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A randomised controlled trial of the Cathpax AIR radioprotection cabin during cardiology procedures

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Ionising radiation is essential in interventional cardiology, but it is associated with occupational health hazards[1]. Personal protective equipment (PPE) is used to limit exposure to radiation, but because it is heavy and cumbersome, it may also have deleterious health effects[2]. New light radiation-attenuating materials can efficiently decrease scattered radiation originating from the patient. However, the increasing number and complexity of interventional cardiology procedures require a more global approach to minimise operator exposure to radiation. In collaboration with Lemer Pax, we designed and optimised the Cathpax AIR cabin to improve operator protection during structural procedures and also during coronary angiography and angioplasty. The feasibility of using the cabin during interventional cardiology procedures has been reported previously[3]. In the present prospective, randomised clinical study performed at Nantes University Hospital (France), we assessed the cabin's performance regarding radiation protection and ergonomics during structural and coronary angiography/angioplasty procedures (no trial registration exists).

All procedures were randomised daily to be performed with or without the Cathpax AIR cabin **(Supplementary Figure 1)**. The 4 participating interventional cardiologists (P. Guerin, J. Plessis, V. Letocart, and T. Manigold) wore their PPE equipped with thermoluminescent dosimeters for all procedures performed with or without the cabin. The left chest dosimeter provided the total dose received. A cumulative dose was collected over time for both groups of procedures. The primary and secondary endpoints were the differences with and without the cabin in total and individual body part radiation exposure, respectively. Medical team satisfaction with cabin ergonomics was assessed with a questionnaire **(Supplementary Figure 2)**. Additional method description is provided in **Supplementary Appendix 1**.

This study included 63 structural procedures and 92 angiography/angioplasty procedures performed between March 2021 and January 2022. Patient demographics and procedure characteristics were similar in the groups with and without the cabin **(Supplementary Table 1)**. Use of the cabin reduced the total radiation dose by 63% – from 490 µSv without the cabin (n=31) to 180 µSv with the cabin (n=32) – for the structural procedures, and by 58% – from 810 µSv without the cabin (n=50) to 340 µSv with the cabin (n=42) – for the angiography/angioplasty procedures **(Figure 1)**. The most important benefit provided by the cabin was the protection of the eyes and brain, which had an exposure below the detection limit (<10 µSv) regardless of the procedure **(Figure 1)**. The extremities were also protected by the cabin, with a dose reduction of more than 70% for the left wrist. The questionnaire indicated that cabin installation and physical burden were the major points of dissatisfaction, while accessibility, visibility and communication were satisfactory **(Supplementary Figure 3, Supplementary Figure 4)**.

This study showed an improvement in radiation protection when using the Cathpax AIR cabin during various structural procedures and angiography/angioplasty with no increase in procedure duration or radiation exposure despite some procedures being lengthy and complex. Based on our results, an interventional cardiologist performing 10 structural and 30 angiography/angioplasty procedures per month would receive an annual dose of approximately 3.6 mSv when

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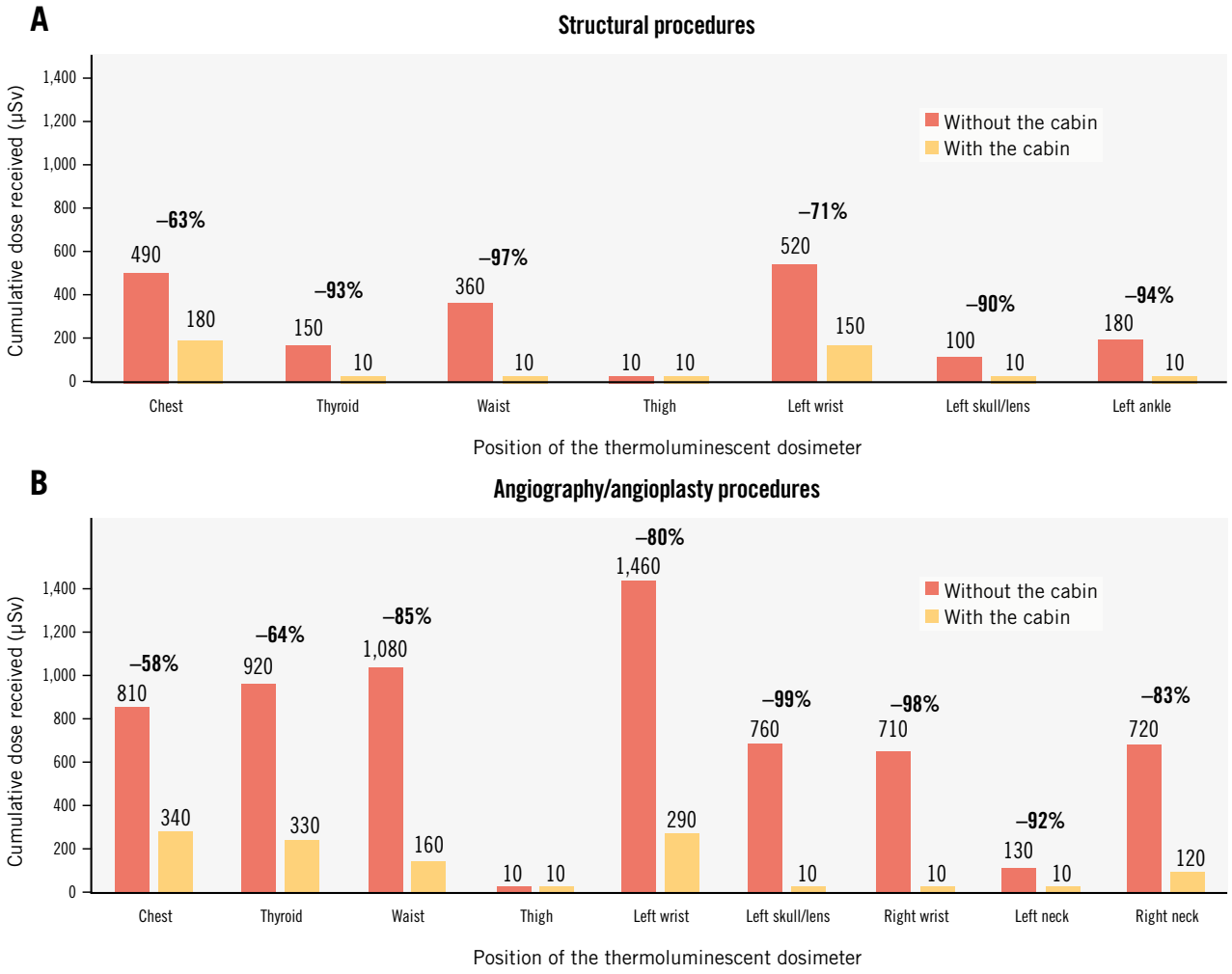

Figure 1. *Cumulative dose received by the operator with and without the cabin. Cumulative dose received by the operator during structural (A) and angiography/angioplasty (B) procedures, with and without the radioprotection cabin. The study included 63 structural and 92 coronary angiography/angioplasty procedures. The left chest dosimeter provided the total dose received by the primary operator (study primary endpoint).*

using the radioprotection cabin, which is below the 5 mSv/year value reported with PPE[1]. The eyes and brain were particularly protected. This is an advantage of the cabin over radiation protection goggles, which are efficacious[4] but not systematically worn because of their weight and the discomfort created. Regarding hand protection, the cabin was superior to PPE, given the lack of reliability of protective gloves[5]. However, the level of radioprotection reported in this real-life study was not as high as anticipated. Further improvement could be achieved by abandoning the local practice of installing the cabin after performing the vascular approach with fluoroscopic guidance, as was the case for 8 structural procedures. In emergency situations (e.g., external cardiac massage), the cabin would have to be rapidly removed. In that respect, the cabin ergonomics need improvement, as the physical burden associated with cabin handling was described as high. Nevertheless, after set-up, the additional strain induced by the cabin during routine work was acceptable. We did not investigate the safety-related aspects of the cabin, but a review of hospital reports in the early post-intervention phase did not indicate any major complication related to cabin use.

One limitation of our study is the small number of procedures, which, given the low irradiation doses perceived behind the cabin, did not always allow for a precise assessment of benefits. The challenge was to collect a sufficient number of coronary angiography or angioplasty procedures using a cabin, which explains the long inclusion period. Also, the wide range of procedures performed led to significant variability in the use of fluoroscopy, but the study was designed to be representative of daily practice. We evaluated the cabin performance on top of PPE, and an additional study would be necessary to assess the combined radiation protection impact of the cabin and PPE.

In summary, the Cathpax AIR cabin reduces radiation exposure during various routine interventional cardiology procedures. The improvement in radiation protection with the cabin is particularly significant for areas of the body insufficiently protected by standard equipment, such as the skull, the eyes, and the extremities.

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Funding

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Conflict of interest statement

P. Guerin is the initiator of the cabin and has been involved in its creation, design, and optimisation; he has a consultancy agreement with Lemer Pax. The other authors have no conflicts of interest to declare.

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Supplementary data

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Supplementary data

Supplementary Appendix 1. Additional methods.

The CathPax AIR cabin

The CathPax AIR cabin provides whole body radiation protection, with an equivalent shielding of 1 to 2 mm of lead. It is 928 mm (deep) x 975 mm (wide), and 974 mm (high), and weighs 275 Kg. It is made up of two side-by side vertical panels with transparent upper parts and one transparent ceiling **(Supplementary Figure 1)**. The front panel is placed in front of the chosen arterial access and the operator can insert his hands between the fixed bottom panel and the mobile top panel. The front panel is to be closed during radiation exposure to ensure maximum protection. The cabin can be wrapped with sterile drapes.

For procedures performed with the cabin, the ceiling suspended device used as collective protection equipment is not to be used as it is replaced by the cabin front panel. For a structural procedure, the cabin is used during the fluorescence guided progression to the heart but not during the vascular approach.

Study participants

Four interventional cardiologists of the Nantes University Hospital participated in the study. For all procedures, performed with or without the cabin, the practitioner wore his PPE, including a lead apron (0.55 mm lead equivalent vest; 0.5 mm lead equivalent skirt for front protection), a thyroid shield (0.5 mm lead equivalent) and eyewear (0.75 mm lead equivalent).

Each participant provided free consent to participate in this study.

Study procedures

Two types of procedures were considered: the structural procedures (transcatheter valve implantation or intracardiac shunt closure) and the procedures involving diagnostic coronary angiography, angioplasty, which could be simple or complex (chronic total occlusion, rotational atherectomy with Rotablator device, or fractional flow reserve calculation) and alcohol septal ablations. Separate cardiac laboratories were used for the structural and the angiography/angioplasty procedures. Each laboratory was equipped with a fluoroscopy system (GE Healthcare).

For structural procedures, the operator wore 7 thermoluminescent dosimeters (6 H'(0.07), 1 Hp (10)): the H’(0.07) dosimeters were placed on the left branch of the radiation protection glasses, the left wrist strap, the left ankle strap, the belt strap, the thigh strap, the collar of the long shield vest (thyroid); the Hp (10) dosimeter was on the left chest.

For angiography/angioplasty procedures, the operator wore 9 thermoluminescent dosimeters (8 H’ (0.07), 1 Hp (10)): the H’(0.07) dosimeters were placed on the left branch of the radiation protection glasses, on the

right /left wrist, the right/left neck, the collar of the long shield vest (thyroid), the belt and skirt; the Hp (10) dosimeter was on the left chest.

At the end of each procedure, we collected the dose area product, the air kerma, and the fluoroscopy exposure time, as well as the number of image sequences for structural procedures. The left chest dosimeter provided the total dose received by the primary operator. Because the radiation doses are decreased to very low levels when the cabin is used, a cumulative dose measure was collected by assigning the surgical gown containing the study dosimeters to one of the 4 study arms (structural procedures with or without a cabin, angiography/angioplasty procedures with or without a cabin), independently of the operator. In the absence of a significant dose result, the default value was set to the thermoluminescent dosimeter detection limit (10 µSv).

Study randomisation

On each study day, the primary operator randomised the day procedures to be performed with or without the cabin. As the inclusion deadline approached, the study groups were balanced by AM guiding operators towards either not using the cabin (in the group of structural procedures) or using it (in the group of angiography/angioplasty).

Study endpoints

The primary endpoint was the difference in the primary operator's cumulative radiation exposure between procedures performed with and without the cabin.

The secondary endpoints were the differences in the primary operator's individual body part radiation exposure between procedures performed with and without the cabin.

The cabin ergonomics was evaluated with a user satisfaction questionnaire **(Supplementary Figure 2)**, which was completed by the 4 study interventional cardiologists and the paramedic team. The cardiologists were asked for their level of satisfaction with cabin use on a scale ranging from 1 (very bad) to 5 (excellent) for 5 criteria: postural comfort, installation and handling of the cabin, screen visibility, accessibility of commands, ease of communication with the patient and the medical team. The paramedic team was asked for its level of satisfaction with cabin use on a scale from 1 (very bad) to 5 (excellent) and provided its appreciation on a scale ranging from 1 (light) to 10 (very high) of the additional (overall and physical) strain associated with the cabin.

Statistical analysis

A previous pilot study (unpublished data) demonstrated that, with the cabin, the radiation exposure of the main operator was reduced by at least 93% during a conventional transaortic valve implantation procedure. This result was used to estimate that a minimum of 30 procedures per randomization arm (with and without the cabin) would be needed to show the benefits of the cabin use.

The data are expressed as a mean +/- standard deviation for continuous variables and compared using the unpaired T-test or the Mann–Whitney U test, as appropriate. Categorical variables are expressed as numbers or percentages and compared using chi-square analysis or the exact Fisher test. A p-value <0.05 is considered statistically significant.

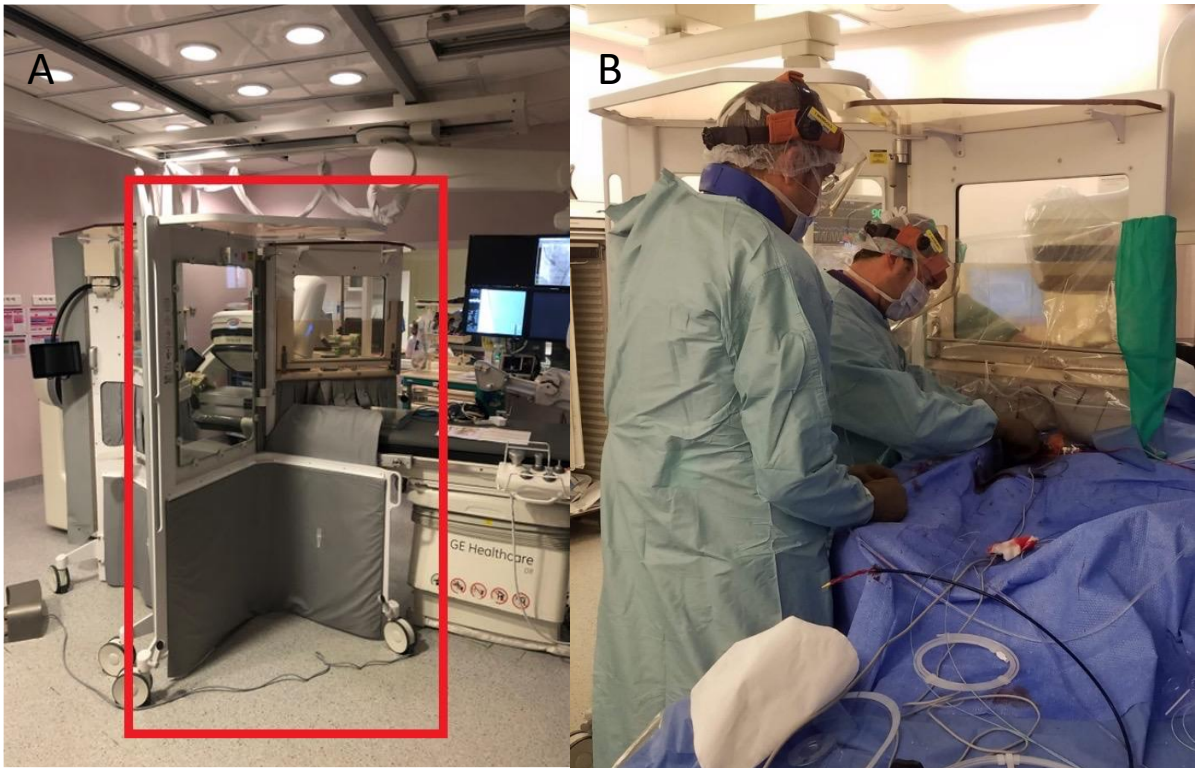
CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	P1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	NA (no abstract)
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	P2
	2b	Specific objectives or hypotheses	P2
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	P2 P3 supplement
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	NA
	4b	Settings and locations where the data were collected	P2
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	P2 supplement
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	P2
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	P4 supplement
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	P3 supplement
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	P3 supplement

Supplementary Table 1. Procedure and patient characteristics.

	Structural procedures			
	All procedures n = 63	**Procedures with cabin n = 31**	**Procedures without cabin n = 32**	**p-values**
Procedures				
TAVI	59	27	32	0.036
MitraClip	2	2	0	0.149
Pulmonary valvuloplasty	1	1	0	0.314
Shunt closure	1	1	0	0.314
Patient characteristics				
Age (years)	80 ± 10 [32-96]	78 ± 13 [32-89]	82 ± 5.5 [70-96]	0.184
Gender (Men)	35 (56%)	18 (58%)	17 (53%)	0.52
Body mass index (Kg/m^2)	26.3 ± 4.4 [19-39.5]	27.3 ± 4.9 [20.4-39.5]	25.4 ± 3.7 [19-34.3]	0.1
Procedure characteristics				
Fluoroscopy duration (min)	7.04 ± 3.35 [1.28-16.5]	7.36 ± 3.8 [3-16.5]	6.77 ± 3.0 [1.28-14.5]	0.491
Dose area product (cGy.cm^2)	1098 ± 947 [4-6016]	1305 ± 1171 [234-6016]	898 ± 617 [4-2751]	0.088
Air kerma (mGy)	124 ± 117 [14-796]	145 ± 148 [14-796]	105 ± 74 [19-333]	0.181
Image sequences	4.4 ± 1.9 [0-9]	4.6 ± 2.5 [0-9]	4.3 ± 1.3 [1-6]	0.519
	Angiography/angioplasty procedures			
	All procedures n = 92	**Procedures with cabin n = 42**	**Procedures without cabin n = 50**	**p-values**
Procedures				
Coronarography	52	21	31	
Cardiac catheterisation*	8	3	5	
Angioplasty	30	16†	14	
Alcohol septal ablation	2	2	0	
Patient characteristics				
Age (years)	66 ± 13 [20-91]	63 ± 14 [20-91]	69 ± 13 [28-87]	0.07
Gender (Men)	73 (79%)	33 (79%)	40 (80%)	0.86
Body mass index (Kg/m^2)	27.3 ± 5.4 [17.5-47.8]	27.1 ± 5.4 [17.5-43.9]	27.5 ± 5.5 [18.9-47.8]	0.71
Procedure characteristics				
Fluoroscopy duration (min)	7.02 ± 6.69 [0.39-30.28]	7.78 ± 7.39 [1.08-30.28]	6.38 ± 6.04 [0.39-30.03]	0.32
Dose area product (cGy.cm^2)	3346 ± 3424 [42-16324]	3289 ± 3324 [458-14652]	3394 ± 3538 [42-16324]	0.88
Air kerma (mGy)	464 ± 501 [5-2449]	426 ± 501 [29-2449]	497 ± 504 [5-2154]	0.5

Values are numbers (percentages) or means ± standard deviations with [minimum-maximum values]
*Right cardiac catheterisation except for 1 patient with right and left catheterization in the group without cabin
†Including 5 chronic total occlusions and 3 angioplasties preceded by positive fractional flow reserve calculation
TAVI: transcatheter aortic valve implantation



Supplementary Figure 1. The Cathpax AIR radioprotection cabin.

The display shows the cabin used in the study (A), and the cabin used in a transcatheter aortic valve implantation (B)

For the paramedic team:

Regarding the use of the new radiation protection booth, please indicate your level of satisfaction with the following items:

1	2	3	4	5
Very bad	*Bad*	*Passable*	*Good*	*Excellent*

	Very bad				*Excellent*
1. Installation of the cabin in the room	1	2	3	4	5
2. Handling the cabin during the intervention	1	2	3	4	5
3. Patient accessibility	1	2	3	4	5
4. Space clutter	1	2	3	4	5
5.Communication with the patient and medical team	1	2	3	4	5

Regarding the arduousness related to the presence of the cabin in the room for the realization of the usual work tasks, thank you to indicate your feelings on a scale of 0 to 10:

1	2	3	4	5	6	7	8	9	10
Light			*moderate*		*High*			*very high*	

Regarding the physical arduousness (shoulder/spine joint constraints) related to the handling of the cabin, please indicate your feelings on a scale of 0 to 10 :

1	2	3	4	5	6	7	8	9	10
Light			*moderate*		*High*			*very high*	

For the interventionnal cardiologists:

Regarding the use of the new radiation protection booth, please indicate your level of satisfaction with the following items:

1	2	3	4	5
Very bad	*Bad*	*Passable*	*Good*	*Excellent*

	Very bad				*Excellent*
1. Postural comfort during the performance of the interventional act	1	2	3	4	5
2. Installation and handling of the cab	1	2	3	4	5
3. Screen visibility	1	2	3	4	5
4. Accessibility to different commands	1	2	3	4	5
5.Communication with patient and team	1	2	3	4	5

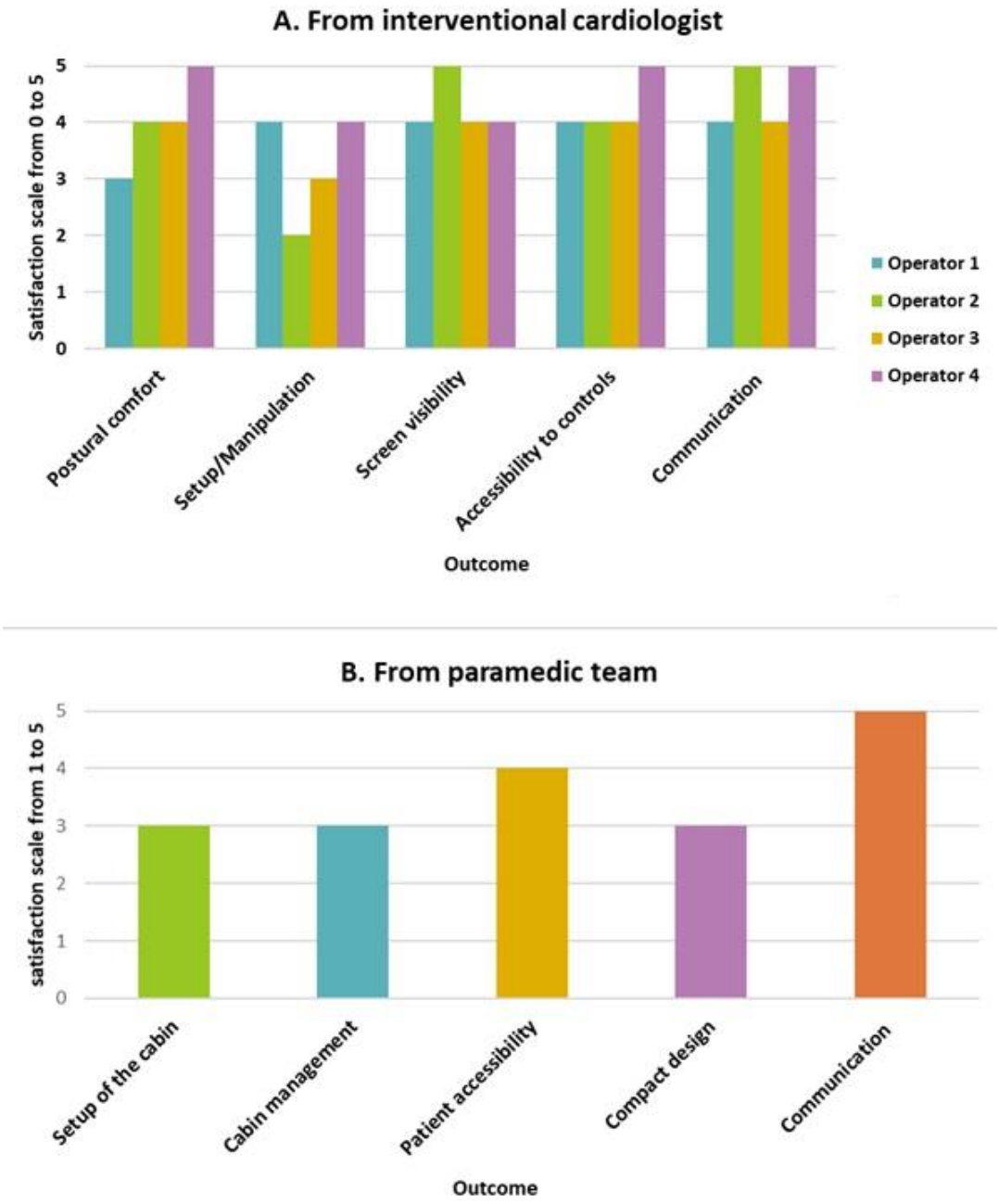
Regarding the arduousness related to the presence of the cabin in the room for the realization of the usual work tasks, thank you to indicate your feelings on a scale of 0 to 10:

1	2	3	4	5	6	7	8	9	10
Light			*moderate*		*High*			*very high*	

Regarding the physical arduousness (shoulder/spine joint constraints) related to the handling of the cabin, please indicate your feelings on a scale of 0 to 10 :

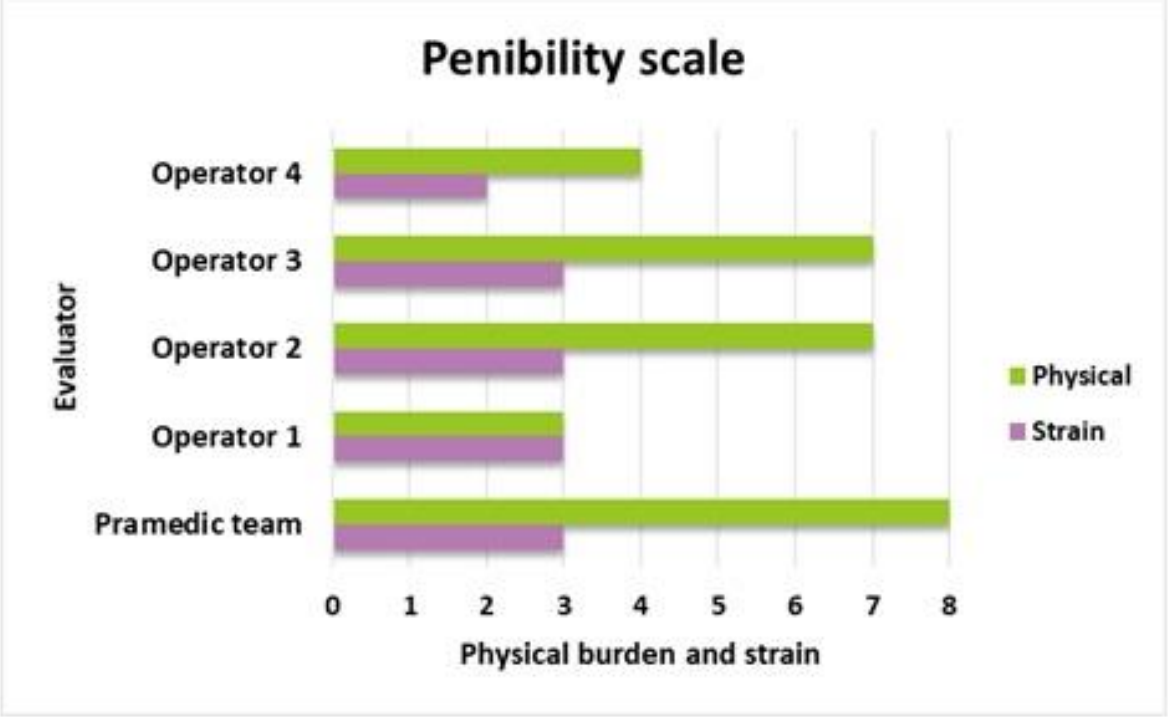
1	2	3	4	5	6	7	8	9	10
Light			*moderate*		*High*			*very high*	

Supplementary Figure 2. The satisfaction questionnaire.



Supplementary Figure 3. Overall satisfaction of the interventional cardiologist and paramedic team with the cabin.

Satisfaction of the interventional cardiologist (A) and paramedic team (B) with the cabin.
A score of 1 was very bad and 5 was excellent.



Supplementary Figure 4. Evaluation of the strain and physical burden associated with the use of the cabin.

A score of 1 corresponded to very light strain or physical burden and 10 was very high.