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Prospective randomized comparison of early versus newer-generation vertebral access devices for kyphoplasty

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Abstract

Introduction Kyphoplasty is an established method of treating osteoporotic vertebral body compression fractures. In recent years, several techniques to enhance the efficiency and outcomes of this surgery have been developed and implemented in clinical practice. In the present study, we assess the impact of two new access instruments on overall operation time and the administered dose area product in comparison with the standard access instrument used in our clinical practice. The two newer comparator devices have been designed with the intention of streamlining intraoperative workflow by omitting several procedural steps.

Materials and methods This was a single-center prospective randomized trial investigating three distinct access instruments compatible with the Joline Allevo balloon catheter system. Specifically, two newer access devices marketed as being able to enhance surgical workflow (Joline RapidIntro Vertebra Access Device with a trocar tip and Joline SpeedTrack Vertebra Introducer Device with a short, tapered tip) were compared with the older, established Joline Vertebra Access Device from the same firm. Consecutive eligible and consenting patients scheduled to undergo kyphoplasty for osteoporotic vertebral compression fracture refractory to conservative, medical treatment during the period May 2012–August 2015 were randomized to receive surgery using one of the three devices. Besides the use of the trial instruments, all other preoperative, intraoperative and postoperative care was delivered according to standard practice.

Results 91 kyphoplasties were performed on 65 unique patients during the study period. The median operation time across the three groups was 29 min (IQR 22.5–35.5) with a median irradiation time of 2.3 min (IQR 1.2–3.4). The median patient age was 74 years (IQR 66–80). The groups did not significantly differ in terms of age ($p=0.878$), sex ($p=0.37$), T score ($p=0.718$), BMI ($p=0.285$) or the applied volume of cement ($p=0.792$). There was no significant difference between the treatment groups with respect to surgical duration ($p=0.157$) or dose area product ($p=0.913$).

Conclusions Although use of the two newer-generation access instruments were designed to involve fewer unique steps per operation, their use was not associated with reduction in surgical duration, irradiation time or dose area product administered compared with the older, established vertebral access device. Care should be taken to evaluate the impact of new instruments on key surgery-related parameters such as surgical duration and radiation exposure and claims made about new instruments should be assessed a structured fashion.

Keywords Kyphoplasty · Access device · Irradiation time · Operation time · Dose area product · Prospective trial

Introduction

Osteoporosis is a skeletal disorder characterized by low bone mineral density caused by altered bone microstructure with consequently increased skeletal fragility and risk of fracture. Owing to population aging in the developed and much of the developing world, osteoporosis is associated with a high level of clinical, social and economic burden. The regions most predisposed to osteoporotic alterations are

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the mid-thoracic spine and the thoracolumbar junction and these areas are at increased risk of osteoporotic fracture as a result [1–5]. Therapeutic option to modify fracture risk in osteoporosis includes administration of calcium, vitamin D and bisphosphonates [6–10]. Osteoporotic fractures that do not improve clinically with conservative management—analgesia and physical therapy—should be considered for operative intervention. A widespread and well-established surgical option is balloon kyphoplasty [11, 12]. Since the introduction of this treatment in the late twentieth century, the general kyphoplasty technique has been subject to modifications to enhance its safety and ease of implementation and the associated surgical workflow.

The present study is a prospective randomized comparison of three different instruments used to permit access to the vertebral body for kyphoplasty. Specifically, an older-generation access instrument, the Joline Vertebra Access Device with a standard trocar tip, was compared against two newer instruments marketed as being able to enhance surgical workflow; these were the Joline RapidIntro Vertebra Introducer Device with a long trocar tip and the Joline SpeedTrack Vertebra Introducer Device with a short, tapered trocar tip. We sought to determine whether use of the newer devices was associated with either shorter surgical duration or shorter intraoperative irradiation time.

Materials and methods

This was a single-center prospective randomized trial. Patients were eligible for study inclusion if they met the following criteria:

(a) Clinical diagnosis of a fresh osteoporotic vertebral compression fracture of the thoracic or lumbar spine with a clear clinico-anatomical correlate based on imaging with X-ray, CT** and MRI
(b) Diagnosis of osteoporosis based on quantitative CT densitometry with a *T* score of – 2.5 or less in each of the non-fractured L1–L4 lumbar vertebrae
(c) Indication for surgical treatment of the fresh fracture with kyphoplasty owing to debilitating pain refractory to conservative measures including analgesia and physical therapy
(d) Absence of medical contraindications to surgery
(e) Ability to provide informed consent to surgery and study participation and to comply with study requirements.

Exclusion criteria included failure to meet the inclusion criteria, presence of a chronic vertebral fracture or other non-osteoporotic, pathological vertebral fracture (e.g., secondary to tumor, cavernoma, spinal tuberculosis, skeletal fluorosis or osteodystrophy), extreme patient frailty or overall condition too poor to tolerate surgical treatment, and inability to provide informed consent to participation.

After assessment of study eligibility and informed patient consent to surgery and study participation, randomization was performed by a study nurse, who was not involved in the surgical procedure, by opening numbered sealed envelopes containing computer-generated random numbers assigning patients to one of the three access instrument groups.

Operative technique and description of vertebral access instruments

All patients underwent surgery under general anesthesia and in a prone position. The fractured vertebral body was located and assessed as required during the procedure using sagittal and coronal fluoroscopy in a biplanar fashion (Fig. 1). Three distinct vertebral access instruments from the Allevo kyphoplasty range manufactured by the firm Joline GmbH & Co. KG (Hechingen, Germany) were compared (Fig. 2). The access instruments differed in construction, design and the intraoperative steps necessitated:

1. The vertebra access device (VAD) with a trocar tip is the established and most widely implemented access instrument manufactured by the firm Joline. When using this access instrument, the vertebral body must first be punctured with a modified Jamshidi needle. This step is followed by the introduction of a K-wire, the removal of the Jamshidi needle and the advancement of the Vertebra Access Device over the K-wire. Balloon expansion and cement application are then performed in standard fashion using via the sleeve (Fig. 3a–h).

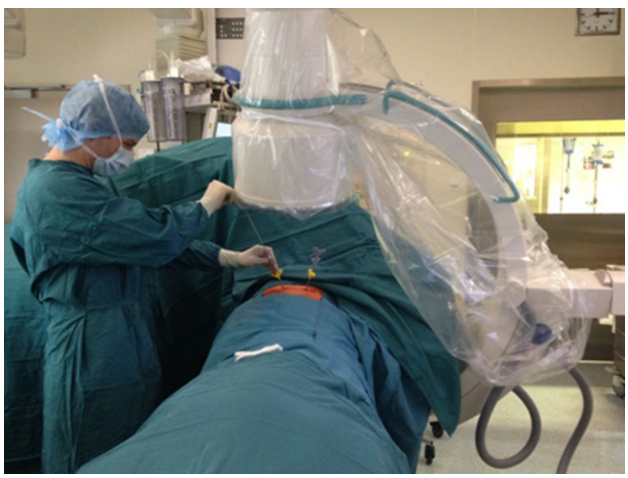

Fig. 1 Intraoperative set-up utilizing two C-arms to obtain intraoperative coronal and sagittal images

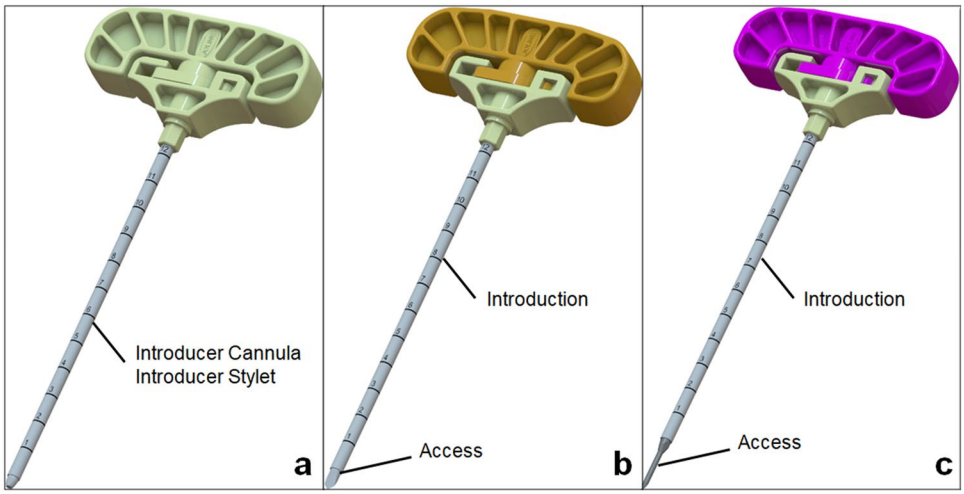

Fig. 2 The three vertebral access instruments assessed in the present study: **a** Joline Vertebra Access Device, **b** Joline RapidIntro Vertebra Introducer Device, and **c** Joline SpeedTrack Verebra Introducer Device

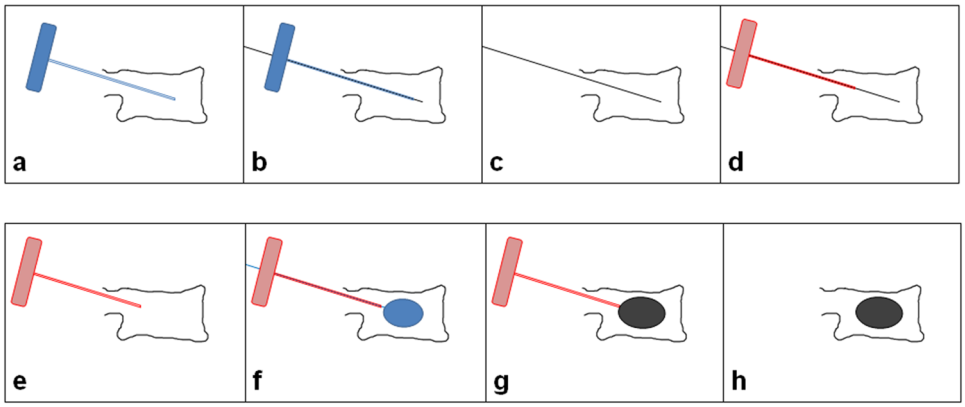

Fig. 3 Steps of a kyphoplasty procedure using the standard Vertebra Access Device (VAD): **a** puncture of the vertebral body using a modified Jamshidi needle, **b** insertion of a K-wire, **c** removal of the Jamshidi needle, **d** advancement of the Vertebra Access Device over the K-wire, **e** removal of the K-wire, **f** insertion and expansion of the balloon until satisfactory height is achieved, **g** cement application, and **h** removal of the Vertebra Access Device and wound closure. Use of the either RapidIntro Vertebra Introducer Device (RI) or the SpeedTrack Vertebra Introducer Device (ST) obviates the need for steps a–d

2. The two newer-generation access instruments—the Joline RapidIntro Vertebra Introducer Device (RI) with a trocar tip and the Joline SpeedTrack Vertebra Introducer Device (ST) with a short, tapered tip corresponding to the diameter of a Jamshidi needle—are one-step access instruments that can be advanced directly into the vertebral body without the need for initial insertion of a Jamshidi needle and K-wire. The balloon expansion and cement application are performed as standard via these access instruments. These workflow for these two newer instruments is shown in panels e–h of Fig. 3. The principal difference between the RapidIntro and SpeedTrack instruments is the shape of their tips for vertebral puncture (Fig. 2).

The Joline Allevo kyphoplasty balloon catheter system was used with each of the access instruments and all procedures were performed according to the manufacturer's instructions. All participating surgeons were trained in the technique required for each access instrument through workshops and videotapes.

Following each kyphoplasty procedure, intraoperative irradiation time and total intraoperative dose area product applied by the two C-arms were determined. Surgical duration was calculated from the time of initial skin incision to skin closure.

Statistical analysis

Data were analyzed using the software SPSS Statistics for Windows (version 22.0, IBM Corp., Armonk, NY, USA).

Discrete variables are expressed as counts (percentages) and continuous variables as means and interquartile range (IQR) unless otherwise stated. Group comparisons were made using a one-factorial analysis of variance (ANOVA) and a generalized linear model. Significance testing was two-sided and p values < 0.05 were considered significant.

Results

91 pathologically fractured vertebral bodies from 65 unique patients [43 females (66.2%), 22 males (33.8%)] were subject to kyphoplasty during the study period. The median patient age at time of surgery was 74 years (IQR 66–80). Thirty fractures were treated using the established VAD instrument, while 32 fractures were treated using the RI instrument and 29 fractures were treated by means of the ST instrument. Six consultants led the surgeries without any differences in the operation time among surgeons ($p = 0.294$). There were no significant differences between the treatment groups with reference to key patient- and injury-related factors. The median patient age was 67 years in the VAD group and 74 years in the RI and ST groups. Females were most commonly treated in all groups (VAD: 21/30, RI: 17/32, ST: 19/29). The median T score was less than − 3.5 in each of the treatment groups (VAD: − 3.98, RI: − 3.54, ST: − 3.70). The median height was between 163 cm (SI) and 170 cm (VAD), and the median weight was between 68 kg (ST) and 75 kg (VAD). The median body mass index (BMI) was in the overweight category in each of the groups (VAD: 29 kg/m^2; RI: 26 kg/m^2; ST: 25 kg/m^2). The median volume of cement applied per vertebral body was between 5.5 ml (VAD) and 6 ml (RI and ST). The groups did not significantly differ in terms of age ($p = 0.878$), sex ($p = 0.37$), T-score ($p = 0.718$), height ($p = 0.068$), weight ($p = 0.073$), BMI ($p = 0.285$) or the applied volume of cement ($p = 0.792$) (Table 1).

The median operation time across the three groups was 29 min (IQR 22.5–35.5) with a median intraoperative irradiation time of 2.3 min (IQR 1.2–3.4). The RI group had the lowest median surgical duration (28 min), followed by the ST group (29 min). Median surgical duration in the standard VAD group was 31 min; however, statistical significance was not reached ($p = 0.157$). The median intraoperative irradiation duration was lowest in the ST group (2.2 min) followed by the RI and VAD groups (both 2.3 min). Again here, there was no statistically significant between-group difference ($p = 0.375$), nor was there a significant difference between groups in the median intraoperative dose area product administered ($p = 0.913$) (Table 2).

Discussion

This study examined three different devices designed to facilitate vertebral access for kyphoplasty and compared two newer-generation, one-step instruments against an

Table 1 Baseline characteristics of the three comparator groups

	VAD ($n = 30$)	RI ($n = 32$)	ST ($n = 29$)	p value
Age (years) (IQR)	67 (56.5 to 77.5)	74 (68.5 to 79.5)	74 (68 to 80)	0.878
Male:female ratio (%)	9:21 (30:70)	15:17 (46.8:53.2)	10:19 (34.5:65.5)	0.370
T score (IQR)	− 3.98 (− 4.65 to − 3.32)	− 3.54 (− 4.28 to − 2.80)	− 3.70 (− 4.51 to − 2.89)	0.718
Height (cm) (IQR)	170 (164 to 167)	169 (160.5 to 177.5)	163 (159 to 167)	0.068
Weight (kg) (IQR)	75 (61.5 to 88.5)	73 (56.5 to 89.5)	68 (61.5 to 74.5)	0.073
BMI (kg/m^2) (IQR)	29.0 (24.7 to 33.3)	26.0 (22.6 to 29.5)	25.2 (23.2 to 27.3)	0.285
Cement volume applied per vertebral body (ml) (IQR)	5.5 (4.5 to 6.5)	6.0 (4.5 to 7.5)	6.0 (5.3 to 6.8)	0.792

Values shown are median (and IQR)

VAD vertebra access device, *RI* RapidIntro Vertebra Introducer Device, *ST* SpeedTrack Vertebra Introducer Device

Table 2 Between-group comparison of surgical duration, intraoperative irradiation time and intraoperative dose area product administered

	VAD	RI	ST	p value
Surgical duration (min) (IQR)	31.0 (23.8–38.3)	28.0 (18.0–38.0)	29.0 (24.4–33.7)	0.157
Intraoperative irradiation time (min) (IQR)	2.3 (2.2–3.3)	2.3 (1.2–3.3)	2.2 (1.5–3.3)	0.375
Intraoperative dose area product (cGy cm^2) (IQR)	868 (335–1402)	906 (685–1128)	863 (392–1333)	0.913

Values shown are median (and IQR)

VAD vertebra access device, *RI* RapidIntro Vertebra Introducer Device, *ST* SpeedTrack Vertebra Introducer Device

established access device, the use of which necessitates more procedural steps. The principal outcome assessed was whether the newer devices reduced surgical duration, intraoperative irradiation time or the intraoperative dose area product administered.

Surgical duration

In general, increased operative duration has been observed to have a strong negative influence on patient outcomes including local and systemic infection, cardiovascular, thromboembolic and respiratory complications, and length of hospital stay across a range of surgeries [11, 12]. In the context of adult spinal deformity surgery, a retrospective analysis of 5338 patients by Phan et al. found that increased surgical duration was associated with an increased rate of complications such as venous thromboembolism, postoperative transfusion, length of stay over 5 days, sepsis, repeat surgery, and unplanned readmission [12]. Nevertheless, it should be noted that the surgeries investigated in this study were generally at least 3 hours in length. Given that kyphoplasty is a shorter operation, with a median duration of 29 min in the present study, it should perhaps be expected that a slightly increased surgical duration enforced by more procedural steps is unlikely to significantly modify the incidence of postoperative complications. With respect to surgical duration, we found no significant difference between the groups treated with the newer-generation RI and ST access instruments, which obviate the need to perform several preliminary steps, and the group treated using the older VAD instrument.

Intraoperative irradiation time and total radiation dose

Two further factors that should not be neglected are the intraoperative dose area product and the irradiation time. These factors affect the patient and, to a lesser degree, the surgeon and the surgical team. Ionizing radiation is classified by the WHO as a carcinogen and it poses a clear health hazard [13]. Spinal surgeons are more likely to be exposed to radiation than surgeons from other specialties owing to their routine use of intraoperative fluoroscopy [14, 15]. As a result, spinal surgeons suffer higher rates of radiation-induced complications such as cataract formation, skin erythema, leukemia, thyroid cancer and other malignancies compared to other surgeons [16, 17]. The highest radiation doses are typically administered during minimally invasive pedicle screw placement, minimally invasive transforaminal lumbar interbody fusion, percutaneous endoscopic lumbar discectomy, vertebroplasty and kyphoplasty. Standard radiation safety precautions aimed at reducing radiation exposure to the surgical team are to wear appropriate lead shielding, to use single-shot and pulsed fluoroscopy rather than continuous fluoroscopy, to maintain a distance of 2–3 feet from the X-ray beam with the head turned 90° away from the patient, to stand away from the X-ray source and close to the image intensifier and to use an O-arm or other stereotactic navigation system when several vertebral levels are involved [18]. However, even if all of these recommendations are complied with, individual radiation exposure rises with increasing irradiation time. For this reason, the irradiation time should be kept as short as possible [19] and some studies have described the use of laser positioning and navigation system that can significantly reduce radiation exposure during kyphoplasty [20–22]. For example, in a randomized comparison between conventional fluoroscopy and a laser navigation system, use of the latter system resulted in a 53% reduction in patient radiation exposure per. Changes to operative workflow and technique thus have clear ability to influence and potentially reduce radiation exposure [20].

Nevertheless, although the two newer-generation vertebral access instruments tested in this study—the RI and ST devices—are designed to streamline operative workflow and obviate the need for steps typically associated with frequent fluoroscopy application, no significant difference in irradiation time or administered dose area product was detected between treatment groups in comparison with the standard system that utilizes a modified Jamshidi needle.

Limitations and future work

A limitation of this study is that this trial involved a single center, a relatively small study group, which may be underpowered to detect small between-group differences in the measured outcomes, and the operators were not blinded to which instrument they were using.

In addition, ergonomic and acceptance aspects should be surveyed, to determine how operators perceive the comfort, intuitiveness and precision of these instruments and the associated workflows.

Future studies should also examine the impact on surgical duration and radiation exposure according to patient characteristics such as BMI, bone mineral density, and the vertebral level affected by fracture.

Conclusions

Despite these limitations, the study revealed that use of either of the two newer-generation devices was not associated with reduced surgical time or reduced radiation exposure or fluoroscopy administration duration. The manufacturer of the devices has claimed that these newer systems allow percutaneous bone access in one step and remove the need for instrument exchange for working channel creation,

but this did not impact on any of the operative parameters assessed in this study. This finding highlights the need to undertake structured evaluation of the impact of new instruments on key surgery-related parameters such as surgical duration and radiation exposure, and manufacturer claims made about new instruments should be assessed a structured, quantitative fashion.

Author contributions (1) The conception and design of the study, or acquisition of data, or analysis and interpretation of data: FS; CE; ALS; ALM; (2) drafting the article or revising it critically for important intellectual content: FS; ALM; AW; (3) final approval of the version to be submitted: AW; CE; RK.

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Compliance with ethical standards

Conflict of interest None of the authors received any compensation for their work on this article, nor have they received compensation from Joline for work undertaken in any other capacity. There are no other relevant financial or non-financial conflicts of interest to declare.

Ethical approval This study was approved by the institutional review board of Jena University Hospital (reference number: 3287-11/11) and conformed to the Declaration of Helsinki in its present form.

Informed consent Informed consent to surgery and trial involvement was provided by each and every participant.

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