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의학석사 학위논문

만성 무릎 골관절염 환자의 영상 증폭 장치하 슬신경 차단과 초음파 유도하 슬신경 차단에 대한 효과 비교

Comparison of the efficacy between ultrasound-guided and fluoroscopic-guided genicular nerve block for knee osteoarthritis; A prospective randomized controlled trial

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의 학 과

김 두 환

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이 논문을 의학석사 학위 논문으로 제출함

2018 년 2 월

울 산 대 학 교 대 학 원

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김두환의 의학석사학위 논문을 인준함

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Abstract

Background: Recently, genicular nerve block and radiofrequency ablation were introduced to alleviate knee pain in the patients with chronic knee osteoarthritis. There are two methods of genicular nerve block; ultrasound-guided versus fluoroscopy-guided. However, the superiority between them is unknown.

Methods: From July 2015 to September 2017, a randomized controlled study was performed to analyze the difference in the efficacy of genicular nerve block between ultrasound- and fluoroscopy-guidance. Numeric Rating Scale (NRS), Western Ontario and McMaster Universities Arthritis Index (WOMAC), Global Perceived Effect Scales (GPES) and complications were recorded at pre-procedure, 1 month, and 3 months after genicular nerve block.

Results: Total 80 patients were enrolled and randomized to the allocated group U (n=40) and the group F (n=40). We excluded patients who had no visit, follow-up loss, and other interventions, and finally analyzed 31 patients in the group U and 30 patients in the group F. There were no differences in NRS and WOMAC between the two groups at baselines and during follow-up period. GPES and complication rates were also similar among the two groups.

Conclusions: Pain relief, functional improvement, and safety were similar between ultrasound- and fluoroscopy-guided genicular nerve block. Therefore, either of two imaging devices can be selected to perform genicular nerve block for relieving chronic knee pain. However, considering radiation exposure, ultrasound might appear to be superior to guide genicular nerve block compared to fluoroscopy.

Keyword: genicular nerve block, ultrasound, fluoroscopy, knee osteoarthritis

Contents

Lists of figures, Tables, and Abbreviations

OA: Osteoarthritis

GNB: Genicular nerve block

RFGN: Radiofrequency ablation of genicular nerves

AP: Anteroposterior

SL: Superior lateral

SM: Superior medial

IM: Inferior medial

WOMAC: Western Ontario and McMaster's Universities Osteoarthritis Index

NRS: Numeric Rating Scale

GPES: Global perceived effects

EMR: Electronic medical record

Introduction

Knee osteoarthritis (OA) is most common joint diseases in the elderly, it causes pain, joint mobility limitation, disability, and worsen quality of life [1)]. Although being various conservative treatments, numerous patients with chronic knee OA have been still suffered from unbearable knee pain prior to total knee joint arthroplasty [2)]. Since Choi et al. introduced genicular nerve block (GNB) and radiofrequency ablation of genicular nerves (RFGN), several reports demonstrate that RFGN or GNB are effective in alleviating pain and improving knee functionality in patients with chronic knee OA [3-7)]. These interventions have been raised a new option to alleviate chronic knee pain.

There are two imaging devices (fluoroscopy and ultrasound) which show the target landmark and help to conduct accurate the procedures. Traditionally, fluoroscopy has been used for regional anesthesia and pain medicine, thus GNB was first performed by fluoroscopy guidance. Then, run of genicular nerves, anatomical relationship with surrounding tissues, and origin and termination of these nerves were more revealed by cadaveric studies [8-10)]. After the known specific anatomical location of genicular nerves, ultrasound-guided RFGN or GNB have conducted interestingly, and many studies have been showed that ultrasound-guided the operation is also efficient [4,6,11)].

Using ultrasound has some advantages compared to fluoroscopy, it can show genicular arteries and sometimes genicular nerves. Therefore, we hypothesized that ultrasound-guided GNB might be more accurately performed than fluoroscopy-guided one, then, in the present study, we aimed to compare the efficacy between ultrasound-guided and fluoroscopy-guided GNB.

Methods

Patients

This study enrolled patients with chronic knee OA scheduled to GNB between April 2015 and September 2017, and was approved by the institutional review board (2015-0369) of Asan Medical Center. Written informed consent was obtained from all participant patients.

Patients were included in this study only if they met the following criteria; 1) chronic knee OA patients with pain duration more than 3 months, 2) patients who had radiological OA grade more than Kellgren–Lawrence grade 2, 3) patients aged 50–80 years, 4) refractory knee OA pain that was not alleviated by analgesics, visco-supplementation, and physiotherapy. Patients were excluded if they had acute knee pain (more less 3 months), connective tissue diseases that affected the knee, serious neurological or psychiatric disorders, steroid injection therapy during the previous 3 months, sciatic pain, prior knee surgery, and used an anticoagulant.

Fluoroscopy-guided GNB (group F)

No sedatives or analgesics were administered before intervention. Patients were placed in the supine position on an operating table with a pillow beneath the popliteal fossa to minimize discomfort during the procedure. The interventional area was draped according to a sterile technique, the anteroposterior (AP) fluoroscopic view of the knee joint was obtained using fluoroscopy. The view was adjusted to assure true AP view which showed an open knee joint space with equal width interspaces on both sides. There are three target points of fluoroscopy-guided GNB which were the medial and the lateral areas connecting the shaft to the epicondyle of the femur, and the medial area connecting the shaft to the epicondyle of the tibia. After identifying target points, local anesthetic (1 mL 1% lidocaine) was administrated to the skin and soft tissues. Using the tunnel technique, the needle (23-gauge Quincke type spinal needle, TaeChang industrial co, Korea) was advanced percutaneously towards areas connecting the shaft to the epicondyle until the needle tip contacted bone under fluoroscopic guidance (Figure 1.A). The final location of needle tip was confirmed by AP and lateral fluoroscopic views, then, a gentle aspiration was performed, and a 2-mL of injectate was administered. Both methods were used to inject a total of 6 mL of 2% lidocaine with 20 mg of triamcinolone.

Ultrasound-guided GNB (group U)

Patients were also positioned supine on a bed with a pillow under the popliteal fossa to reduce discomfort. After sterile preparation of the interventional field and wrapping sterile cover on the 12-MHz linear transducer (XarioTM SSA-660A, Toshiba Medical Systems Corporation, Otawara-shi, Japan), the transducer was first placed on the junctions of the epicondyles and the shafts of the femur and tibia. And it moved up or down to identify the genicular arteries. They were usually discerned near the periosteal areas and confirmed by color Doppler ultrasound. Because genicular arteries including the superior lateral (SL), superior medial (SM), and inferior medial (IM) genicular artery travel along each genicular nerve (Figure 1.B), the needle tip location should be vicinity of each genicular artery. After confirming the genicular artery, the skin and subcutaneous tissue were anesthetized with 1 mL 1% lidocaine at each target point. The needle was inserted in the long-axis view of ultrasound probe. After the needle tip was next to a genicular artery, a gentle aspiration was performed and a 2-mL of injectate was administered.

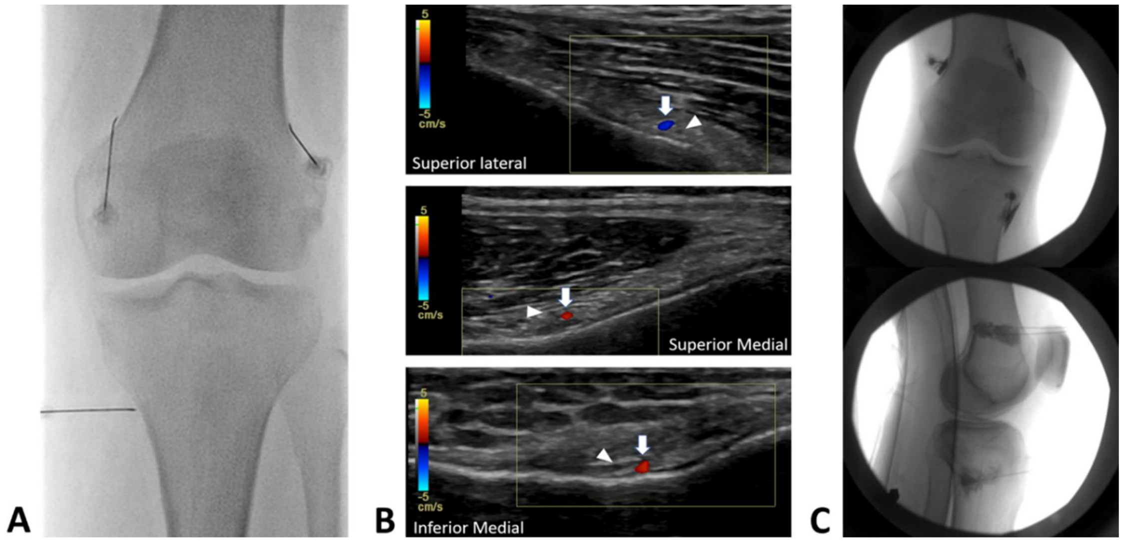

Figure 1. A. Anteroposterior fluoroscopic view after needles insertion on the connecting area of the shaft and epicondyle of the tibia and femur. **B.** Ultrasound views of identification of genicular arteries and nerves by color Doppler mode. White arrows indicate genicular arteries and arrowheads indicate genicular nerves which appear to be a small rounded hypoechoic dot. **C.** Anteroposterior and lateral fluoroscopic images after ultrasound-guided needles insertion for genicular nerve blocks. The needle tips located similar position to ones in figure 1.A. Contrast dye spread showed that needle tips were positioned on the periosteal area which is the junction of the shaft and epicondyle of long bones.

Measured variables and follow-up

All preoperative baseline values assessed before the procedure and post-procedure outcome measurements were evaluated at 4 and 12 weeks. Demographics data were collected for all participants through standard history taking, physical, and radiological examination. Pain intensity was assessed using the single 11-point Numeric Rating Scale (NRS, in which 0 = no pain and 10 = worst pain imaginable). To measure subjective knee functionality, Western Ontario and McMaster's Universities Osteoarthritis Index (WOMAC) were used. The WOMAC measures 5 questions for pain, 2 questions for joint stiffness and 17 questions for functional limitation. All questions are scored on a scale of 0 – 4. The scores for each subscale are summed up, with a possible score range of 0-20 for pain, 0-8 for stiffness, and 0-68 for physical function. Higher scores on the WOMAC indicate worse pain, stiffness, and functional limitations [12)]. To obtain a valid baseline value and outcome measurements, all participants were instructed how to check NRS and WOMAC correctively before the procedure. Patient satisfaction with GNB was measured by assessing global perceived effects (GPES) on a seven-point scale (1 = worst ever, 7 = best ever) [13)].

The primary outcomes were the mean differences baseline levels of pain intensity to 4 and 8 weeks after GNB, as measured using NRS. Secondary outcomes included knee functionality, patient satisfaction with treatment, the incidence of adverse effects, and the proportion of successful responders. According to prior study, the successful responder was defined as: 1) the patient with a reduction of at least 50% of mean NRS and no increase from baseline WOMAC, and ≥ 4 points on the GPES; 2) patient with both a reduction of at least 30% of mean NRS and mean WOMAC scores, or > 5 points on the GPES [14,15)]. All adverse events including numbness, paresthesia, neuralgia, and motor weakness were documented. After the procedure, we requested cooperation to continue analgesics that had been previously prescribed for all kinds of degenerative diseases to the patients. They were asked from making no changes to their medications during the 3 months of their follow-up period.

Statistical analysis

Based on our pilot study, the sample size was calculated. Taking the difference with a mean NRS value of 1.9 at 1 month after the procedure with an SD of 2.3, at a significance level of 0.05 and a power of 0.9, 32 subjects per group would be needed. Then, assuming a dropout rate of 20%, a total sample size of 80 patients would be required (40 in each group). The Statistical Package for the Social Sciences (SPSS. Version 21.0, SPSS Inc, Chicago, IL) were used to analyse obtained data. Kolmogorov–Smirnov test was used to test the normality of the data. Normally distributed demographic data were compared using Student's t-tests and reported as mean ±standard deviation (SD). Non-parametric data were evaluated using Mann–Whitney U tests and presented as median and interquartile range. Categorical data were presented as numbers and percentages, and compared using the chi-square test or Fisher's exact test. NRS and WOMAC scores at baselines, 1 month, and 3 months after the operation between two groups were compared using the two-way repeated measurements analyses of variance with Bonferroni tests. A p value below 0.05 was set as the cut-off point for significance.

Randomization

All patients were randomly assigned to two groups; Group U receiving GNB under ultrasound guidance and Group F receiving GNB under fluoroscopy guidance. Group allocation was accomplished according to a computer-generated randomization schedule by investigators at pain clinic in our institution. They documented all assigned groups on Electronic medical record (EMR). On the operation day, operator reviewed the EMR and confirmed using guided modality of GNB. All procedures were conducted by a single operator who was not blinded to the type of administered treatment.

Results

Eighty patients were enrolled in the present study. Forty patients were assigned to each group. Two patients in group U and seven patients in group F did not received allocated intervention. In group U, 5 patients became lost to follow-up and 2 patients underwent intra-articular steroid injection at 1 month. In group F, one patient received genicular radiofrequency ablation and 2 patients underwent intra-articular steroid injection at 1 month. Finally, 31 patients in group U and 30 patients in group F were analysed (Figure 2). All patients underwent a successful GNB regardless of guided modality, and there were no complications in both groups.

Clinical characteristics were not different in both groups (Table 1). As shown in Table 2, No significant difference was observed in NRS, subset scores, and total score of WOMAC between two groups at baseline, 1 month, and 3 months after the procedure. Notably, NRS and WOMAC scores at 1 and 3 months were significantly lower than baseline values both two groups except pain and stiffness in WOMAC at 3 months in group F. The proportion of successful responders was also similar among two groups at 1 and 3 months (Figure 3). No difference was shown in patient satisfaction ($p = 0.814$; GPES at 1 Month, $p = 0.315$; GPES at 3 Months) during the follow-up period.

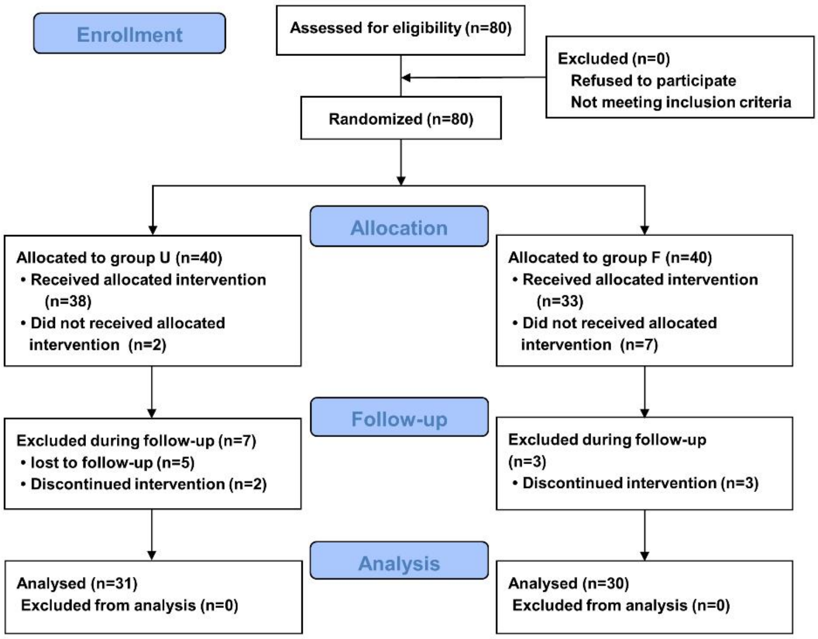

Figure 2. Flow chart of the present study.

Table 1. Clinical characteristics

	Group U (N=31)	Group F (N=30)	P value
Age (years)	65.2 ± 10.4	66.8 ± 9.3	0.544
BMI (kg/m^2)	25.8 ± 3.0	24.1 ± 3.9	0.071
Gender (Male/Female)	9 (29.0%)/22 (71.0%)	8 (26.7%)/22 (73.3%)	0.837
DM	4 (12.9%)	4 (13.3%)	0.960
K-L grade (2/3/4)	13 (43.3%)/13 (43.3%)/ 4 (13.3%)	18 (64.3%)/9 (32.1%)/ 1 (3.6%)	0.195
Affected side (Lt/Rt/bilat)	10 (32.3%)/10 (32.3%)/ 11 (35.5%)	11 (36.7%)/9 (30.0%)/ 10 (33.3%)	0.936
Duration of pain (months)	14.0 [4.0;60.0]	12.0 [5.0;27.0]	0.488

Data are expressed as mean ± SD (standard deviation), number (%), or median (interquartile range). BMI = body mass index; DM = Diabetes mellitus; K-L grade = Kellgren-Lawrence grade.

Table 2. Comparison of pain intensity and functional outcomes between two groups after genicular nerve block

	Group U (N=31)			P value	Group F (N=30)			P value	*P value*
	Baseline	1 month	3 months		Baseline	1 month	3 months		
NRS	6.3 ± 1.6	3.8 ± 2.1*	4.3 ± 2.1*	< 0.001	6.7 ± 1.6	3.9 ± 1.9*	4.9 ± 1.9*	< 0.001	*0.637*
WOMAC_Pain	10.8 ± 4.0	7.2 ± 4.0*	7.9 ± 4.2*	< 0.001	10.7 ± 4.5	6.9 ± 3.7*	9.3 ± 4.5	< 0.001	*0.189*
WOMAC_Stiffness	4.4 ± 2.3	2.7 ± 1.7*	2.9 ± 1.8*	< 0.001	4.0 ± 2.3	2.8 ± 1.9*	3.5 ± 2.0	0.004	*0.153*
WOMAC_Physical function	34.5 ± 16.6	23.3 ± 15.0*	25.0 ± 14.2*	< 0.001	34.3 ± 11.7	22.9 ± 11.5*	27.3 ± 13.0*	< 0.001	*0.320*
WOMAC_Total	50.0 ± 20.6	34.2 ± 19.6*	35.6 ± 18.5*	< 0.001	48.7 ± 16.5	32.1 ± 16.0*	39.6 ± 18.1*	< 0.001	*0.179*

All data values shown as means ± standard deviations. NRS = numeric rating scale; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index. * $P < 0.05$ compared with baseline values in each group. *P value compared to NRS and WOMAC scores between two groups.*

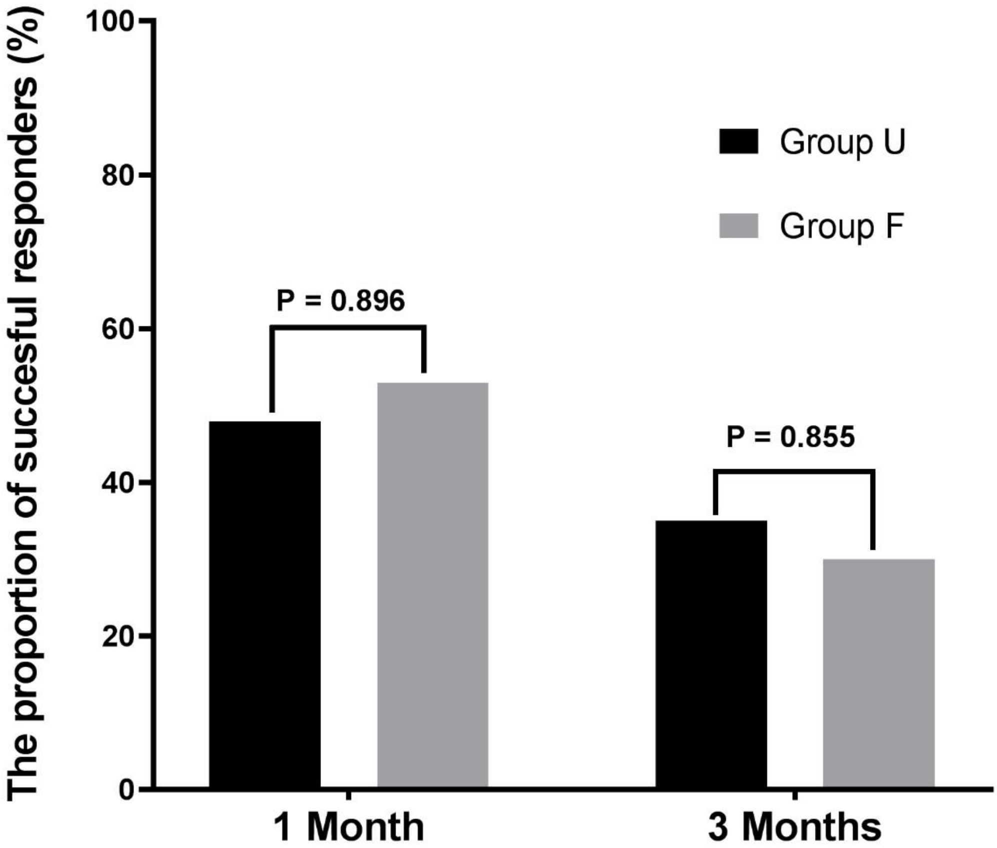

Figure 3. The proportion of successful responders among two groups at 1 month and 3 months after the operation.

Discussion

There were two main findings in the present study. First, post-intervention outcomes were similar for any imaging devices used for GNB. Second, GNB with steroid was effective, but it sustained only 1month after the procedure in patients with chronic knee OA.

When conducting nerve block, imaging devices can help to guide and provide accurate the procedures, and reduce complications compared to a blind technique [16,17]. Therefore, choosing which the imaging devices are essential for increasing success rate of nerve block. For the first time, since Choi et al. introduced fluoroscopy-guided RFGN or GNB, both ultrasound and fluoroscopy are widely used to guide the ones. However, it is still not well known which imaging method is better.

Fluoroscopy guidance has some advantages for GNB. First, the genicular nerves including SL, SM, and IM genicular nerves travel periosteal areas connecting the shaft to the epicondyle [3]. Therefore, the target points of RFGN can be easily identified through fluoroscopic view of the knee joint. Second, at deep tissue levels, ultrasound can not offer a clear visualization with small gauge needles, whereas, fluoroscopic views can provide good needle images on display regardless of tissue depth and size of needle gauge. Third, to use real-time contrast fluoroscopy and digital subtraction angiography can prevent unintentional intravascular injection [18].

Ultrasound guidance to perform the GNB has unique strength compared to fluoroscopy. First, there is no radiation exposure to both patients and clinicians during ultrasound guided procedure. It deemed as best advantages of ultrasound over fluoroscopy. Second, ultrasound can provide a real-time view of soft tissues (nerves, muscles, vessels, etc.), an image of needle tip advancement relevant to surrounding structures, and visualization of injectates spread [19]. Third, it can guide diagnostic and therapeutic procedures not only statically but also dynamically. In case of conducting GNB, there are some merits that genicular arteries can be almost shown and even genicular nerves are sometimes identified in the ultrasound view. They may provide more precise GNB. Therefore, we speculated that using ultrasound may be more efficient than using fluoroscopy when performing GNB.

This study indicated that the efficacy of both imaging devices for GNB seemed to be no different. There are several studies of comparison effectiveness between fluoroscopy and ultrasound-guided block for chronic pain management [20-23]. Similar to our results, these studies reported that there was no significant difference between two modalities for an image-guided block in the post-procedure outcome. This similar effect between two imaging method guiding GNB may be due to anatomical properties of genicular nerves. Genicular nerves travel along each genicular arteries, and simultaneously, these genicular neurovascular bundles run together on the junctions of the epicondyle and the shafts of the femur and tibia [3,9,24]. To demonstrate that targets of GNB locate similarly regardless of imaging devices, after ultrasound-guided needles insertion to target sites, the fluoroscopic image of the knee was obtained in this study (Figure 1.C). As a result, needle tips were located at the junctions of the epicondyle and the shafts of the femur and tibia. Consequently, since the target positions of GNB were similar whatever imaging equipment would be used, the efficacy of both imaging devices performing GNB might be no different.

There was one report that compared the efficacy of ultrasound and fluoroscopy-guided RFGN in literature prior to our study [25]. Their results were similar to our ones. However, they did not demonstrate why the efficacy of the intervention was not different regardless of imaging methods. Thus, we speculated that our study might be more valuable than the previous survey.

Because of showing equal effect between two guided modalities, we suggest that ultrasound may be the more suitable method for GNB. As mentioned above, ultrasound has several advantages compared to fluoroscopy. GNB or RFGN usually is repeated periodically because of its certain duration, Cumulative doses of radiation may lead to damage in many other organs including the skin, bones, thyroid glands, and lungs [26] Thus, no radiation hazard in ultrasound-guided intervention is excellent merit for patients and operators. Easy accessibility, convenience, and portability may be other reasons for choosing the use ultrasound [27-29]. When patient movement changes target views due to interventional pain, ultrasound can restore target views rapidly compared to fluoroscopy. Furthermore, because genicular arteries are almost simply identified by ultrasound, GNB can be performed more accurately. Other studies also propose that ultrasound may be more appropriate imaging device for nerve block for the above reasons [20,21,30]. However, the difference in proficiency of operator and patient obesity can be an obstacle when choosing ultrasound [31,32]. When conducting cooled RFGN or RFGN, fluoroscopy guidance may be beneficial because the needle tip for RF must be positioned parallel to the target nerve. Therefore, fluoroscopy guided GNB may be the first choice depending on the situation.

Generally, a diagnostic GNB with local anesthetic is generally conducted before RF GN to indicate the need for the one. GNB with corticosteroid can be used for therapeutic purposes, not for diagnostic purposes [33]. In the present study, GNB with adjuvant corticosteroid improved knee functionality and alleviated pain intensity until post-procedure 1 month. Although at 3 months after the GNB, statistical significance observed in pain intensity and knee functionality compared to baseline values (mean difference of NRS in group U = 2.0, mean difference of NRS in group F = 1.8, mean difference of WOMAC total in group U = 14.4, difference of WOMAC total in group F = 9.1), (Table 2), however, there was no clinical significance in outcomes when reassessing NRS and WOMAC according to the minimal clinically important changes, with reference to a previous studies (change in NRS scores > 2, change in WOMAC total score > 15 points) [34,35]. Therefore, the effect of diagnostic GNB with adjuvant corticosteroid seemed to sustain only 1 month. In case of being effective in GNB, RFGN would be needed to manage chronic knee pain over 1 month after the GNB instead of repeating GNB with corticosteroid.

There were some limitations in the present study. First, we could not perform double-blind randomized controlled study because of limitation of our budget and manpower. The single operator was one of investigators, thus he was not blinded to the type of interventional method. It may be confounding bias. Second, we did not evaluate the baseline emotional state in the participants. Subjective affect might influence the recognition of pain severity and functional outcomes after the intervention. However, because we excluded the patients with neurological or psychiatric diseases during the enrollment of this study, we suspected that these emotional factors might have minimally affected our results.

Conclusion

Pain relief, improvement of knee functionality, and safety were not significantly different between ultrasound- and fluoroscopy-guided GNB. Therefore, either of ultrasound- and fluoroscopy-guided technique can be chosen for GNB in patients with chronic knee OA. However, considering radiation exposure and other advantages of ultrasound, we suggested that the ultrasound use might be a better option when performing GNB in chronic knee OA patients.

Declaration of Interest

None declared

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국문 요약

배경: 만성 무릎 골관절염 환자에서 무릎 통증을 완화시키기 위해 최근 무릎 신경 차단술이 소개되었다. 무릎 신경 차단술은 초음파 유도 하에 시행하거나 또는 투시 유도 하에 시행하게 된다. 하지만 무릎 신경 차단 시 두 장비 중 어느 쪽이 우수한지는 아직 까지 알려져 있지 않다.

방법: 2015 년 7 월부터 2017 년 9 월까지 무작위 대조 연구를 통해 초음파 또는 투시 유도 하 무릎 신경 차단술의 효과 차이를 분석하였다. 신경 차단 전, 시술 1 개월 및 3 개월에 숫자통증등급 (NRS), 골관절염증상지수 (WOMAC), 환자 만족도 (GPES) 및 합병증을 기록하였다.

결과: 총 80 명의 환자가 등록되어 초음파 그룹 및 투시 그룹에 각각 40 명씩 배정되었다. 시술 받지 않음, 추적 관찰 실패 및 경과 관찰 기간 중 기타 다른 중재 시술이 있었던 환자는 모두 제외하고 초음파 군 31 명과 투시 군 30 명을 최종 분석했다. 두 그룹 사이의 NRS, WOMAC, GPES 및 합병증 모두 두 그룹 간에서 유사한 결과를 보였다.

결론: 통증 완화, 기능적 개선 및 안전성 모두 초음파 또는 투시 안내 하 에 시행한 무릎 신경 차단술에서 유사 하였다. 따라서 만성 무릎 통증을 완화하기 위해 무릎 신경 차단술을 수행하기 위해서는 두 개의 영상 장치 중 어느 것도 선택할 수 있지만, 방사선 노출을 고려한다면 초음파를 이용하는 것이 더 우수 할 수 있습니다.