Randomised Controlled Trial

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Effect of needles distance of arteriovenous fistula cannulation on hemodialysis adequacy based on KT/V: a randomized controlled trial

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Background: This study aims to assess the effect of needle distance of arteriovenous fistula (AVF) cannulation on haemodialysis adequacy based on KT/V.

Materials and methods: This study was a parallel-group, randomized controlled trial. Patients who met the inclusion criteria were divided into two groups with 3 and 6 cm needle distances using block randomization. Data acquisition transpired through a comprehensive checklist encompassing demographic variables such as age and sex, alongside clinical metrics comprising actual weight, dry weight, average dialysis duration, fistula longevity, and KT/V rate.

Results: A total of 42 haemodialysis patients were enroled in this investigation, with 21 allocated to the 3 cm needle distance group and another 21 to the 6 cm needle distance group. The mean post-haemodialysis KT/V values for the 3 cm and 6 cm needle distance groups were 1.25 (SD = 0.25) and 1.42 (SD = 0.24), respectively, demonstrating a statistically significant difference ($P < 0.001$). While there was no significant difference in the average pre-haemodialysis and post-haemodialysis KT/V values within the 3 cm needle distance group ($t = 1.93$, $P = 0.068$), the corresponding values for the 6 cm needle distance group exhibited a notable discrepancy ($t = 9.66$, $P < 0.001$).

Conclusion: In general, a needle distance of 6 cm between arteriovenous points yielded superior enhancements in dialysis adequacy compared to a 3 cm needle distance following haemodialysis. Consequently, health administrators and policymakers may consider instituting efficacious interventions to scrutinize the care and therapeutic protocols for haemodialysis patients, involving the development of policies and applications.

Keywords: arteriovenous fistula, cannulation, dialysis adequacy, haemodialysis, vascular access

Introduction

Haemodialysis stands as the predominant therapeutic modality for individuals afflicted with end-stage renal disease globally[1–4]. A critical determinant in the management of these patients is the efficacy of haemodialysis, a factor known to mitigate disease-related complications, reduce mortality rates, enhance the quality of life, and improve overall survival[5–7]. Notably, a considerable proportion of deaths among this population—ranging from 19 to 24%—are attributed to inadequate dialysis. Despite advancements in technology, there remains a persistent need for improvement in the adequacy of delivered haemodialysis[1]. Typically administered thrice weekly, with each session lasting between three and five hours, haemodialysis involves the establishment of vascular access points through arterial and venous needles in a surgically created fistula[8].

Arteriovenous fistulas (AVFs) represent a preferred method for vascular access in haemodialysis patients due to their high efficiency[2,9,10]. The cannulation technique employed in AVFs is a fundamental skill for dialysis nurses initiating haemodialysis treatment[1]. In Brazil, for instance, AVFs were utilized in 79.3% of haemodialysis patients in 2014, highlighting their preference for catheters[11]. Despite their status as the preferred vascular access type, complications related to routine cannulation, including haematoma, stenosis, thrombosis, aneurysm formation, and infection, can compromise the lifespan, strength, and performance of AVFs[2].

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Optimizing the adequacy of haemodialysis involves employing proper AVF cannulation methods, with the inappropriate distance and direction of inserted needles potentially increasing untreated venous blood recirculation and diminishing dialysis adequacy[12,13]. Arterial needle placement may be antegrade (toward the heart) or retrograde (against the blood flow), while the venous needle is conventionally positioned in the direction of blood flow[1].

Among the methods for evaluating haemodialysis adequacy, urea-based and KT/V-based approaches are commonly employed. Standard practice recommends maintaining a minimum distance of 3 cm from the anastomosis for the arterial needle, advancing towards the heart or end limb, and ensuring a distance of at least 5 cm from the venous needle[12]. The literature presents conflicting findings regarding the impact of needle direction and distance on haemodialysis adequacy. Some studies report no significant difference in recirculation rates and dialysis adequacy with variations in needle direction and distance[14]. Also, in another study, the location of the arterial needle in the antegrade direction compared to the retrograde improved dialysis adequacy, but the retrograde and antegrade directions did not show any significant difference in the amount of dialysis adequacy[1]. Conversely, others suggest that correct needle insertion can positively influence dialysis adequacy[15]. The cannulation technique for vascular access relies on its unique characteristics and the proficiency of the nursing staff. While certain studies underscore the importance of the cannulation technique in vascular access survival, conclusive evidence supporting specific needle distance and direction for AVF remains elusive[11].

Given the presence of disparate findings regarding the efficacy of dialysis at intervals of 3 and 6 cm along the AVF, this study aims to examine the impact of the distance between AVF cannulation needles on haemodialysis adequacy, as assessed through KT/V measurement. The investigation seeks to elucidate the relationship between needle placement and dialysis efficacy, contributing to the understanding of optimal cannulation practices for enhanced haemodialysis outcomes.

Methods

Study design

This investigation is a parallel-group, randomized controlled trial designed to explore the impact of the distance between needles during AVF cannulation on haemodialysis adequacy, as assessed by KT/V. The study adhered to CONSORT criteria[16] (Supplementary File 1, Supplemental Digital Content 1, http://links.lww.com/MS9/A407).

Ethics consideration

Approval for this study was obtained from the ethics committee of Guilan University of Medical Sciences, and the study was duly registered in the Iranian Registry of Clinical Trials Database. Before participation, informed consent was obtained from all participants, accompanied by a comprehensive explanation of the study objectives. Participants were explicitly informed of their right to withdraw from the study at any point in time.

Participants

The research cohort comprises individuals undergoing haemodialysis. The participant selection process initially adopted a convenience sampling approach, followed by allocation utilizing the blocked randomization method. Stratification into two groups was conducted based on the distance between arteriovenous needles: one group encompassed a 3 cm needle distance, while the other group maintained a 6 cm distance (Fig. 1). Inclusion criteria for the study encompassed individuals over 18 years of age undergoing haemodialysis, specifically those diagnosed with end-stage renal disease and receiving haemodialysis at a frequency of at least three sessions per week, each lasting 4 h. Additional inclusion criteria stipulated a minimum three-month history of haemodialysis, possession of an AVF, successful completion of all dialysis sessions, and prescribed blood flow rates of at least 250 ml/min and dialysis flow rates of 500 ml/min. Conversely, exclusion criteria encompassed individuals requiring cardiopulmonary resuscitation, those with incomplete dialysis sessions, and participants displaying non-cooperation during the study.

HIGHLIGHTS

- The mean KT/V after haemodialysis in the 3 and 6-cm needle distance groups was 1.25 ($SD = 0.25$) and 1.42 ($SD = 0.24$), respectively, which showed a significant difference ($F = 100.8$, $P < 0.001$).
- The average KT/V in the 3 cm needle distance group before and after haemodialysis did not show a significant difference ($t = 1.93$, $P = 0.068$), but the average KT/V in the 6 cm needle distance group before and after haemodialysis had a significant difference ($t = 9.66$, $P < 0.001$).
- A 6 cm arteriovenous needle distance showed more improvement in dialysis adequacy than a 3 cm arteriovenous needle distance after haemodialysis.
- Therefore, health managers and policymakers can organize effective measures to review the care and treatment protocols of haemodialysis patients by formulating policies and applications.

Sample size

The sample size for this study was computed using G-Power software version 3.1. Based on the main aim of this research (comparing the mean dialysis adequacy between two groups), an independent samples *t*-test was used. The significance level (α) was set at 0.05, with a power (1-β) of 0.8, and an effect size (f) of 0.9 based on Reyes's study[1]. The resultant sample size amounted to 21 individuals per group, totalling 42 participants across both groups.

t-tests—Means: Difference between two independent means (two groups).

Analysis	A priori: compute required sample size
Input	
Tail(s)	= Two
Effect size d	= 0.9
α err prob	= 0.05
Power (1-β err prob)	= 0.8
Allocation ratio N2/N1	= 1
Output	
Noncentrality parameter δ	= 2.9163333
Critical t	= 2.0210754
Df	= 40
Sample size group 1	= 21
Sample size group 2	= 21
Total sample size	= 42
Actual power	= 0.8121119

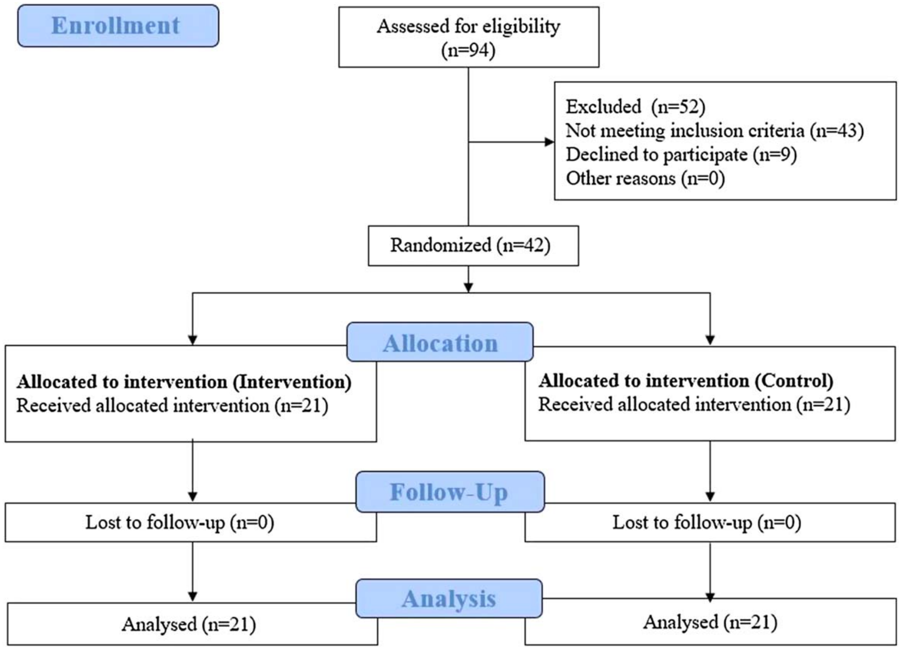

Figure 1. Flow diagram of participants.

Randomization

Patients who met the inclusion criteria were divided into two groups with 3 and 6 cm needle distances using block randomization with 4 and 6 block sizes. An online randomization service (Sealed Envelope Ltd. 2019) was used to generate the randomization list.

Intervention

The participants in this study were allocated to two groups, each distinguished by differing arteriovenous needle distances—specifically, 3 and 6 cm. Data collection was executed through a comprehensive checklist encompassing variables such as age, sex, actual weight, dry weight, average dialysis time, duration of fistula, and KT/V rate. Following the requisite approvals from the ethics committee of Guilan University of Medical Sciences and obtaining informed consent from the participants, a random assignment was employed to distribute individuals into the two groups, wherein the arteriovenous needle distances were 3 and 6 cm, respectively. Uniform needle sizes were utilized for all participants. The decision to maintain consistent needle size was informed by the heterogeneity observed in prior evidence, as indicated by a systematic review and meta-analysis[17]. Previous studies have yielded conflicting results regarding the impact of arteriovenous needle distances on HD adequacy, with some suggesting optimal adequacy at distances of 5 cm or more[15,18], while others proposing greater adequacy at a distance of 2.5 cm[10]. To assess dialysis adequacy, KT/V measurements were conducted over three consecutive sessions for each participant, utilizing both 3 and 6 cm arteriovenous needle distances. The blood flow rate was standardized across all participants at 250 ml/min. KT/V assessments were undertaken three times within each group—before the initiation of haemodialysis and following its completion. KT/V is a metric utilized for gauging the efficiency of renal replacement therapies such as haemodialysis or peritoneal dialysis in eliminating urea, a nitrogenous waste product that accumulates in the bloodstream due to renal insufficiency. In this context, "K" denotes the urea clearance rate, "T" signifies the duration of therapy, and "V" represents the volume of urea distribution within the body[19]. The placement of dialysis needles in the AVF is presented in Figure 2.

Outcomes

The primary results of this study were the evaluation of the average dialysis adequacy at 3 and 6 cm intervals of AVF needles. In addition, the secondary outcome of this study was to compare the mean dialysis adequacy at 3 and 6 cm AVF needle distances.

Statistical analysis

The statistical analysis of the collected data was conducted utilizing SPSS software (version 16.0, SPSS Inc.). Descriptive

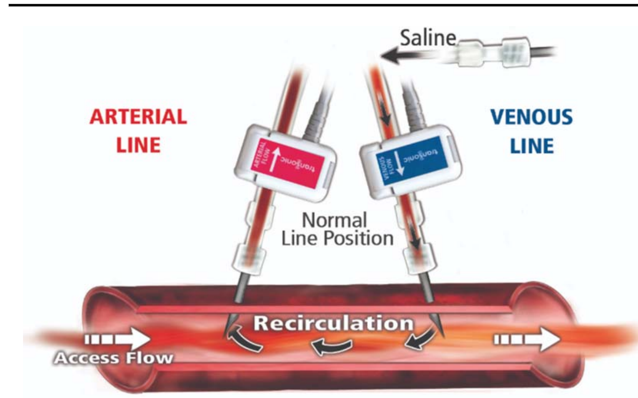

Figure 2. The placement of dialysis needles in the arteriovenous fistula.

statistics, including means with standard deviations (SD) or medians with interquartile ranges (IQR), as well as frequencies with percentages, were employed for continuous and categorical variables, respectively. The normal distribution of variables was assessed utilizing the Shapiro–Wilk test. To assess the comparability of individual and clinical variables between the two groups with needle distances of 3 and 6 cm, independent *t*-tests (or Mann–Whitney tests) were applied for quantitative variables, while χ^2 tests (or Fisher's exact tests) were utilized for qualitative variables. Differences in mean dialysis adequacy before the intervention between the groups with 3 and 6 cm needle distances were examined using an independent *t*-test. For within-group comparisons of average dialysis adequacy before and after the intervention, paired *t*-tests were employed within the groups with 3 and 6 cm needle distances. Furthermore, mean dialysis adequacy after the intervention was compared between the two groups using analysis of covariance (ANCOVA). A significance level of 0.05 was considered for all statistical analyses.

Results

Participants

Table 1 illustrates the inclusion of a total of 42 haemodialysis patients in this study, with 21 individuals allocated to the 3 cm needle distance group and another 21 individuals to the 6 cm needle distance group. Of the participants, 59.5% were male, and the majority (81.0%) underwent haemodialysis three times per week. The mean duration of haemodialysis sessions for patients was 3.79 (SD = 0.38). The average actual weight and dry weight of patients were 72.3 (SD = 15.0) and 75.0 (SD = 15.3), respectively. Importantly, no significant differences were observed in demographic and clinical variables between the two groups ($P > 0.05$).

Normality assumption

The Shapiro–Wilk test was employed to assess the assumption of normality concerning the dialysis adequacy variable among haemodialysis patients, stratified into groups A (needle distance of 3 cm) and B (needle distance of 6 cm). Findings from the Shapiro–Wilk test suggest that the assumption of normality regarding the dialysis adequacy variable, both pre-intervention and post-intervention, is upheld within both groups A and B ($P > 0.05$).

Haemodialysis adequacy

As indicated in Table 2, the pre-haemodialysis mean KT/V values for the 3 and 6 cm needle distance groups were 1.28 (SD = 0.22) and 1.18 (SD = 0.17), respectively, exhibiting no statistically significant difference between them ($t = 1.72$, $P = 0.093$). In contrast, the post-haemodialysis mean KT/V values for the 3 cm and 6 cm needle distance groups were 1.25 (SD = 0.25) and 1.42 (SD = 0.24), respectively, indicating a notable and statistically significant difference ($F = 100.8$, $P < 0.001$). Furthermore, within-group analyses revealed that the average pre- and post-haemodialysis KT/V values in the 3 cm needle distance group did not display a significant difference ($t = 1.93$, $P = 0.068$). Conversely, in the 6 cm needle distance group, a significant difference was observed between the average pre- and post-haemodialysis KT/V values ($t = 9.66$, $P < 0.001$).

Table 1

Individual and clinical characteristics of the participants ($N = 42$).

	Total	Groups		P
	(*N* = 42)	3 cm needles distance (*N* = 21)	6 cm needles distance (*N* = 21)	
Individual characteristics				
Age	55.80 (SD = 11.90)	57.00 (SD = 11.10)	54.70 (SD = 12.80)	0.540*
Sex, *N* (%)				
Male	25 (59.5)	13 (61.9)	15 (57.1)	0.753**
Female	17 (40.5)	8 (38.1)	9 (49.2)	
Clinical characteristics				
No. Haemodialysis in a week, *N* (%)				
2	8 (19.0)	4 (19.0)	4 (19.0)	0.999***
3	34 (81.0)	17 (81.0)	17 (81.0)	
Type of filter, *N* (%)				
F60	21 (50.0)	12 (57.1)	9 (42.9)	0.446***
F70	20 (47.6)	9 (42.9)	11 (52.4)	
F80	1 (2.4)	0	1 (4.8)	
Type of dialysis device in the first haemodialysis, *N* (%)				
B Braun	31 (73.8)	15 (71.4)	16 (76.2)	0.999***
Belco	9 (21.4)	5 (23.8)	4 (19.0)	
ATF	2 (4.8)	1 (4.8)	1 (4.8)	
Type of dialysis device in the second haemodialysis, *N* (%)				
B Braun	35 (83.3)	19 (90.5)	16 (76.2)	0.184***
Belco	1 (2.4)	1 (4.8)	0 (0)	
ATF	6 (14.3)	1 (4.8)	5 (23.8)	
Type of dialysis device in the third haemodialysis, *N* (%)				
B Braun	31 (83.8)	16 (76.2)	15 (71.4)	0.756***
Belco	8 (19.0)	3 (14.3)	5 (23.8)	
ATF	3 (7.1)	2 (9.5)	1 (4.8)	
Duration of haemodialysis (h)	3.79 (SD = 0.38)	3.74 (SD = 0.44)	3.83 (SD = 0.33)	0.429*
History of haemodialysis (month)	33.0 (IQR = 13.8 to 80.8)	24.0 (IQR = 10.0 to 72.5)	48.0 (IQR = 20.0 to 90.5)	0.162****
Duration of fistula survival (month)	35.0 (IQR = 14.5 to 53.5)	34.0 (IQR = 10.5 to 50.5)	35.0 (IQR = 18.5 to 68.5)	0.481****
Real weight	72.3 (SD = 15.0)	72.3 (SD = 13.9)	72.3 (SD = 16.4)	0.999*
Dry weight	75.0 (SD = 15.3)	75.0 (SD = 13.9)	75.1 (SD = 16.8)	0.979*

Values are given as a mean (SD) or median (IQR) for continuous variables and a number (percentage) for categorical variables.

ATF, alternating tangential flow.

IQR, interquartile range.

*P value was obtained with an independent *t*-test.

**P value was obtained with a χ^2 test.

***P value was obtained with a Fisher exact test.

****P value was obtained with a Mann–Whitney U-test.

Discussion

Vascular access in haemodialysis patients predominantly involves AVF, representing a pivotal advancement in the prognosis and treatment of this patient population. The quality of haemodialysis is intricately linked to health improvement, complication

Table 2

Hemodialysis adequacy before and after the haemodialysis ($N = 42$).

	Groups			
	3 cm needles distance ($N = 21$)	6 cm needles distance ($N = 21$)	F or t	P
Pre-intervention	1.28 (SD = 0.22)	1.18 (SD = 0.17)	1.72	0.093*
Post-intervention	1.25 (SD = 0.25)	1.42 (SD = 0.24)	100.8	< 0.001**
t	1.93	9.66		
P value	0.068***	< 0.001***		

Values are given as a mean for continuous variables.
*P value was obtained with an independent t-test.
**P value was obtained with an ANCOVA test.
***P value was obtained with a paired t-test.

reduction, and mortality mitigation in individuals undergoing haemodialysis[18]. Key determinants influencing haemodialysis quality include the technique employed for AVF puncture and access recirculation, both directly impacting dialysis adequacy. Particularly noteworthy is the potential influence of needle distance in the AVF puncture technique on AVF hemodynamics, a facet often overlooked. However, limited and conflicting evidence exists in this domain, positioning the current study as a pioneering contribution to the field[11,20].

The findings of this study reveal a lack of statistically significant difference in the average dialysis adequacy of patients before and after haemodialysis in the group with a needle distance of 3 cm. In contrast, the group with 6 cm needle distance exhibited a statistically significant increase in average dialysis adequacy post-intervention compared to pre-intervention values. This outcome aligns with a Brazilian study exploring vascular access in 260 haemodialysis patients, indicating that needle distances exceeding 5 cm are associated with enhanced haemodialysis adequacy[11]. Conversely, contrary to the present study by Ray *et al.*[1]'s investigation into the effect of arterial needle placement in arterial fistula on dialysis adequacy found no significant relationship in the group with a needle distance of 6 cm. Methodological disparities between studies may account for these divergent findings.

Furthermore, the study results indicate that the average dialysis adequacy after the intervention in the 6 cm needle distance group was significantly higher than in the 3 cm needle distance group. In contrast, Elias *et al.*[12]'s study conducted in France to investigate the effect of arterial fistula cannulation on dialysis adequacy found no significant difference between upward and downward needle directions. Discrepancies in the duration of haemodialysis, blood flow rate, and dialysis flow rate are potential justifications for these variations across studies.

Limitations

In the current investigation, certain factors such as the actual blood flow rate, recirculation rate, variations in needle sizes, the direction of the arterial needle (antegrade vs. retrograde), and the specific type of AVF were not systematically assessed in the two study groups. This omission may introduce potential confounding variables that could impact the validity and generalizability of the study findings.

Recommendations for future research

In summary, the current study represents a pioneering effort in elucidating the impact of needle distance on dialysis adequacy. However, the existing body of literature in this domain remains limited. Consequently, it is advisable to undertake additional research endeavours to reinforce and substantiate the findings of the present study. Given the absence of a statistically significant difference in the average dialysis adequacy of patients before and after haemodialysis in the group with a 3 cm needle distance, it is recommended that future investigations extend their focus to comparing the 3 cm needle distance with alternative distances for a more comprehensive understanding of their comparative effects.

Conclusion

The findings of this study demonstrate that employing 6 cm arteriovenous needle distance yields superior improvements in dialysis adequacy compared to a 3 cm distance following haemodialysis. These results underscore the importance of meticulous training for healthcare professionals, specifically nurses, to ensure the delivery of optimal care to haemodialysis patients. Furthermore, health administrators and policymakers can utilize these findings to enact informed measures aimed at refining care protocols and treatment strategies for individuals undergoing haemodialysis. By incorporating the insights gleaned from this research, policies and interventions can be tailored to enhance the overall quality of care and outcomes for haemodialysis patients, thus addressing a critical aspect of healthcare management in this population.

Ethical approval

The ethics committee of Guilan University of Medical Sciences has given its approval to this study. Also, this study was registered in the Iranian Registry of Clinical Trials Database. The participants gave informed consent after being informed of the current study's goals. It was made clear to participants that they could leave the study at any time.

Consent

Written informed consent was obtained from the patient for publication and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

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Author contribution

Study concept and design by all authors; Data acquisition by all authors; Data interpretation by all authors; drafting the manuscript by all authors; Revision of the manuscript by all authors; the final version of the manuscript is approved by all authors. All authors have agreed on the final version of this manuscript. Those listed as authors are qualified for authorship according to the following criteria: They have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; been involved in drafting the manuscript or revising it critically for important intellectual content; and have given final approval of the version to be published. Each author participated sufficiently in the work, has taken public responsibility for appropriate portions of the content, and has agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflicts of interest disclosure

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Research registration unique identifying number (UIN)

We could not register our manuscript in the Research Registry UIN: www.researchregistry.com due to internet access restrictions and international sanctions. we live in Iran. We hardly even meet the basic needs of our daily life. We do not receive any funding for our research and we cannot pay for our research. Please excuse us from registering this manuscript in the Research Registry UIN: www.researchregistry.com This study was registered in the Iranian Registry of Clinical Trials Database (IRCT20201009048977N1). The participants gave informed consent after being informed of the current study's goals. It was made clear to participants that they could leave the study at any time. https://www.irct.ir/trial/51517 Trial Id: 51517.

Guarantor

Mohammad Taghi Moghadamnia.

Data availability

The datasets generated and analyzed during the current study are available from the corresponding author on reason-able request.

Provenance and peer review

Not commissioned, externally peer-reviewed.

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