Effect of The Arterial Needle Bevel Orientation on Puncture Pain and Post-Removal Bleeding Time Among Patients on Maintenance Hemodialysis.

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Abstract

Background: *The vascular access for hemodialysis is considered a patient's lifeline. Pain and bleeding are common problems facing patients with vascular access. So, nurses bear a large deal of responsibility for selection of cannulation technique whether bevel up or down, to achieve less painful technique and less bleeding.* ***Aim of the Study:*** *Evaluate the effect of arterial needle bevel orientation on puncture pain and the post-removal bleeding time among patients on maintenance hemodialysis.* ***Design:*** *A quasi-experimental research design was utilized for this study.* ***Setting:*** *Hemodialysis unit at Al-Moasat Alexandria university hospital* ***Subjects:*** *A sample of 50 patients (25 patients in each study group (group 1 / group 2) who met the inclusion criteria was involved in the study.* ***Results:*** *There was no statistically significant difference between the two groups regarding level of pain (P value = 0.169), however bleeding time was lower in patients had their arterial needle inserted in bevel down orientation (P value <0.05).* ***Conclusion:*** *Insertion of arterial needle for arteriovenous fistula in bevel down was found to be effective in reducing bleeding time and the need for manual compression, but there were no statistically significant differences in level of pain with bevel up and bevel down orientation.* ***Recommendations:*** *Replication of the study on larger probability sample.*

Keywords: Arterial Needle, Needle Orientation, Bevel, Puncture Pain, Maintenance hemodialysis.
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Introduction

Chronic kidney disease is a chronic disorder marked by structural and functional abnormalities in the kidney caused by a variety of factors. Chronic kidney disease is typically defined as a decrease in kidney function, an estimated glomerular filtration rate (eGFR) of less than 60 mL/min per 1.73 m2, or kidney damage markers such as albuminuria, hematuria, or abnormalities detected through laboratory testing or imaging that have been present for at least 3 months **(Kalantar-Zadeh et al., 2021).** When GFR decreases, CKD progresses, it eventually advances to end-stage renal disease (ESRD), necessitating renal replacement therapy (hemodialysis or peritoneal dialysis) or renal transplantation **(Rysz et al., 2020).**

Renal Replacement Therapy (RRT) in ESRD patients aims to increase not only survival but also quality of life. Each RRT modality, including hemodialysis (HD), peritoneal dialysis (PD), and kidney transplantation has distinct advantages and disadvantages, with hemodialysis being the most frequent modality of dialysis therapy in almost all countries, accounting for over 80%

of all cases, followed by peritoneal dialysis and kidney transplantation **(Chuasuwan et al., 2020).** Hemodialysis (HD) is the primary way of renal replacement therapy for 70% to 90% of patients worldwide. This technique requires well-functioning vascular access. Arteriovenous fistula (AVF) is the best vascular access for hemodialysis when compared to the arteriovenous graft (AVG) or central venous catheter (CVC), due to its longer patency, reduced complications, and lower mortality rates **(Chuasuwan et al., 2020; Gameiro & Ibeas, 2020)**

Vascular access is a critical concern in hemodialysis with an arteriovenous fistula (AVF) on the non-dominant lower arm is the recommended method of access. If the natural vessels are insufficient for such access, an arteriovenous graft for punctures can be constructed by inserting a synthetic vascular graft between an artery and a vein. The European guidelines recommendations (2018) propose that optimal vascular access (VA) in patients who will be provided HD enable cannulation using two needles. The arterial line is one of the two entry points that allow blood to enter the extracorporeal circuit (ECC), which includes the dialyzer. The venous line, the other access, permits blood within the ECC to return to the patient **(Allon, 2019; Stegmayr et al., 2021).**

During the cannulation procedure, puncture can be accomplished in two ways: bevel down (BD) with the needle shaft facing downwards and bevel up (BU) with the needle shaft facing upwards. The clinical practice guidelines for vascular access and the National Kidney Foundation (KDOQI) suggested that the AVF can be cannulated with a 25° puncture angle and a bevel-up needle position. The utilization of bevel down or bevel up needle puncture procedures during cannulation varies amongst hemodialysis centers. Furthermore, according to the literature, several centers commonly employ the arteriovenous fistula puncture procedure with the needle bevel-up position. Few studies, however, have evaluated arteriovenous cannulation procedures (bevel-up or bevel-down punctures) and their impact on puncture pain or post-removal bleeding time **(Yilmaz et al., 2022).**

Pain is one of the most common symptoms among hemodialysis patients. Hemodialysis patients report chronic pain from a variety of causes, mainly and commonly resulting from arteriovenous repeated puncture. The arteriovenous puncture is a recurrent technical treatment that is seen as aggressive, at which two independent puncture locations required every session, three times a week, that is an average of 300 punctures per year, as a norm for patients whose hemodialysis therapy might extend for years, if not forever **(Kortobi et al., 2020; Kosmadakis et al., 2021).**

Controlling bleeding after needle removal is critical for both health-care providers and patients. A long delay has negative influences on the patient since it increases nursing burden, occupies valuable staff time that might be spent monitoring patient treatments, and is likely to disrupt the hemodialysis unit's overall dialysis schedule structure. Furthermore, in observational research, excessive post-dialysis puncture site bleeding measured by the gauze weigh technique, was found to be strongly linked with decreased hemoglobin levels. On the other hand, excessive compression may damage vascular access walls, and has been reported to favor late fistula thrombosis when used with hemostatic devices such as straps, tourniquets, and hard clamps **(Álvaro Cristóbal et al., 2021).**

Arteriovenous fistula cannulation is the vital to the patient thus the selected technique must be the one with the little to no complications, including pain and bleeding, thus it the nurse who bears the greatest

responsibility to select the cannulation technique taking into account its effects on AVF patency, AVF homeostasis, patient discomfort and quality of life.

Aim of the study

This study aims to evaluate the effect of arterial needle bevel orientation on puncture pain and the post-removal bleeding time among patients on maintenance hemodialysis.

Research hypotheses

- Patients on maintenance hemodialysis who are exposed to needle inserted in a bevel down orientation, exhibit lesser pain mean score than those exposed to needle inserted in a bevel up orientation.
- Patients on maintenance hemodialysis who are exposed to needle inserted in a bevel up orientation, exhibit greater post-removal bleeding time than those who have needle inserted in a bevel down orientation.

Materials and Method

Materials

Design: A quasi-experimental research design was utilized for this study.

Settings: the study was conducted at the Hemodialysis Unit at Al -Moassat Alexandria University Hospital.

Subjects: The required sample size was calculated a priori using G-power (3.1.9.7) program. 40 participants were required for a type 1 error of 0.05 and a power of 80% based on a medium effect size. After accounting for a 10% drop-out rate, the sample size was increased to 50. Participants were conveniently selected and allocated into two equal study groups, 25 patients each.

Tools:

Four tools were used to collect the necessary data.

Tool I: Patient's Socio-demographics and clinical data interview schedule: It was developed by the researcher after reviewing of the related literature **(Hanafusa et al., 2017; Hassaballa et al., 2022)**, to identify characteristics of patients and baseline clinical data.

Tool II: Alertness checklist: It was adopted from **Romanelli & Farrell (2022).** it was used to assess patient alertness, consciousness, and orientation it included an assessment of Glasgow Coma Scale (GCS) with a total score of 15 according to eye opening, verbal response and motor response, the scoring system was as follow: 15 = alert, 12-13 = verbally responsive, 5 to 6 = physically responsive and 3 = coma.

Tool III: Pain visual analogue scale: It was adopted from **Byrom et al. (2022),** it was used to assess the severity of pain, patients was asked to points to their pain score on 10 cm long line on a paper with only two indicators, one at the beginning 0 that indicated (no pain) and the other at the end of the line 10 that indicated very severe pain. A ruler was used to measure the score and its corresponding patient degree of pain according to the scoring system which was as follows: 0 = no pain, 1-3 = mild pain, 4-6 = moderate pain, 7-9 = severe pain, 10 = very severe pain.

Tool IV: Bleeding Time record: It was developed by the researcher after reviewing the related literature **(Álvaro Cristóbal et al., 2021; Yilmaz et al., 2022),** it was used to record the duration of time to stop bleeding after needle removal and data obtained was compared against accepted range of bleeding time according to British Columbia (BC) renal guidelines 2020. **(BR Renal Agency, 2020)**. Bleeding time less than or equal to 10 minutes was accepted.

Method

Approval of the Research Ethics Committee, Faculty of Nursing, Alexandria University was obtained before conducting the study. An official letter was directed to the responsible authorities of the selected setting to obtain their approval to collect the data

after explaining the aim of the study. A pilot study was conducted on 5 patients to test the clarity, the feasibility and applicability of the developed tools and to identify problems encountered during sample selection. The necessary modifications were carried out. Those subjects were excluded from the actual study. Data collection was started from May 2023 to September 2023, the data was collected from the study group (1) first, then the study group (2) to prevent data contamination.

The study was conducted in four phases**: phase (I) Assessment phase:** Initial assessment of both study groups was carried out by the researcher in which every patient was interviewed and assessed using: Tool (I), part (I) patient socio-demographic and part (II) patient's clinical data. Assessment of the arteriovenous fistula for bruit and thrill was conducted using tool (I). Tool (II) was used to assess the patient alertness and ability to respond verbally.

Phase (II) Planning phase: Preparation of the following equipment was done: Two16-gauge dialysis needles one arterial and one venous. 2% Chlorohexidine was utilized for skin disinfection before cannulation.

Phase (III) Implementation phase: Hand Hygiene following WHO steps **(World Health Organization, 2009)** before the procedure was conducted. Disinfection of the arteriovenous fistula site before cannulation using 2 % Chlorohexidine. For study group 1 the arterial needle was inserted in bevel down orientation, while venous needle in bevel up orientation, patients were asked about pain score using visual analogue scale. For study group 2 the arterial and venous needles were inserted in bevel up orientation, patients were asked about pain score using visual analogue scale. At the end of dialysis session hemostasis was achieved using a two-fingers compression technique after removal of arterial needle by the researcher.

Phase (IV) Evaluation phase: Puncture pain severity was recorded using tool III for six sessions for each patient in both study groups. Bleeding time after removal of arterial needle was recorded using tool IV for six sessions for each patient in both study groups.

Ethical Considerations

An informed consent was obtained from patient after explaining the aim of the study and the right to refuse to participate in the study and/ or withdraw at any time. Patient's privacy was respected. Data confidentiality was maintained during implementation of the study.

Statistical Analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Shapiro-Wilk test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation, median. The significance of the obtained results was judged at the 5% level.

Results

Table 1 shows the percentage distribution of the patients in both studied groups according to their sociodemographic characteristics, there were no significant differences between the two studied groups ($P < 0.05$) except for the age variable in which there was statistically significant difference between the two studied group ($P = 0.017$).

Table 2 shows distribution of the patients of the two studied groups according to their clinical data. There were no statistically significant differences between the two studied groups except for the laboratory investigations of sodium, potassium, creatinine and urea there were statistically significant differences ($P = 0.002$, <0.001, <0.001, 0.017 respectively).

Table 3 shows the mean score distribution of the patients in both studied groups according to their pain score, there were no significant differences between the two studied groups according to pain score change through the six sessions (P=0.169).

Table 4 shows the mean score distribution of the patients in both studied groups according to their bleeding time after removal of the arterial needle. There were statistically significant differences between the two studied groups through the six sessions (P=0.002).

Discussion

Arteriovenous fistula is considered the golden vascular access for hemodialysis which is considered a patient's lifeline. Pain and bleeding are common problems facing patients during cannulation of arteriovenous fistula. So, nurses bear a large deal of responsibility for selection of cannulation technique. Though different hemodialysis centers use different needle puncture techniques during cannulation, the current international guidelines do not provide clear recommendations regarding the bevel orientation of the needles during cannulation, either down or up **(Arasu et al., 2022).** Thus, the current study was done to evaluate the effect of arterial needle bevel orientation on puncture pain and post-removal bleeding time.

Concerning sociodemographic characteristics, the findings of the current study showed that, more than half of the study sample for both groups were females, this can be attributed to the sampling method of this study which was convenience sampling. However, those results are contradicted with **Loizeau et al., (2023)** carried out a study entitled "Effect of needle orientation during arteriovenous access puncture on needed compression time after hemodialysis: A randomized controlled trial" their results showed that more than half of studied sample were males while the remaining percentage were females for which was attributed due to the prevalence and incidence of ESRD were more in males than females.

Regarding patients' age the current study showed that more than one third of the study group 1 and more than half of the study group 2 were in the age group of 50-60 years old, this could be attributed to aging changes of the renal system and that the older adults often experience deteriorating physical and psychological functions that would affect the renal system. Those results agree with **Loizeau et al., (2023)** and **Yilmaz et al., (2022)** conducted a study entitled "Effect of needle bevel position in arteriovenous fistula cannulation and bleeding during hemodialysis". Also, another study entitled "The Effect of Nursing Intervention Guidelines on Vascular Access Self-Care Practices and Quality of Life Among Patients on Maintenance Hemodialysis" which was conducted by **Abdel Hakeim et al., (2024)** showed that more than half of the sample were in the age of 45 to 60 years old.

In relation to education, the current study showed that more than one third of the study group 1 and roughly the third of the study group 2 had university education, this can be linked to higher awareness and adherence of highly educated groups to seek medical help and also that the current study was conducted at a university hospital which offers its services for all its affiliated personnel , however those results differs from **Ozen et al., (2022)** conducted a study entitled "Effect of the arterial needle bevel position on puncture pain and post removal bleeding time in hemodialysis patients: A self-controlled, single-blind study " their results showed that one third and near half of the group had secondary education, our results also differs from **Abdel Hakeim et al., (2024),** showed that more than one fifth of their sample had primary education with none out of 160 patient had university

education.

In respect to occupation, more than one third of both studied groups were housewives this can be linked to the fact more than half of both groups are females. Those results are in line with **Abdel Monem et al., (2022)** carried out a study entitled " effect of nursing intervention on controlling interdialytic weight and vascular access complications among patients undergoing hemodialysis" they showed that their study group had exactly half of it being housewives and less than half of their control being housewives. **Concerning marital status,** more than two thirds of both groups were married, this could be attributed to the feeling of responsibility, cohesion and affection between the partners. Those results are in line with **Abdel Monem et al., (2022)** mentioned that the majority of both of his two groups were married.

Regarding associated disease, the current study showed that among the patients in study group 1, less than one third had diabetes mellitus, the majority had hypertension, one fifth had cardiovascular disease, and merely one tenth had primary renal disease. In contrast, all the patients in study group 2 had hypertension, almost one-third had diabetes, and less than one tenth had primary renal disease, this can be attributed to hypertension being the most common risk factor for developing renal diseases. Those results agree with **Aragoncillo Sauco et al., (2021)** conducted a study entitled "Effect of preoperative exercise on vascular caliber and maturation of arteriovenous fistula" his results showed that the majority of his patients had hypertension in both of their studied and control group, however their results showed that the percentage of patients diagnosed with diabetes mellitus was more than half of the group which is higher than the percentage of the current study.

Regarding pain score during needle insertion the current study reveals that there was no significant difference between pain score among the two studied groups, our results agree with **loizeau and his colleagues** in a study entitled " Effect of needle orientation during arteriovenous access puncture on needed compression time after hemodialysis: a randomized controlled trial" in which a 40 patients participated, puncture-associated pain was assessed during a two weeks baseline period they stated that the orientation of the access needles had no difference in puncture-associated pain between the two insertion techniques. However, our results differ from the results of **Crespo Montero et al., (2004)** in a study entitled "Pain degree and skin damage during arterio-venous fistula puncture" at which they compared the size of the skin incision with a needle bevel-down insertion approach versus a needle bevel-up technique. They reported that the size of the skin incision was smaller with the needle bevel down method, Montero and his colleagues found that puncture-related pain was less when the needle bevel was oriented downward during insertion; however, they were unable to correlate puncture pain with incision size. Another study conducted by **Ozen et al., 2022**, studying 35 patients over six sessions with bevel-up puncture and six sessions with bevel down, who found significant decrease in pain score using bevel down orientation during puncture of the arteriovenous fistula. This can be attributed to that pain experience is subjective it may differ from a person to another and from a culture to another, also both Ozen and Montero with their colleagues conducted their study using crossover design in which the two techniques were done on the same sample.

Regarding bleeding time after removal of the needle, this current study reveals that bleeding time was significantly lower when arterial needle was inserted in bevel down orientation. This can be attributed to the vessel wall opening caused by bevel down orientation was smaller than

that caused be bevel up orientation, our results agree with **Ozen et al., 2022** found that bevel down orientation resulted in significantly lower bleeding times after removal of arterial needles. Another observational study conducted by **Yilmaz et al., 2022,** their results showed significant decrease in bleeding time when needles were inserted in bevel down orientation. However our results differ from **Loizeau et al., (2023),** that there were no statistically significant differences regarding hemostasis between bevel up and bevel down orientation of the needle.

Conclusion

Based on the study findings, it can be concluded that insertion of arterial needle in bevel down orientation showed no statistically significant differences than bevel up orientation in terms of pain scores differences. However, bevel down orientation showed positive results regarding bleeding times changes against bevel up orientation, as the time required to achieve homeostasis after removal of the arterial needle inserted in bevel down orientation was significantly lower.

Recommendations

on the findings of the current study, the following recommendations are derived and suggested:

- Replication of the current study on larger probability sample, and in multiple hemodialysis session across all the governorates of Egypt for generalization of the results.
- An in-service training program should be carried out for nurses who work in dialysis units and responsible for patient's cannulation, about cannulation techniques.
- Nurses should be informed about updated guidelines regarding pain and AVF bleeding management.

Table (I): Percentage distribution of the patients in both studied groups according to their socio-demographic characteristics (n=50).

Socio-demographic characteristics	Study group (1) (n = 25)		Study group (2) (n = 25)		χ^2	p
	No.	%	No.	%		
Gender						
Male	12	48.0	12	48.0	0.00	1.000
Female	13	52.0	13	52.0		
Age						
20-	3	12.0	2	8.0	9.280*	$^{MC}p=0.017^*$
30-	3	12.0	7	28.0		
40-	9	36.0	1	4.0		
50-60	10	40.0	15	60.0		
Level of education						
Illiterate	2	8.0	4	16.0	4.241	$^{MC}p=0.384$
Read and write	3	12.0	2	8.0		
Basic Education	1	4.0	5	20.0		
Secondary	9	36.0	6	24.0		
University	10	40.0	8	32.0		
Occupation						
Manual	6	24.0	7	28.0	2.743	$^{MC}p=0.677$
Cleric Work	2	8.0	5	20.0		
Housewife	10	40.0	9	36.0		
Retired	6	24.0	4	16.0		
Unemployed	1	4.0	0	0.0		
Marital Status						
Single	6	24.0	4	16.0	0.650	$^{MC}p=0.892$
Married	17	68.0	19	76.0		
Divorced	0	0.0	0	00.0		
Widow	2	8.0	2	8.0		

Table (2): Distribution of the patients of the two studied groups according to their clinical data (n=50).

Clinical Data	Study group 1 (n = 25)		Study group 2 (n = 25)		Significance test	P
Associated diseases:	**N**	**%**	**N**	**%**	χ^2	
Diabetes	6	24.0	8	32.0	0.397	0.529
Hypertension	24	96.0	25	100.0	1.020	^{FE}p=1.000
Renal Disease	2	8.0	1	4.0	0.355	^{FE}p=1.000
Cardiovascular	5	20.0	0	0.0	5.556	^{FE}p=0.050
Arteriovenous fistula site:						
Left arm	18	72.0	16	64.0	0.368	0.544
Right arm	7	28.0	9	36.0		
Laboratory investigations:						
INR (1)	25	100	25	100	-	-
Sodium (mEq/dl)						
Min – Max	127.0 – 141.0		136.0 – 147.0		t=3.355*	0.002*
Mean ± SD	136.3 ± 3.9		139.5 ± 2.7			
Potassium (mEq/dl)						
Min. – Max.	4.90 – 6.40		4.50 – 6.0		t= 4.892*	<0.001*
Mean ± SD.	5.60 ± 0.40		5.08 ± 0.35			
Hemoglobin (g/dl)						
Min. – Max.	8.50 – 12.0		9.0 – 11.50		t= 1.416	0.164
Mean ± SD.	10.44 ± 0.98		10.12 ± 0.61			
Creatinine (mg/dl)						
Min. – Max.	6.0 – 10.60		5.0 – 8.0		t= 5.693*	<0.001*
Mean ± SD.	8.08 ± 1.26		6.47 ± 0.64			
Urea (mg/dl)						
Min. – Max.	70.0 – 180.0		70.0 – 120.0		t= 2.516*	0.017*
Mean ± SD.	108.16 ± 27.59		92.72 ± 13.43			
Dialysis parameters:						
Number of Sessions per week (3	25 (100.0%)		25 (100.0%)		-	-
Session Duration (hours) (4)	25 (100.0%)		25 (100.0%)		-	-
Anticoagulant (Heparin 5000 IU)	25 (100.0%)		25 (100.0%)		-	-
Dry weight (Kg)						

Min. – Max.	52.0 – 107.0	50.0 – 129.0	t= 0.572	0.570
Mean ± SD.	79.28 ± 15.83	82.36 ± 21.77		
UF Volume (ml)				
Min. – Max.	2000.0 – 4000.0	2000.0 – 5000.0	t= 0.674	0.504
Mean ± SD.	3384.0 ± 668.1	3520.0 ± 756.6		

Table (3): Mean score distribution of the patients in the two studied groups according to their pain score (n=50).

Pain Score	Study group 1 (n = 25)	Study group 2 (n = 25)	U	p
1st Session (P1)				
Min. – Max.	2.0 – 4.0	1.0 – 6.0		
Mean ± SD.	3.08 ± 0.76	2.76 ± 1.13	245.0	0.166
Median	3.0	3.0		
2nd Session (P2)				
Min. – Max.	2.0 – 6.0	2.0 – 5.0		
Mean ± SD.	3.40 ± 1.19	3.12 ± 0.83	276.50	0.462
Median	3.0	3.0		
3rd Session (P3)				
Min. – Max.	2.0 – 5.0	2.0 – 5.0		
Mean ± SD.	3.40 ± 1.12	2.72 ± 0.98	204.0*	0.026*
Median	3.0	2.0		
4th Session (P4)				
Min. – Max.	2.0 – 5.0	1.0 – 6.0		
Mean ± SD.	3.32 ± 1.11	2.96 ± 1.17	253.0	0.229
Median	3.0	3.0		
5th Session (P5)				
Min. – Max.	2.0 – 5.0	2.0 – 5.0		
Mean ± SD.	3.40 ± 0.96	2.60 ± 0.82	165.50*	0.003*
Median	3.0	2.0		
6th Session (P6)				
Min. – Max.	2.0 – 5.0	1.0 – 4.0		
Mean ± SD.	3.08 ± 0.86	2.20 ± 0.76	147.50*	0.001*
Median	3.0	2.0		
Decrease (P1 – P6)				
Min. – Max.	-2.0 – 2.0	-2.0 – 4.0		
Mean ± SD.	0.0 ± 1.08	0.56 ± 1.33	244.000	0.169
Median	0.0	0.0		

Table (4): Mean score distribution of the patients in both studied groups according to their bleeding time after removal of the arterial needle (n=50).

Bleeding time (minutes)	Study group (1) (n = 25)	Study group (2) (n = 25)	U	p
1st session (B1)				
Min. – Max.	2.0 – 6.0	4.0 – 10.0		
Mean ± SD.	3.92 ± 1.35	7.32 ± 1.38	32.0*	<0.001*
Median	4.0	8.0		
2nd session (B2)				
Min. – Max.	2.0 – 6.0	6.0 – 15.0		
Mean ± SD.	3.12 ± 1.17	8.36 ± 1.85	2.0*	<0.001*
Median	4.0	8.0		
3rd session (B3)				
Min. – Max.	2.0 – 6.0	6.0 – 10.0		
Mean ± SD.	3.20 ± 1.29	7.44 ± 1.45	11.0*	<0.001*
Median	4.0	8.0		
4th session (B4)				
Min. – Max.	2.0 – 6.0	6.0 – 10.0		
Mean ± SD.	3.20 ± 1.29	7.28 ± 1.28	11.0*	<0.001*
Median	4.0	8.0		
5th session (B5)				
Min. – Max.	2.0 – 4.0	6.0 – 10.0		
Mean ± SD.	2.96 ± 1.02	8.08 ± 1.44	0.00*	<0.001*
Median	2.0	8.0		
6th session (B6)				
Min. – Max.	2.0 – 4.0	6.0 – 10.0		
Mean ± SD.	2.80 ± 1.0	7.92 ± 1.55	0.00*	<0.001*
Median	2.0	8.0		
Change (B1 – B6)				
Min. – Max.	-4.0 – 2.0	-2.0 – 4.0		
Mean ± SD.	-1.12 ± 1.54	0.60 ± 1.91	162.000*	0.002*
Median	-2.0	0.0		

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