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Ideal trajectory for frontal ventriculostomy: Radiological study and anatomical study

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Keywords: Frontal ventriculostomy Freehand technique Kocher's point Hydrocephalus Perpendicular trajectory	<i>Objective:</i> Several techniques have been described to improve the accuracy of the freehand procedure for frontal ventriculostomy and reduce complications due to suboptimal placement or misplacement of the catheter tip. To date, none of the available studies have found a reliable, low cost and consistent technique. We aimed to provide a standardized protocol for freehand frontal ventriculostomy. <i>Methods:</i> In the first part of the radiological study, 125 CT scans were used to measure the length of the catheter using 2 right-sided entry points. In the second part, a grid of 24 entry points on the frontal bone was used in 50 CT scans to record the distance from the cranial surface to the Foramen of Monro (FM). Ventriculostomy was performed on six cadaveric heads using a grid of 9 entry points, comparing a 5 ml syringe with the freehand technique to reach the target. <i>Results:</i> The first part of the radiological study, showed a length from the cranial surface to the FM was overall 67,38 \pm 1,03 mm. For the second part, the mean length of the 24 selected points was 68,54 \pm 2,73 mm without statistical difference. In the anatomical study, the FM was reached 8 times (14.8%) with the syringe vs 31 times (57.4%) with the freehand technique, and the ventricles 43 (79.6%) vs 37 (68.5%). The mean lengths from the skull to the FM were 71.33 \pm 4.21 mm. <i>Conclusions:</i> In this study, we showed the optimal length of a frontal ventricular catheter. We have also demonstrated that the portion of the frontal bone above the superior temporal lines matches a sphere in which the center is the FM.					

1. Introduction

Ventriculostomy is one of the most commonly performed procedures in neurosurgery, [21,27] and consists of drilling a burr hole in the skull to allow the passage of a catheter into the ventricular system for diagnostic and therapeutic purposes. [27] This procedure is often performed under emergency conditions, as a saving-life procedure, using the freehand pass technique with the aid of craniometric landmarks to locate the correct position for the burr hole and to guide the angle of insertion of the catheter. [14,27] For frontal ventriculostomy, the most used entry point is the right-sided Kocher's point, which can be identified approximately 11 cm superior and posterior to the nasion [23] and 2.5/3 cm lateral to the midline. [4,16] This point lies along the midpupillary line and is 1–2 cm anterior to the coronal suture (CS), to prevent damages on the precentral gyrus (motor area). [10,16] The insertion trajectory is perpendicular to the calvarial surface, which can be approximated by aiming in the coronal plane towards the medial canthus of ipsilateral eye or nasion and in anteroposterior plane towards external auditory meatus. [4,10] The insertion depth from the outer cranial table to the foramen of Monro (FM) is between 6 and 7 cm. [4, 10].

The freehand technique, based on anatomical landmarks, is assumed to be relatively simple and is commonly performed by neurosurgical residences. [19,21] However, suboptimal or incorrect position of the

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Received 20 November 2021; Received in revised form 23 March 2022; Accepted 22 April 2022 Available online 26 April 2022 0303-8467/© 2022 Elsevier B.V. All rights reserved. catheter occurs in up to 23–60% of cases. [11–13, 30] Mispositioning of the catheter tip can result in complications, increasing morbidity and mortality risk. [14] The desire for higher precision of ventriculostomy has led many authors to find the ideal location and trajectory for catheter placement. [2-6,15, 28-30, 32] Several devices have been described to guide the angle of insertion of the catheter, such as a tripod, [2,32] endoscopy, [3] real-time ultrasound, [15] stereotactic neuronavigation, [5,30] ultrasonic guidance, [5,30] Ventri-guide, [24] smartphone, [6,28], through magnetic resonance imaging (MRI) [29], and assisted with augmented reality glasses. [25] Nevertheless, none of the available studies have sufficient advantages, like portability, user-friendly, inexpensively, rapidity and reliability. [6] For these reasons, the majority of ventriculostomies are still performed with the freehand technique based on anatomical landmarks. Numerous studies have been focused on understanding the limitations and increase the success rate of the freehand frontal ventriculostomy. [14,20,26,27] Still, they have not consistently guaranteed optimal positioning of the ventricular catheter and have not analyzed all of the aspects of the catheter insertion: the insertion site, the trajectory and the length.

This study aims to identify a standardized protocol for freehand frontal ventriculostomy, providing information about the insertion point, trajectory, and length of the catheter to reach the target (the FM) without adding time and costs at the procedure. In order to do that we systematically investigated a large grid (6×6 cm) of entry points on the frontal bone and analyzed the distance to the FM. This study was carried out both on CT scans (radiological part) and cadaveric heads (anatomical part).

2. Materials and methods

2.1. Radiological study

1. Patients

A total of 175 patients with available thin-slice (1 mm) noncontrast CT brain scans were collected at the Neurosurgery Department of Ferrara University Hospital from March 2019 to February 2020. All the patients were adults with normal intracranial anatomy without any skull, parenchyma and ventricles lesion or anomaly.

2. Radiographic simulation of ventriculostomy trajectory

The radiological study was divided into two parts: the first part was focused on establishing the ideal length of the ventricular catheter and the second on the trajectory and entry point.

To evaluate the ideal length of the catheter, two ventriculostomy entry points on the frontal bone were identified and the distance from the outer cranial table to the FM was recorded. A total of 125 CT scans were used to record this distance. The Kocher's point (1 cm anterior to the CS and 2.5 cm lateral to the midline) and a test point (2.5 cm anterior to the CS and 2.5 lateral to the midline) on the right side of the head were used as entry points. These points were identified by detecting craniometric landmarks (coronal and sagittal suture) on the skull surface using multiplanar reformation (MPR). After marking these two points, a line was drawn from the outer cranial table to reach the FM and each length was recorded (Fig. 1).

The second part of the radiological study was designed to determine the perfect trajectory and entry point to reach the FM. In order to do that, we aimed to demonstrate that each half of the frontal bone surface matches a sphere, in which the ipsilateral FM is the center. If so, a perpendicular trajectory from the surface of the sphere directed inwards always points to the center. Since the radius of a sphere is always the same, the distance from any point on the outer cranial table of the frontal bone to the FM should be identical. Moreover, a perpendicular trajectory from any location on the frontal bone should always reach the target. This would increase the number of entry points available for the procedure. To validate this theory, we measured the distance from the FM to 24 entry points on the frontal bone. Fifty CT scans were used for this second study. These points were selected 2 cm apart from each other, to cover a large area of the frontal bone bilaterally (Model 1).

No IRB approval was required.

2.2. Data analysis

The length data are expressed as mean \pm standard deviation. The distribution of continuous variables in groups was compared with analysis of variance (ANOVA) univariate testing. Results presenting a p \leq 0.05 were considered statistically significant. SPSS 20.0® was used for statistical analysis.

2.3. Anatomical study

Six embalmed and latex-injected post-mortem heads were prepared to assess the radiological results and attempt a rapid and reliable perpendicular trajectory at The Stanford Neurosurgical Training and Innovation Center, Stanford University, California, USA. The heads were



Fig. 1. Overview of the entry points of the first part of the radiological study A. Midline sagittal CT scan showing the distance (horizontal green line) from the coronal suture (superior green vertical line) to the Kocher's point (superior red vertical line). **B.** Sagittal CT image showing the distance (horizontal green line) from the coronal suture (superior vertical green line) to the test point (vertical superior red line). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

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placed in a 3-pin clamp (Mayfield Skull Clamp, Integra, New Jersey, USA) in a neutral position slightly flexed anteriorly, in order to simulate a surgical position for frontal ventriculostomy. A bicoronal incision was performed and the skin flap was everted anteriorly. Then, the galea and periosteum were dissected to expose the skull surface. After identifying the coronal and the sagittal suture, nine points were marked, on the right side of the frontal bone. Three points were marked on the CS starting from 2 cm from the midline and with a 2 cm distance between one and another. The other 6 points were placed on 2 different lines (three- and three-point distancing 2 cm one to the other), 2 and 4 cm anterior to the CS. Nine burr-holes have been carried out using a high spill drill with a 14 mm burr (Midas Rex, Medtronic, Minnesota, USA) (Fig. 2 A). A contralateral frontal craniotomy was performed, and the frontal lobe was removed to expose the midline. Using surgical microscopy (HS Hi-R 1000 G, Haag-Streit, Bern, Switzerland), the septum pellucidum was dissected and cut in order to expose the right lateral ventricle and FM. Afterwards a 5 ml syringe (diameter 14 mm) was inserted on each burr hole, in order to obtain a perpendicular trajectory (Fig. 2B). A rigid metallic guide was inserted inside the syringe to reach the ventricle cavity (Fig. 2 C). To verify this technique, anatomical landmarks (nasion and the external acoustic meatus) were also used to get a perpendicular trajectory. The position on which the catheter was found for each technique, after a 6.5/7 cm trajectory, was recorded (Fig. 2D). Moreover, the length from the nine points to the FM was measured. Since the small sample, we did not perform any statistical analysis on this part of the study.

3. Results

3.1. Radiological study

1. Patients

In the first part of the radiological study, sixty-one patients were men (48.8%) and sixty-four were women (51.2%). No differences regarding age and sex were identified.

In the second part of the radiological study, eighteen patients were men (36%) and thirty-two were women (64%). No differences regarding age and sex were identified.

2. Radiographic simulation of ventriculostomy trajectory

The first part of the radiological study showed a length from the cranial surface to the FM of 67.37 \pm 1.07 mm for the Kocher's Point and 67.40 \pm 1.00 mm for the test point (Fig. 3). No statistical difference was found between the two groups (p = 0,82). The mean length among both groups was 67,38 \pm 1,03 mm.

The mean lengths of all the selected points for the second part of the radiological study are exposed in Table 1 (Fig. 4). The total mean length of the 24 selected points was $68,54 \pm 2,73$ mm. No statistical difference in length between the 24 groups was found.



Fig. 2. Stepwise dissections of the anatomical study. A. After performing skin incision and dissection of the periosteal flap, the craniometric landmarks such as the sagittal suture (SS) and coronal suture (CS) are visible. **B.** Lateral-superior view after performing the 9 burr-holes/entry points. **C.** Superior view after insertion of the 5 ml syringe in one of the burr-holes with the rigid metallic guide inserted. **D.** View of the lateral ventricle (frontal horn, body and foramen of Monro (FM)) with the rigid metallic guide. **E.** Magnification of the lateral ventricle with the guide going into the FM.

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Fig. 3. CT scan showing the result of the first part radiological study. A. Coronal CT scan showing the distance (mm) from the midline (horizontal green line) to the Kocher's point and the radiographic measurement of the length of the catheter from the Kocher's point to the foramen of Monro (oblique green line). B. Coronal CT scan showing the distance (mm) from the midline (horizontal green line) to the test point and the radiographic measurement of the length of the catheter from the test point to the foramen of Monro (oblique green line). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

Table 1

Mean lengths from the 12 points identified on each side of the frontal bone to the ipsilateral foramen of Monro.

Point	Right: mean \pm SD (mm)	Left: mean \pm SD (mm)
1	$\textbf{70.19} \pm \textbf{2.75}$	$\textbf{70.19} \pm \textbf{2.75}$
2	69.20 ± 2.16	69.42 ± 2.35
3	69.75 ± 2.48	69.81 ± 2.62
4	$\textbf{70.83} \pm \textbf{2.59}$	70.65 ± 2.39
5	68.67 ± 2.24	68.63 ± 2.35
6	67.33 ± 1.90	67.28 ± 1.89
7	67.76 ± 2.39	67.82 ± 2.44
8	68.60 ± 2.39	68.54 ± 2.39
9	68.56 ± 2.26	68.45 ± 2.50
10	67.45 ± 2.35	67.48 ± 2.42
11	66.96 ± 2.74	67.04 ± 2.73
12	67.02 ± 2.95	67.36 ± 2.79

3.2. Anatomical study

The position of the catheter inside the ventricle from each burr hole using the syringe and the anatomical landmarks is shown in Table 2.

Using the syringe, the FM was reached 8 times (14.8%) and the ventricles were reached 43 times (79.6%). No constant pattern between the location of the burr hole and the position inside the ventricle was detected using the syringe. Using the anatomical landmarks, the FM was reached 31 times (57.4%) and the ventricles 37 times (68.5%). The mean lengths from the skull to the FM was 71.33 \pm 4.21 mm (Table 3).

4. Discussion

In this study we aim to describe a standardized and efficient protocol for frontal ventriculostomy, providing systematically information about insertion site, trajectory and length of the catheter, without adding time and costs to the procedure, for greater accuracy, precision, and fewer complications. Our results showed that the ideal length of the ventricular catheter is 67.38 ± 1.03 mm. Moreover, we have proved that the portion of the frontal bone above the superior temporal lines match a sphere which the center is the FM. Knowing this, following a perpendicular trajectory the FM will always be detected from any point on the frontal bone surface. Unfortunately, we did not establish an alternative way to accomplish a perpendicular trajectory rather than the freehand technique. These outcomes are crucial to obtain a fast and safe

Fig. 4. CT scan showing the result of the second part radiological study. Coronal CT image showing the distance (mm) from the midline to six entry points on frontal bone and the distance (mm) from the outer cranial table to the foramen of Monro.

Model 1: Volumetric model of the skull and the ventricular system showing the 12 entry points on the right side with the catheter insertion to the Foramen of Monro. https:// sketchfab.com/3d-models/frontal-ventriculostomy-d583861ee6e5422fb765586485de7494.



Table 2

Correlation analysis results for the catheter entry points and their intraventricular location with a perpendicular trajectory using a 5 ml syringe (left) and using anatomical landmark (right). -: catheter not visible/intraparenchymal; B: Body of the ventricle, c-B: contralateral body of the ventricle; FM: foramen of Monro, FH: Frontal horn, c-FH: contralateral frontal horn.

Heads	5 ml Syringe						Anatomical landmarks											
	P. 1	P. 2	P. 3	P. 4	P. 5	P. 6	P. 7	P. 8	P. 9	P. 1	P. 2	P. 3	P. 4	P. 5	P. 6	P. 7	P. 8	P. 9
1	В	c-FH	FH	FM	FH	FH	-	-	-	FM	FM	FM	FM	FM	FM	-	FM	-
2	FM	FM	FH	-	FH	FH	-	-	c-FH	FM	FM	FM	-	FH	FM	-	-	-
3	c-FH	c-FH	FH	FH	c-FH	FH	FH	FH	FM	-	-	-						
4	c-FH	c-FH	c-FH	FM	c-FH	c-FH	FM	c-FH	-	FM	FM	FM	-	FM	-	FM	-	-
5	c-FH	c-FH	FH	c-FH	-	FH	-	-	FH	FM	FM	FH	FM	FM	FH	-	-	-
6	В	FM	FH	В	FM	FH	-	c-B	c-FH	В	FM	FM	В	FM	FM	В	FM	-

Table 3

Mean lengths from the nine points identified on the cranial surface to the foramen of Monro.

HEADS	MEAN \pm SD (mm)
1	69.00 ± 0.01
2	$\textbf{72.00} \pm \textbf{0.01}$
3	$\textbf{78.10} \pm \textbf{0.10}$
4	65.55 ± 0.13
5	70.30 ± 0.15
6	73.00 ± 0.22
Total mean value	$\textbf{71.33} \pm \textbf{4,21}$

ventriculostomy with a low rate of complications.

4.1. Length of the catheter

For the first time in literature, we have measured the distance from the outer cranial table to the FM, which represents the ideal length of the catheter. In the first part of the radiological study, we simulated a frontal ventriculostomy in 125 CT scans. We choose two entry points: the classic (Kocher's point) and a control entry site. The second entry point was determined to overcome the normal range of error when performing the burr hole due to low visibility of the sutures or within the average cranial variations. The average distance from the outer cranial table to the ipsilateral FM was, respectively, 67.37 ± 1.08 mm for Kocher's point and 67.40 \pm 1.00 mm for the control point. The were no statistical difference between the two groups (p = 0.82) and the low standard deviation value suggests the insertion length of the catheter could be considered a standardized measurement. For these reasons, we establish that the perfect length for a frontal ventricular catheter should be 67,4 mm (total mean 67,38 \pm 1,03 mm). Although, the best catheter length should be tailored on each patient CT scan before the procedure, this data could be very helpful when the ventriculostomy is a life-saving procedure or when MPR reconstruction is not available.

4.2. Entry point

The Kocher's point is one of the most common entry points used for frontal ventriculostomy. [4,16,31] The term 'Kocher's point' is attributable to a wide range of entry points and many authors have provided instructions to identify it (Table 4). In all cases, rules are followed to minimize complications, especially to avoid the superior sagittal sinus and the motor cortex. [21] Raabe et al. have analyzed large area for possible entry sites, using a 5×5 cm grid of points to evaluate the accuracy of freehand ventriculostomy. [21] However, they have considered also points 1 cm posteriorly to the CS and, thus, evaluate an smaller area of the frontal bone compared to our study. Moreover, their study is based only on radiological reconstruction.

To identify the best entry point we simulated several frontal ventriculostomies using a wide range of entry points in the frontal bone. On the studied CT scans, for each entry point considered (total=1200) the distance from the outer cranial table to the FM was almost the same

Table 4

Literature review of the reported	coordinates	used to	locate	the site i	for the	burr
hole.						

Authors	Lateral to the midline	From midpupillary line (cm)	Anterior to coronal	Posterior to nasion (cm)
Thomale et al. ⁵⁴	1.5–2.5	line (ciii)	suture (cm)	11–12
Yamada et al. ⁵⁷	1.5–3.5		2	
Huyette et al. ³⁷	2.5		1	
Abdoh et al. ⁶²	2.5			
Hsieh et al. ⁶³	2.5		1	
Greenberg et al. ²⁸	2–3		1–2	10
Elwell et al. ⁶⁴	2–3		1	
Kocher et al. ⁶⁵	2.5–3			
Woo et al. ⁵⁹	3–4		1	
Ghajar et al. ⁶⁶	3–4			10
Kakarla et al. ⁶⁷	3–4			10
Rehman et al. ⁶⁸	3–4			10
Connolly et al. ⁶⁹	2.8–3.5	0	1	
Muirhead et al. ⁷⁰		0	1	
Ehtisham et al. ⁷¹	2–3			11–12

(mean overall 68,54 \pm 2,73 mm). Therefore, the result obtained radiographically confirm the initial hypothesis of the sphere, whose radiuses are all equidistant from the center. The range of variations found are explained by the fact that these are calculations on people, in which the perfection of geometric models cannot be expected. With this knowledge, we can deduce that any entry point within the frontal bone can be used to reach the ventricular cavities. The anatomical study also indicated that the distance between the outer table and the FM was the same for each point with very low standard deviation within each head (Table 3). These results are consistent with the sphere theory which extends the possibility of performing a safe ventriculostomy from most of the surface of the frontal bone. Nevertheless, the catheter was found inside the ventricles in the two most medial row, with low rate of success in the lateral row. This event is due to the difficulties on achieving a perpendicular trajectory with both the tested assisting device (5 ml syringe) and the freehand technique. Plus, surgical simulation on cadaveric specimen has several limitations such as the cerebral tissue resistance, the absence of cerebrospinal fluid and the suboptimal instrumentation material. In our opinion any burr hole on the frontal bone could be an ideal entry point but in the light of the results obtained we have proved that the entry point can be located with a grid on the

frontal bone of 4 cm from the midline and 6 cm from the CS on each side. However, Kocher's point should be still considered the preferred entry point since is the most renowned and easy to detect.

4.3. Trajectory

Despite the occurrence and standardization of ventriculostomy, suboptimal or incorrect positing of the catheter are common, especially in the first attempt. [19] Using the freehand technique accurate catheter placement is achieved with an average of 1.4–2.4 passes. [12,18,19,21] Moreover, a higher number of passes increase proportionally the risk of direct injury and hemorrhage. [12,21] Several studies have been developed to find the ideal trajectory for frontal ventriculostomy, using different devices to guide the insertion of the catheter. [2-5,15,28-30, 32] Until today, no rapid, reliable, practical, and inexpensive method, that could replace freehand ventriculostomy, has been found. [21] Indeed the freehand technique with a perpendicular trajectory to outer cranial table is the most commonly used. [1,7-11,13,17,22,31,32] Althought the anatomical landmarks, needed to establish the perpendicular path, are covered by surgical drapes and, sometimes, difficult to locate during the catheter insertion, therefore, the perfect trajectory toward the target point is challenging to obtain. It was found that there is an important variability of ventricular location using anatomical landmarks, with 90% of the catheters reviewed placed in a 30° cone around the FM. [1,21].

Our results in the second part of the radiological study showed that the perpendicular trajectory allows to obtain the highest accuracy and the achievement of the target from any entry point analyzed. Nevertheless, we know that a reliable 90° trajectory without any assistive device could be tough to achieve during the real procedure. For this reason, in the anatomical study we assessed the perpendicular trajectory both using an assisting device, 5 ml syringe, and the freehand technique with anatomical landmarks. We decided to use the syringe as "device" since is readily available in any operation room and, therefore, with no/ low coast. In this part of the study, we did not analyze the three most anterior entry sites, since they would have been anterior to the hairline in most of the patients and, so, not applicable in a real surgery for aesthetic reason. Using the syringe, the FM was reached only in eight times (14.8%) without any specific entry point correlation. Using the anatomical landmarks, the FM was reached 31 times (57.4%). With both technique we have observed that the first two medial rows of points (2 and 4 cm medial from the sagittal suture) have higher probability to reach the ventricles and, therefore, the FM. Indeed, we had 100% (18/ 18) of success for the ventricle cavities in the 2 cm line from the midline with both techniques and 88.8% (16/18) with the syringe and 83.3% (15/18) with the freehand in the 4 cm row. Whereas the most lateral row of entry points has the highest rate of failure (50% (9/18) with the syringe and 77.7% (14/18) with the freehand). Overall, the catheter was found inside the ventricles 43 times (79.6%) using the syringe versus 37 (68.5%) with the freehand technique. Althought we couldn't prove that the syringe could be a reliable way to achieve perpendicularity, these results demonstrate that we are on the right path. We do believe that an important limitation of this technique can be identified in the inclination of the perforator and, hence, of the burr hole. Less than 1° of incorrect inclination of the syringe could lead to suboptimal or wrong trajectory of the catheter. Moreover, the removal of the contralateral frontal lobe with the reduce of its counterthrust may also lead to mispositioning of the catheter. Further cadaveric anatomical studies should be carried out in the future in order to obtain a perpendicular trajectory using a simple and low coast device such as the syringe. A systematic evaluation of the distance between the entry point (skull) and the roof of the ventricles (when the CSF comes out from the catheter) could be very helpful to direct or redirect the trajectory and avoid damage of crucial neurovascular structure.

4.4. Study limitations

Our study has several important limitations. First, it included only CT scans of Caucasian race patients (West Europe). The difference in craniometry measurements between different ethnicities may result in the different conformation of the frontal bone and, thus, the "sphere theory" may not be always accurate. Additional studies to evaluate the distance from the entry point and the FM should be assessed in order to provide a standardized length of the catheter. Second, we consider only patients with normal ventricle volume and skull anatomy, therefore, did not considered the variabilities in ventricular cavities, intracerebral lesions with midline shift or edema and anomalies on skull conformations. Moreover, we did not include patients under the age of 18th due to the possible inconsistencies of the growing of the head. Third, we considered only the portion of the frontal bone which is above the superior temporal line. Knowing if this inferior portion acts also like a sphere could be useful during many neurosurgical procedures which could require deliquoration. Lastly, in both anatomical and radiological part, entry points posterior to the coronal suture, which could be useful to delimit the sphere posteriorly, were not taken in consideration.

5. Conclusion

In this study, we showed the optimal length of a frontal ventricular catheter which is 67.4 mm. Furthermore, we demonstrate that the curved surface of the frontal bone is a sphere where the FM acts as its center. Therefore, any perpendicular trajectory to the frontal bone surface will lead to the FM. These three findings will be of great assistance during frontal ventriculostomy, minimizing procedural time and complications.

Disclosure of funding

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Ethics approval

No IRB was required for this research.

CRediT authorship contribution statement

Vera Vigo: Conceptualization, Investigation, Methodology, Writing – original draft. Anna Tassinari: Validation, Formal analysis, Writing – original draft. Alba Scerrati: Data curation, Writing – review & editing. Michele Alessandro Cavallo: Supervision, Writing – review & editing. Roberto Rodriguez-Rubio: Resources, Writing – review & editing. Juan Carlos Fernandez-Miranda: Resources, Visualization, Writing – review & editing. Pasquale De Bonis: Conceptualization, Supervision, Formal analysis, Writing – review & editing.

Conflict of interest

The authors declare no conflict of interest.

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