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Research paper

3D printed training simulator for transcatheter edge-to-edge repair of the tricuspid valve: A proof-of-concept

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A R T I C L E I N F O

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TriClip™ procedure
Simulation-based training
3D printing

A B S T R A C T

Background: Tricuspid regurgitation (TR) treatments have gradually shifted toward a more interventional approach and transcatheter edge-to-edge repair (TEER) has assumed a first-order role. TriClip™ by Abbott (Menlo Park, USA) is one of the most widely used devices for tricuspid repair. TEER procedures are recognised as technically challenging, characterized by a steep learning curve. For this reason, specialized training is necessary. The aim of this work is to develop and test a novel 3D printed training simulator, which considers both anatomical and mechanical characteristics, specifically designed for this kind of procedure.
Methods: Starting from routinely acquired computed tomography (CT) images, a 3D digital model of the heart was reconstructed. This was then properly "augmented", so that it could realistically reproduce the key features involved in the procedure. The simulator was manufactured exploiting the Polyjet 3D printed. Proper materials selection was performed to accurately reproduce mechanical properties. The manufactured prototype was then tested by a specialized professional, with the TriClip™ system.
Results: The simulator was assessed to practice access, navigation, catheter steering and leaflet grasping. Throughout the process, appropriately placed cameras ensured that the operators could visualize the crucial steps on a screen. Even if a deeper evaluation is needed, preliminary feedback is satisfactory.
Conclusions: In this study, a new training simulator for TriClip™ procedure was designed, produced, and preliminary assessed. Further studies will have to demonstrate the advantages of using this simulator design to shorten the learning curve and subsequently lead to better clinical outcomes.

1. Background

Tricuspid regurgitation (TR) is a type of valvular disease, in which the valve between the right ventricle (RV) and right atrium (RA) doesn't close properly. As a result, blood leaks backwards into the RA. TR affects an estimated number of 1.6 million people in the USA and 3.0 million in Europe, representing an important public health problem (1,2). The most common form of TR is functional TR, principally due to tricuspid annular dilation and right ventricular (RV) enlargement and dysfunction [2,3]. Historically, TR has long been neglected and often not considered for surgical treatment, also because of the mistaken belief that it could improve after surgical correction of left valvular disease [4]. However, recently, it has become clear that in several cases TR does not regress after correction of left-sided valvulopathy [5]: thus, the indications for TR surgery have shifted toward a progressively more interventional stance [6].

Poor outcomes reported from a sternotomy approach are one of the reasons why surgery is still poorly performed for TV disease [7]. The emerging need to find a treatment for patients at high risk for surgery has encouraged the development of transcatheter interventions, which showed reduced tissue injury and, consequently, trauma during the intervention, as indicated in multiple reports [1,8].

Abbreviations: TR, Tricuspid regurgitation; RV, Right ventricle; RA, Right atrium; TSGC, Triclip™ Steerable guide catheter; TCDS, Triclip™ delivery system; TEE, Transesophageal echography; IVC, Inferior vena cava; LAO, Left anterior oblique; RAO, Right anterior oblique; RVIO, Right ventricular inflow-outflow; 4CH, Four chamber; CT, Computed tomography; PM, Papillary muscle; SVC, Superior vena cava; IAS, Interatrial septum.

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Nowadays, transcatheter therapies provide a promising treatment option for high-risk surgical patients with severe TR, and this is particularly true for edge-to-edge repair treatments, which employ TV coaptation devices [9]. Coaptation devices are designed to reduce TR severity by valve leaflet plication or occupying the regurgitant orifice with a spacer [10].

TriClip™ (Abbott Laboratories, Menlo Park, California, USA) is the counterpart to the MitraClip™ (Abbott Laboratories) device for TV interventions and is currently the most common technique applied for the interventional treatment of TR [11]. It consists of two parts: the Triclip™ steerable guide catheter (TSGC) and the Triclip™ clip delivery system (TCDS). This includes a steerable sleeve, a delivery catheter and the 4 mm (size *NT* and *XT*, with arm lengths of 9 mm and 12 mm, respectively) or 6 mm (size *NTW* and *XTW*, with arm lengths of 9 mm and 12 mm, respectively) wide chrome-cobalt clip, with two articulated arms to grasp and draw the valve leaflets [9]. TriClip™ procedure was assessed in patients with symptomatic moderate to severe TR and high surgical risk in the prospective multicenter TRILUMINATE trial [12]. Results showed good efficacy and safety, with a reduction of post-procedural TR grade [12].

The Triclip™ intervention, as reported in [13], is performed under general anaesthesia with fluoroscopic and transesophageal echography (TEE) guidance. Key steps of the procedure can be summarised as follows:

- to accommodate the TSGC, the standard percutaneous femoral vein access is followed;
- the TSGC is positioned in the RA, passing inside the inferior vena cava (IVC);
- the TCDS is straddled in the TSGC and placed inside the RA under fluoroscopy;
- when the clip is visualized by TEE the C-arm is positioned in the right anterior oblique (RAO) position (fluoroscopic grasping view);
- the clip is closed to 60° to prevent entanglement with the tricuspid subvalvular apparatus, and advanced toward the RV;
- the clip is reopened and positioned relative to the leaflets using the transgastric short-axis view and/or right ventricular inflow-outflow (RVIO) multiplane showing the reversed four chamber 4CH view (long axis grasping view) and the fluoroscopic RAO position;
- once the position is confirmed, the grasping is performed. The leaflet insertion and the degree of TR reduction are confirmed by multiple TEE views;
- the clip is deployed and TR grade is evaluated again before system removal.

Despite recognised benefits, percutaneous procedures are technically challenging, characterized by a steep learning curve [14]. Training in TEER is made challenging by the limited exposure to the valve, the intricacies of the different valve components, and the repair or replacement procedures themselves [14]. To facilitate the learning of surgical techniques on TV by cardiac trainees and junior surgeons, the development of a simulator may be of utmost benefit, to make users proficient in a fairly wide variety of specific tasks, in less time and safely [15]. Compared with traditional approaches to skill development, the use of simulators has been proven to equip trainees with better skills in surgery [16,17]. A reliable simulator should be accurate not just mirroring the anatomies, but also mechanical properties, to guarantee an experience as realistic as possible for the trainee [15].

Even if in recent years a great variety of simulators for cardiovascular procedures appeared [18,19], little attention was paid to TEER for TR and no relevant examples of anatomy-based simulators were found in the literature. From this perspective, the goal of this work was to develop an innovative simulator for the TEER of the TV, to make up for the lack of anatomically accurate and realistic simulators [6]. The experience gained in [20] for the realisation of a MitraClip™ simulator was exploited to extend the approach in the case of the TriClip™ procedure. A digital model of the heart was obtained through segmentation, starting from a stack of computed tomography (CT) scans. This was then "augmented" to be adapted to the training needs of the specific procedure. A physical prototype was obtained through additive manufacturing and then tested with the TriClip™ device.

2. Methods

2.1. Segmentation

Right heart segmentation was performed using Mimics software (Materialise, Leuven, Belgium), starting from a set of anonymized CT scans of an adult patient. The dataset consisted of 393 slices in the axial plane, with a resolution of 512×512 pixels, while the thickness of the slice was 0.75 mm. A thresholding algorithm was chosen to isolate the main structures. Subsequently, two different masks were generated, identifying the RA with caval veins and RV structures (Fig. 1).

CT images, although contrast-enhanced, did not allow for the direct reconstruction of some anatomical details, which had to be manually added at a later stage. In particular, it was essential to manually identify the papillary muscles (PMs) of the RV. These were reconstructed manually out of the individual slices from the CT images in Mimics.

2.2. Computed-assisted design modifications

The right heart model was then exported and post-processed in 3-Matic (Materialise, Leuven, Belgium). Here, subsequent operations including wrapping and smoothing allowed to obtain a clean, watertight mesh. The model was then hollowed, to derive the heart wall from the segmented blood pool.

Modifications were made to shape the simulator, according to training peculiarities. A key element is represented by the TV. However, valve structures could not be clearly identified from the CT. For this reason, an STL model of TV was derived and imported from an average 3D heart model and then adapted. The TV was included in mid-diastolic configuration. A simplified annulus was designed, to make the TV model interchangeable: indeed, a corresponding slot was obtained in the heart model, to guarantee geometric matching. Both structures were created using the sweep feature and a gap of 0.05 mm was left between them, to guarantee an easier assembly (Fig. 2a).

To keep the valve still during simulations of the surgical procedure, four small holes were created along the ring, for the insertion of locking pins. Moreover, to allow a fast positioning of the valve inside the heart in the printed prototype, embossed markers corresponding to the initial letter of the name were placed on each leaflet, as well as in the corresponding positions on the heart, as shown in Fig. 2b.

As anticipated, just the tips of the PMs could be clearly identified in the segmentation phase. So, the rest of the muscles were created by extruding the cross-section of the tips onto the RV wall (Fig. 2c).

The IVC was extruded by 30 mm, as it was not possible to obtain a complete IVC segmentation from the available CT. To provide the connection between the heart model and a basement, a three-cylinders connection system was designed, as shown in Fig. 2d. These were placed in such a way that the final assembled model could properly reproduce the heart orientation when the patient lies in the supine position.

Finally, to allow easy insertion of the TV and a clear view from the outside of the leaflets during the procedure, three large openings have been created in the model: two of them were obtained on the RV and one on the RA.

The resulting digital simulator model is reported in Fig. 3.

2.3. Prototype manufacturing

The model of the right heart was produced by means of 3D printing technology. A Polyjet J835 printer (Stratasys, Eden Prairie, Minnesota,

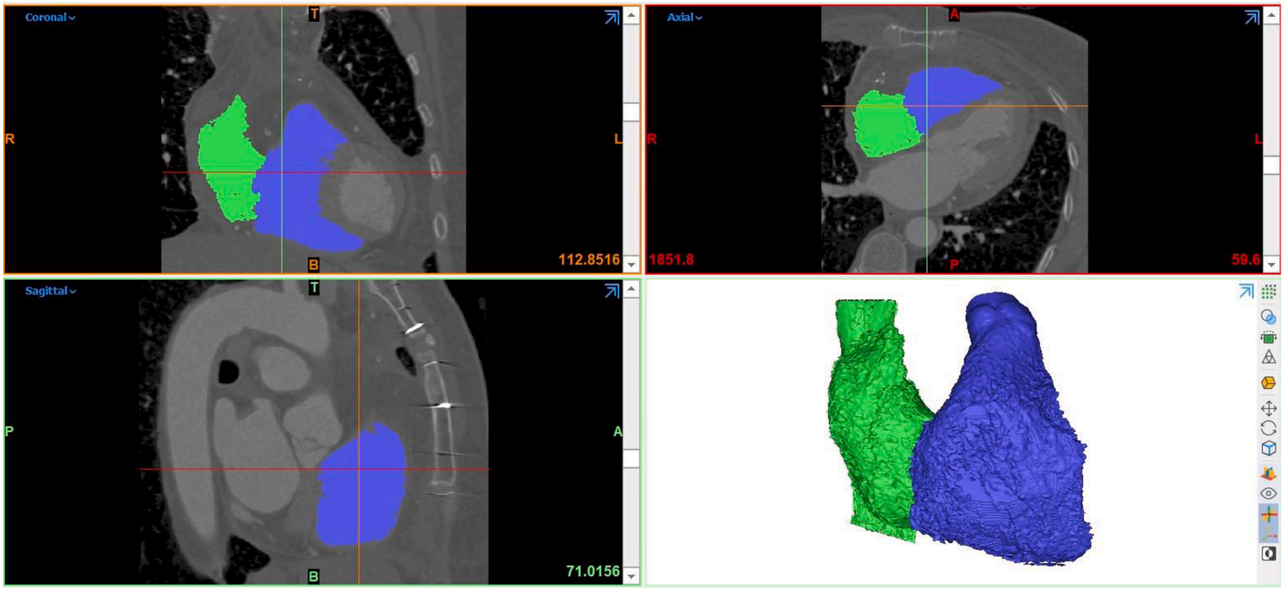

Fig. 1. Segmentation of the RH model (RV and RA) starting from CT scans in Mimics.

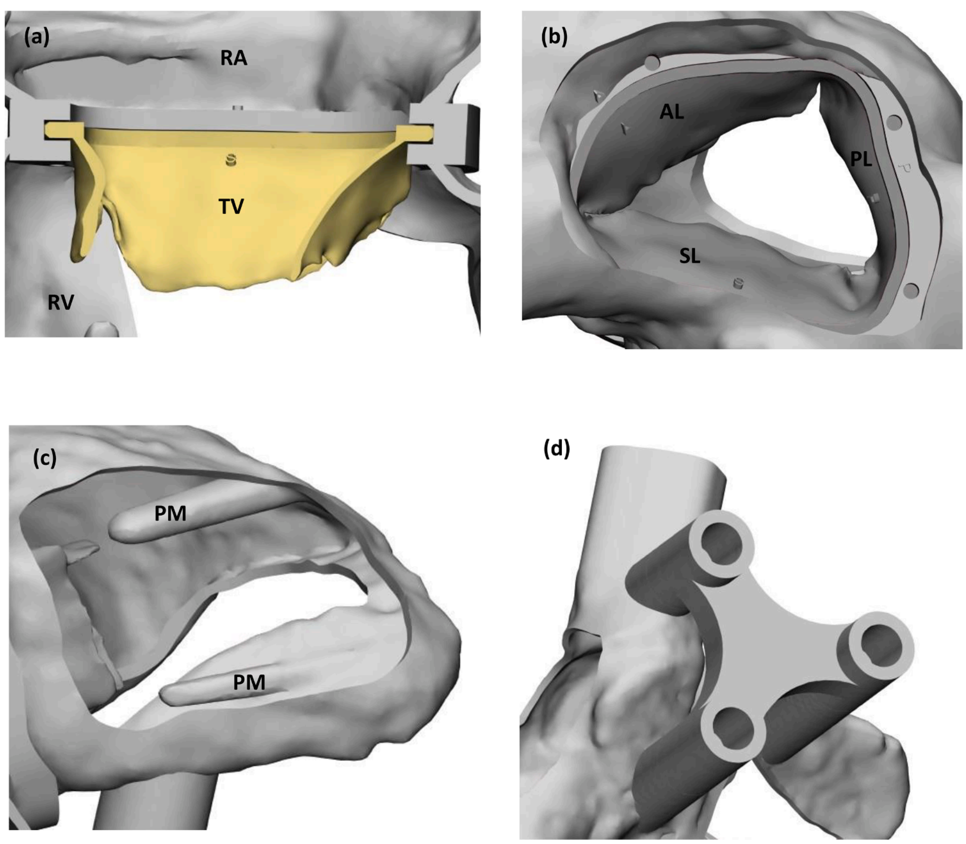

Fig. 2. (a) Detail of the locking system of the valve (yellow) inside the model. (b) Corresponding letters on leaflets and model allow for easier assembly ("A" for the anterior leaflet (AL), "P" for the posterior (PL) and "S" for the septal one (SL)). (c) PMs obtained through extrusion features. (d) Hollowed cylinders to couple the model with the basement.

USA) was used, with VeroClear (rigid) and Agilus30 clear (soft) resins [21]. Based on previous experience in the field [20,21], a differentiation of blends among different parts of the model was pursued: for the ring housing and the supporting part, a stiffer blend, coded RGDA8630-DM, was selected, while RA and RV were printed with a combination resulting in a Shore A hardness of 85. Leaflets were printed with pure Agilus30, because they had to be flexible enough during clipping. The resulting 3D-printed model is presented in Fig. 4.

A heavy basement was designed to withstand the stresses undergone during simulations without damaging or shifting. A simple steel structure was conceived, consisting of a disk and three 115 mm long threaded bars. The bars were screwed into corresponding threaded holes in the

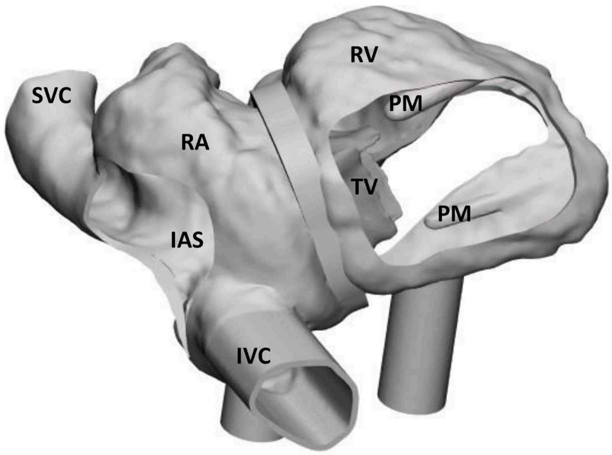

Fig. 3. Resulting digital model of the simulator. The main anatomical refernces are labelled.

disk, positioned to align with the cylinders in the model.

2.4. Testing

The simulator was tested by an expert trainer from Abbott, in order to check whether it complies with the joint use of the equipment for the TriClip™ implantation procedure. A mock testing was performed following the steps detailed below:

I. assembly of the TriClip™ G4 system on a stabilizer and positioning at a proper distance from the model;
II. introduction of the TSGC into the RA through the IVC;
III. insertion and advancement of TCDS inside the TSGC reaching the straddling position;
IV. steering the system and progress in the RV, by crossing the TV;
V. deployment simulation with leaflets grasping (anterior and septal leaflets) and system removal.

Throughout this process, appropriately placed cameras allowed operators to visualize each step of the procedure on a tablet, replicating what the surgeon sees in the operatory room.

3. Results

3D printing technology made possible a qualitatively reasonable reproduction of mechanical properties, from the point of view of flexibility, deformability and, as far as possible, tactile sensation. Moreover, the matching between model and basement and between model and interchangeable TV turned out to be easy and repeatable. The prototype resulted in being translucent, allowing one to see through the walls and observe the catheter when deployed. The presence of windows allowed the operators full view of all the anatomical structures involved in the procedure, also guaranteeing an effective positioning of the cameras.

The mock transcatheter procedure was successfully achieved. All the steps were effectively performed in a reasonable time and the clip was finally implanted. Fig. 5 shows four procedural steps, while in Fig. 6 properly positioned recording cameras are broadcasting images to a tablet.

4. Discussion and conclusions

In this study, a new training simulator for the TriClip™ G4 System procedure was designed, produced, and assessed. Starting from CT images, a three-dimensional right heart model was generated and then properly modified, to reproduce all the main features involved in the edge-to-edge repair procedure.

A key strength of this simulator is its modularity: it is possible to replace individual model components in case of damage over time, but also to increase the training possibilities. The valve constitutes an independent body, and its positioning is simple and safe. This guarantees the possibility to exchange valve models, for example considering different time configurations of the same valve. The created openings proved to be effective in allowing live recording of the whole procedure through cameras, while the metallic basement managed to give great stability to the simulator, without interfering with operations.

While the results of the feasibility assessment were satisfactory, some issues remained unaddressed. This study focused solely on presenting the design concept and conducting a preliminary test. However, the benefits of using such a simulator will have to be properly investigated. A systematic collection of feedback across various demographics and skill levels will be essential not only to evaluate the potential benefit of the proposed model, but also to assess any necessary changes and refinements. This would increase the credibility and reliability of the simulator design and its training effectiveness.

From a design and manufacturing point of view, some improvements could be introduced. First, the presented model lacks chordae tendineae, which connect the TV to the PMs. Given the difficulty of printing such structures, the use of stitched threads could be an effective option, as reported in [18]. Moreover, an important limitation is the static nature of the TV model. One of the main challenges of the TriClip™ procedure is grasping moving leaflets. Reproducing this may be complex; potential solutions could involve the use of shape memory polymers [22] as actuators for the leaflets, to make them move during the training session.

Exploring additional materials would also be beneficial. While the blends currently employed offer a good compromise between resistance and distensibility, they are not specifically tailored for medical 3D printing. New solutions recently appeared on the market, especially designed for this kind of application [23]. Some testing and

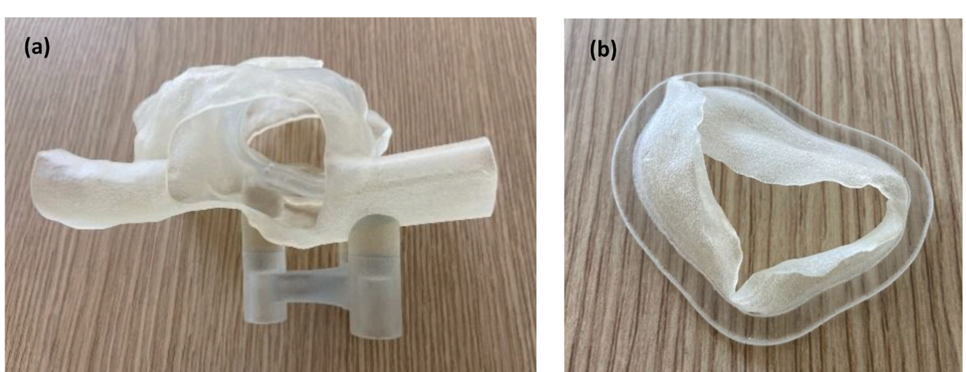

Fig. 4. (a) 3D printed anatomical model. (b) 3D printed TV.

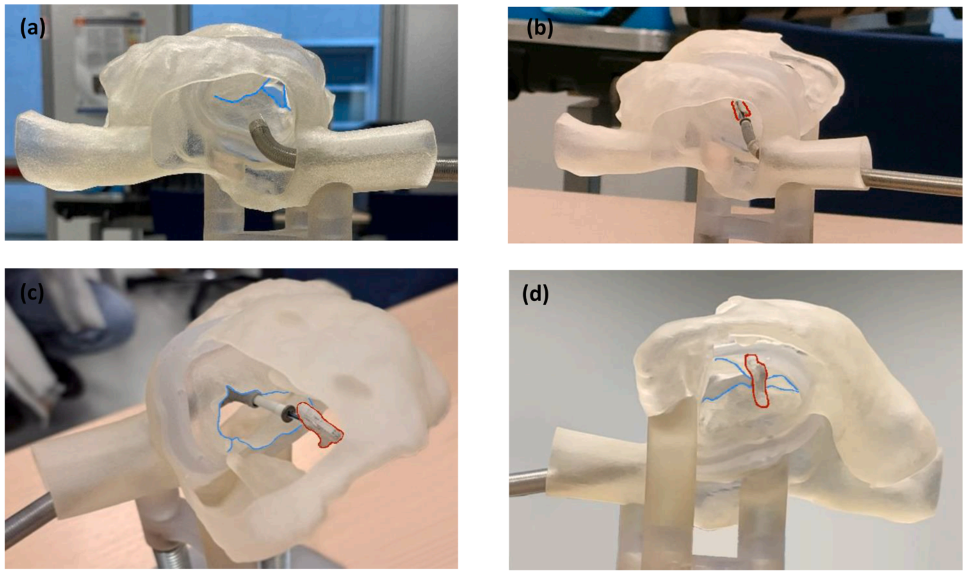

Fig. 5. Testing of the prototype. (a) Introduction of the system through the IVC and advancement in the RA (b) steering of the system inside the RA (c) progress in the RV, by crossing the TV; (d) leaflets grasping. Clip profile is marked with a red line, while MV leaflets with a light blue one.

Fig. 6. The use of recording cameras and a tablet guarantees an effective visualisation/videorecording of each step of the procedure.

characterization will be needed to evaluate their adoption for this project.

Further studies may demonstrate the advantages of using this simulator design to shorten the learning curve and subsequently lead to better clinical outcomes, also in comparison with other types of simulators. The incorporation in data collection of objective outcome measures, such as procedural success rates, reduction in procedure time, or improvement in specific technical skills, could provide more robust evidence of the simulator impact on training outcomes.

To summarize, this study outlines the creation of a novel 3D printed simulator for TEER of the TV and successfully tests its compatibility with TriClip™ equipment. Further research will aim to investigate the advantages of this novel design in comparison to currently available solutions.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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CRediT authorship contribution statement

Michele Bertolini: Conceptualization, Methodology, Writing – original draft, Writing – review & editing, Supervision. **Luca Carlini:** Methodology, Validation, Investigation, Writing – original draft, Writing – review & editing. **Ludovica Clementini:** Methodology, Validation, Investigation, Writing – original draft, Writing – review & editing. **Martina Dall'Aglio:** Methodology, Validation, Validation, Investigation, Writing – original draft, Writing – review & editing. **Giorgio Colombo:** Resources, Supervision. **Claudio Capelli:** Conceptualization, Methodology, Resources, Writing – review & editing, Supervision.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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