CONCEPT
The SEPARPRO™ concept is a combination of a sterile surgical drape and a radio protective fabric reducing the radiation on the operator and the staff working in the intervention room.

BENEFIT
A decrease of 60% up to 80% of the irradiation on the intervention room staff.

REMARKS
The employer (hospitals, clinics) being legally required to minimize any source of nuisance related to the professional practice, it is difficult and inconsistent for hospitals and clinics to overlook the advantages in the use of SEPARPRO™ drapes that significantly lessen the exposure of the intervention room staff to X-Rays.

The only drawback to use the SEPARPRO™ Drapes is an increase in the weight of the drape itself, this extra weight is evenly distributed on the patient’s body.

As of today, practitioner add between 2 and 4 extra layers of protection (i.e. X-Ray protection panel type), which means that the difference in weight between the current practice and SEPARPRO™ drapes is marginal and it also highlights the fact that this extra weight is well tolerated by the patient.
SEPARPROCATH™ by PROMEDICAL AG

ADVANTAGES
✓ Easy to use and to install drapes
✓ Not requiring any additional protection against X-Rays
✓ Less waste to dispose, no need for any additional protection

RECOMMENDED FOR
• Cardiac catheterization.
• Angioplasty and Structural Intervention (CIA, FOP).
• Electrophysiology study.
• Ablations

SEPARPROCATH DRAPE offers maximum protection against radiation for the care staff and the doctor working at the table in addition to the usual protection measures (i.e. X-Ray protection panel type).
SEPARPROPACE DRAPE offers maximum protection against radiation for the care staff and the doctor working at the table in addition to the usual protection measures (i.e. X-Ray protection panel type).

**ADVANTAGES**

- Easy to use and to install drapes
- Not requiring any additional protection against X-Rays
- Less waste to dispose, no need for any additional protection

**RECOMMENDED FOR**

- Implantation of pacemaker
- Implantation of defibrillator
- Resynchronization
- Implantation of Portacath
SEPARPROVASC™

ADVANTAGES
✓ Easy to use and to install drapes
✓ Not requiring any additional protection against X-Rays
✓ Less waste to dispose, no need for any additional protection

RECOMMENDED FOR
• Abdominal arteriography
• Interventional radiology
• Implantation of Percutaneous Valve (TAVI)
• Arteriography and peripheral angioplasty

SEPARPROVASC DRAPE offers maximum protection against radiation for the care staff and the doctor working at the table in addition to the usual protection measures (i.e. X-Ray protection panel type).
PUBLICATION
Patet C. et al:
EFFICACY OF THE SEPARPROCATH™ RADIATION DRAPE TO REDUCE THE RADIATION EXPOSURE DURING CARDIAC CATHETERIZATION: A PILOT COMPARATIVE STUDY.
In print: In Cardiovascular and Cardiovascular Interventions.

STATEMENT:
The development of cardiac catheterization procedures has been associated with increasing numbers of radiation-induced diseases in the medical staff, ranging from «benign» subcapsular cataracts to a presumed higher risk of malignancies. Interventional cardiologists and room staff are exposed to two main sources of radiation: x-ray tube leakage and scatter radiation from the patient.

GOAL:
We sought to compare the radiation exposure (RE) of the cardiac catheterization room staff using SEPARPROCATH™, a novel radio-protective drape versus standard shielding equipment.

RESULTS:
SEPARPROCATH™ was associated with a lower operator radiation exposure corresponding to a RE relative risk reduction of 81% and 99% respectively. Similar reductions were observed for operator and nurse cumulative doses. No difference was found in Dose Area Product.

CONCLUSION:
SEPARPROCATH™ is a novel, lead-free, radioprotection drape, that significantly decreases radiation exposure of the medical staff during cardiac catheterization procedures while guaranteeing patient safety.
Efficacy of the SEPARPROCATH® radiation drape to reduce radiation exposure during cardiac catheterization: A pilot comparative study

Camille Patet MD1 | Nick Ryckx PhD2 | Diego Arroyo MD1 | Stéphane Cook MD1 | Jean-Jacques Goy FESC, MD1,3

Abstract

Background: Interventional cardiologists are exposed to radiation-induced diseases, partly due to patient's scatter radiation.

Objectives: We sought to compare the radiation exposure (RE) of the cardiac catheterization room staff using SEPARPROCATH®, a novel radio-protective drape versus standard shielding equipment.

Methods: This was a two-step prospective, randomized pilot trial: first, in experimental conditions using a phantom model, and second, during cardiac catheterization. Primary end-point was operator RE corresponding to the ratio between operator cumulative dose (CD) and dose area product (DAP). Secondary end-points were nurse RE, operator and nurse CD, DAP, and fluoroscopy time.

Results: A total of 51 patients were included. SEPARPROCATH® was associated with a lower operator RE (0.07 [0–0.19] vs. 0.37 [0.23–0.81] μSv/Gy.cm² without SEPARPROCATH®, p value <0.0001) and lower nurse RE (0 [0–0.05] vs. 0.13 [0.03–0.28] μSv/Gy.cm², p value <0.0001) corresponding to an RE relative risk reduction of 81% and 99%, respectively. Similar reductions were observed for operator and nurse CDs. No difference was found in DAP (19 [11–29] vs. 14 [10–32] Gy.cm² without SEPARPROCATH®, p value 0.81).

Conclusion: SEPARPROCATH® offers significant additional radioprotection to the operator and nurse during cardiac catheterization without affecting patient safety.

KEYWORDS

innovation, interventional cardiologist, percutaneous coronary intervention, radiation exposure, radiation protection

1 INTRODUCTION

The development of cardiac catheterization procedures has been associated with increasing numbers of radiation-induced diseases in the medical staff, ranging from "benign" subcapsular cataracts to a presumed higher risk of malignancies.1,2 Interventional cardiologists and room staff are exposed to two main sources of radiation: X-ray tube leakage and scatter radiation from the patient.3,4 Other than procedural characteristics such as frame rate reduction or minimizing cineangiography, various protective tools have been developed (lead apron, leaded glass mobile panel, RADPAD® drapes) with proven radiation protection. They are however dependent on the staff behavior.5,6 The novel radiation shield SEPARPROCATH® is a single-use, sterile, lead-free shield placed on the patient, and designed to reduce staff exposure to scatter radiation. We sought to compare the radiation exposure (RE) of the cardiac catheterization room staff using SEPARPROCATH® versus standard shielding equipment. We chose a bench-to-bed approach using first an experimental phantom model and second, during cardiac catheterizations.
2 METHODS

2.1 Experimental conditions

The anthropomorphic phantom consisted of nine pieces of polymethylmethacrylate (PMMA) about 5 cm thick. Three pieces measured 30 × 30 cm and six pieces 20 × 20 cm, all stuck together, as shown in Figure 1, to simulate a body about 15 cm thick.

The procedure was performed in a room equipped with a digital single-plane cineangiography unit (Allura FD10; Philips Medical Systems DMC GmbH, Hamburg, Germany) with an under table X-ray tube MRC20025 with a magnification factor leading to a field of view of 21 cm and an acquisition frequency of 15 frames/s.

Cumulative dose (CD) was measured through two personal electronic dosimeters (DMC 3000, Mirion Technologies, Marseille, France). They were silicon-based semi-conductor detectors calibrated in ambient equivalent dose Hp(10). They were positioned on a pole at a height of 128 cm corresponding in real conditions to the operator or nurse's thorax, at 60 cm from the table center axis and 100 cm from the X-ray center. One was located on the right side of the phantom, corresponding to the operator and the second one was on the left side, corresponding to the mobile nurse.

Standard radiation protection consisted of a leaded glass mobile panel with a soft lead shield patient contour cutout (0.5 mm lead equivalent, MAVIG, Munich, Germany) at the left side of the operator and a table lead skirt (0.5 mm lead equivalent) mounted on the side of the table (Figure 2). No RADPAD® drape was used. The SEPARPROCATH® (Promedical AG, Glarus, Switzerland) is a sterile, disposable, surgical drape which is placed on the patient during the intervention. It contains a lead-free shield (0.5 mm lead-equivalent) in the area covering the patient's lower abdomen, pelvis and thighs (Figure 3).

Four conditions were analyzed: operator and mobile nurse RE, with and without the SEPARPROCATH®. In each situation, one measurement was made for a procedure delivering a dose area product (DAP) of about 20 Gy.cm².

2.2 In vivo study

Patients were included non-consecutively when admitted to the catheterization laboratory for an elective coronary angiography, and percutaneous coronary intervention if needed. They were randomized to either SEPARPROCATH® or standard shielding as during the experimental conditions. Previous studies reported an RE relative risk reduction till 59% with partial drape compared to conventional radioprotection.7–9 To demonstrate a difference in operator RE higher with SEPARPROCATH® to partial drape (i.e., 60% difference) with a power of 80%, a minimum of 22 patients was required (11 patients per group).

Standard radiation shields consisted of a leaded glass mobile panel and a table lead skirt as described above. Personal protections included a lead apron, a thyroid lead collar, a disposable radiation protection cap and leaded glasses. No RADPAD® drape was used.

The procedure was performed by senior interventional cardiologists using either right radial or femoral access. Emergency coronary angiography and complex procedures with crossover access site were excluded. A written informed consent was obtained as part of the normal procedure and in accordance with guidelines in Good Clinical Practice and Declaration of Helsinki.

The angiography unit was the same as the one used in the experimental conditions. The personal dosimeters were those in use in the catheterization room (DoseAware, Philips Healthcare, Best, The Netherlands), expressing their measurements in terms of Hp(10). The acquisition frequency was left to the discretion of the interventional cardiologist. The operator and mobile nurse RE was measured using a dosimeter located on the sternum, outside the lead apron.
2.3 | Data collection and statistical analysis

The primary end point of the trial was operator RE (in μSv/Gy.cm²) which corresponds to the ratio between CD (in μSv) received by the operator and the DAP (in Gy.cm²). This has the advantage to correct CD by patient exposure, and therefore interprocedural variance. It also represents the efficiency of the shield equipment. Secondary end points were nurse RE (in μSv/Gy.cm²) as well as CD for the operator and the nurse. DAP (the product of patient absorbed dose by the patient multiplied by the irradiated area, in Gy.cm²) and fluoroscopy time (in seconds) were collected to ensure baseline population comparability.

In experimental conditions, comparisons were assessed with Student’s t test and results are expressed as mean ± standard deviation. Given the small number of patient for the in vivo analysis, Wilcoxon’s tests were used and results are expressed as medians with interquartile ranges. Relative risk reduction was calculated to evaluate the efficacy of SEPARPROCATH® to minimize RE. Data analysis was performed using JMP-14® (SAS Institute, Cary, NC). A p value <0.05 was considered statistically significant.

### TABLE 1 Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>Without SEPARPROCATH®</th>
<th>With SEPARPROCATH®</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>25</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>80 [73–96]</td>
<td>84 [76–94]</td>
<td>0.38</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>170 [163–178]</td>
<td>175 [170–179]</td>
<td>0.12</td>
</tr>
<tr>
<td>BMI (kg.m⁻²)</td>
<td>26.5 [24.8–28.4]</td>
<td>27.7 [24.3–32.6]</td>
<td>0.49</td>
</tr>
</tbody>
</table>

Abbreviation: BMI, body mass index.
The table reports patient characteristics. Data are expressed as medians [interquartile ranges].

3 | RESULTS

3.1 | Experimental conditions

In experimental conditions, the use of SEPARPROCATH® was associated with lower operator RE (0.12 ± 0.04 μSv/Gy.cm²) than without SEPARPROCATH® (1.19 ± 0.09 μSv/Gy.cm²) corresponding to a relative risk reduction of 90%. No difference was found for nurse RE (2.04 vs. 2.02 μSv/Gy.cm² without SEPARPROCATH®).

3.2 | In vivo study

A total of 51 patients were randomized to either SEPARPROCATH® or standard care, the characteristics of which are summarized in Table 1. The acquisition frequency was the same for every patient, that is, 15 frame/s. Table 2 shows RE data for patients with and without SEPARPROCATH®. The use of SEPARPROCATH® was associated with a significantly lower operator and nurse RE as well as a significantly lower operator and nurse CD. This corresponds to a relative risk reduction for the operator and nurse RE of 81 and 99% respectively. Relative risk reduction for operator and nurse CD were respectively 86 and 99%. These measures were independent from DAP and fluoroscopy time as there were no significant differences between the two populations.

4 | DISCUSSION

The main findings of this study are: (1) SEPARPROCATH® provides an effective radioprotection for catheterization room members in experimental conditions; (2) SEPARPROCATH® reduces scatter RE for
4.1 | Experimental conditions

With an operator relative risk reduction of 90%, SEPARPROCATH® provides an effective radioprotection in experimental conditions and can therefore be used, safely, in real-life conditions. In experimental conditions, no significant difference was found regarding nurse RE according to the use of SEPARPROCATH®. This could be explained by the stationary position of the nurse’s dosimeter, on the left side of the phantom. SEPARPROCATH® was designed to reduce scatter radiation from the patient’s body. By standing on the left side of the patient, where there is no mobile leaded glass panel neither lead table skirt, the nurse was directly exposed to X-ray tube leakage and scattered radiation.

4.2 | In vivo conditions

SEPARPROCATH® offers an effective radioprotection to the operator as well as the nurse during cardiac catheterization. The development of radiation-induced diseases mostly affects unprotected body areas such as brain, wrists and hands. The benefit of SEPARPROCATH® is to create a shield decreasing RE of the whole body of catheterization room members, even areas not protected by personal radioprotection equipment.

Various shield equipment have been developed to reduce catheterization room staff’s exposure. Partial protective shields could be compared to SEPARPROCATH® by acting like a non-personal radioprotection shield. Previous studies reported an RE relative risk reduction between 44 and 59% with the RADPAD® partial drape compared to conventional radioprotection. With an operator relative risk reduction around 80%, SEPARPROCATH® appears to be as, if not more effective than RADPAD® with the potential additional advantage of avoiding incorrect placement and sliding (which might decrease the efficacy of a partial drape). Furthermore, some authors described a “shield-induced behavior” where the use of a partial protective drape induces a feeling of security in catheterization room staff and therefore reduces the precaution in relation to RE. With a lead-free shield directly included in the surgical drape and therefore less obvious, we hypothesize that SEPARPROCATH® may reduce the shield-induced behavior, leading to its efficiency. Finally, it is worthwhile noting that contrary to other radioprotection drapes, SEPARPROCATH® is not radio-opaque, and vascular accesses can be easily assessed without the need to remove the drape.

4.3 | Patient safety

No significant differences were found on DAP with the use of SEPARPROCATH®, meaning that backscatter radiation due to its use is not significant. The reason is probably due to the fact that

<table>
<thead>
<tr>
<th>TABLE 2 Radiation exposure according to the presence of SEPARPROCATH®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without SEPARPROCATH®</td>
</tr>
<tr>
<td>------------------------</td>
</tr>
<tr>
<td>Operator RE (μSv/Gy.cm²)</td>
</tr>
<tr>
<td>Nurse RE (μSv/Gy.cm²)</td>
</tr>
<tr>
<td>Operator CD (μSv)</td>
</tr>
<tr>
<td>Nurse CD (μSv)</td>
</tr>
<tr>
<td>DAP (Gy.cm²)</td>
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<tr>
<td>Fluoroscopy time (s)</td>
</tr>
</tbody>
</table>

**Abbreviations:** CD, cumulative dose; DAP, dose area product; RE, radiation exposure. The table shows RE data for patients with and without SEPARPROCATH®. Data are expressed as medians [interquartile ranges].
SEPARPROCATH® is not directly placed in the X-ray area but lower. The increased safety for the medical staff is thus not at the expense of the patient safety.

4.4 Study limitations

The main limitation of this study was the small sample size and the fact that the trial was single-centered with a limited number of interventional cardiologists therefore data may not be generalized. Furthermore, other procedures to reduce staff RE such as training in radioprotection or low frame rate were not taken into account and this needs to be recognized as potential limitation. However, to our knowledge, this is the "first in-man" study to assess the efficacy of SEPARPROCATH®. Therefore, the presented data need to be considered as preliminary and further investigations are needed.

5 CONCLUSION

In conclusion, SEPARPROCATH® is a novel, lead-free, radioprotection drape, that significantly decreases RE of the medical staff during cardiac catheterization procedures while guaranteeing patient safety.

CONFLICT OF INTEREST

JLG participates in the development of the SEPARPROCATH®. All other authors have no conflicts of interest.

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REFERENCES


