의료기술재평가보고서 2019

망막하 경성 삼출물 제거술의 안전성 및 유효성 평가

NECA
한국보건의료연구원

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NECA – 의료기술재평가사업

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2020. 1.

NECA 한국보건의료연구원
National Evidence-based Healthcare Collaborating Agency

주 의

1. 이 보고서는 한국보건의료연구원에서 의료기술재평가사업 (NECA-R-19-001-1)의 일환으로 수행한 연구 사업의 결과 보고서입니다.

2. 이 보고서 내용을 신문, 방송, 참고문헌, 세미나 등에 인용할 때에는 반드시 한국보건의료연구원에서 수행한 연구사업의 결과임을 밝혀야 하며, 연구내용 중 문의사항이 있을 경우에는 연구책임자 또는 주관부서에 문의하여 주시기 바랍니다.

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차 례

표차례

그림 차례

요약문 (국문)

▢ 평가배경

건강보험심사평가원 급여보장실 예비급여부는 신의료기술평가 이전에 등재된 비급여 항목의 (예비급여 도입) 검토를 위하여 본원으로 안전성 및 유효성 평가를 의뢰하였고 관련근거: 비급여 항목에 대한 안전성·유효성 등 평가의뢰(건강보험심사평가원 예비급여부-141, 2018.02.19.)하여, 해당 항목에 포함된 '망막하 경성 삼출물 제거술'을 평가하게 되었다. 해당 의료기술에 대한 대한안과학회 의견은 "안전성 및 유효성"에 대해서는 "필요없음"의 의견과 함께 "실시빈도"에서 "임상에서 활용하지 않는 기술로 삭제가능하다"는 의견을 제시하였다. 따라서 이를 평가하기 위해 안전성 및 유효성을 파악하고, 소위원회를 구성하여 의료기술에 대한 평가를 하고자 하였다.

▢ 위원회 운영

'NECA 재평가 전체 연구진 회의'에서는 해당 의료기술의 소위원회 구성을 위한 관련 임상분과인 대한안과학회가 적절할 것으로 판단하였다. 따라서, 대한안과학회의 추천을 받아 총 5인으로 소위원회를 구성하였다. 소위원회는 총 3회에 걸쳐 운영되었다.

▢ 평가 목적 및 방법

본 연구의 목적은 당뇨병성 황반부종 환자에서 망막하 경성 삼출물 제거술의 임상적 안전성 및 유효성을 체계적 문헌고찰을 통해 평가하였다.

▢ 평가 결과

당뇨병성 황반부종의 망막하 경성 삼출물 제거술에 대한 안전성과 유효성을 총 5편 문헌(비무작위 비교연구 2편, 증례연구 3편)을 바탕으로 평가하였다. 대조군이 각 연구마다 다르고, 안전성 및 유효성 관련 지표들이 수치 등의 요약표가 아닌 개별 증례보고 형태로 되어 있고, 해당 지표별로 보고하지 않아 양적 합성이 불가능하였고, 질적으로 기술하였다.

비교 연구에서는 안전성 관련 지표인 황반원공, 망막(황반)위축, 황반변성 등이 망막하 경성 삼출물 제거술에서 더 많이 발생하는 것으로 보고하였다(망막하 경성 삼출물 제거술 58.3% vs. 유리체절제술 또는 수술거부 44.4%). 증례연구에서는 2편의 문헌에서 황

반원공(5.4%, 57.1%)을 보고하였다.

비교 연구의 시력 개선은 2편에서 반대 방향의 결과를 보고하였다. Takaya 등(2004) 문헌은 유리체절제술과 비교하여 시력개선은 중재군 38.5%, 대조군(유리체절제술) 50%로 대조군의 시력 개선율이 더 높았다. 또한, 최종 평균 시력에 대한 두 군간 비교에서 통계적 차이가 없다고 보고하였다(P value 0.5). Avci(2008) 문헌은 수술거부군과의 비교결과, 망막 경성 삼출물 제거군에서는 72.7% 개선된 반면 대조군(수술거부군)은 시력 개선은 0건이었다.

증례연구는 경성 삼출물 제거술을 받은 환자 중 69.7~83.3%가 수술 전 시력에 비해 개선되었다고 보고하였다. 수술 후 경성 삼출물은 비교연구 2편에서 모두 중재군은 0%, 대조군은 30%, 12.5%가 있다고 보고하였고, 증례연구에서는 2편의 연구에서는 0%, 1편의 연구에서는 14.3%가 있다고 보고하였다. 경성 삼출물 제거 정도는 비교연구와 증례연구 모두 경성 삼출물이 제거되거나 감소했다고 보고하였다.

▢ 결론

본 연구의 체계적 문헌고찰 결과, 가장 최근 문헌은 2008년으로 2010년 이후 최신 문헌이 없고, 선택된 문헌도 근거의 신뢰수준이 매우 낮은 비무작위배정 비교연구 2편과 증례연구 3편 밖에 없었다.

당뇨병성 황반부종 환자에서 망막하 경성 삼출물 제거술은 유리체절제술과 비교에 있어 시력개선 효과가 있다고 보고한 백분율이 낮았고, 최종 평균시력에 대한 두 군간 비교에서는 차이가 없었다(P value 0.5). 안전성 관련 지표인 황반원공, 망막(황반)위축, 황반변성 등은 유리체절제술에 비해 더 높은 것으로 나타났다.

반면, 당뇨병성 황반부종 환자에서 망막하 경성 삼출물 제거술은 미치료 군과의 비교연구 또는 증례연구결과에서는 시력개선 효과가 있고, 안전성 지표인 황반원공, 망막(황반)위축, 황반변성 등도 일부에서 보고되어 안전성의 위험도 일부 있는 것으로 나타났다.

따라서 소위원회는 망막하 경성 삼출물 제거술(유리체절제술과 함께 수행)은 당뇨병성 황반부종 환자에서 유리체 절제술에 비해 시력개선 효과 차이가 없고(부가적인 이득이 없고), 미치료군 비교 또는 증례연구에서는 제한적으로 효과가 있는 것으로 보였으나, 황반원공, 망막박리, 황반변성 등의 발생으로 인해 안전성에 일부 위험이 있는 기술로 평가하였다.

의료기술재평가위원회는 '망막하 경성 삼출물 제거술'에 대해 소위원회의 검토결과에

근거하여 다음과 같이 심의하였다(2020. 1. 10.).

의료기술재평가위원회는 경성 삼출물이 있는 당뇨병성 망막병증 환자에서 망막하 경성 삼출물 제거술을 권고하지 않는다(권고등급 II).

권고사유는 다음과 같다. 망막하 경성 삼출물 제거술은 유리체절제술 후 수행하는 추가시술로 비교기술인 유리체절제술에 비해 임상적 효과성이 낮고, 안전성도 낮은 기술로 의료기술재평가위원회에서는 판단하였다. 현재 망막하 경성 삼출물 제거술보다 더 안전하고 효과적인 약물치료 등이 있어서 임상적 필요성이 낮은 것으로 확인되었다. 또한, 대한안과학회의 시술건수에 대한 설문조사 결과 거의 사용되지 않고 있음을 확인하였고, 해당 기술을 사용하는 임상의에게 근거기반 새로운 정보를 제공할 필요성이 제기되었다.

이에 의료기술재평가위원회는 경성 삼출물이 있는 당뇨병성 망막병증 환자에서 해당 기술을 권고하지 않음(II)으로 결정하였다.

Ⅰ 서론

1. 평가배경

건강보험심사평가원 급여보장실 예비급여부는 신의료기술평가 이전에 등재된 비급여 항목의 (예비급여 도입) 검토를 위하여 관련 학(협)회 의견수렴 절차를 진행한 바 있다. 그 결과, '안전성 및 유효성 검증 필요' 등으로 회신된 19개 항목에 대해 본원으로 안전성 및 유효성 평가를 의뢰하였고[1], 해당 항목에 포함된 '망막하 경성 삼출물 제거술'을 평가하게 되었다.

해당 의료기술은 대한안과학회에서 제안된 의료기술로 아래와 같이 안전성 및 유효성에 대한 검증이 필요없다는 의견과 함께 임상에서 활용하지 않는 기술로 삭제가능하다는 의견을 제시하였다. 따라서 이를 평가하기 위해 안전성 및 유효성을 파악하고, 소위원회를 구성하여 의료기술에 대한 평가를 하고자 하였다.

표 1. 망막하 경성 삼출물 제거술 학회의견

의견수렴 학회	대한안과학회
행위정의	당뇨로 인한 황반부종 등에서 심한 중심와 경성 삼출물이 동반된 경우 삼출물로 인한 망막의 손상을 방지하고 시력개선의 효과 및 차후의 레이저 치료 효과를 높이기 위해 수술적으로 망막하 경성 삼출물을 제거함. 망막에 구멍을 의도적으로 뚫어 그 구멍으로 경성 삼출물을 제거하므로 출혈이나 망막박리 등의 합병증에 유의해야 함
안전성, 유효성 검증 필요성	• 필요없음
실시빈도	• 삭제 가능함. 임상에서 시행되지 않고 있는 시술

출처: 건강보험심사평가원 공문(예비급여부-141 2018.02.19.)

1) 관련근거: 비급여 항목에 대한 안전성·유효성 등 평가의뢰(건강보험심사평가원 예비급여부-141, 2018.02.19.)

1.1. 평가대상 의료기술

가. 행위정의

망막하 경성 삼출물 제거술은 비급여로 건강보험심사평가원의 고시항목 상세내용은 다음과 같으나, 행위설명은 구체적인 내용이 없었다.

표 2. 건강보험심사평가원 고시항목 상세내용

행위명 (보험분류번호)	망막하 경성 삼출물 제거술 (조663)
수가코드	SZ663
급여여부	비급여
적용일자(등재일자)	2001-05-01
행위 설명	-확인안됨

출처: 건강보험심사평가원

나. 시술방법

유리체절제술은 안구 내부로 기구를 삽입해서 유리체를 제거한 후 망막 아래의 삼출물이나 출혈 등을 빼내는 시술이다. 망막하 경성 삼출물 제거술은 유리체절체술에 추가적으로 망막에 조그만 구멍을 내고 포셉이나 겸자를 이용해 경성 삼출물을 제거하는 방법이다(Lu 등, 2016).

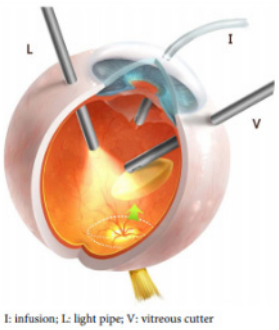


그림 1. 유리체 절제술 (출처: Lu 등(2016))

망막하 경성 삼출물의 시술방법을 찾을 수 없어 자세한 시술방법은 건강보험심사평가원의 유리체절제술 행위설명을 참고하였다. 유리체절제술에 망막절개술로 망막하 포셉을 이용해 경성 삼출물을 제거하고 망막하 주입을 통해 조심스럽게 씻어내는 행위가 추가된다.

표 3. 건강보험심사평가원의 유리체절제술 행위설명

적응증

1. 유리체 혼탁 혹은 출혈
2. 증식 유리체 망막병증
3. 망막박리
4. 기타 다수의 망막질환

실시방법

1. 산동제를 점안(5분간격 3회 점안)한다.
2. 수술전 안저 도해한다.
3. Scrubbing 및 수술복을 착의한다.
4. 안구, 안검 소독 및 draping시킨다.
5. 소독 후 개검기로 눈을 노출시킨다
6. 결막을 절개한다
7. 관류액주입관공정을 위한 전치봉합을 실시한다.
8. 공막 세군데(2시반, 3시반, 9시반)에 공막 천자를 시행한다
9. 공막창을 공막마개로 일시 폐쇄한다.
10. 주입관(3시반)을 설치한다.(BSS plus액 주입구)
11. 유리체 절제술용 콘택트렌즈나 광범위 관찰용 특수렌즈(wide-field system)를 고정하기위한 고리봉합을 실시하여 고정한다.
12. 유리체절제술 기구(망막쑤시개, 눈속가위, 눈속집개, 안내조명침)를 이용하여 뒤유리체 박리를 일으킨다.
13. 대롱바늘을 이용하여 출혈, 삼출물 등을 제거한다.
14. 유리체절단침을 이용하여(750 cut/min) 유리체를 흡인하고 절단하여 제거한다
15. 눈속출혈을 투열침으로 소작한다.
16. 도상검안경으로 안저를 360도 확인한다.
17. 필요에 따라 눈속가스를 주입한다.
18. 공막, 결막을 봉합한다.
19. 스테로이드, 항생제 결막하 주사, eye patching한다.

다. 국내 적용 사례

해당 의료기술은 비급여 항목으로 국내에서 사용되는 현황을 파악하기는 어려웠다. 따라서 해당 의료기술의 사용량 파악을 위해 대한안과학회에 공문(부록 3.1. 공문-경제성평가연구단-1044 (2019.08.27.))으로 문의하였다. 그 결과, 대한안과학회로부터 망막하 경성 삼출물 제거술 관련 대한안과학회의 설문결과를 공문으로 회신 받았으며(부록 3.2 공문- 대안학 12740 (2019-268)) 회신 받은 내용은 아래와 같다.

89명의 응답자 중 해당 기술 및 시술방법을 잘 알고 있는 응답자는 15.7%에 불과했고, 기술을 알고 있으나 시술방법을 모르는 응답자는 33.7%, 기술 및 시술방법을 모른다고 응답한 경우는 50.6%였다. 84.3%의 응답자가 해당 시술의 자세한 시술방법은 모르는 것으로 파악되었다. 또한, 최근 5년 내 망막하 경성 삼출물 제거술을 시행한 적이 있냐는 질문에 3명(3.4%)만이 있다고 답을 하였고, 이들 3명이 5년간 시행한 건수문의 결과, 1건 - 1명, 2건 - 1명, 수 백 건 - 1명이었다.

위 설문조사 자료는 정확한 수술 건수가 아닌 회원 설문조사 결과이지만, 위 결과를 통해 망막하 경성 삼출물 제거술이 활발하게 시행하는 시술이 아님을 확인할 수 있었다.

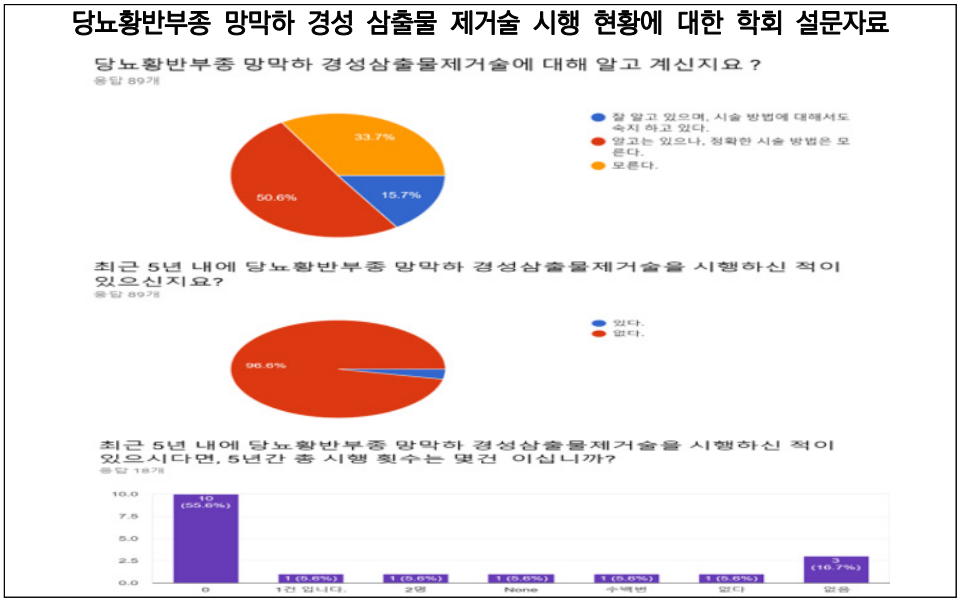


그림 2. 대한안과학회의 망막하 경성 삼출물 제거술 설문조사결과
(출처: 공문- 대안학 12740 (2019-268))

1.2. 질병 및 현존하는 의료기술

가. 당뇨병성 황반부종

1) 정의

당뇨병성 망막병증은 당뇨병의 미세혈관 합병증으로 당뇨병 환자의 3명중 1명이 영향을 받고, 시력 상실의 주요 원인이다. 당뇨병성 황반부종(Diabetic Macular Edema)은 망막의 중심인 황반 부위에 부종이 생길 때를 말하는데, 당뇨병의 또 다른 합병증인 당뇨병성 망막병증의 결과이며 시력 손상을 가져오는 중요한 안과 질환이다. 황반부종은 황반 중심으로부터 1 유두지름(1,500 μm) 이내에 망막이 두꺼워져 있거나 분명한 경성 삼출물이 있을 때를 말하며 모세혈관 내피세포층 즉, 내측 혈액망막장벽의 파괴로 체액과 혈장성분이 누출되어 황반에 고임으로써 일어난다(이용준 등, 2010)

모든 당뇨병 환자의 약 10%에서 발생하고, 이중 40%는 황반중심을 침범한다. 당뇨병성 망막병증이 진행할수록 유병률이 높아져 가벼운 비증식성 당뇨병성 망막병증은 2~6%, 중등도에서 심한 비증식성 당뇨병성 망막병증은 20~63%, 증식성 당뇨병성 망막병증은 70~74%에서 황반부종이 발견된다(이용준 등, 2010).

2) 질병부담

건강보험심사평가원 의료통계정보[2]에서 확인된 가장 최근의 질병통계에 따르면, 당뇨병성 망막병증(H360)으로 의료기관(입원 및 외래)을 찾은 환자 수는 최근 5년간 증가하는 추세로 2018년 총 356,243명으로 확인되었다.

표 4. 2014-2018년 당뇨병성 망막병증(H360) 환자 수

(단위: 명)

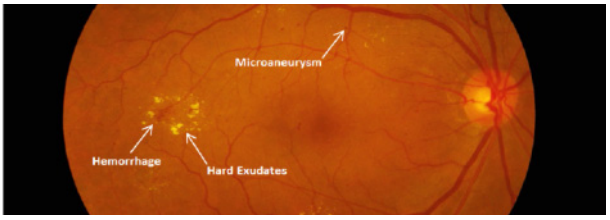
	2014년	2015년	2016년	2017년	2018년
계	297,526	313,956	336,247	353,244	356,243
남자	145,840	155,138	167,496	176,874	180,147
여자	151,686	158,818	168,751	176,370	176,096

2) 보건의료빅데이터개방시스템(https://opendata.hira.or.kr)

나. 당뇨병성 망막병증의 진단 및 치료

임상적으로는 안저검사에서 두꺼워진 망막, 경성 삼출물, 낭포성 변화, 형광안저혈관조영에서 혈관누출과 빛간섭단층촬영 등으로 알 수 있다. 역학 연구와 임상 시험의 결과 혈당, 혈압 및 혈중 지질을 잘 관리하면 당뇨병성 망막병증의 발병 위험을 감소시키고, 진행 속도가 느려질 수 있다고 보고하였다(2017년 ICO 가이드라인).

당뇨성 황반부종은 당뇨병성 망막병증의 단계와는 별도로 평가되는 추가의 중요한 합병증으로, 모든 중증도의 눈에서 볼 수 있고 독립적으로도 발생할 수 있다. 당뇨병성 황반변성은 3단계로 중중도가 분류되고 있으며, 이 중증도에 따라 치료 및 추적 관찰 등을 권고할 수 있다. 당뇨병성 황반부종은 당뇨병성 황반부종 없음(No DME, Diabetic Macular Edema), 중심부 비침범 당뇨병성 황반부종(Noncenteral involed DME), 중심부 침범 당뇨병성 황반부종(Central-involved DME)으로 나눠진다. '당뇨병성 황반부종 없음'은 망막 경화 및 경성 삼출물이 황반에 없는 상태이고, 중심 비침범 당뇨병성 황반부종(Noncenteral involed DME)은 황반중심 유두지름 1mm 이하로 망막 비후 또는 경화가 있는 상태이고, 중심 침범 당뇨병성 황반부종(Central invovled DME)은 황반중심 유두지름 1mm 이상 망막 비후또는 경화가 있는 상태이다. 경성 삼출물은 이전 또는 현재의 황반부종의 징후이다.



출처: 2017 ICO Guidelines for Diabetic Eye Care

그림 3. 경성 삼출물이 있는 당뇨병성 망막병증의 안저검사 결과

표 5. 당뇨병성 황반부종 중증도

	산동검사상 정의기준
No DME	망막 경화 및 경성 삼출물이 황반에 없는 상태
Noncenteral involed DME	황반중심 유두지름 1mm 이하로 망막 경화가 있는 상태
Centeral involed DME	황반중심 유두지름 1mm 이상 망막 경화가 있는 상태

DME: Diabetic Macular Edema, 출처: 2017 ICO Guidelines for Diabetic Eye Care

이들 중 No DME일 경우는 추적관찰이나 안과의뢰가 필요가 없고, 중심부 비침범 DME은 3개월에 한 번씩 추적관찰 및 검사가 필요하고, 의료환경이 고자원 환경에서는 안과의뢰가 필요하고, 중-저자원의 의료환경에서는 안과의뢰가 필요하지 않지만 하게 될 경우 레이저 시술이 가능한 안과로 의뢰할 것을 권고하고 있다. 중심부 침범 DME일 경우 모든 의료환경에서 1개월마다 추적관찰 및 검사를 해야 하고 안과의뢰가 필요하다 (2017년 ICO 가이드라인).

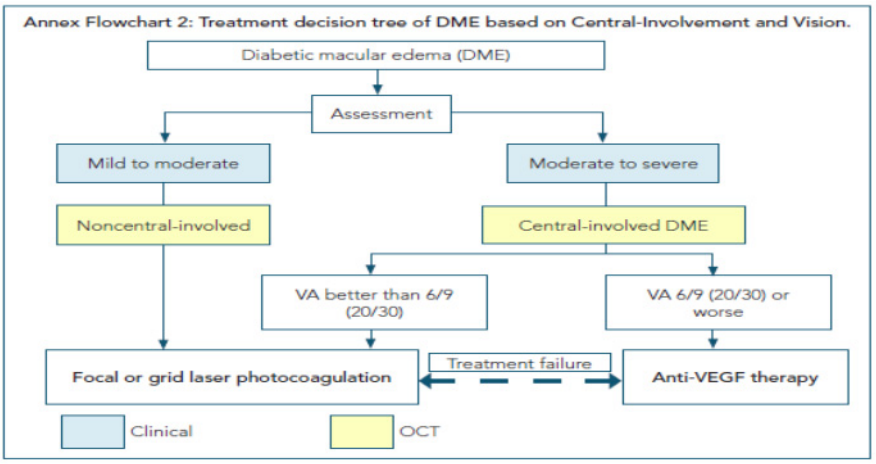


그림 4. 당뇨병성 황반부종 치료 의사결정 흐름도(출처: 2017 ICO 가이드라인)

당뇨병성 망막병증의 치료가 필요한 경우는 비정상 망막 혈관이 생겼을 때(증식성 당뇨병성 망막병증)와 망막의 중심부인 황반 부위에 부종(당뇨병성 황반부종)이 생겼을 때다. 당뇨병성 황반부종 치료를 위한 주사 약제로 항혈관내피성장인자(anti-VEGF, Vascular Endothelial Growth Factor)와 유리체내 스테로이드 삽입물(dexamethasone intravitreal implant)이 널리 이용되고 있다. 각 약제마다 비용, 지속기간, 발생 가능한 부작용 등이 다르기 때문에 약제의 선택은 검사 결과와 환자의 상황에 따라 결정하게 된다. 당뇨병성 황반부종의 치료 의사결정 흐름도는 〈그림 4〉와 같다.

당뇨병성 망막병증에 대한 수술 기술도 크게 발전하고 있다. 40여 년 전만 해도 안구 내부를 수술하는 것은 불가능했다. 하지만 1971년 Machemer가 처음 유리체절제술을 시행한 후 수술기구와 수술방법이 발전하면서 당뇨병성 망막병증을 덜 침습적인 방법으로 짧은 시간 내에 수술할 수 있게 되었고 수술 후 환자들의 평균 시력도 향상되었다 (Machemer 등, 1971). 유리체절제술은 레이저 치료를 할 수 없거나, 치료에도 불구하

고 반복적인 출혈 혹은 망막박리로 시력이 심하게 손상된 경우 시행한다. 최근 수년간 증식 당뇨병성 망막병증에 대한 유리체절제술은 수술 술기의 발전, 눈 속 레이저 도입 등에 힘입어 수술 시기가 점차 빨라지고 수술 적응증 역시 점차 확대되는 추세다. 2017년 ICO 가이드라인에서는 유리체절체술(Vitrectomy)에 대한 적응증을 다음과 같이 제시하였다.

표 6. 유리체절제술 적응증

i. 1~3개월 이상 지속되는 중증의 유리체 출혈 : 치료가 되지 않은 증식성 당뇨병성 망막병증(proliferative diabetic retinopathy)의 경우 빠르게 진행될 수 있으며 4~6주간 유리체 출혈이 있는 경우 유리체 절제술을 시행하는 것이 합리적임
ii. 광범위한 광범위망막광응고술(panretinal photocoagulation, PRP)에도 불구하고 지속되는 진행성 활성 증식성 당뇨병성 망막병증이 있거나 지속적으로 증식성 당뇨병성 망막병증이 재발하는 경우
iii. 최근 황반 견인 박리가 발생한 경우 황반 중심을 위협하거나 황반을 침범하는 경우 견인 시술은 수술의 이점이 있음
iv. 견인-열공 망막박리 병합 접근법(Combined traction-rhegmatogenous retinal detachment)
v. 황반부종 또는 망막 전막을 견인이 필요한 경우

출처 : 2017 ICO 가이드라인

다. 관련 선행연구

Codenotti 등(2010)은 경성 삼출물은 망막하에 축적되어 시력손상의 원인이 되며, 망막하 절개의 외과수술을 통해 이러한 삼출물을 제거하는 방법이 제안되었고, 이 외과수술은 Takagi 등(1999)과 Sakuraba 등(2000)이 처음으로 수행하였다고 보고하였다.

Takagi 등(1999)은 처음으로 경성 삼출물 제거를 위해 수술방법을 사용하였고, Sakuraba 등(2000)은 삼출물 제거술이 효과가 있다고 보고한 반면, Takaya 등 (2004)은 경성 삼출물 제거가 장기적인 시력개선을 제공하지 못한다고 보고하였다. 또한, 수술 후 합병증으로 황반원공이 생길 수 있다고 보고하였다. 삼출물이 있을 때 황반 조직이 얇고 변성되어 수술로 인해 황반원공이 생길 가능성이 높다고 보고하였다.

2. 평가 목적

본 연구는 당뇨병성 황반부종 환자에서 망막하 경성 삼출물 제거술의 임상적 안전성 및 유효성을 체계적 문헌고찰로 평가하고자 하였다.

Ⅱ 평가방법

1. 체계적 문헌고찰

1.1. 개요

망막하 경성 삼출물 제거술은 해당 기술에 대한 명확한 의학용어가 없기 때문에 수술 방법에 “망막의 경성 삼출물을 제거했다”는 표현이 있는 문헌을 선택하기로 소위원회에서 합의하였다. 따라서, 본 연구는 체계적 문헌고찰을 통해 망막하 경성 삼출물 제거술에 대한 의과학적 근거를 평가하였다.

1.2. PICO-TS

최종 확정된 핵심질문 및 평가범위(PICO-TS)는 다음과 같다.

핵심질문

당뇨병성 망막증에서 망막하 경성 삼출물 제거술의 임상적 안전성 및 유효성은 어떠한가?

표 7. PICO-TS 세부 내용

구분	세부내용
대상 환자 (Patients)	당뇨병성 황반부종(경성 삼출물이 있는 대상자)
중재법 (Intervention)	**망막하 경성 삼출물 제거술** 특정 시술명이 없어 **“수술방법에 경성 삼출물을 제거했다”**는 표현이 있는 문헌 선택
비교치료법 (Comparators)	제한없음
결과변수 (Outcomes)	- 안전성 : 시술로 인한 부작용 등(망막구멍, 황반변성, 망막박리, 출혈 등) - 유효성 : 시력(Primary 지표), 경성 삼출물 제거 정도
추적관찰기간 (Time)	제한하지 않음
연구유형 (Study Design)	무작위배정 임상시험(RCT), 비무작위 임상시험연구(비무작위 임상시험, 코호트연구, 환자-대조군 연구), 증례연구

1.3. 문헌검색

문헌검색은 국내외 주요 데이터베이스를 통하여 포괄적으로 수행하였다. 2019년 8월 19일 최종 완료하였다.

가. 국외

국외 문헌검색은 Ovid-MEDLINE, Ovid-Embase, Cochrane Central Register of Controlled Trials (CENTRAL) 3개의 전자 데이터베이스를 사용하여 수행되었다. "경성 삼출물 (hard exudates)"를 기본으로 포괄적으로 검색하였다. 검색전략은 각 DB별 특성에 맞게 MeSH term, 논리연산자, 절단 검색 등의 기능을 적절히 활용하여 구축하였으며 검색기간 및 언어에 제한을 두지 않았다.

Ovid-MEDLINE	http://ovidsp.tx.ovid.com
Ovid-Embase	http://ovidsp.tx.ovid.com
Cochrane Controlled Register of Trials (CENTRAL)	https://www.cochranelibrary.com/

나. 국내

국내 문헌검색은 KoreaMed, 한국의학논문데이터베이스(KMBASE), 학술연구정보서비스(RISS), 한국학술정보(KISS), 국가과학기술정보센터(NDSL) 5개의 전자 데이터베이스를 사용하여 각 데이터베이스별 특성을 고려하여 수행하였다.

KoreaMed	https://koreamed.org/
한국의학논문데이터베이스(KMBASE)	http://kmbase.medric.or.kr/
학술연구정보서비스(RISS)	http://www.riss.kr/
한국학술정보(KISS)	http://kiss.kstudy.com/
국가과학기술정보센터(NDSL)	http://www.ndsl.kr/

1.4. 문헌선정

문헌선정은 두 명의 검토자가 독립적으로 수행하였다. 1, 2차 문헌선정 단계에서는 제목 및 초록을 바탕으로 본 연구의 평가대상과 관련성이 없는 것으로 판단되는 문헌을 배제하였고, 3차 단계에서는 문헌의 전문(full-text)을 검토하여 본 연구의 선택기준에 맞는 문헌을 최종적으로 선정하였다. 의견 불일치가 있을 경우, 제 3자와 논의를 통하여 의견일치를 이루었다.

표 8. 선택배제기준

구분	내용
선택기준 (Inclusion criteria)	① 당뇨병성 황반부종(망막병증 포함) 중 경성 삼출물이 있는 대상자 ② 망막하 경성 삼출물 제거술이 시행된 연구 ③ 적절한 의료결과가 하나 이상 보고된 연구
배제기준 (Exclusion criteria)	① 대상자가 아닌 문헌 ② 중재법이 아닌 문헌(경성 삼출물 제거 수술 표현이 없는 문헌) ③ 적절한 결과가 보고되지 않은 문헌 ④ 원저가 아닌 연구(종설, letter, comment 등) ⑤ 동물실험 또는 전임상시험 ⑥ 동료심사된 학술지에 게재되지 않은 문헌 ⑦ 초록만 발표된 연구 ⑧ 한국어나 영어로 출판되지 않은 문헌 ⑨ 중복문헌 ⑩ 원문 확보 불가

※ PICO-TS 참고

1.5. 비뚤림 위험 평가

문헌의 비뚤림 위험 평가는 두 명의 검토자가 독립적으로 수행하여 의견일치를 이루었다. 개별 문헌은 연구유형에 따라, 무작위배정 비교임상시험은 Cochrane의 Risk of Bias, 비무작위 임상연구(Non-randomized controlled study, NRS)는 ROBANS ver 2.0 사용하여 비뚤림 위험을 평가하였다.

1.6. 자료추출

자료추출은 최종 선택된 문헌을 대상으로 사전에 확정한 자료추출 서식을 활용하여 두 명의

검토자가 각각 독립적으로 수행하고, 의견 불일치가 있을 경우 제3자와 함께 논의하여 합의하였다. 각 문헌에서 저자명, 출판연도, 연구설계, 연구대상자 특성 등 연구의 일반적 특성, 사전에 정한 임상적 안전성 및 효과성 관련 연구결과 값 등을 추출하였다.

1.7. 자료합성

최종 선정된 문헌은 양적 분석(quantitative analysis)이 가능할 경우 메타분석을 수행하였으나, 본 연구의 선택문헌 5편 중 비교연구가 2편밖에 없을 뿐만 아니라 2편의 비교군도 서로 같지 않아 양적 합성을 수행할 수 없었다. 따라서, 질적 검토(qualitative review)를 수행하였다.

1.8. 근거수준 평가

본 연구에서 수행한 체계적 문헌고찰의 주요 결과는 Grading of Recommendations Assessment, Development and Evaluation (GRADE) 방법을 이용하여 근거수준을 평가하였다.

1.9. 위원회 운영

‘NECA 재평가 전체 연구진 회의’에서는 해당 의료기술의 소위원회 구성을 위한 관련 임상분과인 대한안과학회가 적절할 것으로 판단하였다. 따라서, 공문(부록 2. 대한안과학회 소위원회 추천 공문)을 통해 대한안과학회의 추천을 받아 총 5인으로 소위원회를 구성하였다.

소위원회는 총 3회에 걸쳐 운영되었다.

- (1차) 2019년 8월 7일(수) 18시
- (2차) 2019년 9월 23일(월) 18시
- (3차) 2019년 11월 5일(화) 18시 30분

Ⅲ 평가결과

1. 문헌선정 결과

1.1. 문헌선정 개요

국내외 데이터베이스를 통해 총 1,139편(국내 142편, 국외 997편)이 검색되었으며 중복된 문헌을 배제한 후 남은 963편을 대상으로 문헌선택배제를 진행하였다. 제목 및 초록 검토를 통한 1, 2차 선택배제 과정을 통해 25편이 선별되었으며, 선별된 문헌의 원문 검토를 통해 최종 5편의 문헌이 선정되었다.

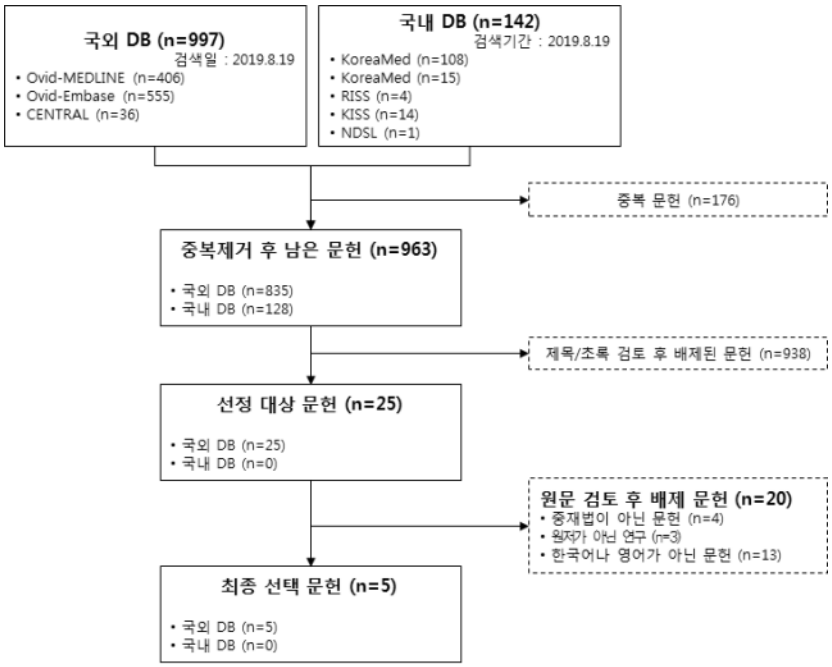


그림 5. 문헌선정 흐름도

1.2. 선정 문헌 특성

총 선택문헌은 5편으로 연구대상자는 총 86명, 111안이었다. 연구국가는 4편이 일본이었고, 1편만 터키였다. 2000년에 출판된 문헌 2편, 2004년 1편, 2008년 2편으로 2010년대 이후 문헌은 없었다. 모든 연구는 후향적 연구였고, 비교연구는 2편이었고, 3편은 모두 증례 연구였다. 비교연구인 Avci 등(2008) 문헌의 비교군은 광응고요법 후 수술을 거부한 환자였고, Takaya 등(2004) 문헌의 비교군은 유리체절제술만 받고 삼출물 제거술 받지 않은 환자였다.

선택문헌들의 대상자수는 4~40명(6~56안)으로 정규분포의 최소 표본수인 30명이 넘는 문헌은 1편밖에 없었다. 대상 질환은 모두 당뇨병성 황반병증이 있는 환자였고, 5편의 문헌의 대상자들은 모두 해당 연구에 등록되기 전 국소레이저(focal or grid laser)나 광응고요법(PRP, Panretinal Photocoagulation)을 받은 환자였다. 평균 나이에 대해 보고한 문헌은 4편이었고, 58.9~62.3세였고, 남성 비율은 27.8~55.6%였다. 각 문헌에서는 평균 추적관찰 기간은 별도 보고하지 않았고, 개인단위로 보고된 추적관찰기간으로 평균을 산출하고, 범위를 제시하였다. 직접 산출한 평균추적관찰 기간은 0.7~3년(범위 1~65.5개월)이었다.

저자의 결론은 총 5편의 문헌 중 4편이 망막의 경성 삼출물 제거술이 시력 등 개선효과가 있는 것으로 보고하였다. Avci 등(2008)은 관찰만 하는 것에 비해 수술로 경성 삼출물을 제거하는 것이 해부학적/기능적으로 더 낫다고 보고하였다. 증례연구인 Naito 등(2008), Sakuraba 등(2000), Takagi 등(2000)의 문헌도 경성 삼출물 제거 또는 시력에 효과가 있다고 결론을 보고하였다.

한편, Takaya 등(2004) 문헌 1편만 장기 시력개선 효과를 기대하기 어렵고, 경성 삼출물이 생기기 전에 당뇨병성 망막병증을 적극적으로 치료해야 한다고 보고하였다. 이 문헌에서는 유효성 측면에서 시력 개선율이 1년 시점 54%에서 최종관찰 시점(장기)에서 38%로 감소하고, 대조군(유리체절제술)과 비교해서도 통계적으로 유의한 차이가 없다는 것과 안전성 측면에서 경성 삼출물과 황반부종은 감소하는 대신 황반의 위축 및 변성이 나타나는 것으로 결과를 보고하고 있다. 선택문헌의 자세한 특성은 아래 표와 같다.

표 9. 선택문헌의 기초특성표

#	1저자 (연도)	국가	연구 유형	대상자수 명(안)	연구대상자*	평균연령	남자	중재∫	비교군	추적 기간∬	저자 결론
1	Takaya (2004)	일본	후향적 비교	18명 (21안)	경성 삼출물 제거가 필요한 당뇨병성 황반 병증 환자	중재군 63.5세 대조군 60.3세	5명 (27.8%)	유리체절제술과 황반하 경성 삼출물 제거술	유리체 절제술로 삼출물 제거술 받지 않은 환자	평균 3.5년 (23~56개월)	장기 시력개선효과를 기대하기 어려움, 경성 삼출물이 생기기 전에 적극적 치료가 필요
2	Avci (2008)	터키	후향적 비교	18명 (21안)	플라그와 같은 경성 삼출물이 있는 당뇨병성 황반병증환자	중재군 61.7±7.8세 대조군 62.3±8.2세	10명 (55.6%)	유리체절제술과 황반하 경성 삼출물 제거술	수술을 거부한 환자	평균 3년 (30~43개월)	관찰만 하는 것에 비해 해부학·기능적으로 효과 있음
3	Naito (2008)	일본	증례 연구	40명 (56안)	당뇨병 및 황반하 경성 삼출물이 있는 환자	58.9±8.5세	20명 (50%)	유리체절제술과 황반하 경성 삼출물 제거술	-	평균 1.1년 (1~65.5개월)	경성 삼출물 제거를 위한 수술의 효과 있음
4	Sakuraba (2000)	일본	증례 연구	4명(6안)	당뇨병성 황반변성 중 PRP 후(5개월)에도 경성 삼출물이 있는 환자	NR	2명 (50%)	유리체절제술과 황반하 경성 삼출물 제거술	-	평균 0.7년 (5~11개월)	중심 시각 기능을 향상 효과 있음
5	Takagi (2000)	일본	증례 연구	6명(7안)	당뇨병성 황반변성 중 경성 삼출물을 제거한 환자	56세 (범주 46-60)	3명 (50%)	유리체절제술과 황반하 경성 삼출물 제거술	-	평균 1.8년 (6~46개월)	저시력 환자에게 효과적

PRP: panretinal photocoagulation

* 수술 전 대상자 모두 국소레이저(focal or grid laser)나 광응고요법(PRP, Panretinal Photocoagulation)을 받음, -: Not reported

∫: 망막절개 후 포셉으로 망막하 경성 삼출물 제거

∬: 문헌에서 환자단위로 보고된 값으로 평균을 산출하고, 범위를 제시함

1.3. 비뚤림 위험 평가 결과

전체 5편의 문헌 중 2편의 NRS 연구는 RoBANS ver.2를 이용하여 문헌의 비뚤림 위험 평가를 수행하였다. '대상군 비교가능성' 관련 비뚤림에 대하여 2편(100%) 모두 일부 지표에 대해서만 기저특성을 비교하여 통계적 유의성을 기술하였고, 기저특성표 등을 제시하지 않아 '불확실(Unclear)'로 평가되었다. 대상군 선정은 Avci 등(2008) 문헌은 수술을 거부한 대상자가 비교군으로 선정되어 비뚤림 위험이 '높음'으로 평가하였고, Takaya 등(2004) 문헌은 두 군 선정 및 배제 기준에 대한 명확한 언급이 없어 '불확실(Unclear)'로 평가하였다. 교란변수는 기저특성에 대한 두 군간 차이가 불확실하고, 이를 통제하려거나 두 군간 명확한 비교 등이 수행되지 않아 '높음'으로 평가하였다.

노출은 중재법에 대한 수행여부로, 후향적 의무기록 등으로 시술여부를 확인하여 모두(2편, 100%) '낮음(Low)'으로 평가하였고, 결과평가 시 '평가자의 눈가림'과 '평가결과'는 시력 등 객관적인 지표를 측정하여 '낮음(Low)'으로 평가하였다.

두 편 연구 모두 프로토콜이 존재하지 않았다. 연구방법에 기술된 두 군간 비교결과도 제시되지 않은 Acvi 등(2008) 문헌은 '불완전한 결과자료' 및 '선택적 결과보고' 모두 '높음(High)'으로 평가하였고, Takaya 등(2004) 문헌은 유효성 지표인 시력 등에 대해 두 군간 비교 및 해당 결과지표를 보고하였으나, 안전성 지표인 부작용과 관련해 환자 개별로 기술되어 언급이 없는 경우 발생유무를 등을 확인할 수 없어 '불확실'로 평가하였다. '민간연구비 지원' 관련하여 2편(100%) 모두 언급이 없어 '불확실(Unclear)'로 평가하였다.

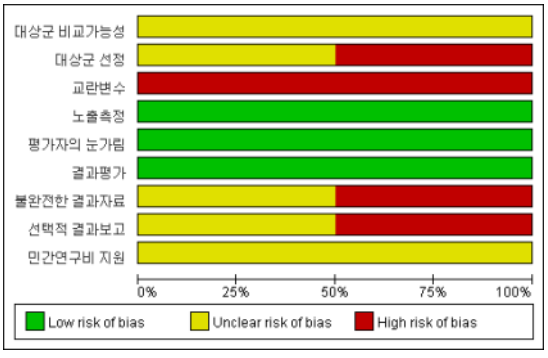


그림 6. NRS 비뚤림 위험 그래프

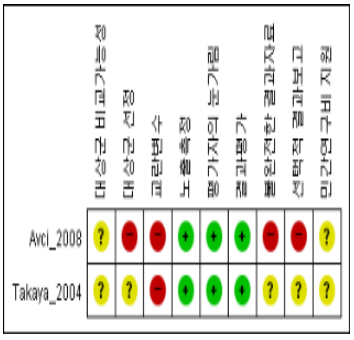


그림 7. NRS 비뚤림 위험에 대한 평가결과 요약표

2. 분석결과

망막하 경성 삼출물 제거술의 결과지표인 시력, 삼출물 정도, 합병증 등 유효성과 안전성에 대해 양적합성을 하고자 하였으나 총 선택문헌 5편 중 비교연구가 2편 밖에 없을 뿐만 아니라 2편의 비교군도 서로 같지 않아 양적 합성을 수행할 수 없었다. 따라서, 선택문헌의 결과를 질적으로 기술하였다.

2.1. 안전성

가. 비교연구

Avci 등(2008) 문헌의 안전성 관련 보고는 중재군에 대해서만 보고하였다. 중재군의 수술중 합병증은 발생하지 않았다고 보고했고, 추적관찰 기간 12~42개월 사이에 수정체 유화술을 받은 백내장이 5명(45.5%)에서 발생하였다고 보고하였다. 또한, 시력과는 관련이 없는 핵경화(nuclear sclerosis)가 3명에서 발생했다고 보고하였다.

망막의 최종상태에 대한 결과 중 안전성과 관련된 지표를 정리하였다. 중재군은 위축(망막색소상피) 5건(45.5%), 망막하 섬유증 1건(9.1%), 흉터(망막색소상피 등) 1건(9.1%)이 발생하였고, 대조군은 위축(망막색소상피) 3건(30%), 흉터(망막색소상피 등) 2건(20%)이 발생했다고 보고하였다. 위축은 중재군이 대조군에 비해 더 발생률이 높았다.

Takaya 등(2004) 문헌은 유리체절제술과 망막하 경성 삼출물 제거술을 동시에 한 군(중재군)과 유리체절제술만 시행한 군(대조군)을 비교한 결과에서는 중재군인의 수술중 합병증은 총 5건(38.5%)이 보고되었고, 황반원공 3건(23.1%), 망막파열 1건(7.7%), 렌즈파열 1건(7.7%)이 발생하였다. 대조군은 수술중 합병증으로 망막열개(oral dialysis) 1건(12.5%)이 보고되었다. 수술 후 합병증은 중재군은 총 3건(23.1%), 즉, YAG Capsulotomy을 시행한 백내장 1건(7.7%), 망막하 출혈 1건(7.7%), 자연적으로 사라진 맥락막 박리 1건(7.7%)을 보고하였고, 대조군은 YAG Capsulotomy을 시행한 백내장 1건(12.5%)을 보고하였다.

망막의 최종상태에 대한 결과 중 안전성과 관련된 지표를 확인한 결과, 중재군은 황반원공 1건(7.7%), 시신경 위축 1건(7.7%), 망막하 섬유증 2건(15.4%), 황반변성 5건(38.5%)이었고, 대조군은 시신경 위축 1건(12.5%), 황반변성 4건(50%)이 보고되었다.

표 10. 비교연구의 안전성 관련 결과

1저자 (연도)	대조군	결과지표	시점	중재군(단위: 안)			대조군(단위: 안)			비고
				Total	Events	%	Total	Events	%	
Takaya (2004)	유리체절제술만 시행	황반원공	수술중	13	3	23.1	8	0	0	
		망막파열	수술중	13	1	7.7	8	0	0	
		수정체피막 파열	수술중	13	1	7.7	8	0	0	
		망막열개	수술중	13	0	0	8	1	12.5	
		백내장 (YAG Capsulotomy)	48개월, 40개월	13	1	7.7	8	1	12.5	
		망막하 출혈 (유리체절제술)	37개월	13	1	7.7	8	0	0.0	
		맥락막 박리 (자연적으로 사라짐)	33개월	13	1	7.7	8	0	0.0	
		망막하 섬유증	평균 3.5년 (23-56개월)	13	2	15.4	8	0	0	최종 망막 상태 중 안전성 관련 결과
		황반변성		13	5	38.5	8	4	50.0	
		황반원공		13	1	7.7	8	0	0	
		시신경 위축		13	1	7.7	8	1	12.5	
Avci (2008)	수술 거부	수술중 합병증*	수술중	11	0	0.0	-	-	-	
		백내장(수정체 유화술)*	12~42 개월	11	5	45.5	-	-	-	
		핵경화(nuclear sclerosis) 진행*	NR	11	3	27.3	-	-	-	시력과 관련 없음
		흉터(망막색소상피 등)	평균 3년 (30~43개월)	11	1	9.1	10	2	20.0	최종 망막 상태 중 안전성 관련 결과
		위축(망막색소상피)		11	5	45.5	10	3	30.0	
		망막하 섬유증		11	1	9.1	10	0	0	

* 수술은 중재군만 시행하여, 중재군의 합병증만 보고, -: Not Reported

나. 증례연구

Naito 등(2008) 문헌은 수술관련 합병증이 총 14건(25%)이 발생했다고 보고하였다. 망막파열 7건(12.5%), 황반원공 3건(5.4%), 핵경화가 4건(7.1%)이 발생하였고, 이들 합병증은 적절한 치료로 인해 심각한 합병증을 발생시키지 않았다고 보고하였다.

Sakuraba 등(2000)은 특발성 열공(iatrogenic lacuna), 망막박리, 또한 병용 수술로 인한 합병증인 수정체 이탈 등은 발견되지 않았다고 보고하였다.

Takagi 등(1998)은 수술중 합병증으로 황반원공 4건(57.1%)을 보고하였고, 수술 후 합병증으로 백내장 3건(42.9%), 망막전막 1건(14.3%), 핵경화 3건(42.9%), 피질혼탁을 2건(28.6%)이 보고되었다.

표 11. 증례 연구의 안전성 관련 결과

1저자 (연도)	결과지표	시점	중재군(단위: 안)		
			Total	Events	%
Naito (2008)	망막파열	평균 12.9개월 (1-65.5개월)	56	7	12.5
	황반원공		56	3	5.4
	수정체 핵경화		56	4	7.1
Sakurab a (2000)	특발성 열공(iatrogenic lacuna)	평균 8.5개월 (5-11개월)	6	0	0.0
	망막박리		6	0	0.0
	안구내 수정체 이탈		6	0	0.0
Takagi (1998)	황반원공	수술중	7	4	57.1
	백내장	평균 21개월 (6-46개월)	7	3	42.9
	망막전막(epiretinal membrane)		7	1	14.3
	핵경화*		7	3	42.9
	피질혼탁*		7	2	28.6

* 최종 망막 상태 중 안전성 관련 결과

2.2. 유효성

가. 비교연구

1) 시력 관련 결과

Avci 등(2008) 문헌은 유효성 지표인 시력에 대해 LogMAR, ETDRS (Early Treatment Diabetic Retinopathy Study) line 개선, Visual acuity 6m 등을 보고하였다. 시력개선 결과는 개별 환자의 눈단위로 보고된 수술전-후 값을 비교하여 개선, 변화없음, 악화를 산출하였다. 망막하 경성 삼출물 제거술의 수술 전후 시력개선 효과 중 LogMAR는 통계적으로 유의하게 수술 후에 개선되는 것으로 나타났고(P value 0.021), 반대로 대조군인 수술거부군은 최종 시점의 LogMAR가 수술 전에 비해 통계적으로 유의하게 나빠지는 것으로 나타났다(P value 0.005). ETDRS 개선효과는 중재군은 8건(72.7%)이 개선을 보고한 반면 대조군은 10건(100%) 모두 변화가 없거나 오히려 감소하는 것으로 보고하였다. Visual acuity 6m 개선효과도 마찬가지로 최종값 기준 중재군은 8건(72.7%)이 개선된 반면, 대조군은 10건(100%) 모두 악화되는 것으로 나타났다.

Takaya 등(2004) 문헌은 유리체절제술과 망막하 경성 삼출물 제거술을 동시에 시행한 군(중재군)과 유리체절제술만 시행한 군(대조군)을 비교한 결과의 LogMAR 시력 개선

효과는 두 군간 차이가 없는 것으로 나타났다(P value 0.5). 개별단위로 보고한 시력결과의 최종 시점 개선유무를 확인한 결과 중재군은 개선 5건(38.5%)인 반면 변화없음 1건(7.7%), 악화가 7건(53.8%)이었다. 대조군은 개선 4건(50%), 변화없음 1건(12.5%), 악화 3건(37.5%)이었다.

표 12. 비교연구의 시력관련 결과

1저자 (연도)	대조군	결과 변수	단위 항목	시점	항목	study group				control group				p value∫
						전체 N(안)	Mean (event)	SD (%)	p value*	전체 N(안)	Mean (event)	SD (%)	p value*	
Takaya (2004)	유리체 절제술만 시행	Log MAR	mean ,SD	baseline		13	1.54	1.3	-	8	1.30	0.38	-	0.23
				1년		13	1.43	0.39	-	8	1.43	0.44	-	-
				평균 3.5년 (23~56개월)		13	1.62	0.59	-	8	1.44	0.72	-	0.5
		시력 개선 (Log MAR)∬	event ,%	1년	개선	13	7	53.8	-	8	3	37.5	-	-
					변화없음	13	1	7.7	-	8	1	12.5	-	-
					악화	13	5	38.5	-	8	4	50.0	-	-
				평균 3.5년 (23~56개월)	개선	13	5	38.5	-	8	4	50.0	-	-
					변화없음	13	1	7.7	-	8	1	12.5	-	-
					악화	13	7	53.8	-	8	3	37.5	-	-
Avci (2008)	수술 거부	Log MAR	mean ,SD	baseline		11	1.35	0.3	-	10	1.06	0.2	-	0.55
				3개월		11	1.15	0.4	0.016	-	-	-	-	-
				1년		11	1.28	0.4	0.01	10	1.34	0.15	0.012	-
				3년		11	1.08	0.5	0.021	10	1.53	0.09	0.005	-
		ETDS line 개선	event ,%	평균 3년 (30~43개월)	+3	11	6	54.5	-	-	-	-	-	-
					1-2	11	2	18.2	-	-	-	-	-	-
					≤0	11	3	27.3	-	10	10	100	-	-
		시력 개선 (Visual acuity, 6m)∬	event ,%	3개월	개선	11	8	72.7	-	10	0	0.0	-	-
					변화없음	11	1	9.1	-	10	4	40.0	-	-
					악화	11	2	18.2	-	10	6	60.0	-	-
				1년	개선	11	10	90.9	-	10	0	0.0	-	-
					변화없음	11	0	0.0	-	10	2	20.0	-	-
					악화	11	1	9.1	-	10	8	80.0	-	-
				평균 3년 (30~43개월)	개선	11	8	72.7	-	10	0	0.0	-	-
					변화없음	11	1	9.1	-	10	0	0.0	-	-
					악화	11	2	18.2	-	10	10	100	-	-

ETDRS: Early Treatment Diabetic Retinopathy Study
* p value: 시술 전-후의 차이 p value, ∫ p value: 두 그룹 간 차이 p value,
∬: 환자의 개별 눈단위로 보고된 전-후값을 비교하여 산출함, -: Not reported

2) 경성 삼출물 관련 결과

Takaya 등(2004) 문헌은 유리체절제술과 망막하 경성 삼출물 제거술을 동시에 한 군(중재군)과 유리체절제술만 시행한 군(대조군)의 잔여 경성 삼출물 결과는 중재군은 0건(0%), 대조군은 1건(12.5%)이 있다고 보고하였다.

Avci 등(2008) 문헌은 망막하 경성 삼출물 제거술군은 수술 후 경성 삼출물은 모든 대상자에서 제거되었다고 보고한 반면, 수술을 거부한 대조군은 3건(30%)의 삼출물이 있다고 보고하였다(석회 삼출물 2건, 흉터 삼출물 1건).

표 13. 비교연구의 경성 삼출물 관련 결과

1저자 (연도)	대조군	결과 변수	단위	항목	시점	study group				control group				p value∫
						전체 N(안)	Mean (event)	SD (%)	p value*	전체 N(안)	Mean (event)	SD (%)	p value*	
Takaya (2004)	유리체 절제술만 시행	경성 삼출물	mean ,SD	크기 (DD)	baseline	13	1.25	0.64		8	0.85	0.54		0.19
			event ,%	유무	평균 3년 (30~43 개월)	13	0	0		8	1∬	12.5		
Avci (2008)	수술 거부	경성 삼출물	mean ,SD	크기 (DA)	baseline	11	1.1	0.4		10	1.2	0.36		0.83
			event ,%	유무	1년	11	0	0		-	-	-		
					평균 3년 (30~43 개월)	11	0	0		10	3∬	30		

DA:disc area, DD: disc diameter
* p value: 시술 전-후의 차이 p value, ∫: 두 그룹 간 차이 p value, - : Not Reported,
∬: 최종 망막상태에서 삼출물 관련 결과

나. 증례연구

1) 시력 관련 결과

Naito 등(2008) 문헌은 2line 이상 시력 개선결과는 Best 시력 기준 45건(80.4%), 최종 시력 기준 39건(69.7%)이었고, Sakuraba 등(2000)은 5건(83.3%)이 시력이 개선되었다고 보고하였다. Takagi 등(1998) 문헌의 시력개선 결과는 Best 시력 기준 6건(85.7%), 최종 시력 기준 39건(71.4%) 이었다.

표 14. 증례연구의 시력 관련 결과

1저자 (연도)	결과 변수	시점	항목	study group			
				전체 N (안)	Event	%	P value*
Naito (2008)	Best 시력의 개선	평균 12.9개월 (1-65.5개월)	+2 line	56	45	80.4	<0.001
			0	56	8	14.3	
			<0	56	3	5.3	
	최종 시력의 개선	평균 12.9개월 (1-65.5개월)	+2 line	56	39	69.7	0.0016
			0	56	11	19.6	
			<0	56	6	10.7	
Sakuraba (2000)	시력개선 (Visual Acuity, Decimal)∬	평균 8.5개월 (5-11개월)	개선	6	5	83.3	
			변화없음	6	1	16.7	
Takagi (2000)	Best 시력의 개선 (Visual Acuity, 20 ft) ∬	평균 21개월 (6-46개월)	개선	7	6	85.7	
			변화없음	7	1	14.3	
	최종 시력의 개선 (Visual Acuity, 20 ft) ∬	평균 21개월 (6-46개월)	개선	7	5	71.4	
			변화없음	7	1	14.3	
			악화	7	1	14.3	

∬: 환자의 개별 눈단위로 보고된 전-후 값을 비교하여 산출함

2) 경성 삼출물 관련 결과

Naito 등(2008) 문헌은 모든 환자에서 수술 후 경성 삼출물이 제거되고, 황반부종이 눈에 띄게 감소했다고 보고하였고, Sakuraba 등(2000)도 모든 환자에서 경성 삼출물이 제거되었다고 보고하였다. Takagi 등(1998)은 잔여 경성 삼출물 없음이 6건(85.7%), 감소 1건(14.3%)이었고, 1건의 황반부종은 광응고요법으로 해결했다고 보고하였다.

표 15. 증례연구의 삼출물 관련 결과

1저자 (연도)	결과					
Naito (2008)	모든 환자에서 수술 후 경성 삼출물이 사라지고, 황반부종이 눈에 띄게 감소함					
Sakuraba (2000)	모든 환자에서 경성 삼출물은 제거되었음					
Takagi (2000)	결과지표		시점	study group		
				전체 N (안)	Event	%
	경성 삼출물	없음	평균 21개월 (6-46개월)	7	6	85.7
		감소		7	1	14.3
	황반부종	없음	평균 21개월 (6-46개월)	7	6	85.7
		광응고요법으로 해결		7	1	14.3

2.3. 연구결과 요약

당뇨병성 망막병증 환자에서 망막하 경성 삼출물 제거술의 안전성과 유효성 관련 결과를 요약하면 다음과 같다.

표 16. 연구결과 요약표 (단위: %)

연구디자인	결과 중요도	비교연구				증례연구		
문헌		Avci (2008)		Takaya (2004)		Naito (2008)	Sakuraba (2007)	Takagi (1998)
중재군/대조군		중재군	대조군	중재군	대조군	중재군	중재군	중재군
1. 안전성								
황반원공	C	-	-	23.1	0	5.4	-	57.1
망막(황반) 위축	C	45.5	30	7.7	12.5	-	-	-
황반변성	C	-	-	38.5	50	-	-	-
Critical outcomes 계†		**45.5**	**30**	**69.3**	**62.5**	**5.4**	**-**	**57.1**
망막출혈	I	-	-	7.7	0	-	-	-
망막박리	I	-	-	7.7	0	-	0	-
망막파열, 수정체막 파열, 망막열개, 특발성 열공 등	I	-	-	15.4	12.5	12.5	0	-
Important outcomes 계†		**-**	**-**	**30.8**	**12.5**	**12.5**	**-**	**-**
핵경화	L	27.3	-	-	-	7.1	-	42.9
백내장	L	45.5	-	7.7	12.5	-	-	42.9
망막 섬유증	L	9.1	0	15.4	0	-	-	-
흉터	L	9.1	20	-	-	-	-	-
수정체이탈	L	-	-	-	-	-	0	-
망막전막	L	-	-	-	-	-	-	14.3
피질혼탁	L	-	-	-	-	-	-	28.6
2. 유효성								
시력개선	C							
- 개선		72.7	0	38.5	50	69.7	83.3	71.4
- 변화없음		9.1	40	7.7	12.5	19.6	16.7	14.3
- 악화		18.2	50	53.8	37.5	10.7	0	14.3
평균 시력 개선효과 (logMAR) - mean	C	-	-	1.62 P-value 0.5	1.44	-	-	-
삼출물 정도	C							
- 경성 삼출물 있음		0	30	0	12.5	0*	0*	14.3

중요도 C: critical outcomes, I: important, but not critical outcomes, L: limited importance outcomes

- : Not reported, †: 문헌에서 증례별로 보고하고 있고, 중복결과지표가 없어 합쳐서 제시하기로 함

* 경성 삼출물은 모두 제거되었다는 기술문을 근거로 0% 작성함

2.4. GRADE 근거수준

GRADE 방법론을 사용하여 근거수준을 평가하였다.

모든 결과지표는 ①핵심적인(critical), ②중요하지만 핵심적이지 않은(important but not critical), ③덜 중요한(limited importance)의 3개 범주에 따라 중요도(importance)를 구분하였고, ①핵심적인(critical), ②중요하지만 핵심적이지 않은(important but not critical) 결과지표를 대상으로 GRADE 근거수준을 확인하였다. 또한, 안전성 관련 결과지표는 증례별로 보고하고 있고, 증례별로 여러 결과지표가 동시에 발생하지 않아 이들을 하나로 합쳐서 결과를 제시하기로 하였다.

표 17. 결과변수의 중요도 결정

구분		결과변수의 중요도 결정사항
안전성	황반원공, 망막(황반)위축, 황반변성	critical
	망막출혈, 망막박리, 망막(수정체) 파열	important but not critical
	그 외 부작용(핵경화, 백내장, 망막 섬유증, 흉터, 망막전막 등)	limited importance
유효성	시력개선	critical
	경성 삼출물	critical

GRADE는 연구유형별로 나누어서 수행하는 것이 원칙으로, 증례연구를 제외한 비교연구에서만 근거수준(certainty of evidence)을 제시하였다.

표 18. [당뇨병성 황반부종: 망막하 경성 삼출물 제거술 vs. 수술거부 또는 유리체절제술]
NRS: GRADE evidence profile

Certainty assessment							№ of patients		Effect	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	망막경성 삼출물 제거술	수술거부 또는 유리체절제술			
황반원공, 망막(황반)위축, 황반변성 등											
1	observational studies	serious[a]	not serious	not serious	very serious[b]	none	14*/24 (58.3%)	8*/18 (44.4%)	• Takaya(2004): 69.3% vs. 62.5% • Avci(2008): 45.5% vs. 30%	⊕○○○ VERY LOW	CRITICAL
시력개선											
2	observational studies	serious[a]	very serious[c]	not serious	very serious[c]	none	13/24 (54.2%)	4/18 (22.2%)	• Takaya(2004): 38.5% vs. 50% 최종 평균시력 두 군간 차이없음 (P value 0.5) • Avci(2008): 72.7% vs. 0%	⊕○○○ VERY LOW	CRITICAL
경성 삼출물											
2	observational studies	serious[a]	not serious	not serious	serious[d]	none	0/24 (37.8%)	4/18 (22.2%)	• Takaya(2004): 0% vs. 12.5% • Avci(2008): 0% vs. 30%	⊕○○○ VERY LOW	CRITICAL
핵경화, 백내장, 망막 섬유증, 흉터, 망막전막 등											
2	observational studies	serious[a]	not serious	not serious	very serious[b]	none	4*/13 (30.8%)	1/8 (12.5%)	• Takaya(2004): 30.8 vs. 12.5 • Avci(2008): not reported	⊕○○○ VERY LOW	IMPORTANT

NRS: non-randomized controlled study

Explanations
a. 비교연구이나 증례연구처럼 개별 환자단위로 보고, 교란요인 통제, 선택적 결과보고 등 비뚤림 위험 높음
b. 환자개별 보고로 결과값에 대한 신뢰수준 확인이 어려움
c. 2편의 연구의 결과의 방향이 서로 반대 방향임
d. 각 문헌의 N수가 30명이 되지 않음
* 모든 event수의 합

[GRADE: Certainty of evidence]
High: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low: Any estimate of effect is very uncertain.

Ⅳ 요약 및 결론

1. 평가결과 요약

당뇨병성 황반부종의 망막하 경성 삼출물 제거술에 대한 안전성과 유효성을 총 5편 문헌(비무작위 비교연구 2편, 증례연구 3편)을 바탕으로 평가하였다. 대조군이 각 연구마다 다르고, 안전성 및 유효성 관련 지표들이 수치 등의 요약표가 아닌 개별 증례보고 형태로 되어 있고, 해당 지표별로 보고하지 않아 양적 합성이 불가능하였고, 질적으로 기술하였다.

비교 연구에서는 안전성 관련 지표인 황반원공, 망막(황반)위축, 황반변성 등이 망막하 경성 삼출물 제거술에서 더 많이 발생하는 것으로 보고하였다(망막하 경성 삼출물 제거술 58.3% vs. 유리체절제술 또는 수술거부 44.4%). 증례연구에서는 2편의 문헌에서 황반원공(5.4%, 57.1%)을 보고하였다.

비교 연구의 시력 개선은 2편에서 반대 방향의 결과를 보고하였다. Takaya 등(2004) 문헌은 유리체절제술과 비교하여 시력개선은 중재군 38.5%, 대조군(유리체절제술) 50%로 대조군의 시력개선율이 더 높았다. 또한, 최종 평균 시력에 대한 두 군간 비교에서 통계적 차이가 없다고 보고하였다(P value 0.5). Avci(2008) 문헌은 수술거부군과의 비교결과, 망막하 경성 삼출물 제거군에서는 72.7% 개선된 반면 대조군(수술거부군)은 시력개선은 0건이었다.

증례연구는 경성 삼출물 제거술을 받은 환자 중 69.7~83.3%가 수술전 시력에 비해 개선되었다고 보고하였다. 수술후 경성 삼출물은 비교연구 2편에서 모두 중재군은 0%, 대조군은 30%, 12.5%가 있다고 보고하였고, 증례연구에서는 2편의 연구에서는 0%, 1편의 연구에서는 14.3%가 있다고 보고하였다. 경성 삼출물 제거 정도는 비교연구와 증례연구 모두 경성 삼출물이 제거되거나 감소했다고 보고하였다.

2. 결론

본 연구의 체계적 문헌고찰 결과, 가장 최근 문헌은 2008년으로 2010년 이후 최신 문헌이 없고, 선택된 문헌도 근거의 신뢰수준이 매우 낮은 비무작위배정 비교연구 2편과 증례연구 3편 밖에 없었다.

당뇨병성 황반부종 환자에서 망막하 경성 삼출물 제거술은 유리체절제술과 비교에 있어 시력개선 효과가 있다고 보고한 백분율이 낮았고, 최종 평균시력에 대한 두 군간 비교에서는 차이가 없었다(P value 0.5). 안전성 관련 지표인 황반원공, 망막(황반)위축, 황반변성 등은 유리체절제술에 비해 더 높은 것으로 나타났다.

반면, 당뇨병성 황반부종 환자에서 망막하 경성 삼출물 제거술은 미치료군과의 비교연구 또는 증례연구결과에서는 시력개선 효과가 있고, 안전성 지표인 황반원공, 망막(황반)위축, 황반변성 등도 일부에서 보고되어 안전성의 위험도 일부 있는 것으로 나타났다.

따라서, 소위원회는 망막하 경성 삼출물 제거술(유리체절제술과 함께 수행)은 당뇨병성 황반부종 환자에서 유리체 절제술에 비해 시력개선 효과 차이가 없고(부가적인 이득이 없고), 미치료군 비교 또는 증례연구에서는 제한적으로 효과가 있는 것으로 보였으나, 황반원공, 망막박리, 황반변성 등의 발생으로 인해 안전성에 일부 위험이 있는 기술로 평가하였다.

의료기술재평가위원회는 '망막하 경성 삼출물 제거술'에 대해 소위원회의 검토결과에 근거하여 다음과 같이 심의하였다(2020. 1. 10.). 의료기술재평가위원회는 경성 삼출물이 있는 당뇨병성 망막병증 환자에서 망막하 경성 삼출물 제거술을 권고하지 않는다(권고등급 II).

권고사유는 다음과 같다. 망막하 경성 삼출물 제거술은 유리체절제술 후 수행하는 추가시술로 비교기술인 유리체절제술에 비해 임상적 효과성이 낮고, 안전성도 낮은 기술로 의료기술재평가위원회에서는 판단하였다. 현재 망막하 경성 삼출물 제거술보다 더 안전하고 효과적인 약물치료 등이 있어서 임상적 필요성이 낮은 것으로 확인되었다. 또한, 대한안과학회의 시술건수에 대한 설문조사 결과 거의 사용되지 않고 있음을 확인하였고, 해당 기술을 사용하는 임상의에게 근거기반 새로운 정보를 제공할 필요성이 제기되었다.

이에 의료기술재평가위원회는 경성 삼출물이 있는 당뇨병성 망막병증 환자에서 해당 기술을 권고하지 않음(II)으로 결정하였다.

V

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Takagi H, Otani A, Kiryu J, Ogura Y. New surgical approach for removing massive foveal hard exudates in diabetic macular edema. Ophthalmology. 1999;106(2):249-56; discussion 56-7.

Takaya K, Suzuki Y, Mizutani H, Sakuraba T, Nakazawa M. Long-term results of vitrectomy for removal of submacular hard exudates in patients with diabetic maculopathy. Retina (Philadelphia, Pa). 2004;24(1):23-9.

VI 부록

1. 소위원회

'NECA 재평가 전체 연구진 회의'에서는 해당 의료기술의 소위원회 구성을 위한 관련 임상분과인 대한안과학회가 적절할 것으로 판단하였다. 따라서, 공문(부록 2. 대한안과학회 소위원회 추천 공문)을 통해 대한안과학회의 추천을 받아 총 5인으로 소위원회를 구성하였다.

소위원회는 총 3회에 걸쳐 운영되었다.

1.1. 제1차 소위원회

- 회의일시: 2019년 8월 7일(수) 18시~
- 회의내용: 행위정의, 평가방법 논의

1.2. 제2차 소위원회

- 회의일시: 2019년 9월 23일(월) 18시~
- 회의내용: 문헌선택결과 보고, 자료분석 방향 논의

1.3. 제3차 소위원회

- 회의일시: 2019년 11월 5일(화) 18시 30분~
- 회의내용: 결과 검토 및 결론 논의

2. 대한안과학회 소위원회 추천 공문

대 한 안 과 학 회
THE KOREAN OPHTHALMOLOGICAL SOCIETY

100-808 서울시 중구 중림로 50-1 SKY 1004빌딩 701호 / 전화 (02) 583-6520 / 전송 (02) 583-6521
홈페이지 http://www.ophthalmology.org / e-mail kos@ophthalmology.org / 담당 신유정

대안학 12616 (2019-144) 2019. 6. 4.
수 신 한국보건의료연구원장
제 목 망막하 경성 삼출물 제거술의 의료기술재평가 관련 임상 전문가 추천

1. 귀 원의 무궁한 발전을 기원합니다.

2. 관련 근거 : 미래보건의료 정책연구단-404 (2019. 5. 22)

3. 본 학회의 망막하 경성 삼출물 제거술 의료기술재평가 관련 임상 전문가를 아래와 같이 추천 합니다.

---------- 아 래 ----------

학회명	이름	소속	연락처	이메일
대한안과학회				

대 한 안 과 학 회 이 사 장 박 [redacted]
보 험 이 사 송 [redacted]

3. 망막하 경성 삼출물 제거술 사용현황

3.1. 요청 공문

경제성평가연구단-1044

보건의료 근거창출을 선도하는 전문기관

NECA 한 국 보 건 의 료 연 구 원

수 신 대한안과학회장
(경유)
제 목 「망막하 경성 삼출물 제거술(SZ663)」 관련 사용현황 요청의 건

1. 귀 학회의 무궁한 번영을 기원합니다.
2. 한국보건의료연구원에서는 비급여 항목에 대한 안전성·유효성 평가 의뢰(건강보험심사평가원 예비급여부-141, 2018.02.19.)를 받아 망막하 경성 삼출물 제거술 소위원회를 구성하여 수행하고 있습니다. 이에 망막하 경성 삼출물 제거술의 최근 5년간 실시현황에 대한 정보를 귀 학회에 문의드립니다.
3. 자세한 요청사항은 다음과 같습니다.

- 다 음-

가. 실시현황 요청 항목:

행위명 (보험분류번호)	망막하 경성 삼출물 제거술 (조663)
수가코드	SZ663
급여여부	비급여
적용일자(등재일자)	2001-05-01
행위정의	당뇨로 인한 황반부종 등에서 심한 중심와 경성 삼출물이 동반된 경우 삼출물로 인한 망막의 손상을 방지하고 시력개선의 효과 및 차후의 레이저 치료 효과를 높이기 위해 수술적으로 망막하 경성 삼출물을 제거함. 망막에 구멍을 의도적으로 뚫어 그 구멍으로 경성 삼출물을 제거하므로 출혈이나 망막박리 등의 합병증에 유의해야 함
대한안과학회 의견	• 안전성, 유효성 검증 필요성 : 필요없음 • 실시빈도 : 삭제 가능함. 임상에서 시행되지 않고 있는 시술

출처 : 건강보험심사평가원 공문(예비급여부-141 2018.02.19.)

나. 요청사유 : 해당 시술은 비급여 시술로 실시현황을 찾기 어려움
제 1차 소위원회에서 대한안과학회에 문의하기로 결정(경제성평가연구단-939)

다. 요청내용 : 최근 5년간 사용현황 - 연단위 실시건수, 실시기관수

라. 회신기한: 2019년 9월 16일(월요일)까지

한국보건의료연구원장

3.2. 회신 공문

대 한 안 과 학 회

THE KOREAN OPHTHALMOLOGICAL SOCIETY

04508 서울시 중구 중림로 50-1 SKY 1004빌딩 701호 / 전화 (02) 583-6520 / 전송 (02) 583-6521
홈페이지 http://www.ophthalmology.org / e-mail kos@ophthalmology.org / 담당 신유정

대안학 12740 (2019-268) 2019. 9. 25.

수 신 한국보건의료연구원장

제 목 망막하 경성 삼출물 제거술 사용 현황 요청에 대한 회신

1. 귀 원의 무궁한 발전을 기원합니다.

2. 관련 근거 : 경제성평가연구단-1044 (2019. 8. 27)

3. 망막하 경성 삼출물 제거술 사용 현황 요청에 대해 본 학회의 설문 자료를 별첨과 같이 회신 합니다.

별첨. 학회 설문자료 1부. 끝.

대 한 안 과 학 회 이 사 장 박 기 호

보 험 이 사 송 종 석

"직인생략"

4. 문헌 검색 전략

4.1. 국외 데이터베이스

4.1.1. Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to May 03, 2019 〈검색일: 2019. 8. 19.〉

	No.	Searches	MEDLINE
Patients	1	exp Diabetic Retinopathy/	23,481
	2	diabetic macular disease.mp.	6
	3	Macular Edema/ or Macular Degeneration/ or macular.mp.	51,780
	4	diabetic macular edema.mp.	3,089
	5	macul*.mp.	71,753
	6	or/1-5	89,740
	7	exudate*.mp.	27,014
	8	hard*.mp.	171,773
	9	hard exudate*.mp.	445
	10	or/7-9	198,154
Intervention	11	(surger* or surgi*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	2,952,121
	12	Surgical Procedures, Operative/	53,863
	13	General Surgery/	37,977
	14	(remov* or excisi*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	755,056
	15	or/11-14	3,439,640
P & I	16	6 and 10 and 15	406

4.1.2. Embase 1974 to 2019 Week 18 〈검색일: 2019. 8. 19.〉

	No.	Searches	EMbase
Patients	1	Diabetic Retinopathy.mp. or exp diabetic retinopathy/	45,443
	2	diabetic macular edema.mp. or exp retina macula edema/ or exp diabetic macular edema/	14,675
	3	Macular Edema/ or Macular Degeneration/ or macular.mp.	69,241
	4	diabetic macular disease.mp.	6
	5	macul*.mp.	108,845
	6	or/1-5	141,910
	7	exudate*.mp.	26,647
	8	hard exudate*.mp.	624
	9	hard*.mp.	207,800
	10	or/7-9	233,564
Intervention	11	(surger* or surgi*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]	3,790,328
	12	Surgical Procedures.mp. or surgical technique/	394,286
	13	General Surgery.mp. or exp general surgery/	21,741
	14	(remov* or excisi*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]	934,150
	15	or/11-14	4,376,836
P & I	16	6 and 10 and 15	555

4.1.3. Cochrane Controlled Register of Trials (CENTRAL) 〈검색일: 2019. 8. 19.〉

	No.	Searches	EMbase
Patients	1	MeSH descriptor: [Diabetic Retinopathy] explode all trees	1,273
	2	diabetic macular edema	1,798
	3	MeSH descriptor: [Macular Edema] explode all trees	973
	4	retina macular edema	1,036
	5	macul*	8,210
	6	(macul* near/2 edema*)	2,863
	7	#1 or #2 or #3 or #4 or #5 or #6	8,911
	8	(hard* near/5 exudate*)	92
	9	hard*	14,868
	10	exudate*	1,023
	11	#8 or #9 or #10	15,742
Intervention	#12	surger* or surgi*	249,870
	#13	MeSH descriptor: [General Surgery] explode all trees	335
	#14	remov* or excisi*	39,742
	#15	#12 or #13 or #14	269,076
P & I	#16	#7 and #11 and #15	87
		Trials	36

4.2. 국내 데이터베이스

4.2.1. KoreaMed 〈검색일: 2019. 8. 19.〉

No.	Searches	KoreaMed
1	(hard*) AND exudate*	24
2	(macular edema*) AND exudate*	23
3	(exudate*) AND (((remov*) OR surg*) OR excisi*)	61
		108

4.2.2. 한국의학논문데이터베이스(KMbase) : 국내발표논문 〈검색일: 2019. 8. 19〉

No.	Searches	KMbase
1	([ALL=경성 삼출물] OR [ALL=망막 부종])	12
2	(([ALL=망막] AND [ALL=삼출물]) AND [ALL=제거])	0
3	([ALL=경성] AND [ALL=삼출물])	3
4	(([ALL=망막] AND [ALL=삼출물]) AND [ALL=수술])	0
		15

4.2.3. 학술연구정보서비스(RISS) : 국내학술지논문 〈검색일: 2019. 8. 19.〉

No.	Searches	RISS
1	전체 : 경성 〈AND〉 전체 : 삼출물	3
2	전체 : 경성 삼출물 〈AND〉 전체 : 제거	0
3	전체 : 망막 〈AND〉 전체 : 삼출물 〈AND〉 전체 : 제거	1
4	전체 : 망막 〈AND〉 전체 : 삼출물 〈AND〉 전체 : 수술	0
		4

4.2.4. 한국학술정보(KISS) : 학술지 〈검색일: 2019. 5. 8.〉

No.	Searches	KISS
1	전체 = 경성 AND 전체 = 삼출물	13
2	전체=망막AND전체=삼출물AND전체=제거	1
3	전체 = 망막 AND 전체 = 삼출물 AND 전체 = 수술	0
4	전체 = 경성 삼출물 AND 전체 = 제거	0
		14

4.2.5. 국가과학기술정보센터(NDSL) : 국내논문 〈검색일: 2019. 5. 8.〉

No.	Searches	NDSL
1	전체=경성 AND 전체=삼출물	1
2	전체=망막 AND 전체=삼출물 AND 전체=제거	0
3	전체=망막 AND 전체=삼출물 AND 전체=수술	0
4	전체=경성 삼출물 AND 전체=제거	0
		1

5. 최종 선택 문헌

No.	서지정보
1	Takaya KS, Y.Mizutani, H.Sakuraba, T.Nakazawa, M. Long-term results of vitrectomy for removal of submacular hard exudates in patients with diabetic maculopathy. Retina. 2004;24(1):23-9.
2	Avci RI, U. U.Kaderli, B. Long-term results of excision of plaque-like foveal hard exudates in patients with chronic diabetic macular oedema. Eye. 2008;22(9):1099-104.
3	Naito TM, S.Sato, H.Katome, T.Nagasawa, T.Shiota, H. Results of submacular surgery to remove diabetic submacular hard exudates. Journal of Medical Investigation. 2008;55(3-4):211-5.
4	Sakuraba TS, Y.Mizutani, H.Nakazawa, M. Visual improvement after removal of submacular exudates in patients with diabetic maculopathy. Ophthalmic Surgery & Lasers. 2000;31(4):287-91.
5	Takagi HO, A.Kiryu, J.Ogura, Y. New surgical approach for removing massive foveal hard exudates in diabetic macular edema. Ophthalmology. 1999;106(2):249-56; discussion 56-7.

6. 배제문헌 목록

문헌배제사유

1. 대상자가 아닌 문헌
2. 중재법이 아닌 문헌(경성 삼출물 제거 수술 표현이 없는 문헌)
3. 적절한 결과가 보고되지 않은 문헌
4. 원저가 아닌 연구(종설, letter, comment 등)
5. 동물실험 또는 전임상시험
6. 동료심사된 학술지에 게재되지 않은 문헌
7. 초록만 발표된 연구
8. 한국어나 영어로 출판되지 않은 문헌
9. 중복문헌
10. 원문 확보 불가

6.1. 국외 배제 문헌 목록

No.	citation	배제 사유
1	Kumagai KO, N.Furukawa, M.Demizu, S.Atsumi, K.Kurihara, H.Iwaki, M.Ishigooka, H.Tachi, N. [Internal limiting membrane peeling in vitreous surgery for diabetic macular edema]. Nippon Ganka Gakkai Zasshi - Acta Societatis Ophthalmologicae Japonicae. 2002;106(9):590-4.	2
2	Furukawa MK, K.Ogino, N.Demizu, S.Ishigooka, H.Tachi, N. [Subretinal washout for subtle subfoveal hard exudates in diabetic macular edema]. Nippon Ganka Gakkai Zasshi - Acta Societatis Ophthalmologicae Japonicae. 2003;107(7):369-74.	2
3	Kameda YK, M.Endo, N.Iwamoto, Y.Kitano, S. Association of systemic health and functional outcomes with changes in hard exudates associated with clinically significant macular oedema over the natural course of the disease. British Journal of Ophthalmology. 2010;94(6):725-9.	2
4	Elwan MMH, S. M.Ellayeh, A. A. Trimanual versus unimanual 23-gauge vitrectomy in patients with diabetes: Limitations and expectations. Ophthalmic Surgery Lasers and Imaging Retina. 2019;50(1):42-9.	2
5	Yamamoto TH, K.Tsukahara, I.Yamamoto, S.Kawasaki, R.Yamashita, H.Takeuchi, S. Early postoperative retinal thickness changes and complications after vitrectomy for diabetic macular edema. American Journal of Ophthalmology. 2003;135(1):14-9.	2
6	Hoerle SP, H.Schmidt, J.Kroll, P. Effect of pars plana vitrectomy for proliferative diabetic vitreoretinopathy on preexisting diabetic maculopathy. Graefes Archive for Clinical & Experimental Ophthalmology. 2002;240(3):197-201.	2
7	Otani TK, S. Localization of hard exudates after resolution of diabetic macular edema.	2

No.	citation	배제 사유
	[Japanese]. Japanese Journal of Clinical Ophthalmology. 2000;54(5):861-5.	
8	Golan SL, A. Surgical treatment for macular edema. Seminars in Ophthalmology. 2014;29(4):242-56.	4
9	Li Yim JFM, J. R. Surgical removal of massive macular hard exudate combined with intravitreal triamcinolone in diabetic maculopathy. Eye. 2007;21(4):562-4.	4
10	Byeon SHC, H. Y.Kwon, O. W. Polyunsaturated Fatty Acid Composition of Surgically Removed Hard Exudates in Diabetic Macular Edema. Ophthalmic Surgery, Lasers & Imaging. 2010:1-3.	4
11	Tomita YK, N.Hajime, S.Yoko, O.Kazuo, T.Susumu, I. Secondary macular hole formation with presumed evulsion of foveal hard exudates in a patient with diabetic retinopathy. Japanese Journal of Ophthalmology. 2010;54(4):366-8.	4
12	Miyabe Y. Subretinal fibrosis in diabetic macular edema. [Japanese]. Folia Ophthalmologica Japonica. 2001;52(3):201-5.	2
13	Sasahara MT, H.Kiryu, J.Nishiwaki, H.Suzuma, K.Uemura, A.Watanabe, D.Suganami, E.Kurimoto, M.Hirose, F.Kimura, T.Honda, Y.Ogura, Y. Long-Term Results of Surgical Removal of Submacular Massive Hard Exudates Associated with Diabetic Maculopathy. [Japanese]. Folia Ophthalmologica Japonica. 2003;54(12):939-42.	8
14	Nakamura SO, N.Kumagai, K.Furukawa, M.Atsumi, K.Demizu, S.Kurihara, H.Ishigooka, H.Iwaki, M.Nishigaki, S. [The influence of hard exudates on the results of vitrectomy for macular edema due to diabetic retinopathy]. Nippon Ganka Gakkai Zasshi - Acta Societatis Ophthalmologicae Japonicae. 2003;107(9):519-25.	8
15	Otani TK, S. Tomographic findings of foveal hard exudates in diabetic macular edema. American Journal of Ophthalmology. 2001;131(1):50-4.	2
16	Gastaud PS, P.Rouhette, H.Folquet, P.Negre, F. [Surgical indications for diabetic maculopathy]. Journal Francais d Opthalmologie. 2002;25(2):166-77.	8
17	Ikai YS, H.Ando, N. Vitrectomy for diabetic lipid maculopathy. [Japanese]. Folia Ophthalmologica Japonica. 2002;53(3):184-7.	8
18	Chiba DK, Y.Yanagidaira, T.Shibuki, H.Yokoyama, A.Akimoto, A.Hanai, T.Yoshimura, N. Submacular surgery for removal of subfoveal hard exudates in cases of diabetic maculopathy. [Japanese]. Folia Ophthalmologica Japonica. 2001;52(2):143-6.	8
19	Ogawa KK, T.Nakao, I.Matsui, Y.Ishigooka, H.Ogino, N. Outcome of vitrectomy in different types of diabetic maculopathy. [Japanese]. Japanese Journal of Clinical Ophthalmology. 2001;55(6):1080-4.	8
20	Yang CM. Surgical treatment for severe diabetic macular edema with massive hard exudates. Retina. 2000;20(2):121-5.	2
21	Naito TA, T.Kajima, M.Shiota, H. Outcome of submacular surgery for diabetic macular exudates. [Japanese]. Japanese Journal of Clinical Ophthalmology. 1999;53(1):69-72.	8
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