

리도카인 관절강 내 주사는 안전한 치료법입니다.

관절강 내 주사와 리도카인 병용 투여는 심평원에서 인정하는 치료법입니다. 7)

항목	제목	세부인정사항
요양급여의 적용기준 및 방법에 관한 세부사항과 심사지침(2018년 7월판)	건강보험심사평가원	
마9 관절강 내 주사	부신피질호르몬제를 이용한 관절강 내 주사 인정기준	부신피질호르몬제를 이용한 관절강 내 주사는 약제에 의한 부작용을 고려하여 동일 관절에는 2~4주 간격으로 1년에 3~4회 인정하고, 동일애 여러 관절에 실시한 경우에는 2관절까지 인정하되, 1개월에 최대 3~4관절까지만 인정함. (고시 제2007-46호, '07.6.1. 시행)
	국소마취제(lidocaine)만으로 시행한 관절강 내 주사 인정여부	국소마취제를 부신피질호르몬제 등 타약제와 병용하여 관절강 내로 주입하는 것은 타당한 방법이므로 마9 관절강 내 주사를 인정하되, 국소마취제만을 관절강내로 주입하는 것은 인정하지 아니함. (고시 제2007-92호, '07.11.1. 시행)

다수의 연구에서 리도카인 관절강 내 주사 투여의 안전성이 입증되었습니다. 5), 6)

The Influence of a Single Intra-Articular Lidocaine Injection on the Viability of Articular Cartilage in the Knee

Klemen Ravnhjar, M.D., Tomaz Marš, Sergej Pirmanjšar, Armin Alibegović, Gordana Koželj, Andraž Sožer, and Matej Drobnik¹

Abstract: To evaluate the in vivo effect of a single intra-articular injection of local anesthetic (LA) lidocaine on the viability of articular cartilage in the intact or osteoarthritic (OA) human knee, and to measure the synovial postinjection concentration of lidocaine in the knee. Design: This study includes 3 interconnected experiments: (A) Synovial LA concentration measurements after a 2% lidocaine injection before knee arthroscopy in 10 patients by liquid chromatography–tandem mass spectrometry (LC-MS/MS). (B) Human osteochondral explants (n = 27) from intact knees prepared at arthroscopy were incubated for different time intervals (0 minutes, 2 hours, 24 hours) with 2% lidocaine, 0.04% lidocaine (freebase), or culture medium (control), and later evaluated for cell viability by LIVE/DEAD staining. (C) Ten out of 19 matched patients scheduled for knee replacement received a single intra-articular injection of 2% lidocaine approximately 30 minutes prior to the procedure; 9 patients served as control. Osteochondral samples with OA changes were harvested during surgery and analyzed for chondrocyte viability by LIVE/DEAD staining. Results: (A) The synovial LA concentration was significantly lower than the primary concentration injected: average 0.23 mg/mL (0.02%), highest measured 0.37 mg/mL (0.04%). (B) In vivo exposure to a reduced LA concentration had no significant influence on chondrocyte viability in intact cartilage explants (24-hour averages control, 93%, 0.04% lidocaine, 92%, 2% lidocaine, 79%). (C) Viability of chondrocytes in OA knees was similar between 2% lidocaine injection (85%) and control (80%). Conclusions: A single intra-articular knee injection of 2% lidocaine did not influence the chondrocyte viability neither in healthy nor in OA cartilage. A fast postinjection reduction of synovial LA concentration (more than 40 times) is the most likely protective mechanism.

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Effect of Intra-articular Local Anesthesia on Articular Cartilage in the Knee

Klemen Ravnhjar, M.D., Ariana Barlič, Ph.D., and Matej Drobnik, M.D., Ph.D.

Purpose: To evaluate the hypothetical toxic effect of local anesthetics on the articular cartilage using patient data from autologous chondrocyte cultivation with different anesthesia types used for arthroscopic cartilage biopsy specimen procurement. Methods: A retrospective analysis of patient data from the national autologous chondrocyte implantation registry and the corresponding hospital records was approved by the National Medical Ethics Committee. Articular cartilage biopsy specimens from the knees of 49 consecutive patients assigned for autologous chondrocyte implantation (aged 14 to 64 years) were procured from the non-weight-bearing articular surface during arthroscopy under general anesthesia (12 patients), spinal anesthesia (18 patients), or local anesthesia (intra-articular injection of 15 to 20 mL of 2% lidocaine hydrochloride) (19 patients). All the biopsy specimens were further manipulated following the same chondrocyte cultivation protocol. General patient data and surgery-related parameters, together with chondrocyte viability, population doubling, and chondrocyte morphology in biopsy specimens and primary cell cultures, were analyzed and compared across different types of anesthesia. Results: Patients in the general, spinal, and local anesthesia groups showed no statistical differences in age (27 years, 29 years, and 32 years, respectively), duration of surgery (16 minutes, 37 minutes, and 39 minutes, respectively), weight of biopsy specimens (119 mg, 178 mg, and 138 mg, respectively), cell viability in cartilage biopsy specimens (67%, 69%, and 78%, respectively) or primary cultures (95%, 95%, and 95%, respectively), and population doubling (0.2, 0.2, and 0.2, respectively). Similar chondrocyte morphology in primary cell cultures was observed among the 3 groups. Conclusions: This retrospective study showed that a single intra-articular injection of lidocaine hydrochloride used for knee arthroscopy did not influence the viability, morphology, and cultivation potential of chondrocytes in articular cartilage biopsy specimens assigned for autologous chondrocyte implantation. Level of Evidence: Level IV, retrospective comparative study.

a single intra-articular injection of lidocaine hydrochloride used for knee arthroscopy did not influence the viability, morphology, and cultivation potential of chondrocytes in articular cartilage biopsy specimens assigned for autologous chondrocyte implantation.

세계 최초 리도카인 함유 폴리뉴클레오티드

릴리이드K

조직수복용생체재료

Polynucleotide Lidocaine

조직수복용생체재료 의료기기

릴리이드K 급여기준

6개월 내 최대 5회 투여

대상환자 : 방사선학적으로 중증도 이하(Kellgren-Lawrence grade I, II, III)의 슬관절의 골관절염 환자
* 히알루론산 나트륨(Sodium Hyaluronate) 의약품 제제와 동일·동시 투여 금지

*건강보험심사평가원 고시 제2021-41호

릴리이드K Product Information 1)

제품명	릴리이드K	
품목명	조직수복용생체재료(B04230.01[4])	
모델명	BM14005	
원재료	폴리뉴클레오티드나트륨(Sodium Polynucleotide) 20mg/mL 리도카인염산염일수화물(Lidocaine HCL Monohydrate) 3.2mg/mL	
사용목적	관절강에 주입하여 물리적 수복을 통해 관절 부위의 기계적 마찰을 줄여주는 목적으로 사용	
포장단위	프리필드실린지 2 mL X 5 Syringe / Box	
보관방법	밀봉용기, 직사광선을 피하여 2~25°C에서 얼지 않도록 보관	

*자세한 제품정보는 의료기기 전자민원창구(https://emed.mfds.go.kr)를 참조바랍니다.

[Reference]

1) 식약처 의료기기 제품정보, http://emed.mfds.go.kr, 2) 릴리이드K 임상3상, 3) J Clin Med. 2021 Mar; 10(5): 1138, 4) 한국BMI 자체 실험 결과, 5) Cartilage. 2021 Dec; 13(1 Suppl): 4565-4635, 6) Arthroscopy. 2014 May; 30(5):607-12, 7) 건강보험심사평가원 심사지침

사내교육용

BMI KOREA

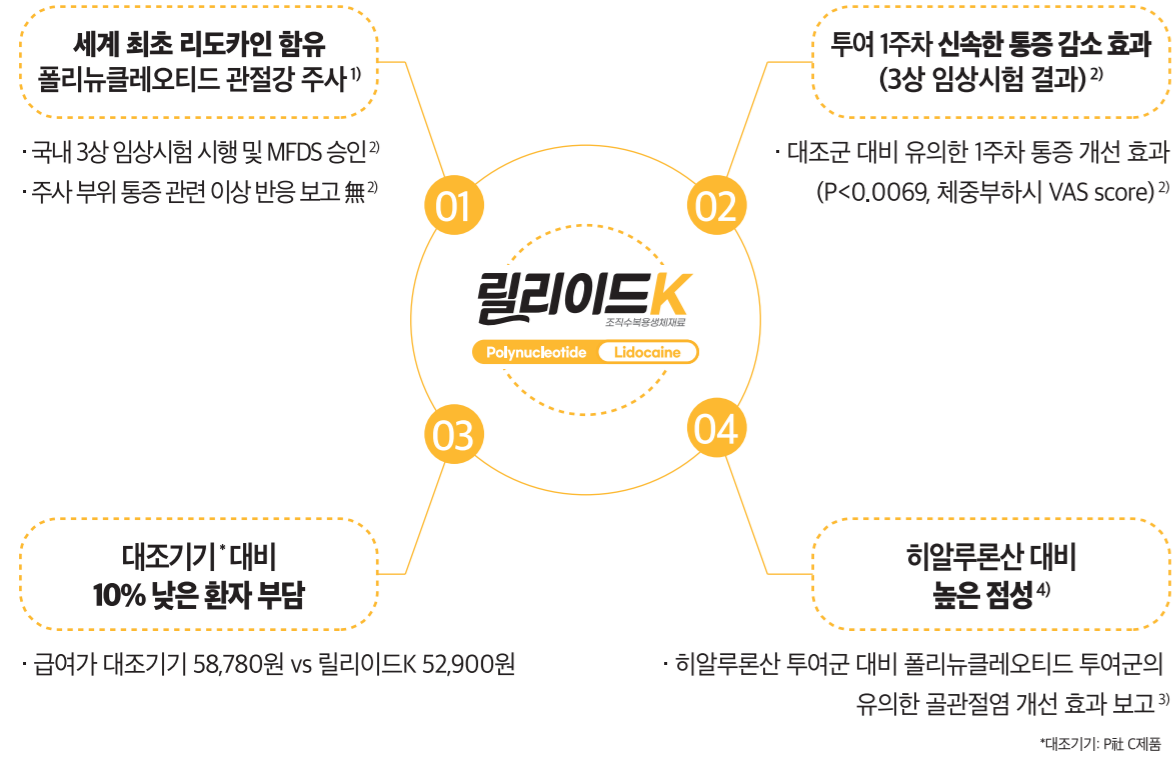
제주본사 : 제주특별자치도 제주시 첨단로7길 11 (우)63309 / TEL 064-724-5101 / FAX 064-724-5104

창계지사-연구소 : 경기도 의왕시 양지편2로 13 (우)16009 / TEL 031-426-4780~3 / FAX 031-426-4784

오송공장 : 충청북도 청주시 흥덕구 오송읍 오송생명 14로 90 (우)28220 / TEL 043-234-5101 / FAX 043-234-5102

BMI KOREA

릴리이드K 특징점



3상 임상연구에서 릴리이드K는 단 한건의 주사 부위 통증도 보고되지 않았습니다.²⁾

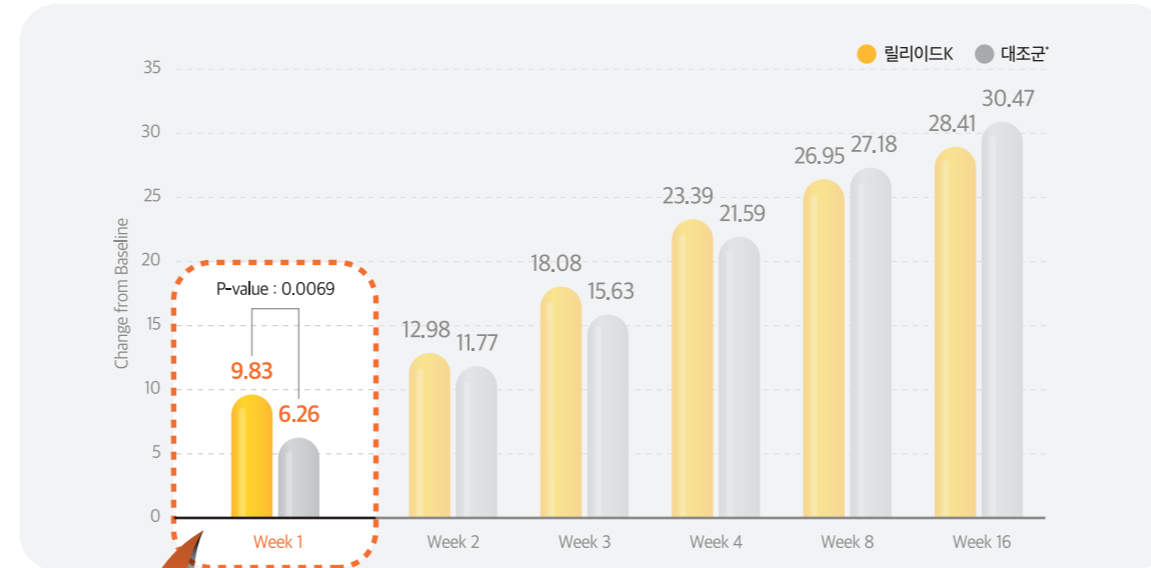
표 11-3 주사부위 국소반응(Solicited) 의료기기 이상반응 분류 - Safety Set

System Organ Class Preferred Term	시험군 (N=128)	대조군* (N=129)	Total (N=257)
Injection site pain	0(0.00), [0]	1(0.78), [1]	1(0.39), [1]

*대조군: P社 C제품

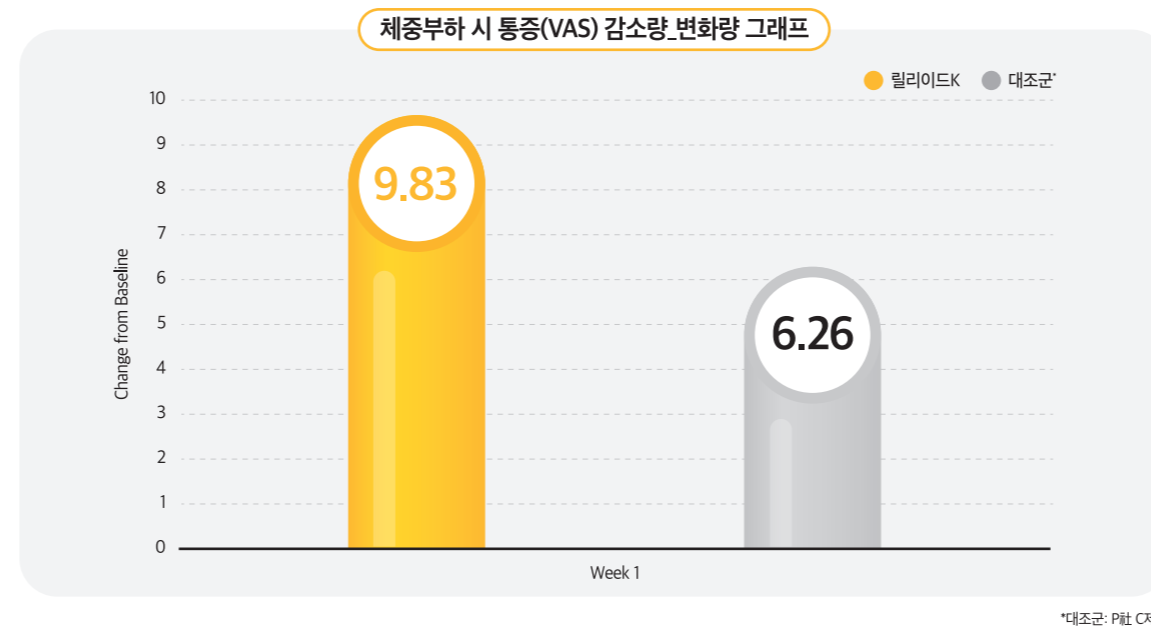
16주간 지속적으로 통증 감소 효과 증가

릴리이드K는 16주간 지속적으로 통증이 개선되었습니다.²⁾



신속한 통증 감소 효과

릴리이드K는 1주차에 대조군 대비 57% 높은 VAS score 개선효과가 보고되었습니다.(3상 임상시험)²⁾



릴리이드K는 높은 점성으로 무릎 관절 내에서 관절의 마찰을 감소시킵니다.⁴⁾

릴리이드K vs 히알루론산나트륨(Sodium Hyaluronate, HA)



HA 투여군 대비 유의한 통증 감소 효과 보고³⁾

통증 감소율 : PN 투여군 -81%, HA 투여군 5%, Crosslinked HA 투여군 -16% (VAS score 평가)

