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Radiation Exposure of Fluoroscopic Guidance during Cervical Epidural Steroid Injection: A prospective study

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Radiation Exposure of Fluoroscopic Guidance during Cervical Epidural Steroid Injection: A prospective study

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Abstract

Backgroud and Purpose: To compare the radiation dose during cervical epidural steroid injection (ESI) under continuous and intermittent fluoroscopic guidance (FG), and to assess the radiation dose according to the three radiologists with different level of experiences.

Material and Methods: IRB approval and informed consent were obtained for this study. Total 231 patients (M:F= 107:124; mean age, 50.3 years) who underwent 233 cervical ESIs from July 2011 to October 2011 were prospectively investigated. The radiation dose using dose area product (DAP) and fluoroscopy time (FT) was compared between continuous and intermittent FG for a senior professor. Among three radiologists (senior professor, junior professor, trainee), radiation dose of ESI under continuous FG were also compared. Mann-Whitney U test and ANOVA test were used for the statistical analysis.

Results: Radiation dose under intermittent FG was significantly lower than under continuous FG in terms of DAP (1084.9 vs 506.4 mGy·cm^2 for interlaminar ESI, and 2423.1 vs 799.7 mGy·cm^2 for transforaminal ESI, $p < 0.05$) and in terms of FT (60.7 vs 25.2 sec in interlaminar ESI, and 119.9 vs 80.6 sec in transforaminal ESI, p-value < 0.05). Among the three operators, trainee showed highest radiation dose, but the calculated dose was within tolerable limit (0.65mSv of effective dose).

Conclusion: Intermittent FG is preferable method to continuous FG during cervical ESI in the perspective of radiation exposures, but cervical ESI under continuous FG was within the tolerable limit even performed by the trainee.

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Keywords: Epidural Steroid Injection

Radiation Dose

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Introduction

Cervical epidural steroid injection (ESI) has been commonly used for the conservative management of neck pain or cervical radiculopathy (1-4). Rather than blind manner, fluoroscopy can improve the accuracy of needle placement and medication injection to the targeted area with increasing treatment outcomes (5-8). It can also reduce procedure-related complications such as dural puncture, paraplegia secondary to cord infarction, intravascular injection with cerebellar infartion, and even death (9-13).Despite these advantages, the radiation exposure in ESI to patients and operators remains a serious concern. The ALARA (as low as reasonably achievable) concept of radiation dose is widely recognized and is followed in the practice of radiology to minimize the potential harmful effect of radiation. Multiple technique including protection equipment, reduction of the pulsed fluoroscopy frame rate, removal of the anti-scatter grid, last image hold, improving image collimation, reducing fluoroscopy time, and intermittent fluoroscopy monitoring have been introduced for reducing the radiation dose (14-17).

In our radiology department, we had performed cervical ESI under continuous fluoroscopic guidance during needle advance to ensure exact placement at targeted point. There were clear potential benefits to using the continuous fluoroscopic guidance as patient's safety or prevention of possible complications during needle advance, saving overall procedure time through decrease of needle reposition chance, and easiness for learning trainees. However, continuous fluoroscopic guidance may have a chance to get more radiation dose during the procedure. In this point, intermittent fluoroscopic guiding method has been described as effective to reduce radiation dose and fluoroscopy time (16, 17). To our knowledge, there was no report about comparison of radiation dose during cervical ESI between continuous and intermittent fluoroscopic guidance.

The main aim of our study was to prospectively compare the radiation dose to a experienced radiologist during cervical ESIs under continuous and intermittent fluoroscopic guidance. Although intermittent fluoroscopic guidance is good for radiation dose reduction, continuous fluoroscopic guidance is required for less experienced operators to avoid potential complication during cervical ESI. We hypothesized that radiation dose for continuous fluoroscopic guidance by a less experienced operator is within the tolerable range of radiation exposure. Another purpose of this study is to assess the radiation dose and fluoroscopy time during cervical ESI by continuous fluoroscopic guidance and to compare those according to the different levels of radiologists' experiences. So, the purpose of this study is to compare the radiation dose during cervical ESI under continuous and intermittent fluoroscopic guidance, and to assess the radiation dose during cervical ESI according to the different radiologists.

Materials and Methods

Subjects

Institutional review board approval and written informed consent were obtained for this study. During a four months period from July 2011 to October 2011, 256 consecutive patients (120 male and 136 female patients; mean age, 54.6 years; range, 22-84 years) who underwent cervical ESIs due to neck pain or cervical radiculopathy at our radiology department were enrolled in this prospective study.

Total 25 patients were eliminated in this study because of incomplete measurement for radiation dose or procedure time (n=2), change of operator from trainee to professor during the procedure (n=4), patients' refusal (n=2), and treatment combination with other procedures such as lumbar ESI or caudal block (n=17). As a result, total 231 patients (107 male and 124 female patients; mean age, 50.3 years; range, 22-84 years) who underwent 233 procedures (229 patients with one-level ESI and two patients with two-level ESIs) during this study period were finally investigated.

Cervical ESI was done by one of three radiologists (a senior professor with more than 10,000 cases of experience in ESI procedures, a junior professor, and a trainee in the process of first year of musculoskeletal radiology fellowship). Patients were divided into three groups based on the operators, and the senior professor's group was further divided into two subgroups according to the fluoroscopic guiding technique (continuous versus intermittent). Demographic data with age, gender, number of patients, and number of procedures are demonstrated in Table 1.

Cervical ESI Technique

All cervical ESIs were performed in an angiography suite in two different ways;

interlaminar and transforaminal ESI. The method and level of injection was determined according to the patient's symptom and location of nerve root compression. We used one of two angiography units: the uni-planar (Allura Xper FD 20; Philips Healthcare, Best, the Netherlands) or bi-planar digital subtraction angiography unit (Intergris Xper FD 20; Philips Healthcare, Best, the Netherlands).

For the interlaminar ESI, patient was placed in the prone position. After skin disinfection, a 22 or 25-gauge 12 cm spinal needle was then advanced to the epidural space with a midline or paramidline approach. Test injections of contrast material [Omnipaque 300 (iohexol, 300 mg of iodine per milliliter); Amersham Health, Princeton, NJ, USA] were administered while the needle was being advanced. If the needle did not puncture the ligamentum flavum, the needle was carefully advanced so as not to puncture the dura. When the contrast material in the needle was spreading in epidural space, we stopped advancing the needle and confirmed the needle tip in the epidural space with a test injection of contrast agent. If the epidural space was not found, regardless of enough advancement, we advanced by twirling the needle and opening the ligamentum flavum. An epidurogram was obtained to document the needle position and evaluate the extent of opacification. When the needle was confirmed in the epidural space, we injected 40 mg (1 ml) of triamcinolone acetonide suspension (Triam 40mg/1ml; Shin Poong Pham, South Korea) and 1.5 ml of a normal saline mixture.

For the transforaminal ESI, the patient was also placed in the supine position. Under fluoroscopic guidance, a 25-gauge 12 cm spinal needle was gently advanced on oblique view, straight from the skin to the anterior surface of the superior articular process, posterior to the targeted nerve root and vertebral artery. Contrast material was injected to confirm the position. After confirmation that the needle was just posterior to the nerve root, we injected 10 mg (2 ml) of dexamethasone sodium phosphate (5 mg per milliliter; Choonwae Pharma

Corporation, Seoul, Korea).

Continuous and Intermittent Fluoroscopic Guidance

Two different technique of fluoroscopic guidance were used only for the senior professor; continuous and intermittent fluoroscopic guidance. Other two radiologists (the junior professor and the fellow) used only continuous fluoroscopic guidance in all patients. For the senior professor, continuous fluoroscopic guidance was executed before September 1st, 2011, and intermittent fluoroscopic guidance was done after that time. Intermittent fluoroscopic guidance was applying radiation during short time which is enough to check the location of the needle, unlike continuous fluoroscopic guidance which applies radiation during the advance of the needle, continuously.

Radiation Dose, Fluoroscopy time, and Procedure time Measurement

Radiation exposure was assessed by measurement of two parameters; the dose area product (DAP) and fluoroscopy time. DAP is a quantity used in assessing the radiation risk from diagnostic x-ray examinations and interventional procedures. It is defined as the absorbed dose multiplied by the area irradiated, expressed in gray square centimetres ($Gy \cdot cm^2$) (18). Also, fluoroscopy time has been widely used as a surrogate marker of radiation exposure in variety field of interventions (15, 19, 20). These two parameters were automatically measured and recorded by the uni-planar or bi-planar digital subtraction angiography units.

Procedure time was measured manually from the start to the end of procedure by one of two research assistants. Starting and end point was defined as when the spinal needle penetrated the skin and was out from the skin after injection, respectively..

Statistical Analysis

The Mann-Whitney U test was used to evaluate the differences in the DAP, fluoroscopy time and procedure time between continuous and intermittent fluoroscopic guidance for the senior professor.

For the analysis of different three radiologists, all the ESIs under intermittent fluoroscopic guidance by the senior professor were excluded, because other two radiologists used continuous fluoroscopic guidance only. The analysis of variance (ANOVA) was used to test for statistically significant differences in average DAP, fluoroscopy time and procedure time for ESIs under continuous fluoroscopic guidance according to the three radiologists. Post-hoc analysis was done using Mann-Whitney U test.

A p-value < .05 was considered statistically significant. All analyses were performed using the SPSS software package (Version 17.0, SPSS Inc, Chicago, IL).

Results

In the senior professor, the average DAPs, fluoroscopy times, and procedure times are summarized in Table 2. The average DAPs and fluoroscopy times under intermittent fluoroscopic guidance were significantly lower than under continuous fluoroscopic guidance in all two kinds of injection methods. The average DAPs were 506.4 mGy·cm^2 versus 1084.9 mGy·cm^2 (intermittent versus continuous fluoroscopic guidance) in interlaminar ESI (p-value = 0.0003), and 799.7 mGy·cm^2 versus 2423.1 mGy·cm^2 (intermittent versus continuous) in transforaminal ESI (p-value = 0.0001).The average fluoroscopy time were 25.2 sec versus 60.7 sec (intermittent versus continuous) in interlaminar ESI (p-value = 0.0001), and 80.6 sec versus 119.9 sec (intermittent versus continuous) in transforaminal ESI (p-value = 0.0372).

However, the average procedure times did not show the statistically significant difference between continuous and intermittent fluoroscopic guidance. The average procedure time were 91.6 sec versus 92.2 sec (continuous versus intermittent) in interlaminar ESI (p-value = 0.5926), and 132.3 sec versus 120.7 sec (continuous versus intermittent) in transforaminal ESI (p-value = 0.7172).

The average DAPs, fluoroscopy time and procedure time based on different level experiences of the performing radiologist under continuous fluoroscopic guidance are demonstrated on Table 3. The average DAPs among all three groups (senior professor, junior professor, and trainee) were not significantly different with two different injection methods.

In terms of fluoroscopy time, the senior professor had the shortest average fluoroscopy time, followed by junior professor, and then trainee in both interlaminar and transforaminal ESI. One way ANOVA test revealed that there was a significant difference in the average fluoroscopy times among the three groups with interlaminar ESI (p=0.002). When comparing each group to one another, the difference was found to be statistically

significant between senior professor and trainee (p=0.0002) and between junior professor and trainee (p=0.00075). In the transforaminal ESI, the average fluoroscopy time was not significantly different among all three groups.

In terms of procedure time, the senior professor also had the shortest average procedure time. One way ANOVA test revealed there was a significant difference in the average procedure times among the three groups with all two injection methods (p=0.006 for interlaminar ESI and p=0.019 for transformainal ESI). When comparing each group to one another, the difference was found to be statistically significant between senior professor and trainee (p<0.0001), between senior professor and junior professor (p=0.0230) with interlaminar ESI. With transforaminal ESI, the difference was found to be statistically significant only between senior professor and trainee (p=0.0002).

Discussion

In our study, the intermittent fluoroscopic guidance significantly reduced the radiation dose. The average DAP was significantly reduced in half in interlaminar ESI and in one third in transforaminal ESI. Like DAP results, average fluoroscopy time was also significantly reduced in one third in interlaminar ESI and in two thirds in transforaminal ESI.

Previously, some reports have recommended that physicians record the time that a patient spends undergoing fluoroscopy-guided interventional procedures (21), although the relationship between the fluoroscopy time and the maximum radiation skin dose is not clear. Chida et al. (22) previously revealed that the correlation between the maximum radiation skin dose with DAP is more striking than that with fluoroscopy time in both Radiofrequency Catheter Ablation (RFCA) and percutaneous coronary intervention procedures. Then they recommend that physicians record the DAP when it can be monitored and that physicians record the fluoroscopy time when DAP cannot be monitored for estimating the maximum patient skin dose in RFCA procedures. Therefore, it can be stated that DAP is more reliable than fluoroscopy time for radiation dose estimation, but still many reports use the fluoroscopy time as the parameter of radiation dose. In our study, these two parameters showed similar results between continuous and intermittent fluoroscopic guidance. So, our results may support meaningfully that intermittent fluoroscopic guidance actually reduce the radiation dose compared to continuous fluoroscopic guidance.

In recent clinical settings, total procedure time should be considered as an important factor to choose the intervention method. Although, it can be thought that the technical difficulty of the intermittent fluoroscopic guidance may influence the total procedure time of the cervical ESI, our study revealed there was no statistically significant difference regarding procedure times between continuous and intermittent fluoroscopic guidance if they would be

performed by an experienced clinician. So, we can conclude that intermittent fluoroscopic guidance seems to be a preferable method to continuous fluoroscopic guidance in the perspective of radiation exposure without delay of procedure time.

During this prospective study, there was no serious procedure-related complication. However, procedure-related complications might occur more frequently with intermittent fluoroscopic guidance. As previously mentioned, a variety of procedure-related complications have been reported (4, 9-13, 23, 24). These adverse events are thought to arise from the incorrect needle position and inadvertent intravascular injection. Smuck et al. (25) prospectively evaluated the inadvertent intravascular injection during transforaminal ESI, and recommended the use of live fluoroscopy to observe dynamic contrast flow during transforaminal ESI.

This recommendation is especially important to the less-experienced operators, who may not be familiar with the overall procedure, accurate anatomical relationship and actual fluoroscopy images. Under these conditions, continuous fluoroscopic guidance is preferred for the operator, since decrease of procedure-related complications might be more important than potential risk from increased radiation exposure. In the clinical practice, the direct measurement of effective dose is not straightforward, thus they may be estimated using conversion factors from DAP. Because of the absence of the conversion factors in pain intervention, we adopted published conversion factor from cardiac intervention and used the highest value among them in order to estimate the radiation effect, 9.7 mGy/Gy·cm^2 for skin dose and 0.27 mSv/Gy·cm^2 for effective dose (26, 27). Then, 22.8mGy of the radiation dose on skin and 0.65mSv of effective dose can be obtained regarding transforaminal cervical ESI performed by trainee, which showed the highest amount of radiation. Considering that the 2 Gy is a threshold of radiation-induced skin injury and 50mSv is annual exposure allowance limit (28, 29), cervical ESI under continuous fluoroscopic guidance can be executed within

the tolerable limit in terms of the potential risk of radiation, even performed by the less-experienced trainee.

In our study, the average fluoroscopy times are substantially higher than the results reported by Manchikanti et al. (14, 30-31), Botwin et al. (32), and Zhou et al. (33). As we included the patients who underwent only the cervical ESI, we could not make a direct comparison with their results. The majority cases of ESI in their studies were performed at lumbar and caudal level (14, 30-32).

Actually, senior professor did have the shortest average fluoroscopy time and procedure time in all two kinds of procedures followed by junior professor, and then trainee. Our results suggest that a higher level of radiologist experience has an inverse effect on average fluoroscopy time and procedure time as expected.

There are some limitations to our study. First, the comparison between continuous and intermittent fluoroscopic guidance was possible only for a senior professor. Second, when we performed the procedure, we used two kinds of angiography units. So, the radiation dose and fluoroscopy may be influenced. Li et al. (34) reported that bi-planar fluoroscopic technique during percutaneous vertebroplasty provides not only a shorter operative time but also is performed with less radiation dose to the patient compared to the one-fluoroscopic technique. However, considering that the procedure time is relatively short in cervical ESI than other kinds of interventions, we think that the influence to the radiation dose and fluoroscopy time according to the type of fluoroscopy might be limited.

In conclusion, intermittent fluoroscopic guidance is preferable method to continuous fluoroscopic guidance during cervical ESI in the perspective of radiation exposures, but cervical ESI under continuous fluoroscopic guidance was within the tolerable limit even performed by the trainee.

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Table 1. Demographic data of the patients

		Senior Pf (Intermittent†)	Senior Pf. (continuous*)	Junior Pf.	Trainee
Number of patients		31	55	43	102
Age (mean ± SD)		54.1 ± 10.6	55.0 ± 12.2	56.8 ± 10.8	52.5 ± 12.1
Gender	Male	29	19	27	32
	Female	26	12	16	70
Number of procedures	ILESI	44	24	36	87
	TFESI	11	7	8	16

* Continuous means continuous fluoroscopic guidance during epidural steroid injection.

† Intermittent means intermittent fluoroscopic guidance during epidural steroid injection.

Note.___SD= standard deviation, ILESI = interlaminar epidural steroid injection for cervical spine, TFESI = transforaminal epidural steroid injection for cervical spine

Table 2. Comparison of DAP, fluoroscopy times, and procedure times between two different fluoroscopy guidance (continuous versus intermittent) for a senior professor.

		Intermittent†	Continuous*	p-value
DAP(mGy·cm^2)	ILESI	506.4 ± 341.3	1084.9 ± 628.1‡	0.0003
	TFESI	799.7 ± 222.8	2423.1 ± 1371.5	0.0001
Fluoroscopy	ILESI	25.2 ± 15.0	60.7 ± 19.0	<.0001
Time (sec)	TFESI	80.6 ± 40.4	119.9 ± 31.5	0.0372
Procedure	ILESI	92.2 ± 33.3	91.6 ± 33.6	0.5926
Time (sec)	TFESI	132.3 ± 69.7	120.7 ± 42.8	0.7172

* Continuous means continuous fluoroscopic guidance during epidural steroid injection.
† Intermittent means intermittent fluoroscopic guidance during epidural steroid injection.
‡ Mean ± Standard deviation

Note.___DAP = dose area products, ILESI = interlaminar epidural steroid injection for cervical spine, TFESI = transforaminal epidural steroid injection for cervical spine

Table 3. Comparison of DAP, fluoroscopy times, and procedure among different operators (a senior professor, a junior professor, and a trainee) under continuous fluoroscopy guidance.

		Senior professor	Junior professor	Trainee	p-value for all	p-value for senior vs junior pf	p-value for senior pf vs trainee	p-value for junor vs trainee
DAP ($mGy \cdot cm^2$)	ILESI	1084.9±628.1*	1280.2±1420.7	1496.0±1375.5	0.191	0.5716	0.0714	0.0781
	TFESI	2403.1±1371.5	2153.9±1716.8	2409.9±1443.9	0.910	0.3950	0.7897	0.4896
Fluoroscopy Time(sec)	ILESI	60.7±19.0	69.7±46.6	86.7±45.1	0.002	0.9575	0.0002†	0.00075†
	TFESI	119.9±31.5	144.0±101.1	187.3±99.4	0.131	0.4570	0.0642	0.1500
Procedure Time(sec)	ILESI	91.6±33.6	135.5±95.7	126.6±65.0	0.006	0.0230†	<.0001†	0.6346
	TFESI	120.7±42.8	214.4±172.4	290.5±172.6	0.019	0.1087	0.0002†	0.1683

* Mean ± Standard deviation
† p-value less than 0.05

Note.___DAP = dose area product, ESI = epidural steroid injection ILESI = interlaminar epidural steroid injection for cervical spine, TFESI = transforaminal epidural steroid injection for cervical spine

초 록

서론: 이 연구는 임상적으로 경부통 또는 경추 신경근 병증이 있는 환자들에서 투시 유도 하 경추 경막 외 스테로이드 주입술 시 방사선 노출의 정도에 대한 전향적 연구이다. 투시 유도 하에 경추 경막 외 스테로이드 주입술을 시행할 경우 원하는 위치에 정확한 스테로이드 주입이 가능함으로써 치료 효과를 높이며 시술 관련 합병증을 줄일 수 있다는 장점이 있으나 방사선의 노출이 문제가 된다. 간헐적 투시 유도법은 이러한 방사선 노출을 줄이기 위한 효과적인 방법으로 제시되어 왔다. 이에 이번 연구에서 경추 경막 외 스테로이드 주입술 시 지속적 또는 간헐적 투시 유도 하에서 방사선 노출 정도의 차이를 분석하고 서로 다른 경험치를 갖는 세 명의 영상의학과 전문의들 사이에서 지속적 투시 유도하의 방사선 노출의 차이를 비교해 보고자 하였다.

방법: 본 연구는 전향적 연구로 임상시험심사위원회(IRB)의 승인을 받았으며 환자들의 사전 동의를 취득하였다. 2011년 7월에서부터 2011년 10월까지 총 4개월간 총 233회의 투시 유도 하 경추 경막 외 스테로이드 주입술을 시행 받은 총 231명의 환자(남:여= 107:124; 평균 연령, 50.3세)를 대상으로 하였다. 방사선량은 면적선량과 투시 시간으로 측정하였으며 이를 이용하여 지속적 투시 유도와 간헐적 투시 유도 하에서 방사선 노출 정도의 차이를 분석하였다. 그리고 지속적 투시 유도 하에서 서로 다른 경험을 가진 세 명의 영상의학 전문의들(부교수, 조교수, 임상 강사)간의 방사선량을 비교하였다. 통계적 분석은 만-휘트니 유 검증과 일원분산분석을 사용하였다.

결과: 방사선량은 간헐적 투시 유도 하에서 지속적 투시 유도와 비교하여 통계적으로 의미 있게 감소되었다. 면적 선량의 경우 추궁 경막 외 주입술 시 1084.9 $mGy \cdot cm^2$ 에서 506.4 $mGy \cdot cm^2$로 감소하였으며 추간공 경막 외 주입술 시 2423.1 $mGy \cdot cm^2$ 에서 799.7 $mGy \cdot cm^2$로 감소하였다. 투시 시간은 추궁 경막 외 주입술 시 60.7초에서 25.2초로 감소하였으며 추간공 경막 외 주입술 시 119.9초에서 80.6초로 감소하였다. 세 명의 영상의학과 전문의 중에서 임상 강사가 가장 높은 방사

선량을 보였으나 계산된 유효 선량 (0.65mSv)은 허용 가능치 이내였다.

결론: 경추 경막 외 스테로이드 주입술 시에 간헐적 투시 유도는 지속적 투시 유도에 비하여 방사선 노출이라는 측면에서 더 좋은 시술 방법이다. 그러나 지속적 투시 유도하의 경추 경막 외 스테로이드 주입술은 경험이 부족한 시술자에서도 허용 가능치 이내의 방사선량을 보였다.

주요어: 경막 외 스테로이드 주입술
방사선량
투시
척추

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