point of the study was to evaluate which ablation strategy increases the rate of PV isolation, validated by mean of a duodecapolar LASSO (Biosense-Webster, Diamond Bar, California) catheter, after first encirclement (first pass isolation), from 70% to 80%. Secondary end points were: a) incidence of early PV reconnection 30 minutes after acute PV isolation; b) difference in procedural and fluoroscopy time between the two groups; c) incidence of AF recurrence during the blanking period (3-months after ablation); d) safety of the ablation procedure.

Study Procedures. Ablation was usually performed under effective oral anticoagulation. Anticoagulation could be withdrawn before admission, so as antiarrhythmic drugs were

usually removed before scheduled procedure. Patients in AF or with a CHA_2DS_2-VASc score ≥ 1 underwent transesophageal echocardiography within 48 hours prior to the ablation. For all other patients transesophageal echocardiography was optional according to center and operators' preference. A pre-acquired computed tomography or magnetic resonance scan was used according to operators' preference. Ablation was carried out under mild or conscious sedation or general anesthesia according to operators' preference. At least 2 femoral vein access were obtained and in some patients one subclavian vein. One diagnostic catheter was positioned in the coronary sinus. One or two transseptal accesses to the left atrium were achieved using a standard approach. Then, the LASSO catheter and the ablation catheter (ST or STSF) were placed in the left atrium. Left atrium mapping was performed in sinus rhythm. Patients with AF at the beginning of the index procedure underwent electrical cardioversion. After left atrium reconstruction the effective PV-left atrium electrical connection was checked with LASSO catheter (Figure 1). Radiofrequency pulses were delivered using the 3.5-mm Thermocool ST or STSF Catheter in power control mode. Radiofrequency power was set between 20 and 35 W depending on different left atrial sites and the catheter tip was irrigated by saline at a flow rate of 2 mL/min during mapping and of 8 mL/min and 15 mL/min used for outputs of less than and greater than 30 W, respectively (12). Radiofrequency energy was delivered to produce a wide area circumferential ablation around the proximal part of each PV's ostium or around ipsilateral PVs according to the patient's anatomy or operator's preference. The lesion around the PV ostium was created by sequential point-by-point application of radiofrequency energy. Real-time automated display of RF applications (Carto VISITAG™ Module, Biosense Webster) was used with predefined settings of respiration adjustment, catheter stability (3 mm for 3 s), minimum contact force (3 g over minimum 25% of time), with the lesion tag display size of 3 mm, and AI thresholds: 500 for anterior wall and 380 for posterior wall or 450 for anterior wall and 330 for posterior

wall. In case of dislocation, a new RF application reaching the AI target was applied. Maximal inter lesion distance between 2 neighboring lesions was ≤ 6 mm (9,13). Upon completion of circumferential ablation a circular mapping LASSO catheter was used to confirm PV isolation (first pass isolation) (Figure 2). In the absence of isolation after completing the circle, touch-up ablation was delivered until PV isolation. Resumption of left atrium to PV conduction was evaluated for 30 minutes after ablation. In case of reconnection PVs were newly isolated targeting the residual electrical breakthroughs.

All patients underwent a post-procedural ECG and, optional, an echocardiogram to exclude pericardial effusion or other acute complications.

Follow-up. After ablation, patients underwent regular follow-up assessments (scheduled at 3, 6, and 12 months) including a detailed history, physical examination, 12-lead standard electrocardiography, and 24-h Holter monitoring.

Statistical analysis. All continuous data were expressed in terms of the mean and the standard deviation of the mean, the categorical data were expressed as frequency and percentages. The Kolmogorov Smirnov test was performed to test normality of continuous variables. The Levene test was performed to assess homoscedasticity of the studied groups. The ANOVA test was performed to assess the between groups differences of continuous, normally distributed and homoscedastic data, the Mann Whitney test was used otherwise. The ANOVA test followed by the Scheffè post hoc pairwise comparison was also used to assess the differences of continuous, normally distributed and homoscedastic data, among the groups, the Kruskal Wallis test followed by the Mann Whitney test with the Bonferroni correction for multiple comparison was used otherwise. Fisher Chi square test was performed to investigate the relationships between dichotomous variables. Pearson Chi square test evaluated by Monte Carlo Methods for small samples was performed to investigate the relationships between grouping variables. For all tests $p<0.05$ was considered significant.

All statistical analysis was performed using SPSS v.19.0 (IBM Corp., Armonk, NY, USA)

RESULTS

Study population. A total of 490 patients were enrolled in the study: in 96 patients in ST 330-450 Group, 81 in ST 380-500 Group, 162 in STSF 330-450 Group, and 151 in STSF 380-500 Group. The clinical characteristics of the study population are summarized in the Table 1.

Procedural data. At the beginning of the procedure 13.3% (13,5% in ST 330-450 Group, 17.3% in ST 380-500 Group, 13.6% in STSF 330-450 Group, and 10.6% in STSF 380-500 Group, p=0.539) of patients were in AF and underwent electrical cardioversion. In the Table 2 are summarized the main procedural data. Although the incidence of a PV common ostium, the mean procedural time, fluoroscopy time, and contact force were different among the four study groups, the rate of first pass isolation was similar. Also the mean impedance drop did not differ among the four study groups. Saline infusion was lower when catheter ablation was performed using a STSF catheter. Resumption of left atrium to PV conduction 30 minutes after ablation was observed in 5.6% (2.5% in ST 330-450 Group, 5.5% in ST 380-500 Group, 5.5% in STSF 330-450 Group, and 7.8% in STSF 380-500 Group, p<0.001) of PVs.

Reproducibility of first pass pulmonary vein isolation. A total of 44 operators, in 25 centers, performed the 490 ablation procedures. Figure 3 shows the distribution of first pass PV isolation among the 12 operators that performed at least 15 ablation procedures. All operators reached a rate of first pass PV isolation ≥ 84%. The difference in the rate of first pass isolation was not statistical different (p=0.06) among these 12 operators.

Complications. A complication (3 pericardial effusions, 2 transient phrenic nerve pulsy, 1 cardiac thamponade, 1 pneumonia, 1 other) was observed in 8 (1,6%) patients without any difference among the four study groups (p=0.55).

DISCUSSION

Main findings. This study, evaluating the inter-operator reproducibility of acute PV isolation, shows that an ablation protocol respecting strict criteria for contiguity and quality lesion results in high and comparable rate of acute PV isolation among operator with different skill performing ablation with different catheters, AI settings, procedure and fluoroscopy times. The difference in the patients' clinical characteristics and left atrium volume and morphology did not impact the rate of PV isolation. These results were obtained without compromising safety. When a lower AI value was chosen it did not impact the safety and the acute efficacy of the ablation.

Reproducibility of AF ablation. The HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of AF (14) reports that among the unanswered questions in AF ablation the need of improving the efficacy and safety of catheter ablation. As ablation extends to more and less experienced operators, the statistical occurrence of complications will increase. We need newer techniques to minimize complications and institute standards for operators to improve the reproducibility of ablation results and safety profiles at a variety of centers worldwide. Our study seems to give some answer to this query. We did not have measures of centers volume or operators' experience, nevertheless the procedure and fluoroscopy time were significantly different among the four study groups. Previous studies have shown that lower operator experience leads to increased fluoroscopy use (15,16). In our registry this parameter did not impact the rate of first pass PV isolation. Neither the patient's anatomy or the ablation catheter type affect it, thus it seems that when

we perform a point-by-point radiofrequency PV isolation guided by the AI and delivering pulses with a short interlesion distance, the acute success is high and reproducible irrespective of patient and operator variables.

Clinical use of AI. The likelihood of obtaining permanent PV isolation is related to the quality of ablation energy delivery and lesion formation. Catheter stability, contact force, power output, temperature, and duration of radiofrequency delivery are the variables that mainly impact lesion size and transmurality with radiofrequency energy. The AI is a novel marker of radiofrequency application quality that incorporates stability, contact force, time and power in a weighted formula, and has been shown to accurately estimate lesion depth and diameter in canine studies (17) and humans (18,19). Preliminary data on AF ablation guided by the AI have demonstrated acute durable PV isolation followed by a high single-procedure arrhythmia-free survival at 1 year (8-10). Significantly, in all these studies the rate of first pass PV isolation after a wide antral circumferential ablation was high similar and very high (ranging from 95 to 98%). In our multicenter study we confirmed that an ablation protocol respecting strict criteria for contiguity and quality lesion results in high and comparable rate of first pass PV isolation.

A major concern is the AI value that should guide the ablation. From a theoretical point of view a higher AI value could led to a high possibility of damage of the left atrium and of the anatomical structure surrounding it. Das et al (18) reported that no reconnection was seen where the minimum AI value was ≥370 for posterior/inferior segments and ≥480 for anterior/roof segments. In Hussein et al (8) series AI targets were increased to 550 for anterior/roof and 400 for posterior/inferior left atrial segments. Taghij et al (9) used an AI ≥ 400 at posterior wall and ≥ 550 at anterior wall. In our study we tested two AI (380 posterior-500 anterior and 330 posterior-450 anterior) and we did not find any difference in the rate of fist pass PV isolations as well as in the complication rate. Although we need data on one-year

outcome, these prelimary results seem to support Ullah et al (19) findings that ablation beyond 430 AI provides minimal additional biophysical efficacy, suggesting an upper limit to use for clinical ablation.

Limitations. Several limitations of our study have to be addressed. The first is that this is a non randomized study. No deviation from the clinical practice of each center and operator was required. This might justify the clinical and procedural differences in the four study groups. Nevertheless we believe that the reproducibility rate of the first pass PV isolation we observed in different patients, with different tools and operators is a strong point of our study. Second, although all patients underwent the same ablation protocol, some aspects, as pre-procedural imaging, and oral anticoagulant management, were not standardized. However, this observational prospective study may provide a representative image of the real-life scenario on the use of AI module and ST and STSF catheter for AF ablation. Third, we evaluated the impact of the AI on reproducibility of acute PV isolation. No data are currently available on its impact on the mid- and long-term outcome.

CONCLUSIONS

In conclusion, an ablation protocol respecting strict criteria for contiguity and quality lesion resulted in high and comparable rate of acute PV isolation among operator performing ablation with different catheters, AI settings, procedure and fluoroscopy times. Neither the difference in the patients' clinical characteristics and left atrium volume and morphology impacted the reproducibility of PV isolation.

PERSPECTIVES

CORE CLINICAL COMPETENCIES. Outcome of atrial fibrillation catheter ablation is still operator dependent. This prospective, multi-center, study shows that an ablation protocol respecting strict criteria for contiguity and quality lesion results in high and comparable rate of acute PV isolation among operator with different skill performing ablation with different catheters, AI settings, procedure and fluoroscopy times. The difference in the patients' clinical characteristics and left atrium volume and morphology did not impact the reproducibility of PV isolation.

TRANSLATIONAL OUTLOOK. An AI value of 330 at posterior wall and 450 at anterior wall was as effective and safe as an higher one (380-500). This is a first step in identifying the best AI setting.

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FIGURE LEGENDS

Figure 1. Distribution of procedure time (min) among the 12 operators that performed at least 15 ablation procedures.

Figure 2. Distribution of fluoroscopy time (s) among the 12 operators that performed at least 15 ablation procedures

Figure 3. Distribution of ablation time (min) among the 12 operators that performed at least 15 ablation procedures

Figure 4. Distribution of rate of first-pass pulmonary vein isolation (%) among the 12 operators that performed at least 15 ablation procedures

Table 1. Patient demographics for the total cohort of subjects, and for each study group.

	Overall population (n=490)	**Group ST 330-450 (n=96)**	**Group ST 380-500 (n=81)**	**Group STSF 330-450 (n=162)**	**Group STSF 380-500 (n=151)**	**p**
Mean age (yrs)	59±11	58±10	59±13	60±12	59±10	0.309
Male sex (%)	71	71	77	68	72	0.58
BMI	27.1±4.2	27.2±3.8	28.1±4.8	27.5±4.3	26.2±4	0.018
LA volume (ml)	104±49	95±30	134±65	114±46	79±34	<0.001
LVEF (%)	58±8	52±10	57±7	58±8	60±7	<0.001
Paroxysmal AF (%)	80.4	81.3	75.3	79.6	83.4	0.47
Hypertension (%)	36.8	31.3	39.5	30.4	45.7	0.024
Ischemic heart disease (%)	6.3	3.7	6.2	5.3	5.5	0.88
Valvulopathy (%)	2.4	1	6.2	1.2	2.6	0.88
Dilated cardiomyopathy (%)	2.9	4.2	1.2	4.9	0.7	0.071
Previous TIA/Stroke (%)	2.7	1	1.2	4.3	2.6	0.44
Diabetes mellitus (%)	6.3	2.1	6.2	11.1	4	0.018
Chronic renal failure (%)	1.4	0	3.7	1.9	0.7	0.17

NS= not significant; BMI= body mass index; LA= left atrium; LVEF= left ventricle ejection fraction; AF= atrial fibrillation; TIA= transient ischemic attack.

Table 2. Procedural data for the total cohort of subjects, and for each study group.

	Overall population (n=490)	**Group ST 330-450 (n=96)**	**Group ST 380-500 (n=81)**	**Group STSF 330-450 (n=162)**	**Group STSF 380-500 (n=151)**	**p**
Common ostrium (%)	18.4	11.5	23.5	12.3	26.5	0.002
Accessory PV (%)	5.7	2.1	3.7	6.8	7.9	0.19
Procedure time (min)	127±64	129±44	144±44	120±72	125±73	<0.001
Fluoroscopy time (s)	400±404	542±285	540±416	257±356	379±454	<0.001
Ablation time (min)	31.9±11.8	30.7±10	28.8±13.7	33.3±11.5	33±11.7	0.089
First pass isolation (%)	90±16	90±16	87±19	90±17	91±15	0.585
Mean CF (g)	11±4	11.2±3.3	9.2±5.3	11.9±4.1	11.1±3.1	0.008
Mean impedence drop (Ω)	10.4±4.7	11.1±4.2	9.3±5.9	10.2±4.2	10.8±4.8	0.053
Saline volume infusion (ml)	974±599	1105±573	1732±664	701±287	836±503	<0.001

NS= not significant; PV= pulmonary vein; CF= contact force.

Figure 1.

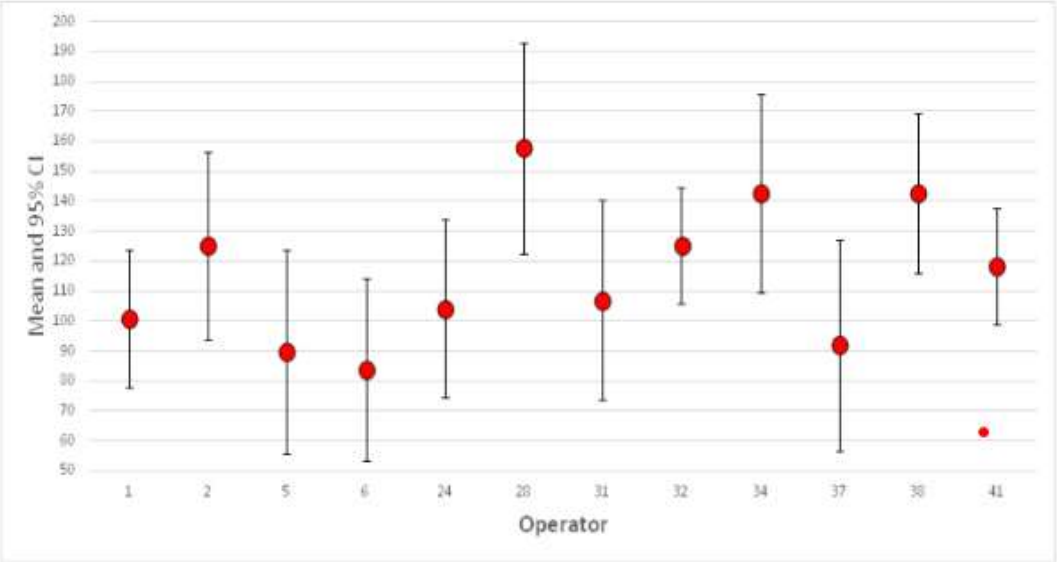

Figure 2.

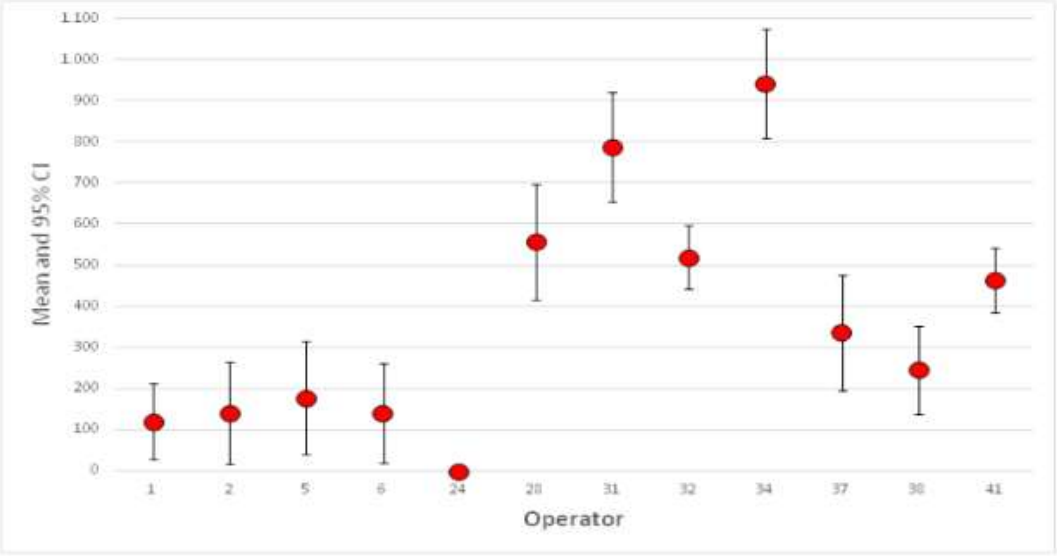

Figure 3.

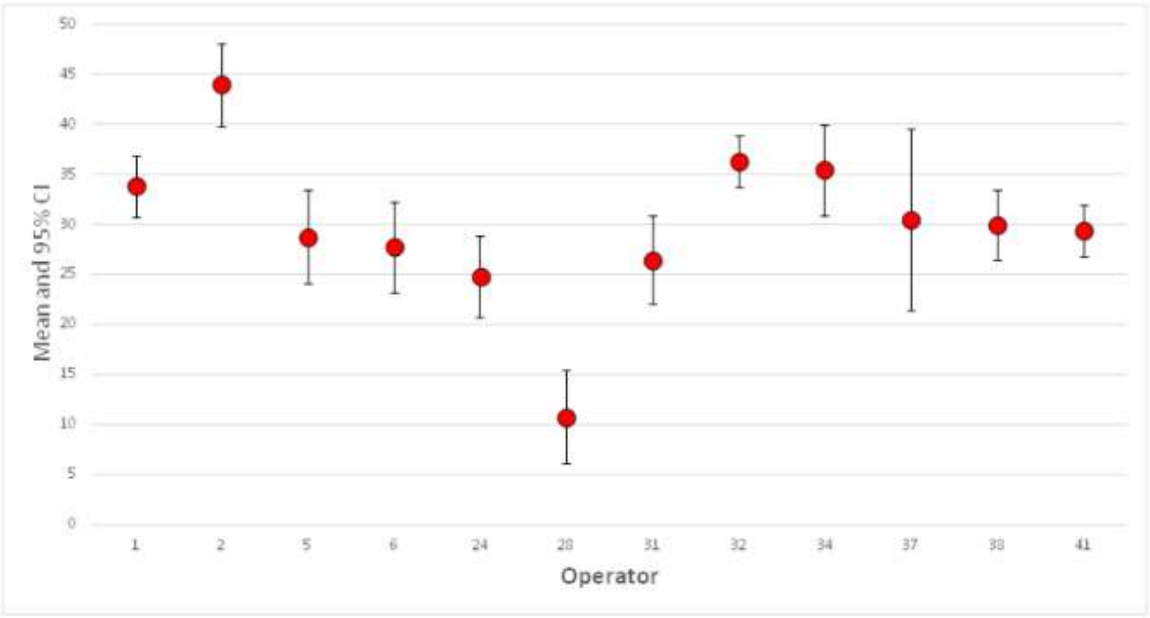

Figure 4.