Observational Study

Medicine®

OPEN

Significant reduction of fluoroscopy repetition with lumbar localization system in minimally invasive spine surgery

A prospective study

Guoxin Fan, MD, Hailong Zhang, MD, Xin Gu, MD, Chuanfeng Wang, MD, Xiaofei Guan, MD, Yunshan Fan, MD, Shisheng He, MD*

Abstract

The conventional location methods for minimally invasive spinal surgery (MISS) were mainly based on repeated fluoroscopy in a trial-and-error manner preoperatively and intraoperatively. Localization system mainly consisted of preoperative applied radiopaque frame and intraoperative guiding device, which has the potential to minimize fluoroscopy repetition in MISS. The study aimed to evaluate the efficacy of a novel lumbar localization system in reducing radiation exposure to patients.

Included patients underwent minimally invasive transforaminal lumbar interbody fusion (MISTLIF) or percutaneous transforaminal endoscopic discectomy (PTED). Patients treated with novel localization system were regarded as Group A, and patients treated without novel localization system were regarded as Group B.

For PTED, The estimated effective dose was 0.41 ± 0.13 mSv in Group A and 0.57 ± 0.14 mSv in Group B ($P < .001$); the fluoroscopy exposure time of PTED was 22.18 ± 7.30 seconds in Group A and 30.53 ± 7.56 seconds in Group B ($P < .001$); The estimated cancer risk of radiation exposure was 22.68 ± 7.38 (10^{-6}) in Group A and 31.20 ± 7.96 (10^{-6}) in Group B ($P < .001$). For MISTLIF, the estimated effective dose was 0.45 ± 0.09 mSv in Group A and 0.58 ± 0.09 mSv in Group B ($P < .001$); The fluoroscopy exposure time was 25.41 ± 5.52 seconds in Group A and 32.82 ± 5.03 seconds in Group B ($P < .001$); The estimated cancer risk was 24.90 ± 5.15 (10^{-6}) in Group A and 31.96 ± 5.04 (10^{-6}) in Group B ($P < .001$). There were also significant differences in localization time and operation time between the 2 groups either for MISTLIF or PTED.

The lumbar localization system could be a potential protection strategy for minimizing radiation hazards.

Abbreviations: AP = anteroposterior, DAP = dose-area product, E = effective dose, ET = fluoroscopy exposure time, FT_{AP} = anteroposterior fluoroscopy times, FT_L = lateral fluoroscopy times, ICRP = International Commission on Radiological Protection, L = lateral, MISS = minimally invasive spinal surgery, MISTLIF = minimally invasive transforaminal lumbar interbody fusion, MRI = magnetic resonance imaging, PTED = percutaneous transforaminal endoscopic discectomy, R_C = radiation-induced cancers, R_H = hereditary disorders, SD = standard deviation.

Keywords: minimally invasive spinal surgery, novel lumbar localization methods, percutaneous transforaminal endoscopic discectomy, radiation exposure, transforaminal lumbar interbody fusion

1. Introduction

Degenerative lumbar disease is a common spinal disease. Although a selected group of patients with degenerative lumbar disease can be managed with conservative treatment, many patients require surgical intervention to relieve pain, restore function, and improve quality of life. The efficacy of surgical treatment for degenerative lumbar disease has been confirmed by prospective randomized controlled trials.[1] Recently, minimally invasive spine surgery (MISS) has been rapidly spread all over the world, among which minimally invasive transforaminal lumbar interbody fusion (MISTLIF) [2] and percutaneous transforaminal endoscopic discectomy (PTED) [3] are 2 of the most popular and representative techniques for degenerative lumbar disease. MISTLIF has been confirmed by robust data with noninferior efficacy to open TLIF as well as merits of less intraoperative blood loss, lower infection rates, cost saving, and shorter hospital stay.[4,5] Similarly, PTED was well validated by numerous studies with minimal tissue injury, local anesthesia, no neuromuscular retraction, rapid recovery, and short operation time.[6,7]

However, MISS technique requires radiographic fluoroscopy to compensate the lack of open visualization, which is associated with great radiation concerns among medical staff and

Editor: Johannes Mayr.

Authorship: GF and SH conceived and design the study. XG and YF undertook acquisition of data. HZ and XG analyzed and interpreted the data. GF drafted the manuscript. HZ and XG performed critical revision of the manuscript.

The authors have no conflicts of interest.

No funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

This profile of work has not been under publish consideration elsewhere or submitted elsewhere for publication, in whole or in part.

Orthopedic Department, Shanghai Tenth People's Hospital, Tongji University School of Medicine, Shanghai, China.

** Correspondence: Shisheng He, 301 Yanchang Road, Shanghai 200072, China (e-mails: tjhss7418@foxmail.com; tjhss7418@tongji.edu.cn).*

Medicine (2017) 96:21(e6684)

Received: 29 October 2016 / Received in final form: 15 March 2017 / Accepted: 19 March 2017

http://dx.doi.org/10.1097/MD.0000000000006684

patients.[8] It is well validated that MISS induced more radiation exposure than open procedures.[9] Therefore, it is essential to minimize the iatrogenic radiation exposure to surgeons and patients during MISS. The implication of fluoroscopy for MISS is to induce an accurate preoperative localization of the spine and guiding the instruments and therapy. The conventional localization methods for MISS were mainly based on repeated fluoroscopy in a trial-and-error manner preoperatively and intraoperatively.[10] The fluoroscopy repetition increases the radiation exposure to patients and operators with a higher risk of radiation-related hazards, even at low radiation doses.[11] Therefore, a lumbar localization system consisted of practical preoperative radiopaque frame and intraoperative guiding devices were developed for MISS to modify the fluoroscopy methods and minimize fluoroscopy repetition.[3] The primary goal of the study was to investigate the efficacy of the lumbar localization system in reducing radiation exposure and risks of radiation-induced disease in MISTLIF and PTED.

2. Methods

2.1. Participants

This prospective obervational study was approved by the Ethical Committee of Shanghai Tenth People's Hospital, and informed consent was obtained from all subjects. We confirmed that all methods were carried out in accordance with relevant guidelines and regulations. We identified patients who have persistent or recurrent low back pain or leg pain and a significant reduction of quality of life, despite conservative therapy, including physical therapy and pain management. The eligible patients were degenerative lumbar disease confirmed by imaging assessment [e.g., magnetic resonance imaging (MRI), computed tomography, X-ray radiography] with corresponding symptoms and signs. The inclusion criteria for PTED was symptomatic lumbar disc herniation with/without calcification or foraminal stenosis or lateral recess stenosis, and the inclusion criteria for MISTLIF was symptomatic lumbar stenosis or degenerative disc disease combined with segmental instability. The exclusion criteria of the current study were severe mental illness; severe obesity or osteoporosis; active infection, vertebral fractures, lumbar sacralization at L5/S1 level; combination of coronal and/or sagittal deformities that needed a surgical correction; and age less than 18 years. Patients receiving novel localization methods were regarded as Group A, and those with a conventional localization method were regarded as Group B. There were 3 spine surgeons involved in the study, and all of them conducted MISS in both groups.

2.2. Localization system

Localization system mainly consisted of preoperative applied radiopaque frame and intraoperative guiding device. The radiopaque frame is portable and can be used repeatedly without sterilization. It is made up of radiopaque material with a size of 9×18 cm, which consists of 4 longitudinal crossbars and 19 horizontal crossbars with 1 cm interval (Fig. 1A). For rapid recognition of surrounding anatomic features, sequential numbers of different patterns (circle, triangles, rectangular, etc) are made on horizontal crossbars. For PTED, preoperative applied radiopaque frame was used to plan the puncture trajectory on the skin. For MISTLIF, preoperative applied radiopaque frame can be used to identify the related vertebral arch of the surgical level.

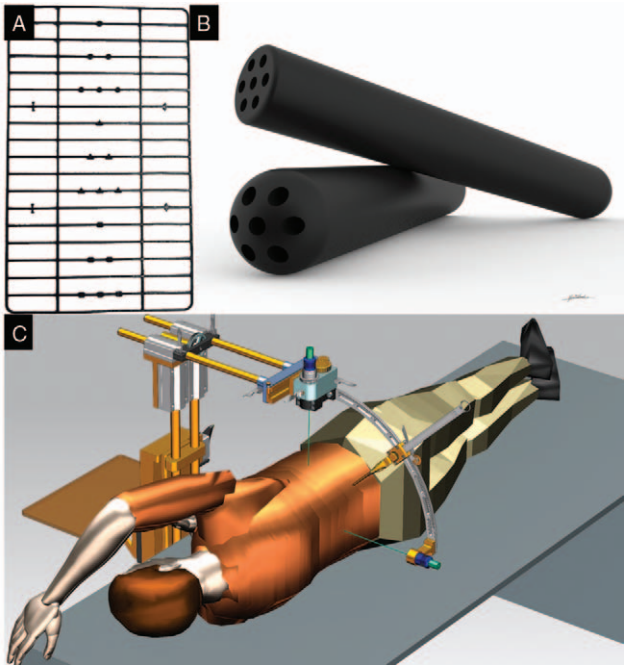

Figure 1. Lumbar localization system for modifying the fluoroscopy in minimally invasive spine surgery. (A) Radiopaque frame for preoperative localization; (B) Intraoperative screw-assisted tool for minimally invasive transforaminal lumbar interbody fusion; (C) Intraoperative puncture-guided instrument for percutaneous transforaminal endoscopic discectomy.

For MISTLIF, the intraoperative guiding device is a plastic bullet-shaped screw-assisted tool with 7 tubes 12 cm in length and 1.5 cm in diameter (Fig. 1B). The tubes of the screw-assisted device are used for the insertion of K-wires, among which we can identify the most ideal one for percutaneous pedicle screw placement under fluoroscopy. The screw-assisted device reused several times after plasma sterilization. For PTED, the intraoperative guiding device is a puncture-guided instrument that is mainly based on isocentric theory keeping the puncture trajectory in tract (Fig. 1C). The arc can be rotated freely along the vertical axis and is equipped with a slider. There are 2 beam generators in the terminal vertex of the arc for localization. The rotation of the arch creates a sphere that can keep the puncture target always remain at the center of a virtual sphere.

2.3. Localization methods

2.3.1. Conventional localization methods. Patients in Group B underwent the conventional localization methods. For preoperative localization, we used surgical instruments (e.g., K wire or nucleus pulposus clamp) with repeated fluoroscopy to identify the surgical target in a trial-and-error manner (Fig. 2A). In PTED, the intraoperative fluoroscopy was repeated on the basis of a trial-and-error manner to conduct an ideal puncture and obtain an optimal placement of working channel (Fig. 2B). In MISTLIF, the intraoperative fluoroscopy was also repeated on the basis of a trial-and-error manner to achieve accurate placement of percutaneous pedicle screws (Fig. 2C). The abovementioned methods have been well documented in previous studies.[2,12–14]

2.3.2. Novel localization methods. In Group A, the novel lumbar localization method for MISS was modified by adding localization. For preoperative localization, the radiopaque frame

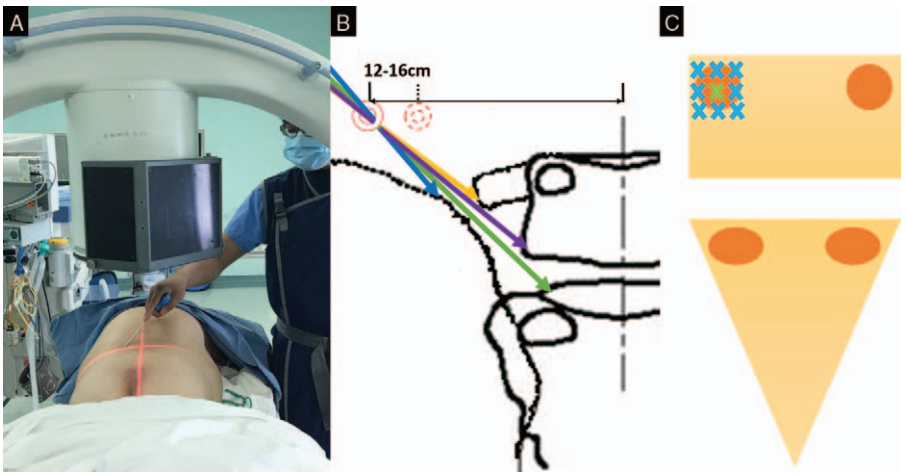

Figure 2. Conventional localization methods with trial-and-error manner for minimally invasive spine surgery. (A) Preoperative localization with surgical instrument obtained by repeated fluoroscopy. (B) Ideal puncture trajectory (green) was obtained by repeated fluoroscopy. (C) Ideal insertion spot for Kirschner wires was obtained under repeated fluoroscopy.

was attached to the skin by adhesive tape (Fig. 3A). Generally, we might just need 1 fluoroscopy to identify all the anatomic features with the surrounding markers on the radiopaque frame (Fig. 3B). Then, we marked the anatomic details on the skin with the surrounding relationship of the radiopaque frame (Fig. 3C). Usually, we marked the upper and the inferior vertebral arches of the surgical level, as well as the midline and the edge of inferior vertebrae (Fig. 3D). A trajectory was planned for PTED (yellow arrow) and incisions lateral to the vertebral arches were made for MISTLIF (short blue line). The intraoperative modified fluoroscopy methods are demonstrated as follows.

For PTED, we conducted the anteroposterior (AP) fluoroscopy and lateral fluoroscopy with radiopaque frames attached to the back and the lateral skin (Fig. 4A). Then, we planned the ideal

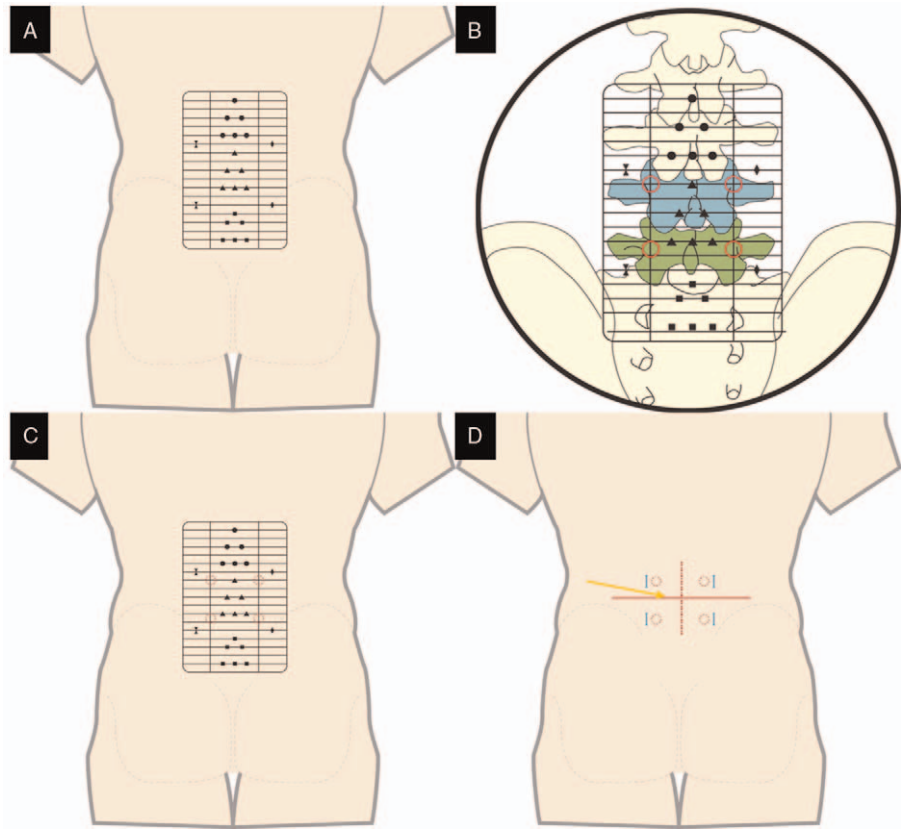

Figure 3. Preoperative localization method modified with radiopaque frame. (A) Radiopaque frame attached to the skin; (B) Anatomic features were identified with the surrounding relationship of various markers under one fluoroscopy; (C) Identified features were marked on the skin; (D) Puncture trajectory for percutaneous transforaminal endoscopic discectomy was planned and surgical incision for minimally invasive transforaminal lumbar interbody fusion was made.

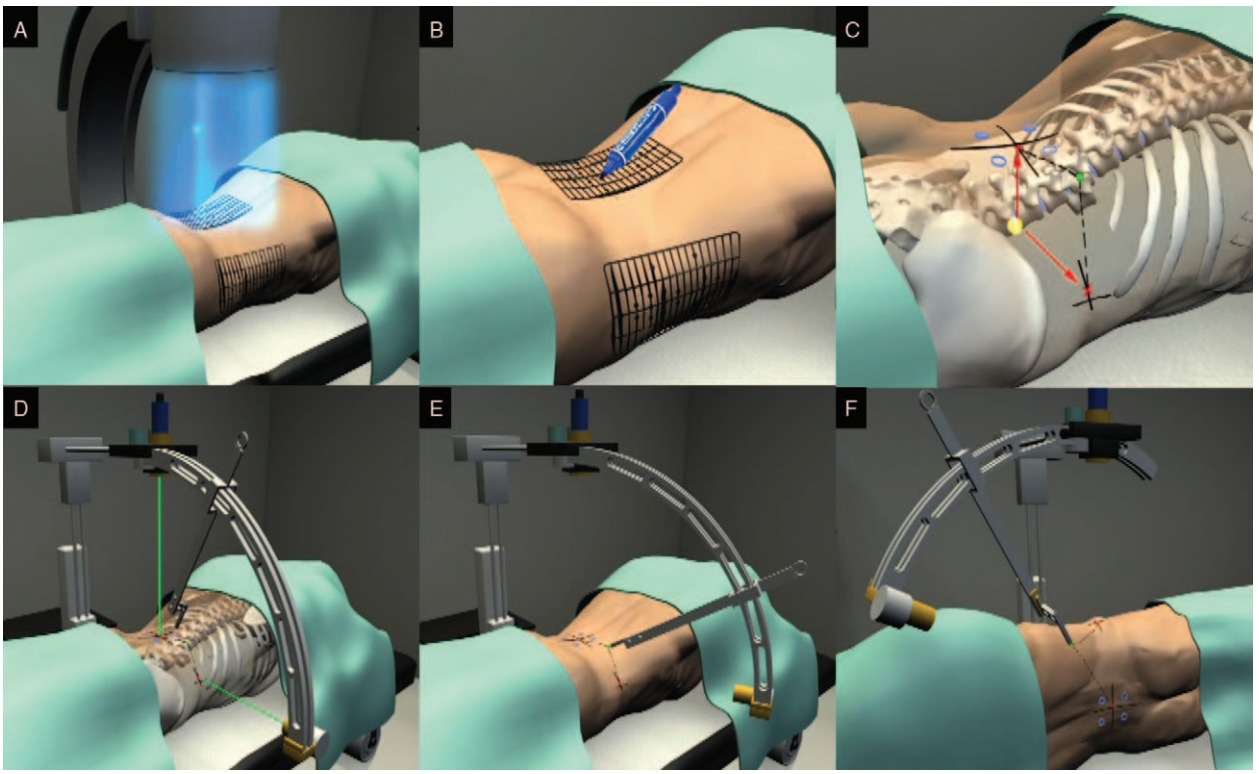

Figure 4. Intraoperative localization method for percutaneous transforaminal endoscopic discectomy. (A) Anteroposterior and lateral fluoroscopy with radiopaque frames attached to the back and lateral skin; (B) ideal trajectory marked on the skin for planning the procedure; (C) Entry point (green point) for puncture was the intersection of the posterior projection line and the lateral projection line of the planned trajectory to the puncture target; (D) vertical beam onto the posterior projection of the puncture target and the lateral beam onto the lateral projection of the puncture target; (E) Puncture target still remained at the center of a virtual sphere when the arch was rotated along the vertical axis; (F) Puncture-guided instrument could also be used in lateral position.

trajectory on the skin with the references of anatomic features (Fig. 4B). The entry point (green point) for puncture was the intersection of the posterior projection line and the lateral projection line of the virtual trajectory to the puncture target (Fig. 4C). Thereafter, the puncture-guided instrument was positioned with the vertical beam onto the posterior projection of the puncture target and the lateral beam onto the lateral projection of the puncture target (Fig. 4D). At the moment, the puncture target remained at the center of a virtual circle. When the arch was rotated along the vertical axis, the puncture target still remained at the center of a virtual sphere (Fig. 4E). The puncture-guided instrument could also be applied for PTED in lateral position (Fig. 4F).

For MISTLIF, we inserted the screw-assisted tool with several Kirschner wires (Fig. 5A). Under fluoroscopy, we identified the most ideal Kirschner wire and selected it for percutaneous pedicle screw placement (Fig. 5B). Several Kirschner wires were placed; ideally, we selected a suboptimal one and used it for rotation (Fig. 5C). Then, we inserted several Kirschner wires again for fluoroscopy (Fig. 5D). The most appropriately placed Kirschner wire was identified and the others were removed (Fig. 5E). Then, we inserted the guide wire to replace the Kirschner wire and removed the screw-assisted tool (Fig. 5F). The following procedure of MISTLIF was as usual.

2.3.3. Observational outcomes. Basic information of the patients in the 2 groups including age, gender, surgical segment, and surgical technique were collected. The primary outcome was estimated effective dose (E) and radiation-induced risks, and the secondary outcomes were fluoroscopy exposure time (ET), fluoroscopy times, preoperative localization time, and operation time. Other clinical outcomes such as estimated blood loss, hospital stay, perioperative complications, and postoperative satisfaction (MacNab criteria: excellent, good, fair, poor) were also recorded.

In order to estimate effective dose and ionizing radiation induced risks, we adopted a well-validated estimation method primarily referenced in a systematic review.[15] In our study, the surgical site was L4/5 level and L5/S1 level, and the focus to image intensifier distance of the C-arm fluoroscope was 90 to 100 cm. Thus, we could generally suppose the mean values for tube voltage, tube current, and source to skin dose to be the same.[15] Because the dose-area product (DAP) in the AP and lateral (L) position were not measured in the study, we might not directly calculate the skin entry dose and effective dose. However, we could use the fluoroscopy ET in minutes to estimate the corresponding DAP summarized in a previous regression study.[16] The DAP values ($cGy \times cm\text{^}2$) could be calculated using the following formula.

$$DAP_{AP} = 4.77 \times ET_{AP}$$
$$DAP_{L} = 6.19 \times ET_{L}$$

We might not directly obtain the ET_{AP} or ET_{L} from the C-arm fluoroscopy machine, but we recorded the AP fluoroscopy times (FT_{AP}) and lateral fluoroscopy times (FT_{L}). As we assumed linear relationship between fluoroscopy times and fluoroscopy ET, ET_{AP} and ET_{L} could be calculated with the following formula.

$$ET_{AP} = ET_{TOTAL} \times FT_{AP} / FT_{TOTAL}$$
$$ET_{L} = ET_{TOTAL} \times FT_{L} / FT_{TOTAL}$$

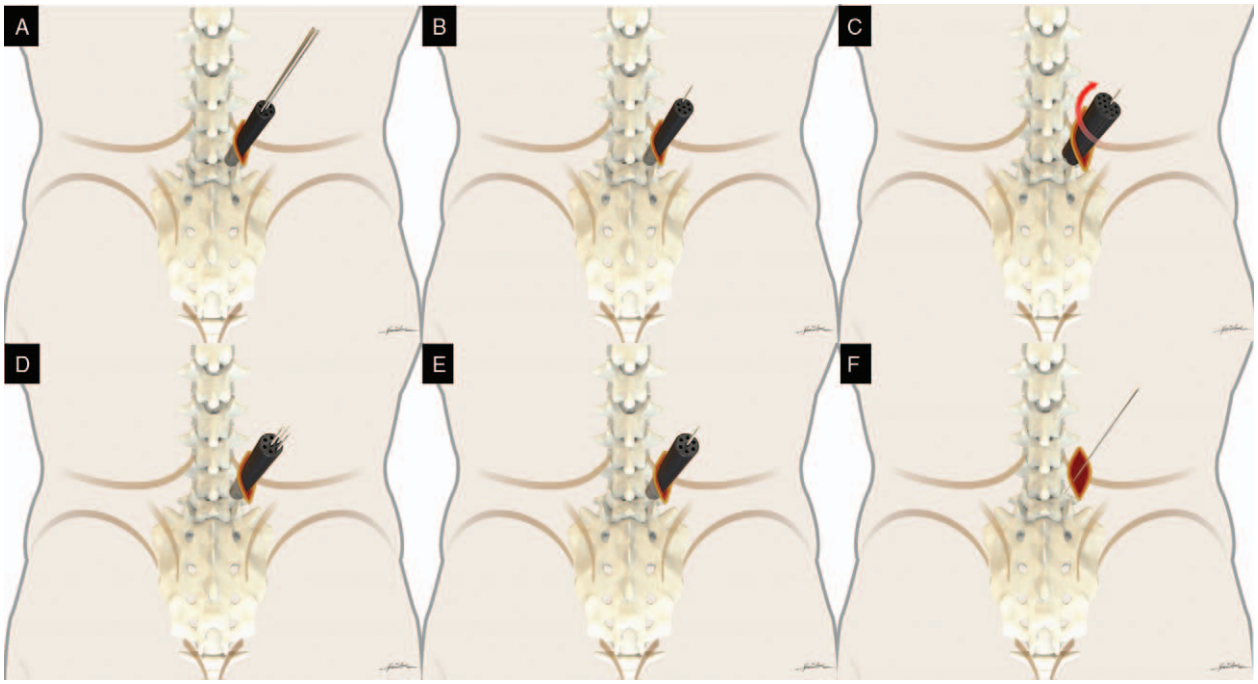

Figure 5. Intraoperative localization method for minimally invasive transforaminal lumbar interbody fusion. (A) Insertion of screw-assisted tool with Kirschner wires in the tubes; (B) Most appropriate Kirschner wire was identified with one fluoroscopic scan; (C) Screw-assisted tool was rotated along with the suboptimal Kirschner wire if none of the inserted Kirschner wires were ideal; (D) Several Kirschner wires near the optimal position were inserted again for fluoroscopy; (E) Most ideal Kirschner wire was selected and the others were removed; (F) The guide wire was inserted to replace Kirschner wire and the screw-assisted tool was removed.

Thereafter, we calculated E by weighting the radiation concentration stored in organs with constants that reflect the radiation type and the potential for radiation hazards to organs in a reference subject.[17,18]

$$E_{TOTAL} = E_{AP} + E_L = (\varepsilon_{AP} \times DAP_{AP}) + (\varepsilon_L \times DAP_L)$$

As demonstrated in a prior validated study,[19] the dose conversion coefficients (ε_{AP} and ε_L) in the lumbar spine (L5) were 3.47 and 0.93, respectively.

According to the International Commission on Radiological Protection (ICRP) publication 103,[20] the risk for radiation-induced cancers (R_C) and detrimental hereditary disorders (R_H) could be calculated by the following formulae:

$$R_C = 0.055 \times E \text{ (Sv)}$$
$$R_H = 0.002 \times E \text{ (Sv)}$$

2.3.4. Statistical analysis. Statistic software SPSS17.0 (SPSS, Inc., Chicago, IL) was used to conduct the statistical analysis of the study. Measurement data were demonstrated as mean ± standard deviation (SD). Mann–Whitney *U* test was used to compare the difference of continuous variables between the 2 groups. Chi-square test was used to compare the difference of enumeration data of the 2 groups. Statistical differences were regarded as significant when the probability value was less than 0.05.

3. Results

A total of 249 eligible patients were included from July 2015 to May 2016 in our center (Table 1). There were no significant differences in gender, age, surgical levels, surgical technique, and surgeons ($P > .05$). All included patients successfully completed PTED (Fig. 6) or MISTLIF (Fig. 7) without transfer to open surgeries.

As demonstrated in Table 2, the fluoroscopy ET of PTED was 22.18 ± 7.30 seconds in Group A and 30.53 ± 7.56 seconds in Group B ($P < .001$). The estimated effective dose was 0.41 ± 0.13 mSv in Group A and 0.57 ± 0.14 mSv in Group B ($P < .001$). The estimated cancer risk was 22.68 ± 7.38 (10^{-6}) in Group A and 31.20 ± 7.96 (10^{-6}) in Group B ($P < .001$). The estimated risk for detrimental hereditary disorders was 0.82 ± 0.27 (10^{-6}) in Group A and 1.13 ± 0.29 (10^{-6}) in Group B ($P < .001$). However, there were no significant differences in hospital stay, patients' satisfaction of MacNab criteria, and perioperative complications ($P > .05$).

As demonstrated in Table 3, the fluoroscopy ET of MISTLIF was 25.41 ± 5.52 seconds in Group A and 32.82 ± 5.03 seconds in Group B ($P < .001$). The estimated effective dose was 0.45 ± 0.09

Table 1

Basic information of included patients undergoing minimally invasive spine surgery.

Variables	Group A (n = 123)	Group B (n = 126)	*P*
Gender (male: female)	60:63	59:67	.261
Age, y	51.83 ± 8.77	53.06 ± 8.02	.272
Surgical levels			.261
L4/5	63	65	
L5/S1	60	61	
Surgical technique			.135
PTED	89	92	
MISTLIF	34	34	
Surgeons			.285
Surgeon 1	52	51	
Surgeon 2	39	38	
Surgeon 3	32	37	

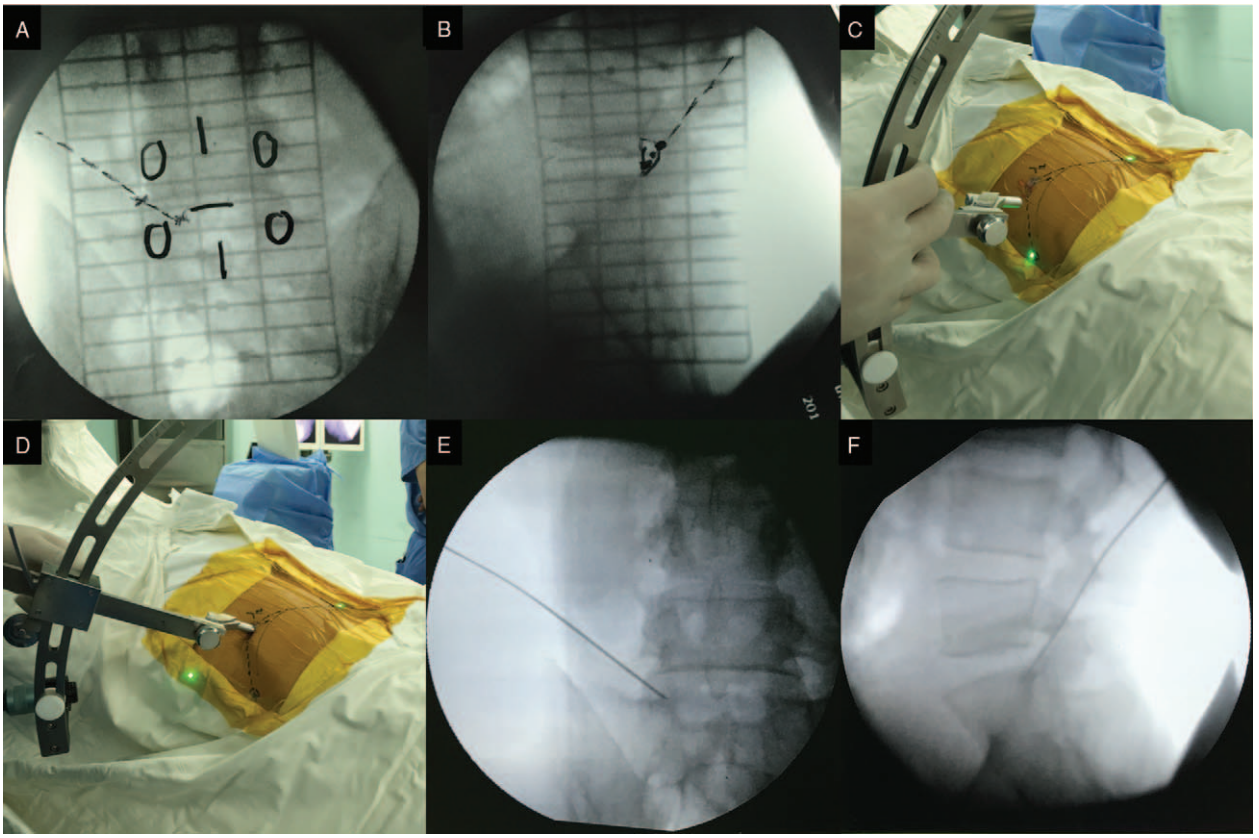

Figure 6. Typical case of percutaneous transforaminal endoscopic discectomy with localization methods. (A) Posterior projection of planned trajectory; (B) lateral projection of planned trajectory; (C) positioning of puncture-guided instrument with puncture target at the center of the arch; (D) arch was rotated along the vertical axis with needle guider to the entry point; € anteroposterior fluoroscopic scan with needle pointing to the puncture target; (F) lateral fluoroscopic scan with needle pointing to the puncture target.

mSv in Group A and 0.58 ± 0.09 mSv in Group B ($P < .001$). The estimated cancer risk was 24.90 ± 5.15 (10^{-6}) in Group A and 31.96 ± 5.04 (10^{-6}) in Group B ($P < .001$). The estimated risk for detrimental hereditary disorders was 0.91 ± 0.19 (10^{-6}) in Group A and 1.16 ± 0.18 (10^{-6}) in Group B ($P < .001$). However, there were no significant differences in hospital stay, estimated blood loss, patients' satisfaction of MacNab criteria, and perioperative complications ($P > .05$).

4. Discussions

Repeated fluoroscopic scanning is essential for MISS such as PTED and MISTLIF, which increased the radiation exposure to patients. Therefore, the tactics of minimizing radiation exposure is reducing the necessity of repeating fluoroscopic scanning. The novel lumbar localization was developed to reduce the necessity of repeated fluoroscopic scanning. Applying this technique, we achieved a significant reduction of fluoroscopy ET, and radiation dose, lower radiation-induce disease risks, shorter localization time, and operation time in PTED and MISTLIF. The novel localization system could be a potential protection strategy for minimizing ionizing radiation hazards.

Radiation exposure is a great concern, as it is associated with an increased risk of cancer and other disorders in fluoroscopically guided procedures.[21] High-dose ionizing radiation could directly induce cancer, hereditary disease, cataract, cardiovascular disease, and so on, and even low-dose radiation is associated with them.[22,23] Although MISS offers numerous advantages over open spine surgery in reducing blood loss, hospital stay, and perioperative complication rates, it is associated with a prolonged operation time and an increased ionizing radiation exposure.[24] A recent systematic review found that patients who underwent MISTLIF were exposed to 2.4-fold more radiation than those who underwent open TLIF.[15] Similarly, Bindal et al[25] found that annual dose limits recommended by ICRP for surgeons would be potentially exceeded if a large volume of MISTLIF was conducted. They also quantified patient's skin dose with 59.5 mGy in AP fluoroscopy and 78.8 mGy in lateral fluoroscopy. As for PTED, the data quantifying the radiation exposure dose to patients was scarce. Only 1 study found that the average radiation exposure dose to patients was 1.5 mSv at L4/5 level and 2.1 mSv at L5/S1 level.[26] The only other study concerning radiation exposure for PTED focused on measuring the radiation dose to surgeons, and they found that only 291 PTED cases could be conducted annually to stay occupational dose limits without any protection.[27] However, there were no studies to demonstrate the risk of radiation-induced cancer or hereditary disease in PTED. To the best of our knowledge, the present study is the first to estimate R_C ($22.68 \sim 31.20 \times 10^{-6}$) and R_H ($0.82 \sim 1.13 \times 10^{-6}$) of patients in PTED. We also estimated R_C ($24.90 \sim 31.96 \times 10^{-6}$) and R_H ($0.91 \sim 1.16 \times 10^{-6}$) of patients in MISTLIF, which were similar with a previous report.[15] The estimated radiation-induced disease risks might be tolerable, but the stochastic effects of radiation exposure in MISS should not be disregarded.

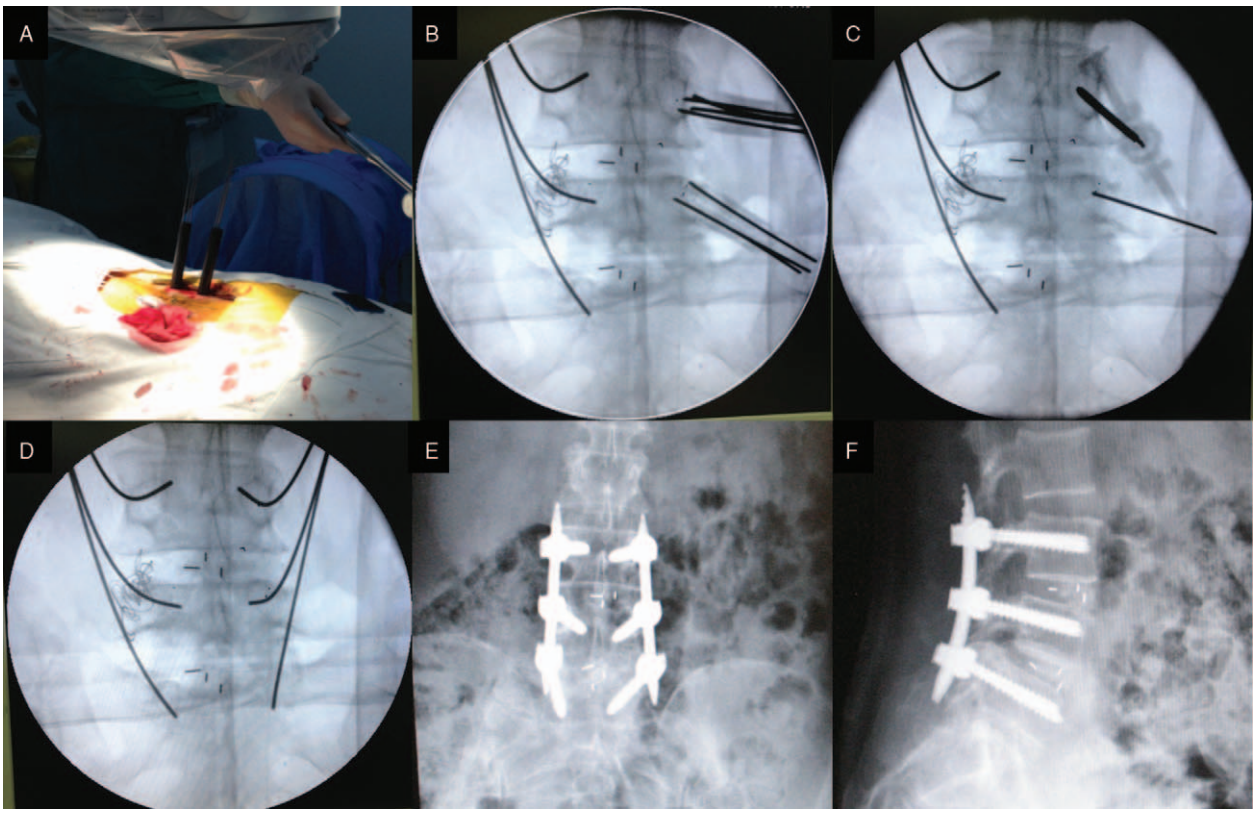

Figure 7. Typical case of minimally invasive transforaminal lumbar interbody fusion with localization methods. (A) Insertion of screw-assisted tools with several Kirschner wires; (B) We obtained 1 fluoroscopic image to identify the most appropriate Kirschner wire; (C) The screw-assisted tool was removed and the puncture needle was inserted; (D) Guide wires were inserted; (E) final anteroposterior fluoroscopic scan of minimally invasive transforaminal lumbar interbody fusion; (F) final lateral fluoroscopic scan of minimally invasive transforaminal lumbar interbody fusion.

Table 2

Clinical outcomes of percutaneous transforaminal endoscopic discectomy with modified fluoroscopy methods or conventional fluoroscopy methods.

Variables	Group A (n = 89)	Group B (n = 88)	*P*
Exposure time, s	22.18 ± 7.30	30.53 ± 7.56	<.001
Fluoroscopy times	24.98 ± 7.87	33.85 ± 8.04	<.001
Fluoroscopy times (AP)	12.49 ± 3.91	16.91 ± 4.16	<.001
Fluoroscopy times, L	12.48 ± 3.88	16.94 ± 4.17	<.001
Estimated DAP_{AP}, cGy·cm^2	88.19 ± 28.87	121.25 ± 31.00	<.001
Estimated DAP_L, cGy·cm^2	114.32 ± 37.06	157.66 ± 40.35	<.001
Estimated effective dose, mSv	0.41 ± 0.13	0.57 ± 0.14	<.001
Estimated cancer risk, 10^{-6}	22.68 ± 7.38	31.20 ± 7.96	<.001
Estimated risk for detrimental hereditary disorders, 10^{-6}	0.82 ± 0.27	1.13 ± 0.29	<.001
Location time, min	4.64 ± 1.04	5.95 ± 1.21	<.001
Operation time, min	69.40 ± 12.59	77.42 ± 14.90	.001
Hospital stay, d	3.31 ± 1.18	3.24 ± 1.16	.764
MacNab criteria			.155
Excellent	48	51	
Good	36	33	
Fair	4	3	
Poor	1	1	
Perioperative complications			.382
Superficial surgical site infection	1	0	
Postoperative dysesthesia	1	2	
Asymptomatic residual disc	2	3	

However, people were endeavored to take all kinds of protection strategies for minimizing the radiation exposure. In brief, all kinds of radiation protection methods could be summarized into several strategies, including extending the distance, enhancing the shielding, and controlling the source of radiation. Extending the distance and enhancing the shielding are 2 conventional strategies that surgeons adopted routinely in practice.[28] For patients, however, we have to focus on the strategy of source control, including improvement of the imaging guidance system and their frequency of use. More and more novel instruments such as O-arm fluoroscopy and MRI guidance systems were developed to obtain more accurate 3-dimensional reconstruction for navigation in MISS.[29,30] However, while O-arm fluoroscopy provided more facilities and less scatter radiation to surgeons, it also increased more iatrogenic radiation exposure to patients than conventional fluoroscopy.[31] MRI-guided technique did not gain widespread adoption because of the high cost of the technology.[32] A feasibility also introduced the ultrasound-tracked techniques for navigation, but this technique was still under development and further studies are required to improve and validate this technology.[33] On the contrary, robotic guidance systems were also found to facilitate reduction of radiation exposure of surgeons.[34] However, the robotic guidance system is very costly and space consuming, and it theoretically requires absolute immobilization. Moreover, the registration has inherent localization errors, and conventional surgical table will disturb the referencing process.[35] Instead, the novel and practical localization system is characterized by high

Table 3

Clinical outcomes of minimally invasive transforaminal lumbar interbody fusion with modified fluoroscopy methods or conventional fluoroscopy methods.

Variables	Group A (n = 34)	Group B (n = 38)	*P*
Exposure time, s	25.41 ± 5.52	32.82 ± 5.03	<.001
Fluoroscopy times	28.82 ± 5.76	36.21 ± 5.49	<.001
Fluoroscopy times (AP)	13.00 ± 2.53	16.34 ± 2.72	<.001
Fluoroscopy times, L	16.11 ± 3.30	19.84 ± 2.91	<.001
Estimated DAP_{AP}, cGy·cm^2	91.16 ± 19.10	117.76 ± 19.91	<.001
Estimated DAP_{L}, cGy·cm^2	146.58 ± 32.09	185.49 ± 27.26	<.001
Estimated effective dose, mSv	0.45 ± 0.09	0.58 ± 0.09	<.001
Estimated cancer risk, 10^{-6}	24.90 ± 5.15	31.96 ± 5.04	<.001
Estimated risk for detrimental hereditary disorders, 10^{-6}	0.91 ± 0.19	1.16 ± 0.18	<.001
Location time, min	4.00 ± 0.36	6.63 ± 1.16	<.001
Operation time, min	147.47 ± 13.89	167.50 ± 16.62	<.001
Hospital stay, d	11.94 ± 2.32	11.71 ± 2.81	.390
Blood loss, mL	306.18 ± 71.43	295.53 ± 75.00	.377
MacNab criteria			.155
Excellent	14	20	
Good	19	16	
Fair	1	2	
Poor	0	0	
Perioperative complications			.238
Cerebral fluid leakage	1	1	
Superficial surgical site infection	0	1	

compatibility with conventional fluoroscopy methods. The core tactic was to reduce the fluoroscopy repetition, resulting in lower radiation exposure in both patients and surgeons. Nearly 30% reductions were observed in fluoroscopy ET, estimated effective dose to patients, R_C and R_H for PTED in the study. Similarly, over 20% reductions were observed in fluoroscopy ET, estimated effective dose, R_C and R_H for MISTLIF with novel localization system. In addition, the localization time and operation time with the novel localization system were also significantly lower than those with the conventional fluoroscopy, either for PTED or MISTLIF.

Several limitations should be noted when interpreting our data. First of all, several assumptions were made to estimate the effective dose and disease risk of radiation exposure. We admit that there are many other affecting factors such as fluoroscopy setting and body habitus, but estimation calculations of effective dose have been widely used in many other robust studies including one published in *New England Journal of Medicine*.[16,17,31,36–38] Regardless, clinical trials are still needed to quantify the actual radiation dose to patients. In addition, we could not apply double-blinded procedures in our study. Last but might not least, we did not estimate the effective dose or potential risks to medical staff because of complex situations. This was another major concern. However, we are currently conducting a study to measure the radiation dose to sensitive organs of surgeons.

5. Conclusions

The whole tactics of the novel localization system reduced the necessity of repeated fluoroscopic scanning. We achieved a 20% to 30% reduction in ET to ionizing radiation, estimated effective dose to patients, and Rc and R_H for MISS. The radiation protection tactic of reducing fluoroscopy repetition was feasible and practical. This novel localization method could be a potential protection strategy for minimizing the radiation hazards.

Acknowledgment

We thank the academic club SHEPHERD for providing linguistic support.

References

[1] Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical compared with nonoperative treatment for lumbar degenerative spondylolisthesis. Four-year results in the Spine Patient Outcomes Research Trial (SPORT) randomized and observational cohorts. J Bone Joint Surg Am 2009;91:1295–304.

[2] Fan G, He S, Gu G, et al. Minimally invasive transforaminal lumbar interbody fusion for isthmic spondylolisthesis: in situ versus reduction. World Neurosurg 2016;90:580–7. e1.

[3] Fan G, Guan X, Sun Q, et al. Puncture reduction in percutaneous transforaminal endoscopic discectomy with HE's Lumbar LOcation (HELLO) system: a cadaver study. PLoS One 2015;10:e0144939.

[4] Phan K, Rao PJ, Kam AC, et al. Minimally invasive versus open transforaminal lumbar interbody fusion for treatment of degenerative lumbar disease: systematic review and meta-analysis. Eur Spine J 2015;24:1017–30.

[5] Goldstein CL, Phillips FM, Rampersaud YR. Comparative effectiveness and economic evaluations of open versus minimally invasive posterior or transforaminal lumbar interbody fusion: a systematic review. Spine (Phila Pa 1976) 2016;41(Suppl 8):S74–89.

[6] Gadjradj PS, Van Tulder MW, Dirven CM, et al. Clinical outcomes after percutaneous transforaminal endoscopic discectomy for lumbar disc herniation: a prospective case series. Neurosurg Focus 2016;40:E3.

[7] Rasouli MR, Rahimi-Movaghar V, Shokraneh F, et al. Minimally invasive discectomy versus microdiscectomy/open discectomy for symptomatic lumbar disc herniation. Cochrane Database Syst Rev 2014;9:Cd010328.

[8] Tumialan LM, Clark JC, Snyder LA, et al. Prospective evaluation of a low-dose radiation fluoroscopy protocol for minimally invasive transforaminal lumbar interbody fusion. Neurosurgery 2015;11: DOI: 10.1227/NEU.0000000000000960.

[9] Yu E, Khan SN. Does less invasive spine surgery result in increased radiation exposure? A systematic review. Clin Orthop Relat Res 2014;472:1738–48.

[10] Grelat M, Greffier J, Sabatier P, et al. Assessment of the radiation exposure of surgeons and patients during a lumbar microdiscectomy and a cervical microdiscectomy: a French prospective multicenter study. World Neurosurg 2016;89:329–36.

[11] Srinivasan D, Than KD, Wang AC, et al. Radiation safety and spine surgery: systematic review of exposure limits and methods to minimize radiation exposure. World Neurosurg 2014;82:1337–43.

[12] Fan G, Guan X, Zhang H, et al. Significant improvement of puncture accuracy and fluoroscopy reduction in percutaneous transforaminal endoscopic discectomy with novel lumbar location system: preliminary report of prospective hello study. Medicine (Baltimore) 2015;94:e2189.

[13] Fan G, Gu X, Liu Y, et al. Lower learning difficulty and fluoroscopy reduction of transforaminal percutaneous endoscopic lumbar discectomy with an accurate preoperative location method. Pain Physician 2016;19:E1123–e1134.

[14] Fan G, Han R, Gu X, et al. Navigation improves the learning curve of transforamimal percutaneous endoscopic lumbar discectomy. Int Orthop 2017;41:323–32.

[15] Kim CH, Lee CH, Kim KP. How high are radiation-related risks in minimally invasive transforaminal lumbar interbody fusion compared with traditional open surgery? A meta-analysis and dose estimates of ionizing radiation. Clin Spine Surg 2016;29:52–9.

[16] Boszczyk BM, Bierschneider M, Panzer S, et al. Fluoroscopic radiation exposure of the kyphoplasty patient. Eur Spine J 2006;15:347–55.

[17] Fazel R, Krumholz HM, Wang Y, et al. Exposure to low-dose ionizing radiation from medical imaging procedures. N Engl J Med 2009;361:849–57.

[18] Le Heron JC. Estimation of effective dose to the patient during medical x-ray examinations from measurements of the dose-area product. Phys Med Biol 1992;37:2117–26.

[19] Perisinakis K, Damilakis J, Theocharopoulos N, et al. Patient exposure and associated radiation risks from fluoroscopically guided vertebroplasty or kyphoplasty. Radiology 2004;232:701–7.

[20] The 2007 recommendations of the International Commission on Radiological Protection. ICRP publication 103. Ann ICRP 2007; 37:1–332.
[21] Fan G, He S, Chen Z. Musculoskeletal pain and cancer risk of staff working with fluoroscopically guided procedures. J Am Coll Cardiol 2015;66:759–60.
[22] Little MP. A review of non-cancer effects, especially circulatory and ocular diseases. Radiat Environ Biophys 2013;52:435–49.
[23] Busby C, Schmitz-Feuerhake I, Pflugbeil S. Genetic radiation risks: a neglected topic in the low dose dabate. Environ Health Toxicol 2016;31: e2016001.
[24] Mariscalco MW, Yamashita T, Steinmetz MP, et al. Radiation exposure to the surgeon during open lumbar microdiscectomy and minimally invasive microdiscectomy: a prospective, controlled trial. Spine (Phila Pa 1976) 2011;36:255–60.
[25] Bindal RK, Glaze S, Ognoskie M, et al. Surgeon and patient radiation exposure in minimally invasive transforaminal lumbar interbody fusion. J Neurosurg Spine 2008;9:570–3.
[26] Iprenburg M, Wagner R, Godschalx A, et al. Patient radiation exposure during transforaminal lumbar endoscopic spine surgery: a prospective study. Neurosurg Focus 2016;40:E7.
[27] Ahn Y, Kim CH, Lee JH, et al. Radiation exposure to the surgeon during percutaneous endoscopic lumbar discectomy: a prospective study. Spine (Phila Pa 1976) 2013;38:617–25.
[28] Lee K, Lee KM, Park MS, et al. Measurements of surgeons' exposure to ionizing radiation dose during intraoperative use of C-arm fluoroscopy. Spine (Phila Pa 1976) 2012;37:1240–4.
[29] Nottmeier EW, Pirris SM, Edwards S, et al. Operating room radiation exposure in cone beam computed tomography-based, image-guided spinal surgery: clinical article. J Neurosurg Spine 2013;19:226–31.
[30] Gianaris TJ, Helbig GM, Horn EM. Percutaneous pedicle screw placement with computer-navigated mapping in place of Kirschner wires: clinical article. J Neurosurg Spine 2013;19:608–13.
[31] Lange J, Karellas A, Street J, et al. Estimating the effective radiation dose imparted to patients by intraoperative cone-beam computed tomography in thoracolumbar spinal surgery. Spine (Phila Pa 1976) 2013;38: E306–12.
[32] Moses ZB, Mayer RR, Strickland BA, et al. Neuronavigation in minimally invasive spine surgery. Neurosurg Focus 2013;35:E12.
[33] Ungi T, Moult E, Schwab JH, et al. Tracked ultrasound snapshots in percutaneous pedicle screw placement navigation: a feasibility study. Clin Orthop Relat Res 2013;471:4047–55.
[34] Lieberman IH, Hardenbrook MA, Wang JC, et al. Assessment of pedicle screw placement accuracy, procedure time, and radiation exposure using a miniature robotic guidance system. J Spinal Disord Tech 2012;25:241–8.
[35] Roser F, Tatagiba M, Maier G. Spinal robotics: current applications and future perspectives. Neurosurgery 2013;72(Suppl 1):12–8.
[36] Theocharopoulos N, Damilakis J, Perisinakis K, et al. Fluoroscopically assisted surgical treatments of spinal disorders: conceptus radiation doses and risks. Spine (Phila Pa 1976) 2006;31:239–44.
[37] 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;30:1893–8.
[38] Fitousi NT, Efstathopoulos EP, Delis HB, et al. Patient and staff dosimetry in vertebroplasty. Spine (Phila Pa 1976) 2006;31:E884–889. discussion E890.