BJR

Received: 8 January 2016 | Revised: 23 June 2016 | Accepted: 29 June 2016

http://dx.doi.org/10.1259/bjr.20160030

Cite this article as:
Hui TCH, Tan GZL, Tan AKW, Pua U. The use of cone beam CT in achieving unipedicular spinal augmentation. *Br J Radiol* 2016; **89**: 20160030.

FULL PAPER

The use of cone beam CT in achieving unipedicular spinal augmentation

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Objective: To assess the feasibility of cone beam CT (CBCT) in achieving unipedicular access during spinal cement augmentation.
Methods: A retrospective review of all patients who underwent CBCT-guided unipedicular spinal augmentation procedures between 1 January 2012 and 15 June 2015 was performed. 59 patients (43 females 16 males; mean-age, 74.0 years; range, 52–90 years) underwent unipedicular spinal augmentation in 78 vertebral levels (T5–T9, $n = 14$; T10–L2, $n = 42$; L3–L5, $n = 22$). Degree of cross-over in contralateral hemivertebral body, complications and 30-day mortality were recorded.
Results: 97% (76/78) of procedures were technically successful. Two procedures failed owing to vertebral sclerosis. For vertebroplasty, all cases (6/6) demonstrated cross-over filling of cement and 50% (3/6) showed cement cross-over >50% of contralateral half of the vertebral body. For kyphoplasty, 13 out of 15 procedures demonstrated balloon and cement cross-over >50% of contralateral half of the vertebral body. Two kyphoplasty procedures required the second pedicle after midline cross-over of cement failed. Of the kyphoplasty procedures that were successfully performed with the unipedicular approach, 76.9% (10/13) showed cement cross-over >50% of contralateral half of the vertebral body. For stentoplasty, all cases (55/55) showed midline stent–cement complex cross-over and 78.2% (43/55) exhibited stent–cement complex cross-over >50% of contralateral half of the vertebral body. There was no major complication or mortality. Minor complications included asymptomatic cement extravasation (6.4%, $n = 5$) and self-limiting haematoma (1.3%, $n = 1$).
Conclusion: Unipedicular access for spinal augmentation procedures is achieved at a high success rate with the use of CBCT.
Advances in knowledge: This article describes the novel use of CBCT to achieve unipedicular spinal augmentation. Unipedicular spinal augmentation has the potential to reduce risk, duration, radiation and cost while achieving similar results.

INTRODUCTION

Percutaneous spinal augmentation procedures (SAP) are increasingly used for the treatment of patients with vertebral body fractures whom have failed conservative management.[1–3] Techniques include vertebroplasty, balloon kyphoplasty and stentoplasty, and needle trajectory planning and deployment were traditionally performed using fluoroscopy.

With the advent of cone beam CT (CBCT), real-time "CT-like" images can be obtained in flat-panel-based interventional suites; with enhancements, the overlay of these CBCT images can be integrated with real-time fluoroscopy. SAPs represent ideal applications for CBCT as it allows for precise adjustment of trajectory in the axial and sagittal planes to ensure a safe and effective needle trajectory. The aim of this study was to assess the feasibility of CBCT in achieving unipedicular SAPs.

METHODS AND MATERIALS

The approval from the Tan Tock Seng Hospital institutional review board was obtained. A retrospective review of all consecutive patients who underwent CBCT-guided unipedicular SAPs (vertebroplasty, kyphoplasty and stentoplasty) between 1 January 2012 and 15 June 2015 was performed. Inclusion criteria were background of osteoporosis or metastatic disease, acute vertebral compression fracture causing pain and limiting function and failed conservative management. Osteoporosis is defined as T-score of ≤ -2.5 standard deviation on bone mineral densitometry. All diagnoses of metastatic disease and multiple myeloma were made on histology. Exclusion criteria included severe cardiopulmonary comorbidity, systemic infection and severe coagulopathy.

59 consecutive patients (43 females 16 males; mean-age, 74.0 years; range, 52–90 years) underwent SAPs on 78 vertebral levels. Aetiologies of the vertebral body fractures

include osteoporosis ($n = 60$), metastatic disease ($n = 13$) and multiple myeloma ($n = 5$), occurring in the thoracic (T5–T9, $n = 14$), thoracolumbar (T10–L2, n = 42) and lumbar (L3–L5, $n = 22$) regions. Pre-procedural MRI of the spine was performed on 77 occasions (98.7%) to demonstrated bony oedema, performed on average 13 days prior to SAP (range, 2–110 days). The coagulation profile of each patient was reviewed, and uncorrectable coagulopathy was defined as an international normalized ratio >1.3 and platelet count of $<70{,}000\ \mu l^{-1}$.

All procedures were performed in a flat-panel-based angiographic suite using CBCT (Allura Xper FD20; Philips Medical Systems, Netherlands) by four interventional radiologists with at least 4 years' experience. Written informed consent was obtained for all procedures, and the patients were placed in the prone position. Conscious sedation and analgesia were administered and consisted of midazolam (intravenous infusion at 0.5–1 ml h^{-1} with 1 mg bolus at interval, total 2.2–5 mg), fentanyl (25–100 mg) and ketorolac (15–30 mg). Intravenous cefazolin 1 g was given as prophylaxis, and clindamycin 500 mg was used as an alternative for patients with penicillin allergies.

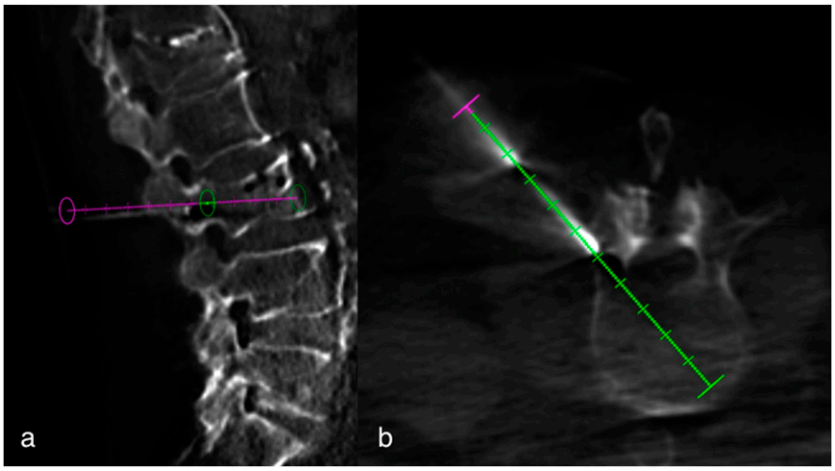
Images were acquired using CBCT with a 220-degree rotation of the C-arm, and the XperGuide software (Allura, XperGuide; Philips Medical Systems, Netherlands) was used for image reconstruction in the sagittal and axial planes on the workstation. The trajectory was first plotted parallel to the axis, through the centre of the pedicle on the sagittal plane. On the axial images, midline cross-over of trajectory was confirmed by adjusting the trajectory end point to terminate at the 4–5 or 7–8 o' clock position on the contralateral side of the vertebra (Figure 1). The needle trajectory was further tuned to transverse the thickest portion of the pedicle; it is also confirmed to be lateral to the medial wall of the pedicle in the anteroposterior (AP) view and at the upper part of the pedicle in the sagittal view to avoid injury of the exiting soft tissue and structures within the spinal canal. The planned trajectory is subsequently displayed on fluoroscopy as an en face view or "bullseye" view (with the trajectory as a dot) or tangential view as the "progress view" (with the trajectory in profile).

Local anaesthesia was provided and a small skin incision was made to facilitate the passage of a vertebroplasty needle. Either an 11-French (Fr) or 13-Fr vertebroplasty needle was advanced down to the pedicle with the bullseye view guidance and in later cases, with additional aid from external laser guidance (SimpliCT; NeoRad AS, Oslo, Norway). Once the needle tip is engaged within the cortex of the pedicle base, recheck CBCT was performed; repositioning of the needle would be performed at this time if needed. A biopsy is performed at this point for vertebral body fractures unexplained by osteoporosis or recent trauma; this is performed by removing the inner stylet of the entry needle and inserting a bone biopsy needle coaxially into the vertebral body. Once good trajectory is confirmed, the needle is then driven into the middle using handheld mallet under real-time monitoring on progress view, and in lateral and AP views on fluoroscopy.

For vertebroplasty, the inner stylet was removed once the needle had reached the target, and a mixture of polymethyl methacrylate (PMMA) bone cement and barium sulphate was infused into the vertebral body under direct fluoroscopic visualization. Cement injection was terminated once the cement reaches the junction between the middle third and posterior third of the vertebral body on the lateral projection. The needle was withdrawn once complete hardening is confirmed. An average of 2.5 ml (range, 2–5 ml) of cement was used for vertebroplasty.

For kyphoplasty, with the needle at the posterior cortex of the vertebral body, the stylet of the needle is exchanged for a Kirschner wire (K-wire), which is advanced using the progress view to the end point on the initial CBCT. Successful midline cross-over is confirmed by AP fluoroscopy, and 15-mm or 20-mm Inflatable Bone Tamp (Spasy Kyphoplasty System, Seoul, Republic of Korea) was inserted and inflated under careful control until balloon pressures reached an average of 135

Figure 1. An 89-year-old gentleman undergoes cone beam CT for acute pathological L3 compression fracture. (a) The sagittal plane is used for initial needle trajectory planning, through the centre of the pedicle. (b) On the axial plane, the trajectory is adjusted to terminate at the 4–5 o' clock position on the contralateral side of the vertebra to ensure midline cross-over.



atmospheres (atm) (with a maximum pressure of 400 atm). Balloon inflation was terminated when the balloon approached the subchondral plate, the lateral borders, or the anterior cortex. Then, the balloon is deflated and removed, and the PMMA mixture was infused. A volume of roughly 0.5 ml beyond the inflation volume of the balloon was used; an average of 3.8 ml (range, 3.0–5.0 ml) of cement was injected per level.

Similarly, for stentoplasty, the stylet of the needle was exchanged for a K-wire at the posterior cortex of the vertebral body and advanced using the progress view to the designated end point. Successful midline cross-over is confirmed by AP fluoroscopy. The OsseoFix titanium mesh cage system (Alphatec Spine, Carlsbad, CA) was utilized for all stentoplasty procedures. The soft-tissue dilator and sleeve are advanced over the K-wire to sit at the base of the pedicle; a cavity is created within the vertebral body with a bone drill to accommodate the stent. Under fluoroscopic guidance, the stent was deployed and expanded by the rotation of delivery handle (as per manufacturer instruction). When there is either contact of the stent with the subchondral bone or when the maximum stent expansion is reached, stent expansion was terminated. After removal of the delivery device, PMMA mixture is used to fill the implanted stent through a cement cannula, and the entire stent is filled with cement (average 1.6 ml; range, 0–4.6 ml). However, should cement flow into pre-existing fluid cleft within the vertebral body; more cement was injected to stabilize the cleft.

Once the cement has hardened, the devices are removed and the entry sites closed using absorbable sutures. Post-procedural AP and lateral fluoroscopy as well as CBCT images were obtained.

The images acquired during the procedures were reviewed by two radiologists with at least 4 years of diagnostic radiology experience. Degree of cross-over to the contralateral hemi-vertebral body, procedure-related complications and 30-day mortality were recorded. Our stance is that the biomechanical balance achieved with the unipedicular approach is dependent on the distribution of cement or stent. When the cement, balloon or stent crosses the midline, both sides of the vertebral bodies increase in stiffness equally and biomechanical balance is achieved. If bone cement is augmented only on one side, the stiffness of non-augmented side will be significantly lower than the augmented side, resulting in an imbalance of stress on the vertebral body.[4,5]

Technical success was defined as achieving midline cross-over of the cement and/or instrument on CBCT or AP fluoroscopic image. Cross-over of >50% of the contralateral half of the vertebral body is considered ideal. Figure 2 illustrates how cross-over and cross-over of >50% of contralateral half of the vertebral body was determined objectively. The following observations were recorded: for vertebroplasty, (i) midline cement cross-over and (ii) cement cross-over >50% of contralateral half of the vertebral body; for kyphoplasty, (iii) midline balloon cross-over, (iv) balloon cross-over of >50% of contralateral half of the vertebral body, (v) midline cement cross-over and (vi) cement cross-over >50% of contralateral half of the vertebral body; for stentoplasty, (vii) midline stent–cement complex cross-over and (viii) stent–cement complex cross-over of >50% of contralateral half of the vertebral body.

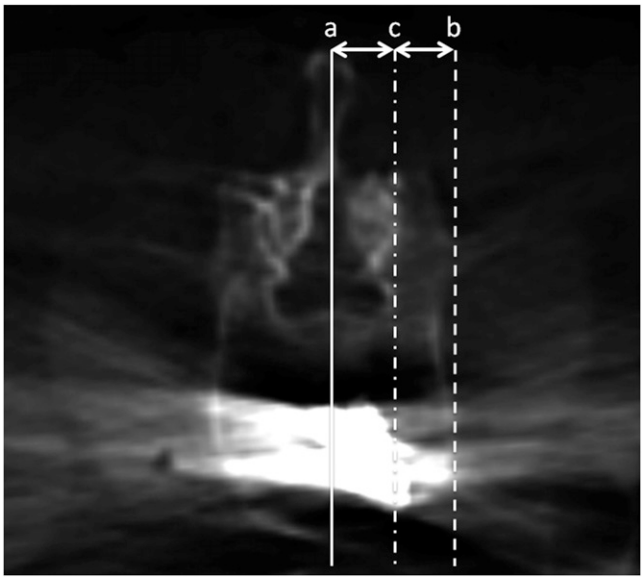
RESULTS

SAPs included in this study are stentoplasty ($n = 55$), kyphoplasty ($n = 13$) and vertebroplasty ($n = 6$). On eight occasions, vertebral augmentation was performed on two vertebral levels during a single procedure. On two occasions, vertebral augmentation was performed on three vertebral levels during a single procedure. On one occasion, vertebral augmentation was performed on seven vertebral levels in a single procedure.

97% (76/78) of all procedures were technically successful. Two (kyphoplasty, $n = 1$, and stentoplasty, $n = 1$) of the procedures failed owing to the sclerosis of the vertebral body and were abandoned.

Of the procedures that were successfully performed, all vertebroplasty cases (6/6) demonstrated cross-over filling of cement, and 50% (3/6) showed cement cross-over >50% of contralateral half of the vertebral body. For kyphoplasty, 13 out of 15 demonstrated balloon and cement cross-over >50% of contralateral half of the vertebral body. Two kyphoplasty procedures required the use of the second pedicle (bipedicular approach) after cement cross-over was not achieved. Of the

Figure 2. The vertebral body in the axial plane. Using an axial cone beam CT image of the vertebral body post-augmentation, we draw an anteroposterior line through the centre of vertebral body and spinous process (line a). The second line, parallel to line a, is drawn at the lateral most aspect of the vertebral body on the contralateral side (line b). The last line, parallel to lines a and b, is drawn at the midpoint between line a and line b, and this is denoted as line c. The material (cement, balloon or stent) is said to have >50% cross-over of contralateral half of the vertebral body when it exceeds the line c.



kyphoplasty procedures that were successfully performed with the unipedicular approach, 76.9% (10/13) showed cement cross-over >50% of contralateral half of the vertebral body. For stentoplasty, all cases (55/55) showed midline stent–cement complex cross-over and 78.2% (43/55) exhibited stent–cement complex cross-over >50% of contralateral half of the vertebral body.

There was no major complication or mortality. Minor complications included asymptomatic cement extravasation (6.4%, $n = 5$) and self-limiting haematoma (1.3%, $n = 1$).

DISCUSSION

SAPs have emerged as an important treatment modality in acute vertebral fractures. They offer immediate relief of pain, mobility and in the case of kyphoplasty and stentoplasty, height restoration and kyphosis angle correction, achieved through percutaneous incisions.[2,3,6] Traditionally, SAPs were performed with the bipedicular approach achieved with the cannulation of both pedicles.

The unipedicular approach has many advantages. Theoretically, there would be a 50% reduction in the risk associated with cannulation of the pedicles. These include pedicle fracture, injury to dura and injury to nerves; time of sedation and anaesthesia would also be reduced. Furthermore, the unipedicular approach bypasses the increased complexity of having to inject cement in an already cement-opacified vertebral body (which clouds the field and potentially risking cement extravasation). From a financial perspective, procedural cost would be reduced from savings in additional cement mixing, balloons and stents. Such an approach is ideal if it has analogous biomechanical, clinical and radiographic results when compared to the bipedicular approach.

It has been previously suggested that unipedicular kyphoplasty is not as effective in restoring vertebral body height when compared to bipedicular approach and may result in unilateral wedging. However, several studies have proven this to be not the case.[7–9] Rebolledo et al[10] showed no significant difference in kyphotic angle and vertebral body height corrections in a prospective study of 56 kyphoplasty procedures on 44 patients (23 unipedicular and 21 bipedicular).

CBCT is a relatively new imaging technology that enables acquisition of cross-sectional images in the flat-panel-based angiographic suite. Three-dimensional portrayal of structures permits precise adjustment of trajectory in the axial and sagittal planes with the aid of navigation software, providing the procedurist with an informed platform to perform these procedures. With the aid of the navigation software, we achieved consistent midline cross-over of instruments to reach the 4–5 or 7–8 o'clock positions with the unipedicular approach as described above. We believe that using cross-sectional imaging is essential when planning SAPs to achieve safe unipedicular cannulation with a high success rate.

The navigation software and greater appreciation of soft-tissue allow more accurate needle placement, potentially reducing the possibility of complications. Owing to the inherently straight pedicular axis, the costotransverse approach with the needle traversing the costotransverse facet and lateral margin of the pedicle was utilized most of the time (63/78) to achieve consistent midline cross-over. Though this approach is relatively avascular and aneural, additional complications may arise. These include haematoma, nerve root damage, rib fractures and injury to surrounding the organs such as pleura in the thoracic spine. The spinal cord is possibly in greater risk of damage owing to the increased insertion angle of the cannula; a breach of the medial cortex of the pedicle can potentially damage the thecal sac, spinal cord and surrounding vasculature. Avoiding these key soft-tissue structures is essential; this is especially relevant in the thoracic spine given its smaller size and the added risk of pneumothorax. Braak et al[11] demonstrated in a prospective study using spine phantoms that needle placement with CBCT guidance is significantly more accurate than placement of the needle using fluoroscopy alone (average needle tip-to-target distance 2.61 mm *vs* 5.86 mm, $p < 0.0001$).

In addition, CBCT also offers the procedurist an accurate modality for performing post-procedural assessments. Post-procedural CBCT has been shown to be comparable to Multidetector CT (MDCT) in detecting vertebral cortical defects, vacuum phenomena in adjacent discs and cement leakage immediately post-procedural.[12] As late cement migration is a rare occurrence, the use of CBCT as a post-procedural assessment may deem post-procedural conventional CT to be obsolete, making SAPs more cost-effective while limiting the patient's exposure to ionizing radiation.

While CBCT offers many advantages, fluoroscopy with AP and lateral projections remains a familiar tool in the angiography suite and the most dose-effective means of monitoring real-time device trajectory, delivery of PMMA or deployment of stent. Braak et al[11] reported longer procedural time and higher radiation dose (dose–area product, 514 mGy cm^2 vs 174 mGy cm^2) when using CBCT compared with conventional fluoroscopy. We believe that the combination of CBCT and fluoroscopy offers the best means of performing unipedicular SAPs.

Our study has its limitations. This is a retrospective, single institution analysis performed on a relatively small group of patients. Also, as the incidence of bipedicular approach was low in our institution, a comparison study was not feasible. In addition, we used technical end points to determine success; the clinical symptoms were not taken into account. While we have demonstrated encouraging results from the use of CBCT, larger prospective studies with long-term clinical outcomes are required. Radiation dose and procedural duration are important issues that need to be studied.

CONCLUSION

Unipedicular access for SAPs is achieved at a high success rate with the use of CBCT.

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