The surgeon's real dose exposure during balloon kyphoplasty procedure and evaluation of the cement delivery system: a prospective study

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Abstract

Purpose Balloon kyphoplasty is currently widely used for the treatment of vertebral compression fractures (VCFs). Procedure safety is directly linked to precise radiological imaging generated by various X-ray systems (C-arm, O-arm[®], angiography table, etc.). This minimally invasive spinal surgery is, by definition, associated with significant radiation exposure for both patient and surgeon. Real dose exposure received by the surgeon is usually difficult to precisely record. In our center, all Balloon Kyphoplasty Procedures (BKP) are now performed using an O-arm[®] image guidance system to control cement augmentation in VCF. Our preliminary experience described reduced dose exposure compared to C-arm guided procedures. We present here an additional way to considerably reduce the amount of radiation received by the surgeon during BKP using a new injection system.

Methods We prospectively evaluated O-arm[®] guided BKP in 20 consecutive patients alternatively allocated to either classic O-arm[®] BKP with direct bone filler injection or BKP using a new Cement Delivery System (CDS). Eye, wrist, finger and leg measurements were taken bilaterally and compared between the two groups.

Results The radiation dose received by the surgeon's finger, wrist and leg was reduced by greater than 80 % when using the CDS. It allows the surgeon to work way below the most severe annual limit of dose exposure, which may not be the case when using a classical bone filler direct injection mechanism.

Conclusion We believe that when using this new intra-operative injection system, the surgeon's overall anatomic exposure is significantly reduced without compromising the critical procedure steps.

Keywords Balloon kyphoplasty · Vertebral compression fractures · Radiation exposure · Minimal invasive spinal surgery · Cement delivery system

Purpose

As the population continues to age, the challenge for treating vertebral compression fractures (VCFs) due to osteoporosis, trauma, metastases and myeloma, and their respective complications will become increasingly prevalent. VCF mainly due to osteoporosis represents today a major concern amongst elderly patients, frequently leading to pain, disability and deterioration of quality of life. Every year worldwide an estimated 1.4 million VCFs cause pain and suffering [1–3]. Annually, there are an estimated 700,000 osteoporotic VCFs in the United States [4, 5]. Approximately, 26 % of women over the age of 50 and 40 % of women over 80 years of age are reported to have sustained a VCF [4, 6].

At present, conservative non-surgical treatment of VCFs with drugs, surgical braces and rehabilitation still has shortcomings. Recently, the development of minimal invasive surgery (MIS), such as balloon kyphoplasty, has

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been used to treat a large number of VCF patients who remained refractory to the previously cited conventional treatments [7]. BKP offers fast and sustained pain reduction and improved function while avoiding kyphosis progression [7, 8].

Popularity of these minimal invasive solutions to treat fractures is growing, thus parallel concern about possible excessive X-ray exposure to the health professional is being raised. Recent studies [9–11] have demonstrated that extremity and eye lens doses may surpass operational limits in interventional radiology and cardiology. Interestingly, ways to reduce X-ray exposure were recently published for spinal procedures [12, 13].

Although the literature contains an impressive number of papers concerning balloon kyphoplasty, there are few data concerning fluoroscopy time during surgery or X-ray exposure dose to both the patient and the surgeon [14, 15]. However, MIS is often associated with a high radiation exposure for both the patient and the surgeon due to a limited view of the surgical field [16]. Depending on the patient, the surgeon's experience and the level of the fractured vertebra, the average patient effective radiation dose during balloon kyphoplasty can be more than 12 mSv [16], which is 3–4 times greater than a full CT body scan [17, 18].

In view of the previously cited high radiation values, and due to the growing popularity of minimally invasive spinal surgery, efforts to reduce X-ray exposure both to the patient and the surgeon during surgery may become a critical goal in the future. We previously demonstrated [12, 13] that new intraoperative tools such as the O-arm[®] Complete Multidimensional Surgical Imaging System (Medtronic Navigation, Louisville, CO, USA) will help to achieve this goal. We now present the next step concerning the use of a new cement delivery system, the CDS[®] (Kyphon[®] Cement Delivery System, Medtronic Spinal and Biologics, Memphis, TN, USA).

Materials and methods

Patients and procedure

From October 2010 to March 2011, we initiated the prospective inclusion of new VCF patients admitted to our hospital. We previously documented our experience concerning 54 patients [12] treated by O-arm[®] BKP. With respect to the subsequent 20 consecutive patients we have included to date, patients were eligible for enrollment if they experienced one to three acute painful VCFs from T5 to L5. A hyper-intense signal on MRI T2 and/or STIR (short time inversion recovery) sequences was required for the definition of acute compression fracture. VCFs due to osteoporosis and multiple myeloma were included.

However, those due to other tumors and metastases were excluded from the study due to the absence of reimbursement for these kyphoplasty indications in Belgium.

In our institution, osteopenia evaluation via a bone mineral density DEXA scan was systematically performed in all of our recruited osteoporotic fracture patients. Osteoporosis was defined as a T-score of less than -2.5 in the lumbar spine (either L1–L4 or L2–L4; Working Group Guidelines from the World Health Organization) or hip [19, 20]. The definition of trauma was a serious bodily injury or shock due to a high-energy force, as from an accident, independent of osteoporosis which may or may not have been present. Candidates for the study also had to have a minimum back pain score of 6 on a 0–10 visual analog scale. Patients with chronic fractures, rupture of any kind of the posterior wall of the vertebrae, infectious conditions or any neurological deficit were excluded from this study.

The same experienced neurosurgeon performed all of the BKPs using the O-arm[®]. Twenty consecutive patients with 28 vertebral compression fractures were involved in this prospective case series and underwent balloon kyphoplasty (Medtronic Spinal and Biologics, Memphis, TN, USA) guided by the O-arm[®] Complete Multidimensional Surgical Imaging System (Medtronic Navigation, Louisville, CO, USA). During BKP, these patients were alternatively allocated to either classic injection (direct cement injection) where the cement is directly delivered through bone fillers in the vertebral body or to the CDS group where the cement is delivered through a cartridge connected to bone filler. Nine patients underwent BKP with direct cement injection for their 13 VCFs and 11 underwent BKP with CDS injection of their 15 VCFs. VCF etiology was found comparable in both groups (one multiple myeloma patient in each group). Mean patient age was 73 years in the “direct” injection group and 71 years in the “CDS” group. Both groups showed female predominance as expected (seven and eight, respectively). All 28 fractured levels were treated (12 patients with one level, eight patients with two levels and no patient with three levels). Anatomy location was considered comparable in both groups: seven VCFs at the lumbar level (L1–L5) and six at the thoracic level (T5–T12) in the “direct injection” group; and eight and seven, respectively, in the “CDS” group. All procedures were performed under general endotracheal anesthesia in the prone (ventral decubitus) position on a radiolucent operating table (Maquet GmbH & Co, Rastatt, Germany; reference 1150.45BC).

Balloon kyphoplasty was performed in all patients via a bilateral pedicular or extrapedicular (for the highest thoracic levels) approach using traditional surgical instruments: introducers, inflatable bone tamps, polymethylmethacrylate

bone cement and delivery devices (manufactured by Medtronic Spine LLC, Sunnyvale, CA, USA).

The surgeon was equipped with eight thermoluminescent dosimeters (TLDs) located on fingers, wrists, eyes and legs. These dosimeters were calibrated by the Belgian Nuclear Research Center to precisely record extremity and eye lens radiation doses. The measurement protocol was validated by a European project focus on radiation dose measurement in interventional radiology [9, 10]. The overall operation time was also collected for each patient.

Thermoluminescent dosimeters

Thermoluminescent dosimeters are very small crystals (4.5 mm in diameter) and are tissue equivalent, which makes them very suitable for skin dosimetry. TLDs absorb radiation and this energy stays trapped until they are heated. When heating to a certain temperature (200–250 °C), visible light is emitted and collected. The amount of light pulses that is counted is proportional to the absorbed dose.

Imaging system

The O-arm[®] complete multidimensional surgical Imaging system [12] is an intraoperative system based on a conventional X-ray tube and a flat panel detector (40 × 30; Varian Medical Systems, Palo Alto, CA, USA) [12]. The system can be used in 3-D mode, multi-plane 2-D and as a conventional fluoroscopic system. The 3-D mode is particularly useful to evaluate cement distribution in the vertebral body immediately after the procedure and to detect any cement leakage in the vascular system, spinal canal or intervertebral disc.

The O-arm[®] system's robotic movements enable the gantry to move to a maximum of four preset working positions and one park position. The park position gives the surgeon unfettered access to the surgical field and one can return from the park to the imaging position in seconds with the push of a button. The 2 × 1.5 K (3 megapixel) digital flat panel detector permits a very high dynamic range and a greater spatial resolution for better accuracy. The system's ability to memorize imaging positions (M-2D) eliminates manual repositioning. The 3-D image data set, which includes patient reference as well as AP and lateral images, can be automatically registered and optionally transferred to a StealthStation[®] S7[®] System (Medtronic Navigation, Louisville, CO, USA).

The Cement Delivery System (CDS)

The CDS acts like a gun to deliver the cement into the vertebral body through a cartridge connected to classical bone filler and separated from the gun itself by a distance of 1.2 m

(Medtronic Spine LLC, Sunnyvale, California USA). This one-handed operation provides enhanced control (and preservation of tactile feedback for the surgeon) with 0.2 cc of cement delivered per squeeze. Picture 1 (in Supplementary material 1) shows the extra distance between the surgeon and the fluoroscopic field. The 1.2 m of extra distance from the fluoroscopic field also acts to decrease the surgeon's hand exposure during the procedure without interfering with cement polymerization (keeping the advantage of low pressure filling during cement filling). This additional 1.2 m distance is the result of a compromise between keeping the device compact and manageable (if too long it will add potential sterility errors during surgery) and offering important dose exposure reduction to the surgeon's extremities (dose is the inverse square correlated to distance). A quick release button is able to immediately stop the cement flow if the injection volume has been reached or if leakage is observed.

Results

Between October 2010 and March 2011, 20 consecutive patients with 28 VCFs, 18 due to osteoporosis and 2 due to multiple myeloma were treated by balloon kyphoplasty using the O-arm[®]. Nine patients were treated using direct cement injection and 11 using cement injection via the CDS. All BKP were performed under O-arm[®] fluoroscopy (2-D mode) allowing for AP and lateral views. The O-arm's[®] position memory was used to store the ideal AP and lateral positions. After the initial set-up, scouting was no longer required and this helped to reduce radiation exposure. The precise and rapid repositioning of the O-arm[®] streamlined the procedure and thus made sure that two consecutive images were taken from exactly the same angle and easy to compare. Cement injection was performed under continuous lateral fluoroscopy either using direct cement injection or cement injection via the CDS.

The mean patient age was 72 years (range 62–84 years). The mean surgical time (needle insertion to withdrawal) for the procedure was 29 min (range 18–46 min) with a mean fluoroscopy procedure time of 2.5 min (range 1.1–4.3 min). The variations in exposure time were due to technical operative factors such as visualization, fracture complexity and the number of levels treated. An average of 4.9 ml of bone cement was injected into the fractured vertebral body. No symptomatic cement leakage was found outside the vertebral body: there was no leak in 17 cases and an asymptomatic leak in three cases (two intradiscal leaks and one paravertebral leak; no epidural or foraminal leaks were observed).

No intraoperative complications occurred during any of the procedures. No procedures had to be aborted because of

Table 1 Specific radiation dose measurements for each patient

Group	Patient	Hp(0.07) (mSv)							
		Middle Eye	L/R Eye	R Finger	L Finger	R Wrist	L Wrist	R Leg	L Leg
Direct	1	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.008
	2	0.008	0.022	0.008	0.008	0.012	0.008	0.013	0.019
	3	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.008
	4	0.009	0.009	0.131	0.204	0.094	0.131	0.009	0.015
	5	0.008	0.008	0.008	0.0478	0.075	0.285	0.008	0.008
	6	0.008	0.008	0.015	0.098	0.058	0.272	0.008	0.008
	7	0.008	0.008	0.175	0.442	0.211	0.641	0.008	0.008
	8	0.013	0.027	0.559	1.165	0.640	0.994	0.008	0.008
	9	0.008	0.008	0.148	0.465	0.181	0.613	0.008	0.008
CDS	1	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.008
	2	0.030	0.031	0.196	0.216	0.164	0.317	0.031	0.022
	3	0.027	0.023	0.008	0.025	0.032	0.049	0.027	0.019
	4	0.008	0.126	0.008	0.024	0.008	0.008	0.008	0.053
	5	0.008	0.056	0.008	0.008	0.020	0.025	0.008	0.031
	6	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.008
	7	0.008	0.008	0.008	0.008	0.008	0.008	–	–
	8	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.008
	9	0.008	0.008	0.008	0.123	0.034	0.083	0.008	0.008
	10	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.008
	11	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.008

Note: 0.008 mSv = detection limit

inadequate image visualization and no re-interventions were required. All patients were ambulatory at post-procedure day one.

Table 1 (specific radiation dose measurements for each patient included in the study) provides all the patient dose measurements. Table 2 (comparison of radiation dose exposure reduction) gives an overview of all the extremity and eye lens radiation doses measured for each patient in the CDS and direct injection groups. We can observe that the highest radiation doses are recorded in the hands, especially in the left finger in both groups. An average dose of 0.272 mSv is reported in the left finger in the direct injection group, as opposed to an average dose of 0.04 mSv in the CDS group. Similar drastic dose exposure reduction was found in the CDS group as follows: for the right finger, the measured radiation dose was 0.025 versus 0.118 mSV

in the classic group; in the right wrist, it was 0.028 versus 0.143 mSv; and in the left wrist, it was 0.048 versus 0.329 mSv. Dose reduction in the CDS group achieved a factor of five for all measurements. For nearly all the eye measurements, the doses recorded were so low that they were at the dosimeters' detection limit (0.008 mSv).

Discussion

In the past years, the number of BKPs has increased mainly due to the growing prevalence of osteoporotic vertebral compression fractures [21]. This surgical technique is also used to treat traumatic and oncologic VCFs. The advantages of this surgical technique compared to conservative treatment options are the reduction in postoperative pain within days after the procedure, potential restoration of vertebral height and partial correction of the kyphotic angle [22].

When performing BKP, the surgeon must achieve perfect visualization of the pedicles in several planes and be aware of possible cement leakage during the filling of the vertebral body. However, BKP is associated with non-negligible radiation exposure for the patient, as well as for the surgeon [15, 23]. There are frequent reports of surgeons achieving or exceeding the annual radiation dose limit.

Table 2 Comparison of radiation dose exposure reduction

Anatomic location	CDS group (mSv)	Direct injection group (mSv)
Right finger	0.025	0.118
Right wrist	0.028	0.143
Left wrist	0.048	0.329
Eyes	0.008	0.008

Note: 0.008 mSv = detection limit

This has important consequences for both the surgeon's health and their way of working. Due to the growing number of MIS procedures, the surgeon should try to reduce as much as possible X-ray exposure to the patient, the operating room staff and of course him or herself. Izadpanah et al. [24] stated that patient high radiation dose exposure might be due to frequent X-ray controls related to increased C-arm manipulation during conventional procedure. The increased risk to the surgeon of radiation contamination may be due to the same reason but also to the repetitiveness of the surgical procedure.

Several efforts to reduce radiation time and dose have been attempted and described by different surgical teams [24]. Logical and rational examples of this may be the use of preventive protection measures such as protective whole body aprons and lead collars, protective gloves and eyeglasses; standing an appropriate distance from the radiation source; and using radiologic imaging sparingly [only take the necessary images and use the lowest possible radiation dose, also known as the ALARA principle (“as low as reasonably achievable”)]. All these are basic steps but not necessarily sufficient.

Radiation dose could be reduced using two image intensifiers (C-arms) which would decrease the number of unproductive images. Unfortunately, at the same time, it would also reduce the surgeon's work area [24] and increase the non-surgical phase of the procedure due to the initial time required to correctly position the two C-arms.

In order to reduce fluoroscopy time, the use of navigation has been proposed by some authors. Izadpanah et al. [24] found that using a computer navigation system significantly reduces the radiation exposure to patients and surgeons in the two-dimensional (2-D) navigated procedure of the lumbar spine and in the three-dimensional (3-D) navigated procedure of the thoracic spine. In addition, the increased technical expenditure does not lead to a significantly longer operation time. They did, however, report a mean operation time greater than 60 min with computer navigation in BKP. Due to the reduced radiation exposure, Izadpanah et al. [24] recommend the use of computer navigation when performing BKP. However, these neuro-navigation systems are only available in certain neurosurgical centers. Even though radiologists and orthopedists are also performing BKP, they may not have access to the navigation equipment.

From our own experience, the positioning of the needle is the step that requires the least X-ray time during surgery (in our hands around 15 s of fluoroscopy time). Therefore, the use of navigation for needle placement does not significantly affect the total radiation exposure since it does not reduce fluoroscopy time during cement injection. In addition, we are using the pulse mode during needle

introduction and not the cine mode, thus preventing too much radiation.

Concerning economics, the use of a navigation system when performing BKP can be thought to increase overall costs. However, there is evidence in the literature that this is not automatically the case [25, 26]. On the other hand, due to numerous disposable single-use tools, “computer” navigation can be a possible recurrent financial cost both to the patient and the hospital.

With the advancement of MIS, traditional C-arms do not completely address the imaging requirements of the modern operating room and intraoperative CT scanners do not offer lateral patient access or 2-D modalities.

After having described the advantage of systematic use of the O-arm[®] to perform BKP, we found that using the new CDS device, radiation doses were reduced to levels that were thought to be unattainable. In reality, most of the radiation dose received by the surgeon's anatomy is consecutive to cement injection under continuous fluoroscopy. The possibility of having 1.2 m of extra distance from the radiation field offers additional substantial protection with a factor of five radiation dose reduction. This is true for fingers (left and right), wrists (left and right) and legs (left and right). Due to very low eye doses in both groups, it would have required a greater number of patients to measure the effect of the CDS. Another advantage of CDS is the fact that despite additional distance between the surgeon and the surgical field, the tactile feedback of the cement injection, as well as the ability to immediately stop the injection in case of observed leakage, is preserved. The very low dose reported when O-arm and CDS are associated during BKP will allow the surgeon to maintain their annual VCF treatment workload without facing the risk of reaching dangerous radiation dose exposure levels. To our knowledge, the association of O-arm[®] and CDS is actually the safest way to fill a vertebral body with cement while maintaining the specific advantage of BKP (height restoration, reduction of kyphosis and decrease leakage rate) and reducing as far as possible the surgeon's X-ray dose exposure. In the future, this latest parameter will probably be of tremendous importance in terms of health and insurance.

Conclusions

Several recent studies have demonstrated the efficacy of BKP to provide pain relief, improve quality of life, limit the days of restricted activity and reduce the use of analgesics [27–31]. Recent publications also demonstrated the superiority of BKP over non-surgical, conservative treatment [8, 30]. Due to these observations and the growing

Fig. 1 Radiation dose reduction

prevalence of osteoporotic VCFs, the number of BKP has increased within the past years [22]. Thus, there is a growing concern among surgeons about radiation exposure and the need for solutions, as previously mentioned. We already know that systematic O-arm® use is able to substantially reduce dose exposure to the surgeon. In this article, we add another tool, the CDS, to further decrease dose exposure during BKPs. We demonstrate by comparison with a classic injection group that the reduction is highly significant as shown in Fig. 1 (radiation dose reduction) with a radiation dose reduction of greater than 80 %.

The O-arm®–CDS BKPs were conducted exactly in the same way as C-arm procedures, without any modification of the instruments and without any additional recurrent cost. The fluoroscopy time by level was 2.5 min and the average procedure time 29 min. These numbers seem to be lower than those traditionally reported for surgical or fluoroscopy times. We are convinced that the use of the combined O-arm®–CDS allows the surgeon to perform a BKP at one-fifth of the radiation dose normally reported when using the classical injection system. In addition, we found that there is no real learning curve required in order to master the use of the CDS. New intraoperative devices such as the O-arm® Complete Multidimensional Surgical Imaging System and a new tool such as the CDS may permit the surgeon to perform continuously increasing numbers of VCF treatments with increasing safety.

To our knowledge, this paper is the first precise description and quantification that uses a prospective and systematic approach for determining the radiation dose and its reduction with respect to the surgeon's exposed anatomy.

Conflict of interest None.

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