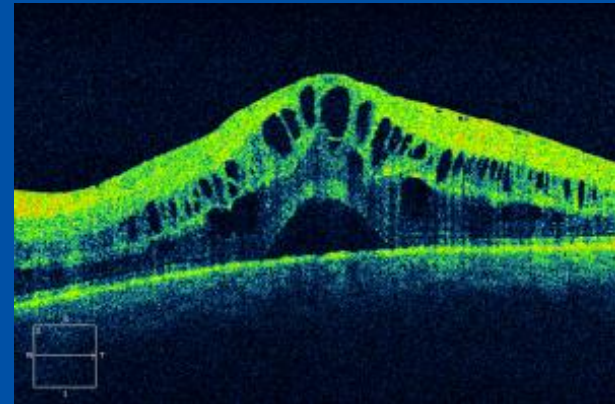


PREMED-STUDIEN

-

Vad förde den med sig?



Björn Johansson, Linköping

Intressekonflikter: Alcon, Bausch&Lomb, Carl Zeiss Meditec, Johnson&Johnson, Théa Laboratoires

Kirurgdagen 2019-11-07, Stockholm





PREMED-studien

- Syfte: "...att ge evidensbaserade rekommendationer som kan tjäna som underlag för kliniska riktlinjer för att förhindra CME [cystiskt makula ödem] efter kataraktoperation."
- Handuppräkring:
 - "Jag har ändrat anti-inflammatorisk behandling vid kataraktoperation utifrån PREMEDI-studiens rekommendationer"*
 - "Jag har läst hela PREMEDI-studien"*



PREMED-studien

ARTICLE

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European multicenter trial of the prevention of cystoid macular edema after cataract surgery in nondiabetics: ESCRS PREMED study report 1

Laura H.P. Widders, MD, Jan S.A.G. Schouten, MD, PhD, Bjorn Winkens, PhD, Frank J.H.M. van den Biggelaar, PhD, Claudette A. Veldhuizen, MD, Oliver Findl, MD, PhD, Joaquim C.N. Murta, MD, PhD, Willem R.O. Goslings, MD, PhD, Marie-José Tassinon, MD, PhD, Maurits V. Joesse, MD, PhD, Ype P. Henry, MD, Alexander H.F. Rulo, MD, José L. Güell, MD, PhD, Michael Amon, MD, PhD, Thomas Kohlen, MD, PhD, Rudy M.M.A. Nuijts, MD, PhD, on behalf of the ESCRS PREMED Study Group

Purpose: To compare the efficacy of a topical nonsteroidal anti-inflammatory drug, topical corticosteroid, and a combination of both drugs to prevent the occurrence of cystoid macular edema (CME) after cataract surgery in nondiabetic patients.

Setting: Twelve European study centers.

Design: Randomized clinical trial.

Methods: Nondiabetic patients having uneventful cataract surgery were included in this study. Patients were randomized to receive topical bromfenac 0.09% twice daily for 2 weeks or dexamethasone 0.1% 4 times daily with 1 drop less per day every following week, or a combination of both. The primary outcome was the difference in central subfield mean macular thickness 6 weeks postoperatively. Secondary outcome measures included corrected distance visual acuity as well as the incidence of CME

and clinically significant macular edema (CSME) within 6 weeks and 12 weeks postoperatively.

Results: The study comprised 914 patients. Six weeks postoperatively, the central subfield mean macular thickness was 288.3 µm, 296.0 µm, and 284.5 µm in the bromfenac group, dexamethasone group, and combination treatment group, respectively (overall P = .008). The incidence of clinically significant macular edema within 12 weeks postoperatively was 3.6%, 5.1%, and 1.5%, respectively (overall P = .043).

Conclusion: Patients treated with a combination of topical bromfenac 0.09% and dexamethasone 0.1% had a lower risk for developing CSME after cataract surgery than patients treated with a single drug.

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Supplemental material available at www.jcrjournal.org.

Worldwide, cataract is the leading cause of preventable and treatable blindness. Cataract surgery can improve visual acuity in many patients with mild to severe visual impairment and is considered one of the most cost-effective of all healthcare interventions.¹ Even though improvements in modern cataract

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3

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ARTICLE

Randomized controlled European multicenter trial on the prevention of cystoid macular edema after cataract surgery in diabetics: ESCRS PREMED Study Report 2

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Purpose: To compare the efficacy of preoperative treatment strategies, in addition to topical bromfenac 0.09% and dexamethasone 0.1%, to reduce the risk for developing cystoid macular edema (CME) after uneventful cataract surgery in diabetic patients.

Setting: Twelve European study centers.

Design: Randomized clinical trial.

Methods: Diabetic patients having phacolytic cataract surgery were randomly allocated to receive no additional treatment, a subconjunctival injection with 40 mg triamcinolone acetonide, an intravitreal injection with 1.25 mg bevacizumab, or a combination of both. The main outcomes were the difference in central subfield mean macular thickness, corrected distance visual acuity, and the incidence of CME and clinically significant macular edema within 6 and 12 weeks postoperatively.

Results: The study comprised 213 patients. At 6 and 12 weeks postoperatively, the central subfield mean macular thickness was 123 µm and 9.7 µm lower, respectively, in patients who received subconjunctival triamcinolone acetonide than patients who did not (P = .007 and P = .014, respectively). No patient who received subconjunctival triamcinolone acetonide developed CME. Intravitreal bevacizumab had no significant effect on macular thickness.

Conclusions: Diabetic patients who received a subconjunctival injection with triamcinolone acetonide at the end of cataract surgery had a lower macular thickness and macular volume at 6 and 12 weeks postoperatively than patients who did not. Intravitreal bevacizumab had no significant effect.

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PREMED 1

12 kliniker i Europa.

Primärt utfall: Skillnad i central makulatjocklek (CSMT) före operation – 6 v efter operation.

- Bromfenac x2 (B)
- Dexametason x4 (D)
- Bromfenac + Dexametason (BD)
- 2 dagar före => 2veckor efter op
- – 2 dagar före => 4 v efter op, nedtrappn.
- n=307/270
- n=304/265
- n=303/267



PREMED 1, resultat

CSMT [μm], medel	B	D	BD
Preop	274 \pm 25	275 \pm 27	273 \pm 25
6v	288 \pm 47	296 \pm 52	284 \pm 36
12v	283 \pm 28	284 \pm 29	283 \pm 27

BCDVA [LOGmar] medel	B	D	BD
Preop	0,29 \pm 0,23	0,29 \pm 0,21	0,29 \pm 0,22
6v	0,01 \pm 0,12	0,02 \pm 0,14	0,01 \pm 0,12
12v	-0,02 \pm 0,10	-0,01 \pm 0,11	-0,01 \pm 0,11



PREMED 1, resultat

CME=ökning av CSMT 10% eller mer jämfört preop + cystor på SD-OCT

CME, incidens	Bfn	Dxm	Comb
6v	11/269 (4,1%)	22/270 (8,1%)	5/266 (1,9%)
12v	11/269 (4,1%)	23/270 (8,5%)	6/266 (2,3%)

CSME=CME visat med OCT + <0.2 logMAR förbättring*

CSME, incidens	Bfn	Dxm	Comb
6v	10/274 (3,6%)	14/273 (5,1%)	2/275 (0,7%)
12v	10/274 (3,6%)	11/273 (5,1%)	4/275 (1,6%)

*) Ögon med visus 0,2 eller bättre inkluderades om besvärande katarakt



PREMED 1, diskussion

- Signifikant skillnad CME, D vs B/BD vid 6v, ej 12v
- Ingen signifikant skillnad i visus mellan grupper
- " The odds ratio of developing CSME within 12 weeks postoperatively was 2.6 in patients treated with topical bromfenac and 3.7 in patients treated with topical dexamethasone compared with the combination treatment group." (*NS efter Bonferroni korrektion*)
- " Nevertheless, individual patients will benefit most from optimum prevention of visually significant CME."
- *Och..*
- **"Future work will evaluate the cost-effectiveness of topical NSAIDs, corticosteroids, and combination treatments after cataract surgery."**



PREMED 2

12 kliniker i Europa.

Primära utfall: Skillnad i central makulatjocklek (CSMT),
före operation – 6 v och 12v efter operation.

CDVA, CSME incidens

- Ingen extra behandling
- 40mg triamcinolon subkonj.
- 1,25mg bevacizumab intavitrealt
- Kombination TA/BEV
- n=60/48
- n=51/39
- n=50/41
- n=52/47



PREMED 2

- “Diabetic patients who received a subconjunctival injection with triamcinolone acetonide at the end of cataract surgery had a lower macular thickness and macular volume at 6 and 12 weeks postoperatively than patients who did not.”
- “Intravitreal bevacizumab had no significant effect.”
- “There were no statistically significant differences between treatment groups with respect to CDVA at 6 and 12 weeks postoperatively.”



PREMED 2

- Handuppräckning:
 - Jag injicerar triamcinolon subkonjunktivalt vid kataratkoperation på diabetiker med central retinopati.
- "...patients should be monitored for at least 1 year postoperatively because IOP might rise later."
 - Jag följer upp IOP regelbundet ett år efter kataraktop.



Tack för uppmärksamheten!

