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Multicentric Evaluation of an Extra-Low Dose Protocol to Reduce Radiation Exposure in Superior Mesenteric Artery Stenting.

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Short title: Radiation Exposure in Mesenteric Stenting

WHAT THIS PAPER ADDS

As radiation exposure is currently a burning issue in the vascular community, this study shows that endovascular mesenteric repair in occlusive mesenteric disease exposes patients, physicians, and staff to high levels of ionising radiation. Moreover, this study highlights that once awareness on radiation safety is ensured, the use of extra-low dose protocol easily and

significantly reduces radiation in mesenteric stenting without compromising treatment safety and effectiveness.

Objective: Radiation dose in mesenteric stenting (MS) remains underevaluated. Yet, MS can lead to high levels of radiation mainly because lateral angulation is needed. The aim of this study was to evaluate the efficacy of an extra low dose protocol (ELDP) to reduce radiation exposure in MS.

Methods: From November 2017 to November 2019, all patients presenting with either acute or chronic atherosclerotic mesenteric ischaemia treated by antegrade MS using either fixed or mobile imaging systems in three university hospitals were included. In November 2018, an ELDP including ≤ 3 frames/s fluoroscopy and digital subtraction angiography (DSA) was introduced. Prospectively enrolled ELDP patients (Nov2018 – Nov2019) were compared to retrospectively captured patients (Historical group, Nov2017 – Nov2018). Radiation data including dose area product (DAP), cumulative air kerma (CAK), and fluoroscopy time (FT) were analysed.

Results: Overall, 46 patients (median age 73 years [63 – 72], 59% males) were included (ELDP group, $n = 21$; Historical group, $n = 25$). Thirty-three patients (72%) underwent MS in a hybrid room. Median DAP (ELDP group, 10 [4.7 – 26] Gy.cm² vs. Historical group, 45 [24 – 88] Gy.cm², $p = .002$), median CAK (ELDP group, 170 [58 – 260] vs. Historical group, 262 [152 – 460], $p = .037$), and median number of DSA run (ELDP group, 4 [1.5 – 5] vs. Historical group, 5.5 [3.7 – 5], $p = .030$) were statistically significantly lower in patients receiving the ELDP, whereas median FT (ELDP group, 16 min [11 – 23] vs. Historical group, 14 min [9 – 25], $p = .71$) and technical success (ELDP group, 95%; Historical group, 92%, $p = .65$) were not statistically significantly different between groups.

Conclusion: MS exposes both patients and physicians to high ionising radiation. Awareness on radiation safety and seeking dose reduction is paramount in these highly irradiating procedures. The use of ELDP significantly reduces radiation without compromising technical success.

Keywords: Hybrid room, Low dose, Mesenteric ischaemia, Mesenteric stent, Radiation, Superior mesenteric artery

INTRODUCTION

As recommended in the latest guidelines from the European Society for Vascular Surgery (ESVS), stenting of the superior mesenteric artery (SMA) has become the first-line treatment over open repair in mesenteric occlusive disease (MOD), in both acute and chronic mesenteric ischaemia.¹ As in many other fields of vascular surgery, mesenteric stenting (MS) offers satisfactory long term patency rates, with a significant decrease of post-operative morbidity and quicker recovery as compared to open repair.^{2,3} As a consequence, both incidence and complexity of endovascular procedures have massively increased over the past few years, which means that both patients with MOD and staff are being exposed to more and more doses of radiation.⁴ Awareness on radiation safety emerged in our discipline along with the widespread use of complex endovascular aortic repair (EVAR) and the rise of hybrid rooms.^{5,6} But still, large efforts remain to be made to decrease exposure to radiation and improve radioprotection. Short term and long term risks of stochastic effects are hardly predictable but are unquestionable.^{7,8} Recent findings such as acute DNA damage found in a surgeon's blood after EVAR can legitimately raise concern, especially in our young community where a “shields up! spirit” is rising. In this call to arms, radiation dose references must be defined to help us discriminate what is reasonable for staff and patients to spread a documented awareness on radiation safety. Many recently published reports regarding radiation dose reduction and staff protection have begun to provide answers.^{9–12} Reported median dose area product (DAP) for EVAR ranged from 12 to 177 Gy.cm² in a large review conducted by Monastiriotis *et al.*¹³ As radiation dose is directly proportional to complexity of the endovascular repair, complex EVAR leads to a significant increase in radiation, with median DAP varying from 159 to 173 Gy.cm² at an expert complex EVAR centre.¹⁴ Meanwhile, literature regarding radiation in MS procedures is scarce. To the present authors' knowledge, the only available data are mixed data from MS procedures and/or renal artery stenting procedures, with median DAP and cumulative air kerma (CAK) ranging from 190 to 250 Gy.cm² and 1600 to 2300 mGy, respectively.^{15,16} Sticking to the “as low as reasonably achievable” (ALARA) principle, the use of hybrid rooms with image fusion and dedicated low-dose protocol significantly reduces the dose of radiation during both standard and complex aortic repair.^{17,18} But these reports mainly address the aortic field, while data are lacking regarding other fields of vascular surgery, MOD in particular. Yet, MS can potentially lead to high levels of radiation because of the need for extreme beam angulation, which results in a higher radiation rate and alters imaging quality.¹²

The aim of this study was to evaluate the efficacy of an extra low dose protocol (ELDP) to reduce radiation exposure in MS.

METHODS

Patients, inclusion and exclusion criteria.

Data from consecutive patients with MOD presenting with either acute or chronic mesenteric ischaemia and treated by antegrade MS were collected at three French university hospitals over a 24-month period (November 2017 and November 2019). All patients underwent a pre-operative high-resolution computed tomography angiogram. Indication for MS was a collegial decision, discussed whenever possible within a “Mesenteric Team” gathering gastroenterologists, anaesthetists, vascular surgeons, general surgeons, and radiologists. At the three participating centres, the endovascular approach was the preferred treatment option over open repair whenever feasible, according to the latest ESVS guidelines, in both acute and chronic mesenteric ischaemia.¹ The first-line endovascular strategy was a single target vessel approach, i.e. the SMA. Stenting of the celiac artery was reserved for patients with associated sus-mesocolic ischaemia, short bowel syndrome with persistent mesenteric ischaemia, failure or unfeasibility of MS. The inclusion criterion was antegrade isolated MS. Patients who underwent retrograde open MS, *in situ* fibrinolysis, iliac stenting, celiac artery stenting, or inferior mesenteric artery stenting were excluded.

Study design

In November 2018, a specific training and awareness session on radiation safety was conducted at all three institutions with a systematic approach to radiation safety, involving surgeons, nurses, anaesthetists, and radiographers. Procedural details of patients undergoing MS from November 2018 to November 2019 (ELDP group) were compared to data from a historical cohort of patients treated at the same institutions in the immediate 12 months prior to the introduction of the new radiation protocol (Historical group). The study flow chart is given in Figure 1. Patients from the Historical group were retrospectively captured and procedural data, including measures of radiation output, were gathered from the PACS system and imaging system records, and from the patients’ medical records. For ELDP patients, procedural and peri-operative data were collected prospectively by the following investigators (NM, IBA, SL, SEB) as part of routine clinical auditing practice. This database was approved and registered (ref: 2212456V0) by the French National Data Protection Agency (Commission Nationale Informatique et Libertés). Procedural details of ELDP and Historical patients were compared and analysed.

Procedures

Procedures were performed either using a mobile C-arm in a standard operating theatre or a fixed imaging system in a hybrid room. The mobile C-arm systems were a Cios Alpha

(Siemens Healthcare, Germany) at two centres and an OEC 9900 (GE Healthcare, UK) in the other one. Three different fixed imaging systems were used: Axiom Artis Zee (Siemens Healthcare, Germany), Infinix-i Sky+ (Canon Medical Systems, France S.A.S), and Philips Azurion 7M20 (Philips Healthcare, Netherlands) (Table S1). Fusion imaging was not routinely used for MS procedures in hybrid rooms as it was not available in all the centres at the time of the study.

Procedures were performed either electively or in an emergent setting, under local or general anaesthesia depending on vascular access, patient condition, and team habits. Vascular access was either an open left brachial approach or a percutaneous transfemoral approach. When using a transfemoral approach in the ELDP group, the patient was positioned with hands fixed by straps over their head on a dedicated pillow. This specific position allowed subtracting both humerus, thus minimising radiation dose rate and improving imaging quality. All procedures were performed by experienced endovascular operators (primary operator), following ALARA principles, supported by an assistant operator with or without a scrub nurse. In conventional theatres, team radiation protection equipment included lead aprons and goggles, thyroid collars, and mobile lead barriers. Ceiling suspensions and additional lead table shields were also available in hybrid rooms with a fixed system. A radiographer was present at two centres. In all cases, the primary operator was operating the radiation pedal. Covered stents were used in this study. When needed, an additional distal bare metal stent was used to overcome any kinking or dissection. Contrast agent (Visipaque 270 mg I/mL) was diluted to 50% strength for hand-injections. Technical success was defined by successful SMA catheterisation and stent placement, with no residual stenosis > 30%, no dissection, and satisfactory downstream patency of the SMA.

Extra low dose protocol (ELDP)

From November 2018, consecutive patients who received MS were included in the ELDP group. ELDP included imaging system parameters set at ≤ 3 frames per second for both fluoroscopy and DSA mode. In addition to imaging system parameters, specific attention was given to dose reduction, such as:

- Use of fusion imaging whenever available
- No DSA before first attempt of SMA catheterisation
- Use of landmarks from the spine or aortic calcifications
- Use of spot fluoroscopy whenever available (Infinix-i Sky+ - Canon Medical Systems, France S.A.S)

- Favouring digital zooming (i.e. “live zoom”) instead of standard magnification.

Based on pre-operative CTA, catheterisation of the SMA in the ELDP group was systematically first attempted in an antero-posterior position, facing the corresponding vertebral body to limit lateral angulations as much as possible. No limit of irradiation or time was defined to consider the antero-posterior catheterisation attempt as a failure. However, the need for a road-map DSA and/or a lateral view was left at the operator’s discretion. Also, hand-injections in spot fluoroscopy were preferred over power injector DSA to minimise radiation.

Procedural data and study endpoints

Radiation dose was assessed by the cumulative air kerma (CAK, in mGy) and the dose area product (DAP, in Gy.cm²). As reported by Hertault *et al.*, CAK is the air kerma (AK) accumulated at the interventional reference point, 15 cm from the isocentre towards the anode.⁹ This measure appears to be well correlated with the peak skin dose (PSD) that is used to estimate the risk of deterministic effects like skin lesions.¹⁹ The DAP is the product of the AK and the exposed surface area. To provide external validity to the values reported by the system, the DAP values were double-checked by a senior radiophysicist (SL). Other variables affecting radiation, including total fluoroscopy time (FT, minutes), angulation of the tube (not available for C-arm procedures), imaging system parameters (fr/s for fluoroscopy and DSA Runs), number of DSA runs, and contrast agent volume, were recorded. Demographic, anatomical, intra-operative and post-operative data were collected by means of a prospectively maintained database.

The aim of this study was to evaluate the efficacy of an ELDP on radiation exposure in MS.

Statistical analysis

Continuous variables are expressed as median (interquartile range) or mean (\pm standard deviation). Categorical variables are presented as count and percentage. Statistical analysis was performed with JMP 9.0.1 software (SAS Institute Inc., Cary, NC), using the chi square test or analysis of variance (ANOVA). A *p* value < .050 was considered to be statistically significant.

RESULTS

Demographic data

During the study period, 46 consecutive patients who underwent antegrade MS (including both technical success and attempt) were included (ELDP group, *n* = 21; Historical group, *n* = 25). The cohort included 27 males (58%), with a median age of 73 years (63 – 82). Median

BMI was 23.5 kg/m² (20 – 28). No statistically significant difference was observed between both groups in terms of BMI ($p = .14$). All patients presented with symptomatic atheromatous MOD. Clinical presentation of mesenteric ischaemia was chronic in 29 cases (63%) and acute in 17 cases (37%). Acute cases included acute-on-chronic cases with permanent abdominal rest pain ($n = 10$) and *de novo* presentations with sudden abdominal pain ($n = 7$), with no need for open abdominal exploration based on a low estimated – clinical/radiological/biological – prediction of intestinal necrosis. Morphologic lesions were either severe SMA stenosis ($n = 38$, 83%) or SMA occlusion ($n = 8$, 17%). No statistically significant difference was observed between both groups in terms of type of lesion (occlusion *vs.* stenosis, $p = .061$). Noteworthy, 15 (33%) symptomatic patients in this cohort had a previous MS and underwent MS reinterventions for either in-stent restenosis ($n = 6$), improvement of technical imperfections ($n = 3$), stent occlusion ($n = 2$), or progression of disease ($n = 4$). Demographic data are reported in Table 1. The number of patients included in each centre and imaging equipment used are reported in Table S1.

Procedural data

MS procedures were performed either in a hybrid room using a fixed-system in 34 (74%) cases (Historical group: 14/25 [56%]; ELDP: 20/21 [95%]) or in a standard theatre using a C-arm in 12 cases (26%). Vascular access was either transfemoral or open brachial in 27 (59%) and 19 (41%) procedures, respectively. General anaesthesia was used in 29 cases (63%). Overall technical success was 93% (43/46). In the three remaining cases where technical success could not be achieved (catheterisation failure across proximal calcified plug occlusions), open repair was subsequently performed during a staged procedure. Overall, 49 SMA stents were implanted in 46 patients, including 45 balloon-expandable covered stents and four self-expandable bare metal stents. The median diameter of SMA stents was 7 mm (6 – 8), with a median length of 32 mm (22 – 38).

Radiation outcomes: Historical vs. ELDP groups

Major radiation data for both groups are reported in Table 2. Median DAP (ELDP group, 10 [4.7 – 26] Gy.cm² *vs.* Historical group, 45 [24 – 88] Gy.cm², $p = .002$), median CAK (ELDP group, 170 [58 – 260] *vs.* Historical group, 262 [152 – 460], $p = .037$), and median number of DSA run (ELDP group, 4 [1.5 – 5] *vs.* Historical group, 5.5 [3.7 – 5], $p = .030$) were significantly lower in patients receiving the ELDP (Fig. 2A). Within the Historical group, median CAK and DAP were significantly higher when using a hybrid room (median CAK with C-arm *vs.* hybrid room: 233 [143 – 345] mGy *vs.* 384 [203 – 945] mGy; $p = .048$; median DAP with C-arm *vs.* hybrid room: 46 [30 – 70] *vs.* 51 [21–93] Gy.cm²; $p = .038$).

Meanwhile, no significant difference in median CAK or DAP was observed regarding the vascular access in both groups (Fig. 2B) (Historical group, DAP Brachial vs. Femoral approach: 47 [29 – 76] Gy.cm² vs. 40 [26 – 83] Gy.cm², $p = .98$; ELDP group, DAP Brachial vs. Femoral approach: 6 [5 – 23] Gy.cm² vs. 22 [7 – 28] Gy.cm², $p = .27$). Regarding morphological lesions, treating SMA occlusions led to higher cumulated radiation compared to SMA stenosis in both the Historical and ELDP groups (median DAP, 77 [40 – 156] Gy.cm² vs. 24 [10 – 45] Gy.cm², $p < .001$; median CAK, 839 [385 – 1467] mGy vs. 202 [100 – 269] mGy, $p < .001$). Also, there was no significant difference between both groups in terms of median FT (ELDP group, 16 min [11 – 23] vs. Historical group, 14 min [9 – 25], $p = .70$) and contrast agent volume (ELDP group, 66 ± 33mL vs. Historical group, 76 ± 32 mL, $p = .38$). In all, ELDP did not affect technical success, as 95% of procedures were successfully completed in the ELDP group (20/21) vs. 92% in the Historical group (23/25) ($p = .65$).

DISCUSSION

This study reveals that MS in MOD exposes patients, physicians, and staff to high levels of ionising radiation. Moreover, this study highlights that once awareness on radiation safety is ensured, the use of ELDP significantly reduces radiation in MS, without compromising treatment safety and effectiveness. This study links to the overall work of the vascular surgery community on radiation safety and awareness to integrate radiation reduction into daily practice.^{18,20,21}

To reduce radiation, first, the starting point must be known, and that applies to all fields of vascular surgery: aortic disease, visceral and renal artery diseases, iliac stenting, complex peripheral disease, and so on. Reporting “radiation outcomes” will allow for definition of standards of radiation levels. Regarding MS procedures, data are particularly scarce, despite the high level of radiation involved. Nevertheless, more substantial data have been reported in both standard and complex EVAR with heterogeneous outcomes, depending on the team and the operator.^{9,10,13,22} This series shows that MS involves higher radiation doses than standard EVAR reported by expert aortic centres, both in terms of median CAK and DAP.⁹ The specificity of MS procedures is the need for lateral angulations during a major part of the procedure, especially when SMA catheterisation fails using antero-posterior angulation. When using lateral angulations, the delivered rate of mGy/min significantly increases, along with the thickness of the tissues penetrated by the x-rays. This change of beam flow is systematically adjusted by the system to maintain sufficient imaging quality. The use of extreme beam angulations has been demonstrated to increase radiation exposure of the operator’s head.¹² To limit operators’ exposure to scattered radiation in such angulations,

the radiation sensor might be placed on the side of the operator, with the source facing the operator.²³ The present study shows that even in those expected high dose procedures, reducing radiation can be easily achieved by following simple rules: applying ALARA principles, limiting extreme beam angulations, limiting DSA runs to as few as possible, and paying particular attention to the adjustment of machine parameters, especially fluoroscopy pulse rate, which can be turned down to 3 frames per second for much of the procedure.

Consideration of these findings leads on to consideration of every parameter that could be targeted to reduce radiation. These parameters fall into three categories: human factors, imaging technology, and endovascular device development. Human factors include awareness, first of all. Raising awareness is mandatory to lead the action of dose reduction. Strengthening awareness comes through teaching by introducing specific radiation issues in training programmes for the entire vascular team, including young vascular surgeons, anaesthetists, scrub and anaesthetist nurses. Interestingly, Rolls *et al.* highlighted the benefit of an original concept: “the team-based approach to radiation dose reduction”. Their study stressed that radiation reduction is the concern and responsibility of all in the angiography suite.¹⁸ In addition, procedural planning including numerical and hands-on simulation, as well as operator’s experience, are determining factors in radiation reduction.

Regarding imaging technology, the introduction of hybrid rooms equipped with fusion imaging clearly brought radiation reduction and radioprotection to a brand new level. This technological breakthrough has been a key step in the quest for radiation reduction.^{17,18,24–26} The benefit of fusion imaging on radiation dose has been well demonstrated in many reports regarding complex EVAR. Fusion might provide the same benefit in MS or complex peripheral arterial disease. In this series, unfortunately, fusion guidance was not used routinely in hybrid rooms and was not available in standard operating rooms with C-arm. Although the benefits of fusion imaging were not evaluated in the present study, it is reasonable to assume that levels of radiation in MS will be lowered in the near future thanks to increased use of fusion imaging. To take this further, current research and development on fusion imaging integrating vessel deformation,^{14,17} as well as artificial intelligence and virtual reality are likely to be determining factors through simplifying and increasing the speed of navigation and cannulation.

The third element of radiation dose reduction is related to cannulation device development. Among recent technological innovations, tracking and robotic navigation systems for application in complex EVAR have demonstrated improved aortic vessel cannulation.^{27–29} Regarding radiation dose, the benefit is reserved for the operator who is

protected behind the lead glass of the control room during the procedure. Furthermore, the present authors' recent experience with the use of a manually steerable sheath – under current evaluation – combined with fusion in MS procedures leads them to believe that these additional tools could facilitate transfemoral catheterisation of the SMA in MOD, especially in complex anatomy (i.e. acute aorta-SMA angle and flush SMA occlusion), and therefore potentially reduce the related radiation. However, the widespread use of such technology is limited by its high cost.^{29,30}

Limitations

Limitations of this multicentric study include the use of different imaging systems in different hybrid rooms and in standard operating rooms using a C-arm, where procedures are not performed under the same conditions of imaging quality. In addition, differences regarding concerns on radiation exposure can be observed between operators within a single team composed of several generations of physicians. This study is limited to one aspect of radiation safety, excluding occupational exposure. It was a deliberate decision to start with a study on global radiation exposure, as an occupational exposure study would require at least the same personal and collective radiation safety equipment within the different centres. Hence, this study did not provide any occupational radiation reference levels for MS; such a prospective study on occupational exposure is currently in progress. It is acknowledged that sample sizes appear relatively small, but it must be borne in mind that MOD remains niche. The aim of multicentric inclusion, besides increasing the size of the cohort, was to provide a representative overview reflecting current practices in MS. Nonetheless, despite small samples, significant radiation reduction was found in the ELDP group, which shows that there is much room for improvement in radiation reduction. Meanwhile, the absence of anticipated sample size number in the ELDP group was another limitation of the study.

Conclusion

MS exposes both patients and physicians to high levels of ionising radiation. Awareness of radiation safety and the need to seek dose reductions is paramount in MS procedures that might be performed with access to machine parameter settings and adequate radioprotection tools. In the present authors' experience, the use of an ELDP significantly reduces radiation without compromising technical success. Further studies could investigate which variables could be targeted to enhance radiation reduction.

CONFLICT OF INTEREST

None.

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Table 1. Characteristics and procedural details of 46 patients presenting with atherosclerotic mesenteric ischaemia treated with mesenteric stenting by traditional imaging protocol (Historical group) or by extra low dose protocol (ELDP) to reduce radiation exposure.				
Characteristics	Overall (n=46)	ELDP group (n=21)	Historical group (n=25)	p*
Male sex	27 (59)	11 (52)	16 (64)	.43
Age – y	73 (63–82)	65 (59–78)	73 (69–77)	.053

BMI – kg/m ²	23.5 (20–28)	23 (19–25)	25 (18–31)	.14
SMA occlusions	8 (17)	3 (14)	5 (20)	.061
Acute mesenteric ischaemia	17 (37)	5 (24)	12 (48)	.090
Femoral access	27 (59)	12 (57)	15 (60)	.84
Previous mesenteric stenting	15 (33)	12 (43)	4 (16)	.17

Data are presented as *n* (%) or median (interquartile range [IQR]). BMI = body mass index; SMA = superior mesenteric artery.

* *p* value of difference between ELDP and Historical group.

Table 2. Radiation outcomes of 46 patients presenting with atherosclerotic mesenteric ischaemia treated with mesenteric stenting by traditional imaging protocol (Historical group) or by extra low dose protocol (ELDP) to reduce radiation exposure.

Procedure outcomes	Overall (<i>n</i> =46)	ELDP group (<i>n</i> =21)	Historical group (<i>n</i> =25)	<i>p</i> *
DAP – Gy.cm ²	26 (10–57)	10 (4.7–26)	45 (24–88)	.002
CAK – mGy	223 (101–360)	170 (58–260)	262 (152–460)	.037
DSA run	5 (3–7)	4 (1.5–5)	5.5 (3.7–5)	.030
Fluoroscopy time – min	16 (9–25)	16 (11–23)	14 (9–25)	.71
Contrast agent volume – mL	73 ± 34.7	66 ± 33	76 ± 32	.38
Technical success	43 (93)	20 (95)	23 (92)	.65

Data are presented as *n* (%), mean ± standard deviation or median (interquartile range [IQR]).

DAP = dose-area product; CAK = cumulative air kerma; DSA = digital subtraction angiography.

* *p* value of difference between ELDP and Historical groups.

Figure 1. Study flow chart to identify the 46 patients presenting with mesenteric occlusive disease (MOD) treated with mesenteric stenting by traditional imaging protocol (Historical group) or by extra low dose protocol (ELDP) to reduce radiation exposure.

Figure 2. Cumulative air kerma (CAK) in mGy in 46 patients presenting with mesenteric occlusive disease treated with mesenteric stenting by traditional imaging protocol (Historical group) or by extra low dose protocol (ELDP) to reduce radiation exposure depending on a study group (A) and depending on vascular access (B). Circles represent outliers (≥ 3 interquartile range [IQR]).

Figure 1. Study flow chart





