Evaluation of Operator Radioprotection Using a New Injection Device during Vertebroplasty

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Summary

This study aimed to evaluate the protection granted by a simple device (X'TENS®, Thiebaud, France) and to provide operators with information on the performance of this new device, which has not yet been assessed. Our assumption is that this device efficiently reduces the radiation dose to the operator.

In a prospective clinical study, the radiation dose the operator's hand receives has been assessed using a specific sensor (UNFOR Instrument). Each patient included in the study was to receive at least two injections of cement during the procedure. Exposure was measured with and without the range extender. The data collected were then processed using a Wilcoxon matched pairs test.

During 14 interventions, 20 vertebrae were treated with both procedures. Eleven women and three men were included. Seven patients underwent vertebroplasty for metastatic lesions and seven for osteoporotic lesions, bone fractures or vertebral compressions. The average injection time was 1.35 minutes with the device and 1.20 without ($p=0.75$). The dose to the hand per ml injected was 111.37 vs. 166.91 ($p<0.05$).

Theoretically, the protection granted by the range extender depends on the length of the device. Our results are consistent with the inverse-square law. However, the variations in our results indicate that a proper and rigorous use is mandatory for the device to be effective. Given that radioprotection during fluoroscopy proce-

dures is a frequently raised issue, the need for information for a safer practice increases likewise.

Introduction

Percutaneous vertebroplasty is a procedure in which bone cement is injected into vertebrae affected by a compression fracture, osteoporosis or myeloma¹. During the injection, the cement flow is monitored using fluoroscopy to assess the absence of cement leaks, which may lead to severe complications. During percutaneous vertebroplasty, the dose received by operators varies depending on the procedure type, the operator's practice and the equipment used²⁻⁸.

Several types of devices reduce this dose. In addition to radioprotective gloves or aprons^{9,10}, several new devices are available which allow the operator to inject the cement away from the field of fluoroscopy (mobile barrier, cement injector and range extender). Although there is a lack of specific standards for the evaluation of the radioprotective performance of the range extender, the literature shows that some of them have already been assessed¹¹⁻¹³. As radioprotection during radiologically controlled procedures is a frequently raised issue, there is a need for more information about safe practice. Thus, the objective of this study was to evaluate the protection granted by a simple device (X'TENS®, Thiebaud, France) and provide

Figure 1 The bone cement injector allows the operator's hand to remain outside the fluoroscopy field.

operators with information on the performance of this new device, which has not yet been assessed.

Materials and Method

Patient group

We set up a prospective study during which 14 procedures were monitored. Each patient received at least two injections of cement in the same region (vertebrae, cotyla, or femur). One of the injections was performed using the device, and the other with a 3 ml cement-filled syringe. Thus, we obtained paired injections suitable for comparison. The order of injection - with or without the device - was randomly determined. These procedures took place during three months. Patient characteristics are described in Table 1.

Presentation of the device

The device tested is a new type of range extender (Figure 1) designed to inject at a distance high-viscosity filling products (bone cement) through transcutaneous puncture. It is made up of a 30 cm long metallic tube in which the cement flows, propelled by a metallic mandrel. This mandrel is set with a handle which allows the user a firm grip to achieve high-pressure injection. The device contains 3 ml and may inject up to 2.5 ml of cement. Marks on the mandrel indicate the volume injected. At the end of the injection, a dead space of 0.275 ml remains inside the device.

Vertebroplasty technique

Procedures were performed with flat panel DSA guidance. The measurements were made under normal conditions: automatic brightness control in which the tube voltage (60-120kV)

Table 1 Patient and intervention characteristics

Patient characteristics		Mean	SD
Indications	Age (years)	69.83	15.10
	Height (cm)	160.83	7.20
	Weight (kg)	59.25	11.35
Injection location	Metastatic lesion	7	
	Osteoporosis	1	
	Fracture	6	
	Total	14	
	Dorsal	9	
	Lumbar	2	
	Acetabulum	6	
	Femur	2	
	Iliac crest	1	
	Total	20	

Table 2 Mean time and doses to operator

		<i>m</i>	σ	<i>Min.</i>	<i>Max.</i>	<i>Test</i>	<i>p</i>
A	Injection time per ml injected with device (min)	1.35	0.44	0.42	3.64	NS	0.75
	Injection time per ml injected without device (min)	1.20	0.89	0.50	3.19		
B	Finger dose with device (μGy)	248.18	261.6	2.22	844.00	S	<0.05
	Finger dose without device (μGy)	508.72	1 255.8	10.45	3 504.00		
C	Finger dose per ml cement injected with device	111.37	118.55	1.11	568.00	S	<0.05
	Finger dose per ml cement injected without device	166.91	311.61	5.23	876.00		
D	Finger dose per minute with device (μGy / min)	75.53	73.25	0.74	288.05	NS	0.21
	Finger dose per minute without device (μGy / min)	143.15	244.19	4.88	693.86		

and tube current are adjusted. Collimation was used in every procedure to see three or four vertebral levels as well as front and back 5 cm of the vertebral body. All procedures were performed via a bipedicular approach under fluoroscopic control on an AXIOM Artis dFA (Siemens - US).

All procedures were performed by the same operator. After placement of the needles through which the cement was to be injected, a radiographic control was made to confirm the correct positioning. The cement was then injected using alternatively the device and the syringe only, and each patient was treated with both methods. Given that cement had already been injected, the second injection of cement may be hindered, which may lead to an increased radiation exposure. The use order was randomly decided to prevent any bias. At the beginning and at the end of each stage, time duration, dose value indicated by the dosimeter placed at the operator's hand and the radiation produced by the fluoroscopic equipment were recorded. Each injection was performed under intermittent fluoroscopy. The operator always used radiation protective gloves (Radiaxon® – WRP® Malaysia). Our operating room did not include other protective devices such as a lead glass shield with lead skirt or a mobile lead shield.

Radiation dose measurement

The radiation dose to operators was measured using a digital dosimeter (EDD 30; UNFORS Instruments, Billdal, Sweden) designed to measure the dose, the dose rate and the exposure time to a specific body part (eye, body, hand). The minimum dose it can record is 1 nGy and its dose range begins at 10nGy/s. It

was positioned at the base of the left small finger, under the radiation-protective glove (Radiaxon®, WRP, Malaysia). This sensor specifically allows real time dose monitoring, and an assistant recorded the data at the end of each phase of the procedure (Figures 4 and 5). In order to assess the effectiveness of the device, we recorded the injection time per ml (A) in minutes, the dose to the fingers (B), the dose to the fingers per ml of cement injected (C) and the dose to the fingers per minute (D). Distance from the source was not measured as each patient can make his own comparison at the injection points, located at the same level.

Protection evaluation

In order to quantify the protection granted by the device, we deduced a custom indicator T from the general formula which statutorily applies to radio-protective devices such as gloves. Using the formula recommended in the IEC 1331-1 standard¹⁴, we calculated a mitigation index I based on this indicator (Equation 1). From Equation 1, we then deduced a protection index T, which is the incremental reduction of radiation exposure (Equation 2) and is expressed as a percentage. The use of a percentage to assess the protection granted by the device is more convenient for the purpose of this study.

$$I = Q_0 / Q$$

Q₀: rate of exposure without protection (Gy/min)
Q: rate of exposure with protection (Gy/min) (1)

$$T = (Q_0 - Q) / Q_0 = 1 - I$$

Q₀: rate of exposure without protection (Gy/min)
Q: rate of exposure with protection (Gy/min) (2)

Figure 2 Rate of exposure (operator's finger) depending on the procedure.

Figure 3 Attenuation ratio and intervention area.

Figure 4 Dose repartition in each stage of a vertebroplasty.

Figure 5 Duration of each stage of a vertebroplasty.

Data processing

Our comparison is based on a small population where each patient provides both experimental data and control data. We matched each pair using a paired Wilcoxon signed-ranks test and the NCSS 2006® software.

Results

During the 14 interventions, 11 vertebrae and nine other areas were treated by both procedures. Eleven women and three men were included. Seven patients underwent vertebroplasty for metastatic lesions and seven for osteoporotic lesions, bone fracture or vertebral compression. On average, two devices were used per intervention, and for six patients one device was refilled with several syringes. Eleven injections were performed in the acetabu-

lum or lumbar spine and nine in the thoracic spine. The results are presented in Table 2. The average volume of cement injected per patient with the device was 8.79 ml vs. 10.5 without ($p=0.40$). The average injection time (A) was 1.20 minutes per syringe with the device vs. 1.35 with syringe only. The paired Wilcoxon tests showed no difference between groups ($p=0.75$).

Dose to the operator's hand

The average radiation dose measured on the operator's fingers during the injection (B) was 248.2 µGy with the device versus 508.7 without ($p=0.0024$). Adjusted to the quantity of cement injected (C), the dose received on the finger was 111.37 µGy per ml with the device vs. 166.91 µGy per ml ($p=0.04$). Adjusted to the duration of injection (D), the dose received

was 75.53 $\mu\text{Gy}/\text{min}$ vs. 143.2 $\mu\text{Gy}/\text{min}$ ($p=0.209$) without the device.

Dose to the patient

During the injection, the mean radiation produced by the fluoroscope was 203.1 mGy with the device and 214.43 mGy without ($p=0.67$). This indicator is adjusted to the volume of cement injected and shows that the dose is 82.54 mGy per ml with the device vs. 81.84 mGy per ml ($p=0.68$) without.

Device efficacy

Figure 3 gives the protection index calculated on our entire results, and with adjustment to the region where the vertebroplasty was performed. Comparing these results to zero, it appears that there is no protection with intervention on the dorsal area ($p=0.625$), whereas in lumbar and inferior regions the mitigation index is significantly different from zero ($p=0.039$).

Discussion

Our results showed that the bone cement injector device did not modify the dose emitted by the fluoroscope but reduced the dose to the operator. We thus consider this device to be effective to protect the operator, and to have no impact on patient exposure.

The dose to the fingers per ml of cement injected showed no difference between groups, in spite of an important trend shown in Figure 2. We think this is related to the significant standard deviation of our results and to the size of our groups.

The main limitation of our study is the small size of our sample. We used non-parametric statistics to overcome it and we designed this study for rapid assessment of a new device. We identified two patients that minimize our results, specifically in the dorsal region. The first had two thoracic and one lumbar vertebra treated. When matching the result for this patient, the vertebra treated with the device was exposed to a greater radiation than the two others; the device thus failed to reduce exposure, with a mitigation rate of -118.6% . The second patient was injected cement in the iliac crest. Although these results seemed abnormal, we did not remove them from our study.

One explanation for these results is related

to the position of the radiation field. While normally located under the table during the procedure, the operator may feel the need to rotate the field to get a better view of the injection, thus nullifying the protection when the field is horizontally displayed. Another explanation could be that given that the device is rigid, it may fall due to gravity when operating in areas where the needle is not perpendicular to the plane of the table. Maintaining it appropriately for the injection requires the operator's hand to be placed under the radiation field, which increases the radiation exposure. As such, we suggest limiting the use of this device to lumbar procedures. Indeed, the small number of interventions included in our study is justified by our objective which was to provide a quick answer to the question of the device's utility by providing information to decision-makers in our hospital. Although this study demonstrated the radiation protection the device brings, further investigation is needed, including a comparison of its efficacy with other range extenders.

The wide range of medical devices available on the market¹⁵ makes it hard for the operator to identify one s/he can make use of. To confirm the usefulness of a previously unknown device, accurate information is needed. While no comprehensive norms exist for the evaluation of this kind of device (range extender), operators have to resort to the medical literature. The lack of a normative methodology to assess range extenders makes direct comparison of the studies irrelevant as the evaluation criteria chosen by authors may present some bias (equipment, operator's technique, skills...).

Although the Extens[®] device has never been assessed to date, other bone cement injectors devices have. Several authors focused on the performance of different injectors¹¹⁻¹³, but methods and results vary from one study to another. Kallmes et al. studied the same device but reached different conclusions. We likewise used the rate of exposure as an indicator to show the level of radiation to the operator. The variations of our results compared to previous studies can probably be explained by the absence of a mobile barrier in our operating environment, which increases the exposure rate of the operator's hand. Another point to consider is that we used a finger dosimeter which is probably more sensitive than a pocket dosimeter¹³ or one positioned on the apron¹². Moreover, the injection time with the device seemed

different from other reports (3.7 min. in Ortiz et al.¹³, 4.2 minutes in Kallmes et al.¹¹, 2.40 minutes in Komemushi et al.¹²). This is consistent with the fact that exposure may be operator-dependant (operator's technique, practice variation or needle location).

During our study, we segmented each procedure into different stages (needle placement, placement control, injection, final control). It appears (Figures 4 and 5) that the injection stage is the one during which the operator is the most exposed. In this regard, devices reducing radiation exposure are of importance in radioprotection programs. In our study, the bone cement injectors were assessed concomitantly with flexible radio-protective gloves. Bone injectors increase the distance from the radiation field and gloves protect the operator. Using both mechanisms seemed efficient although we could not assess the interdependence (if any) of the protection in simultaneous use.

According to the ALARA principle (As Low As Reasonably Achievable), radioprotection shall be achieved under the constraint of resources available. The decision to use such devices is then subject to a balance between incremental radioprotection gain and the marginal cost of this gain when introducing a new medical device¹⁶⁻¹⁷. In this study, we demonstrated that this gain is greater when operating on pelvis and lumbar areas than on dorsal vertebrae. Efficiency considerations would suggest a restrictive use of this device for the pelvis, but

this requires specific research in medico-economics.

Conclusion

Reducing radiation exposure to the operator is an obligation that may be met using radio-protective devices. Unfortunately, these medical devices are not subject to any specific standard defining their mitigation characteristics. The X'Tens® is a simple range extender whose length allows bone cement injection to be performed away from the radiation field during percutaneous vertebroplasty, so that the operator may benefit from the so-called "inverse-square law". Thus, according to existing literature, our evaluation using appropriate indicators showed the use of the device is efficient only in a limited number of cases, reaching a 40% reduction of radiation in lumbar procedures only. Confronted with the decision to use this device or not in routine practice, we conducted this simple study to inform the operator on the real performances of this new device. Thus, we demonstrated a specific gain and restricted its use to appropriate procedures.

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References

- 1 Masala S, Massari F, Fiori R, et al. Future directions in percutaneous vertebroplasty. *Radiol Med*. 2009; 114: 976-983.
- 2 Artignan S, Conso F, Hazebroucq V. Radiodermatitis in interventional radiology (hand dose measurement, screening and compensation). *J Radiol*. 2003; 84: 317-319.
- 3 Damilakis J, Koukourakis M, Hatjidakis A, et al. Radiation exposure to the hands of operators during angiographic procedures. *Eur J Radiol*. 1995; 21: 72-75.
- 4 Fitousi NT, Efstathiopoulos EP, Delis HB, et al. Patient and staff dosimetry in vertebroplasty. *Spine (Phila Pa 1976)*. 2006; 31: E884-889; discussion E890.
- 5 Synowitz M, Kiwit J. Surgeon's radiation exposure during percutaneous vertebroplasty. *J Neurosurg Spine*. 2006; 4: 106-109.
- 6 Vehmas T. What factors influence radiologists' finger doses during percutaneous drainages under fluoroscopic guidance? *Health Phys*. 1993; 65: 161-163.
- 7 Vehmas T. Radiation exposure during standard and complex interventional procedures. *Br J Radiol*. 1997; 70: 296-298.
- 8 Tappero C, Barbero S, Costantino S, et al. Patient and operator exposure during percutaneous vertebroplasty. *Radiol Med*. 2009; 114: 595-607.
- 9 Harstall R, Heini PF, Mini RL, et al. Radiation exposure to the surgeon during fluoroscopically assisted percutaneous vertebroplasty: a prospective study. *Spine (Phila Pa 1976)*. 2005; 30: 1893-1898.
- 10 Mehdizade A, Lovblad KO, Wilhelm KE, et al. Radiation dose in vertebroplasty. *Neuroradiology*. 2004; 46: 243-245.
- 11 Kallmes DF, O E, Roy SS, et al. Radiation dose to the operator during vertebroplasty: prospective comparison of the use of 1-cc syringes versus an injection device. *Am J Neuroradiol*. 2003; 24: 1257-1260.
- 12 Komemushi A, Tanigawa N, Kariya S, et al. Radiation exposure to operators during vertebroplasty. *J Vasc Interv Radiol*. 2005; 16: 1327-1332.
- 13 Ortiz AO, Natarajan V, Gregorius DR, et al. Significantly reduced radiation exposure to operators during kyphoplasty and vertebroplasty procedures: methods and techniques. *Am J Neuroradiol*. 2006; 27: 989-994.
- 14 EN 1331-1: Protective devices against diagnostic X radiation. 1994.
- 15 Hunter TB, Yoshino MT, Dzioba RB, et al. Medical devices of the head, neck, and spine. *Radiographics*. 2004; 24: 257-285.
- 16 Pauly MV, Burns LR. Price transparency for medical devices. *Health Aff (Millwood)*. 2008; 27: 1544-1553.
- 17 Robinson JC. Value-based purchasing for medical devices. *Health Aff (Millwood)*. 2008; 27: 1523-1531.

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