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Comparison Between Sedated and Non-Sedated Colonoscopy Out Comes at Kurdistan Centers

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Original Article

Abstract

Background: *The colonoscopy is a popular screening and diagnostic tool for lower intestinal disorders. The colonoscopy is safe procedure, but pain and discomfort are frequently reported.*

Objective: *To compare the need for sedation during colonoscopy in relation to patients' characteristics and colonoscopy outcomes in addition to assess the factors related to pain in colonoscopies without sedations.*

Methodology: *This study was a clinical prospective follow up study implemented in Kurdistan center for Gastroenterology and Hepatology (KCGH) in Sulaimani city and Hawler Gastroenterology and Hepatology Center (HGHC) Erbil city-Kurdistan region/Iraq during the period of six months from 1st of January to 30th of June, 2022 on convenient sample of 201 patients undergoing colonoscopy divided into two study groups (100 patients were sedated and 101 patients were not sedated). All enrolled patients in the study were referred for colonoscopy with indications (constipation, bleeding per rectum, abdominal pain, diarrhea,) or screening colonoscopy or surveillance.*

Results: *The sedation-free colonoscopy was significantly better than sedated colonoscopy in regard to abdominal compression, position changes, cecal and ileal intubation time, patients' satisfaction, endoscopists' satisfaction and time of stay in colonoscopy unit. However, the abdominal pain was high in sedation-free colonoscopy. Factors related to need for sedation in colonoscopy are younger age, female gender, low body mass index, clinical co-morbidity, previous surgery and absence of prior abdominal pain. Male gender and negative history of previous surgery are the common risk factors of high abdominal pain score in sedation-free colonoscopy.*

Conclusions: *The non-sedated colonoscopy is possible and can be better than sedated one in certain situations without increase in serious complications rates specially perforations, moreover it can be more cost effective and less time-consuming especially in resource scarce areas.*

Keywords: *Colonoscopy, Sedation, pain.*

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1. INTRODUCTION

The colonoscopy is the essential investigation of lower gastrointestinal tract that helped in lowering incidence of future colorectal cancer through screening, diagnosis and therapy (1, 2). Additionally, the colonoscopy is helpful in diagnosis and treatment of many intestinal diseases including cancer. Despite publicity of colonoscopy, some cancers cases are recorded post-colonoscopy (3). However, high efforts in colorectal cancer screening (CRC) screening nowadays are accompanied by higher frequency of colonoscopy implementation all over the world (4). The pain and discomfort accompanying colonoscopy needs in some cases earlier stopping of colonoscopy before providing complete vision of colon and may lead to unwilling to perform future colonoscopy.(1) The anxiety of patients before and through colonoscopy might also play role in reducing the willing in performing the colonoscopy. For that, the sedation plans are needed for optimizing patient experience (6). The satisfaction of patients undergone colonoscopy is affected by pain experience during this procedure which also affects the patients adherence to screening programs (7). Better patients' tolerance during colonoscopy is important in allowing the physician in visualization of colon perfectly. Many measures are used in improving the patients tolerance such as sedation (conscious or deep), carbon dioxide or water (inflating colon) and robotic technology (8). Higher percentage of colonoscopies is implemented without sedation in different countries. In United Kingdom, 10.7% of colonoscopies were done without sedation, while 0.4% of colonoscopies were implemented with administering propofol (deep sedation) (9). On other hand, 35% of colonoscopies performed in United States are using propofol and anesthesia for reducing pain and discomfort (10). In Canada, the deep sedation use in colonoscopies had increased in last years from 19% to 44% of implemented colonoscopies (11). Choosing sedation along with colonoscopy aimed to provide analgesia and anxiolysis during the procedure and it is advised for most of patients. Traditionally, the sedation is performed through combining benzodiazepines and opioids that causing mild to moderate level of sedation (12). In most cases, the moderate sedation is commonly selected with combining midazolam and fentanyl that is decided by responsible endoscopists and monitored by nurses without additional health staff. Those patients undergone colonoscopy with plan of sedation are receiving lower doses of sedatives with minimum tactile stimulation (7). Conversely, the deep sedation (propofol) affect the respiratory and

cardiovascular systems and sometimes followed by general anesthesia that needs the intervention of trained anesthetist and associated with hazards of general anesthesia (13). The deep sedation is recommended only in patients with repeated or painful stimulation (14). The indications of deep sedation of colonoscopy are preference of patients, preference of endoscopist, increasing patients tolerance and fastening the recovery. However, many countries are not allowing use of propofol administration for colonoscopy due to medical hazards, legal polices and financial cost (15). The propofol has many advantages like quick action, short recovery duration and better satisfaction of patients in comparison to traditional sedation measures (16). Many play major role in making decision regarding use of sedation in patients prepared for colonoscopy in addition to decide type and dose of selected sedative or analgesic medication like the type of procedure (screening, diagnostic or therapeutic), clinical co-morbidities, patients age, general health, prior anxiety and baseline medications (16). Although general safety of traditional sedatives and analgesics, these medications are also associated with many health hazards and complications (17). For that, many authors discussed the different options in selecting types of sedatives, appropriate drug dose and timing of administration (16, 18, 19). Moreover, the cost of anesthesia also had impact on decision of endoscopists and preferences of patients (20,21). In Iraq, the incidence of colorectal carcinoma is increased in last two decades with higher predominance in younger age population (22, 23). Additionally, the colonoscopy is helpful in assessment of other intestinal disorders among Iraqi population such as nonspecific colitis, ulcerative colitis, hyperplastic polyp, and internal hemorrhoid (24). In Kurdistan region, the incidence of colorectal carcinoma is highly reported since two decades ago and till now (25-27). The colonoscopies are widely used in Kurdistan Gastroenterology centers for purpose of screening, diagnosis and treatment of lower intestinal disorders (28). This study aimed to compare the need for sedation during colonoscopy in relation to patients' characteristics and colonoscopy outcomes in addition to assess the factors related to pain in colonoscopies without sedations.

2. PATIENTS and METHODS

The design of present study was a clinical prospective follow up study implemented in Kurdistan center for Gastroenterology and Hepatology (KCGH) in Sulaimani city and Hawler Gasteroenterology and hepatology Center (HGHC) Erbil city-Kurdistan region/Iraq during the period of three years from 1st of January to 30th of June, 2022. The studied population was all patients underwent colonoscopy in KCGH and HGHC during study duration. Inclusion criteria were adult patients (age≥ 18 years) underwent colonoscopy with indications for elective colonoscopy (e.g., constipation, bleeding per rectum, abdominal pain, diarrhea, or screening surveillance for colon cancer) and willingness to participate in the study in addition to cases referred to screening and survillane. Exclusion criteria were younger age patients, underwent both gastroscopy and colonoscopy simultaneously, interventional procedures were planned ahead of the colonoscopy, refused to participate in the study, incomplete colonoscopy and lost to follow up. The study ethics were implemented in regard to Helsinki Declaration by approval of Ethical Committee of Kurdistan Board, documented approval of health authorities and oral consent of selected patients. A convenient sample of 201 patients undergoing colonoscopy divided into two study groups (100 patients were sedated and 101 patients were not sedated) was enrolled in current study after eligibility to inclusion and exclusion criteria. Information of patients was collected directly from patients by researcher through a prepared questionnaire designed by the researcher according to previous literatures (4,9,12). The questionnaire included general characteristics of patients underwent colonoscopy (age, gender, marital status, body mass index and educational level), clinical history of patients underwent colonoscopy underwent kidney transplant (smoking, alcohol consumption, chronic diseases, medications and previous surgery), pre-procedure characteristics (indications of colonoscopy, abdominal pain, anemia, weight loss, diarrhea, constipation, bleeding, others and Boston scale) colonoscopy characteristics (cecal intubation time, terminal ileal intubation time, withdrawal time, abdominal compression, position changes, polyps number, polyps size, polyps location and other locations) and colonoscopy outcomes (abdominal pain score, time of stay in colonoscopy unit, patients wish to repeat procedure, patients satisfaction score and endoscopist satisfaction score). All enrolled patients in the study were referred for colonoscopy with indications (constipation, bleeding per rectum, abdominal pain, diarrhea, or screening surveillance for

colon cancer) or for screening and surveillance. Patients who undergo colonoscopy in our endoscopy unit are offered sedation with standard intravenous sedatives (Pethidine and midazolam according to body weight) and an attempt at unsedated colonoscopy, without any attempt to pressure or persuade patients for having unsedated procedures. Olympus-Optera CF-170 AL and Olympus-Exera CF-260 AL have been used for colonoscopy. The Boston bowel preparation, dividing colon in to left, transverse, right giving score, (0,1,2,3) for each section and collecting all three area scores, if all three equal 9 and less than 5 bad prep. The outcome parameters were assessed by the researcher. The patients were followed up by phone calling for one week following colonoscopy in order to assess the outcomes. The patients' information were entered and interpreted statistically by SPSS program-26. Suitable statistical tests (Fishers exact test) for data were implemented accordingly and p value of ≤ 0.05 was significant.

3. RESULTS

This study included 201 patients undergoing colonoscopy divided into two study groups (100 patients were sedated and 101 patients were not sedated). Younger age patients were significantly related to sedation ($p<0.001$). There was a highly significant association between female gender patients and need for sedation ($p<0.001$). A significant association was observed between lower body mass index and need for sedation ($p=0.01$). No significant differences were observed between patients undergoing colonoscopy with or without need for sedation regarding marital status ($p=0.48$) and educational level ($p=0.06$). (**Table 1**). There was a significant association between absence of chronic diseases and need for sedation ($p=0.02$). A significant association was observed between previous surgery and need for sedation ($p=0.01$). No significant differences were observed between patients undergoing colonoscopy with or without need for sedation regarding smoking ($p=0.49$), alcohol consumption ($p=0.24$) and medications ($p=0.13$). (**Table 2**). No significant differences were observed between patients undergoing colonoscopy with or without need for sedation regarding colonoscopy indications ($p=0.3$), anemia ($p=0.66$), weight loss ($p=0.88$), diarrhea ($p=0.66$), constipation (0.81), bleeding ($p=0.82$), other symptoms ($p=0.15$) and Boston scale ($p=0.4$). The BBS mean was not significantly different between patients undergoing colonoscopy with or without need for sedation ($p=0.16$). There was a significant association between absence of abdominal pain and

need for sedation (p=0.04). (**Table 3**). Mean cecal intubation time was significantly shorter in patients not needed sedation (p=0.009). Mean terminal ileal intubation time was significantly shorter in patients not needed sedation (p=0.003). Mean withdrawal time was not significantly different between patients with or without need for sedation (p=0.6). There was a highly significant association between abdominal compression and patients not needed sedation (p<0.001). A highly significant association was observed between position changes and patients not needed sedation (p<0.001). No significant differences were observed between patients undergoing colonoscopy with or without need for sedation regarding polyps number (p=0.24), size (p=0.12), location and other findings (p=0.059). (**Table 4**). Mean abdominal score was significantly higher in patients not needed sedation (p<0.001). Mean time of stay in colonoscopy unit was significantly longer in patients needed sedation (p<0.001). No significant differences were observed between patients undergoing colonoscopy with or without need for sedation regarding procedure related complications (p=0.24), and patients wish to repeat the procedure (p=0.84). Mean patients satisfaction score was significantly higher in patients not needed sedation (p<0.001). Mean endoscopist satisfaction score was significantly higher in patients not needed sedation (p=0.002). (**Table 5**). No significant differences were observed between not sedated patients with low or high abdominal score regarding age (p=0.74), marital status (p=0.16), body mass index (p=0.32) and educational level (p=0.28). There was a significant association between male gender of not sedated patients and high abdominal pain score (p=0.03). (**Table 6**). No significant differences were observed between not sedated patients with low or high abdominal score regarding smoking (p=0.96), alcohol consumption (p=0.53), chronic diseases (p=0.32), medications (p=0.14) and Boston scale (p=0.48). There was a significant association between negative history of previous surgery and high abdominal pain score (p=0.02). (**Table 7**).

Table 1. Distribution of patient's general characteristics according to study groups.

Variable		Study groups				P-Value
		Sedated		Not sedated		
		No.	%	No.	%	
Age (years)	<40	37	37	6	5.9	<0.001*
	40-49	20	20	22	21.8	
	50-59	19	19	33	32.7	
	60-69	16	16	31	30.7	
	≥70	8	8	9	8.9	
Gender	Male	26	26	61	60.4	<0.001*
	Female	74	74	40	39.6	
Marital status	Single	22	22	16	15.8	0.480
	Married	72	72	80	79.2	
	Widow	6	6	5	5	
Body mass index	Normal	40	40	24	23.8	0.010*
	Overweight	45	45	47	46.5	
	Obese	15	15	30	29.7	
Educational level	Illiterate	30	30	28	27.7	0.060
	Elementary	26	26	42	41.6	
	Secondary	23	23	12	11.9	
	High	21	21	19	18.8	

* significant

Table 2. Distribution of patient's clinical history according to study groups.

Variable		Study groups				P. value
		Sedated		Not sedated		
		No.	%	No.	%	
Smoking		29	29.0	25	24.8	0.490
Alcohol consumption		4	4.0	8	7.9	0.240
Chronic diseases		41	41.0	57	56.4	0.020*
Medications		43	43.0	54	53.5	0.130
Previous surgery	Abdominal	6	6.0	8	7.9	0.010*
	Pelvic	19	19.0	4	4.0	
	Others	8	8.0	5	5.0	
	Abdominal and pelvic	0	-	2	2.0	
	Pelvic and others	0	-	1	1.0	
	Abdominal, pelvic &others	1	1.0	0	-	
	None	66	66.0	81	80.2	

* significant

Table 3. Distribution of pre-procedure characteristics according to study groups

Variable		Study groups				P. value
		Sedated		Not sedated		
		No.	%	No.	%	
Indications	Screen	6	6.0	10	9.9	0.300
	Surveillance	12	12.0	7	6.9	
	Diagnostic	82	82.0	84	83.2	
Abdominal pain		29	34.5	41	50.0	0.040*
Anemia		29	34.5	26	31.3	0.660
Weight loss		19	22.6	18	21.7	0.880
Diarrhea		15	17.9	17	20.5	0.660
Constipation		17	20.2	18	21.7	0.810
Bleeding		18	21.4	19	22.9	0.820
Others		2	2.4	0	-	0.150
Boston scale	Excellent	50	50.0	46	45.5	0.400
	Good	36	36.0	45	44.6	
	Poor	14	14.0	10	9.9	
BBS (Mean ±SD)		7.2 ±1.1		7.4±1		0.160

* significant

Table 4. Distribution of colonoscopy characteristics according to study groups

Variable	Study groups		P. value
	Sedated	Not sedated	
Cecal intubation time (min.)	11.7 ± 4.5	10.1 ± 3.5	0.009 *
Terminal ileal intubation time (min.) (mean ±	13.4 ± 5.0	11.5 ± 3.3	0.003*
Withdrawal time (min.) (mean ± SD)	10.3 ± 2.8	10.5 ± 2.6	0.600
Polyps number (mean ± SD)	5.3 ± 18.9	1.3 ± 0.7	0.240
Polyps size (mm) (mean ± SD)	9.5 ± 4.0	8 ± 3.2	0.120
Abdominal compression n (%)	70 (40.0)	92 (91.1)	<0.001*
Position changes n (%)	43 (43.0)	70 (69.3)	<0.001*
Location n (%)			0.690
Rectum	7 (25.9)	7 (22.6)	
Sigmoid	1 (3.7)	4 (12.9)	
Cecum	4 (14.8)	7 (22.6)	
Trnsverse colon and sigmoid	1 (3.7)	1 (3.2)	
All colon	7 (25.9)	9 (29.0)	
Ascending colon	1 (3.7)	1 (3.2)	
Transverse and ascending colon	4 (14.8)	1 (3.2)	
Cecum and sigmoid	2 (7.4)	1 (3.2)	
Other findings n (%)			0.059
Normal	35 (38.9)	32 (32.2)	
Proctitis	1 (1.1)	1 (1.0)	
Segmoiditis	1 (1.1)	0 (0.0)	
Proctosegmoiditis	3 (3.3)	0 (0.0)	
Pancolitis	2 (2.2)	2 (2.0)	
Internal pile	17 (18.9)	7 (7.1)	
Diverticulosis	5 (5.6)	14 (14.1)	
Polypectomy	7 (7.8)	20 (20.2)	
Biopsy taken	1 (1.1)	1 (1.0)	
CRC	3 (3.3)	4 (4.0)	
Terminal ileal nodularity	1 (1.1)	1 (1.0)	
Melanosis coli	0 (0.0)	2 (2.0)	
SRUS	1 (1.1)	1 (1.0)	
Terminal ileal ulcers	2 (2.2)	0 (0.0)	
RAVE	1 (1.1)	0 (0.0)	
FAP	1 (1.1)	0 (0.0)	
Others	9 (10.0)	14 (14.1)	

SD: standard deviation , * significant

Table 5. Distribution of colonoscopy outcomes according to study groups.

Variable		Study groups		P. value
		Sedated	Not sedated	
		No.	No.	
Abdominal pain score (mean ± SD)		4.6 ±2	5.5±1.5	<0.001 *
Time of stay in colonoscopy unit (min.) (mean ± SD)		85.6± 24.1	34.8±7	<0.001 *
Patients' satisfaction score (mean ± SD)		7.3±0.9	8.1±1.2	<0.001 *
Endoscopist satisfaction score (mean ± SD)		7.5±1.3	8±1.1	0.002 *
Procedure-related complications n (%)	Bleeding	5 (5.0)	2 (2.0)	0.240
	No	95 (95.0)	99 (98.0)	
Patients wish to repeat the procedure n (%)	Yes	58 (58.0)	60 (59.4)	0.840
	No	42 (42.0)	41 (40.6)	

SD: standard deviation , * significant

Table 6: Distribution of not sedated patient's general characteristics according to abdominal

Variable		Abdominal pain score				P. value
		≤5		>5		
		No.	%	No.	%	
Age (years)	<40	3	7.5	3	4.9	0.74
	40-49	9	22.5	13	21.3	
	50-59	10	25.0	23	37.7	
	60-69	14	35.0	17	27.9	
	≥70	4	10.0	5	8.2	
Gender	Male	19	47.5	42	68.9	0.030 *
	Female	21	52.5	19	31.1	
Marital status	Single	6	15.0	10	1 .4	0.160
	Married	30	75.0	50	82.0	
	Widow	4	10.0	1	1.6	
Body mass index	Normal	9	22.5	15	24.6	0.320
	Overweight	22	55.0	25	41.0	
	Obese	9	22.5	21	34.4	
Educational level	Illiterate	11	27.5	17	27.9	0.280
	Elementary	19	47.5	23	37.7	
	Secondary	6	15.0	6	9.8	
	High	4	10.0	15	24.6	

* significant

Table 7. Distribution of not sedated patient's clinical history according to abdominal

Variable		Abdominal pain score				P. value
		≤5		>5		
		No.	%	No.	%	
Smoking	Yes	10	25.0	15	24.6	0.960
	No	30	75.0	46	75.4	
Alcohol consumption	Yes	4	10.0	4	6.6	0.530
	No	36	90.0	57	93.4	
Chronic diseases	Yes	25	62.5	32	52.5	0.320
	No	15	37.5	29	47.5	
Medications	Yes	25	62.5	29	47.5	0.140
	No	15	37.5	32	52.5	
Previous surgery	No	27	67.5	54	88.5	0.020*
	Abdominal	3	7.5	5	8.2	
	Pelvic	3	7.5	1	1.6	
	Others	5	12.5	0	-	
	Abdominal	1	2.5	1	1.6	
	Pelvic and	1	2.5	0	-	
Boston scale	Excellent	21	52.5	25	41.0	0.480
	Good	15	37.5	30	49.2	

* significant

4. DISCUSSION

The colonoscopy is a common screening and diagnostic tool for small intestine. The decision of taking sedation or not prior to procedure might be affected by national and cultural discrepancies between different countries, in addition to patients preferences and endoscopists practice (29). Present study showed that younger age patients were significantly related to need for sedation ($p<0.001$). This finding is consistent with Lin study (30) in USA which reported that elderly age patients can tolerate colonoscopy pain better than younger age patients in addition to more sedation complications in elderly age patients. Our study showed a highly significant association between female gender patients and need for sedation ($p<0.001$). This finding is similar to results of Childers et al (31) study in USA which reported that low tolerance of pain among women required sedation with higher doses required for men. Inconsistently, Cassell et al (32) found that younger age and female gender are significant predictors of failed conscious sedation in patients undergoing an outpatient colonoscopy. This

inconsistency might be due to differences in preferences and pain tolerance between societies. Our study also found a significant association between lower body mass index and need for sedation (p=0.01). This finding coincides with results of Qureshi et al (33) retrospective study in UK which reported that patients with low BMI had less colonic fat which increase failure chance of colonoscopy and need for sedation. In our study, there was a significant association between absence of chronic diseases and need for sedation (p=0.02). Consistently, Sayin et al (34) prospective study in Turkey revealed that co-morbidity with diabetes mellitus and hypertension affecting the decision of sedation in colonoscopy. The present study found a significant association between previous surgery and need for sedation (p=0.01). This finding is inconsistent with results of Goodwin et al (35) study in USA which reported that previous abdominal surgery is a significant factor of failed conscious sedation of colonoscopy. This inconsistency may be due to low tolerance of pain in our study patients following previous surgery and preference of sedation. In current study, there was a significant association between absence of abdominal pain and need for sedation (p=0.04). This finding is consistent with results of Holme et al (36) study in Norway which reported that patients' preferences and intolerance to pain was the common indications for sedation in colonoscopy nowadays. However, our study found that means of cecal intubation and terminal ileal intubation times were significantly shorter in patients not needed sedation (p=0.009 and p=0.003, respectively). In Germany, a prospective study carried out by Zuber-Jerger et al (37) reported that cecal and ileal intubation time was affected by experience of endoscopy team and preparation of bowel in addition to patients' tolerance to pain. In our study, there was a highly significant association between abdominal compression and patients not needed sedation (p<0.001). This finding is parallel to results of Hsieh et al (38) study in Taiwan which stated that minimal use of sedation during colonoscopy is associated with high abdominal compression which help in shortening time of cecal and ileal intubation. Present study found a highly significant association between position changes and patients not needed sedation (p<0.001). Similarly, Arya et al (39) study in USA reported that not sedation is helpful in position changes during colonoscopy and reducing colonoscopy duration. Our study revealed that mean abdominal score was significantly higher in patients not needed sedation (p<0.001). This finding is similar to results of Aljebreen et al (40) study in Saudi Arabia which found that mean abdominal pain score was low in patients

undergone colonoscopy with sedation. In our study, the mean time of stay in colonoscopy unit was significantly longer in patients needed sedation ($p<0.001$). Consistently, Nishizawa et al (41) retrospective study in Japan found that elderly age, female gender and sedation use were risk factors for prolonged stay in colonoscopy unit. Current study showed that both patients and endoscopist satisfaction scores were higher in association with colonoscopies not needed sedation ($p<0.001$ and $p=0.002$, respectively). These findings are in agreement with results of Kumar and Pathak study (42) in Nepal which reported higher efficacy and satisfaction of both patients and endoscopist from sedation free colonoscopy. In present study, there was a significant association between male gender of not sedated patients and high abdominal pain score ($p=0.03$). Previous study conducted in USA by Rex et al (43) reported that male gender patients were highly used sedation-free colonoscopy and this might explain high perception of abdominal pain score. Our study found a significant association between negative history of previous surgery and high abdominal pain score ($p=0.02$). This finding coincides with results of Suzuki et al (44) prospective study in Japan which reported that younger age, no previous surgery, not using anti-spasmodic agents and large diameter endoscope were associated with high pain scores in sedation-free colonoscopy.

5. CONCLUSIONS

This study concluded that although sedated colonoscopy is the gold standard in colonoscopy, being a painful procedure generating from inflation with passing bends and flextures, but our results indicate that non-sedated colonoscopy is possible and can be better than sedated one in certain situations without increase in serious complications rates specially perforations, moreover it can be more cost effective and less time-consuming especially in resource scarce areas. However, the abdominal pain was high in sedation-free colonoscopy. Factors related to need for sedation in colonoscopy are younger age, female gender, low body mass index, clinical co-morbidity, previous surgery and absence of prior abdominal pain. Male gender and negative history of previous surgery are the common risk factors of high abdominal pain score in sedation-free colonoscopy. This study recommended the use of sedation-free colonoscopy generally, while use of sedation in special circumstances.

Ethical Clearance:

Ethical issues were taken from the research ethics committee. Informed consent was obtained from each participant. Data collection was in accordance with the World Medical Association (WMA) declaration of Helsinki for the Ethical Principles for Medical Research Involving Human Subjects, 2013 and all information and privacy of participants were kept confidentially.

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