Control of Inflammation and Prophylaxis of Endophthalmitis After Cataract Surgery: a Multicentric Study Comparing the Betamethason-Chloramphenicol vs. Tobramycin-Dexamethasone

Fabrizio Camesasca – Matteo Piovella

ASCRS 2006

Matteo Piovella[1]
Fabrizio Camesasca[2]
Costantino Bianchi
Giorgio Beltrame[3]
Aldo Caporossi[4]
Antonello Rapisarda[5]
Giorgio Tassinari[6]
Lucio Zeppa[7]

[1] Centro Microchirurgia Oculare, Monza
[2] U.O. Oculistica, Istituto Clinico Humanitas, Milano
[3] Centro Medico San Biagio, Fossalta di Portogruaro – Venezia
[4] Dipartimento del Distretto Cefalico e Scheletrico, Azienda Ospedaliera Universitaria Senese, Siena
[5] Unità Complessa Oftalmologia, Azienda Ospedaliera Umberto I, Siracusa
[6] U.O. Oculistica, Ospedale Maggiore di Bologna, Bologna
[7] U.O. Oculistica Azienda Ospedaliera S.G. Moscati, Avellino

The Author aknowledges a financial interest in the subject matter of this presentation

Cataract Surgery

- 460.000 interventions every year in Italy
- Well established and standardized technique
- Postoperative period:
  - Control of inflammation
  - Prevention of endophthalmitis

  (300-400 cases/year in Italy)

Inflammation: Steroid

- Most frequently used
- Possible complications of steroids:
  - Increased intraocular pressure
  - Delayed healing of corneal wound
- To reduce administrations and increase efficacy: gel
- Gel has been showed to be more efficient than acqueous solution

Ghelardi E, Antimicrob Agents Chemother 2004;48:33906-401

Endophthalmitis:Antibiotic
ASCRS Analysis

- Ofloxacin
- Oxyfloxacin
- Gentamicin
- Tobramicin
- etc.

Leaming DV, J Cataract Refract Surg 2004;30:892-900

Use of Gel in Ophthalmology

- Use of gel is based on physical and physiological theories
- Rational: increasing drug permanence on the ocular surface
- Greater pharmachological effect
- Reduction in concentration and administrations

Bianchi C, Monografie SOI, Anno X, Num. 1997, 83-4
Ghelardi E, Antimicrob Agents Chemoter 2004;48:3396-41
Sultana Y, J Ocul Pharmacol Ther 2004;20:363-71

Use of Gel in Ophthalmology: reducing…

- Loss of compliance
- Side effects
- Allergic reactions
- IOP increase (with steroid)

Goal of the Study

Comparing clinical findings and patients satisfaction after post-cataract surgery treatment with two different antibiotic/steroid associations, one in acqueous solution, the other in gel

Materials and Methods

- Multicentric, prospective, randomized study
- Patients undergoing bilateral cataract surgery
- April – December 2005
- Eight Centers in Italy

Surgeons and Centers

Matteo Piovella

Centro Microchirurgia Oculare, Monza

Giorgio Beltrame

Centro Medico San Biagio, Fossalta di Portogruaro – Venezia

Aldo Caporossi

Dipartimento del Distretto Cefalico e Scheletrico, Azienda Ospedaliera Universitaria Senese, Siena

Antonello Rapisarda

Unità Complessa Oftalmologia, Azienda Ospedaliera Umberto I, Siracusa

Giorgio Tassinari

U.O. Oculistica, Ospedale Maggiore di Bologna, Bologna

Lucio Zeppa

U.O. Oculistica Azienda Ospedaliera S.G. Moscati, Avellino

Inclusion Criteria

- Bilateral cataract
- BSCVA > = 0.2 logMAR

Exclusion Criteria

- Preoperative:
  - Diabetes mellitus, sistemic steroids, uveitis, glaucoma, previous ocular surgery, subluxated lens, endotelial cell count < 1000/mm^2, midriasis < 5mm
- Intraoperative:
  - Posterior capsule break, anterior vitrectomy, iris capture, corneal suture

Surgical Technique

- Standardized and consistant in the Centers:
  - Topical/peribulbar anesthesia
  - Temporal incision
  - Capsulorrhexis
  - Idrodissection
  - Phacoemulsification
  - I/A
  - Foldable IOL
  - Intraocular antibiotic injection

Materials and Methods

- Second eye undergoing surgery at least 7 days after first eye surgery
- Randomized postoperative treatment:
  - Group 1 – chloramphenicol 0.25% - betamethasone 0.13% GEL TRID (Betagel)
  - Group 2 - tobramycin 3% - dexamethasone 1% EYEDROPS QUID (Tobradex)
  - For 15 days

Materials and Methods

- Follow-up intervals: 1, 3, 7, 15 days
- Complete ophthalmological examination
- Evaluation of subjective impressions of each patient

Monitored Surgical Parameters

- Anesthesia
- Temporal incision
- Capsulorrhexis
- Type and model of IOL
- Intraocular antibiotic
- Drugs in the infusion
- Time of surgery
- Time of ultrasounds
- Type of viscoelastic
- Type of phaco
- Intracamerular myotic drug
- Intraoperative complications

Results

- 284 eyes of 142 patients
- Age (mean ± SD): 73.7 ± 8.9 yrs
- Age range: 43 – 91 yrs
- Sex: 53 males (37.06%), 90 females (62.94%)
- Disinfection of periocular skin and conjunctival sac with iodopovidone
- Anesthesia: topical 263, peribulbar 21
- Time of US:
  - 70.64 ± 3.42 sec (Group 1)
  - 68.80 ± 3.31 sec (Group 2) (n.s.).

Preoperative Clinical Data

	Group 1 Betagel (mean ± S.D.)	Group 2 Tobradex (mean ± S.D.)	*p*
Intraocular Pressure	15.55 ± 2.52	15.62 ± 2.83	n.s.
Pupil Diameter (mm)	7.12 ± 1.71	7.40 ± 1.09	n.s.
Endotelial Cell Counts, mean	2124.03 ± 431.76	2150.34 ± 441.71	n.s.
Endotelial Cell Counts, Standard Deviation	186.92 ± 87.95	185.78 ± 90.04	n.s.
UCVA logMAR	0.70 ± 0.49	0.73 ± 0.48	n.s.

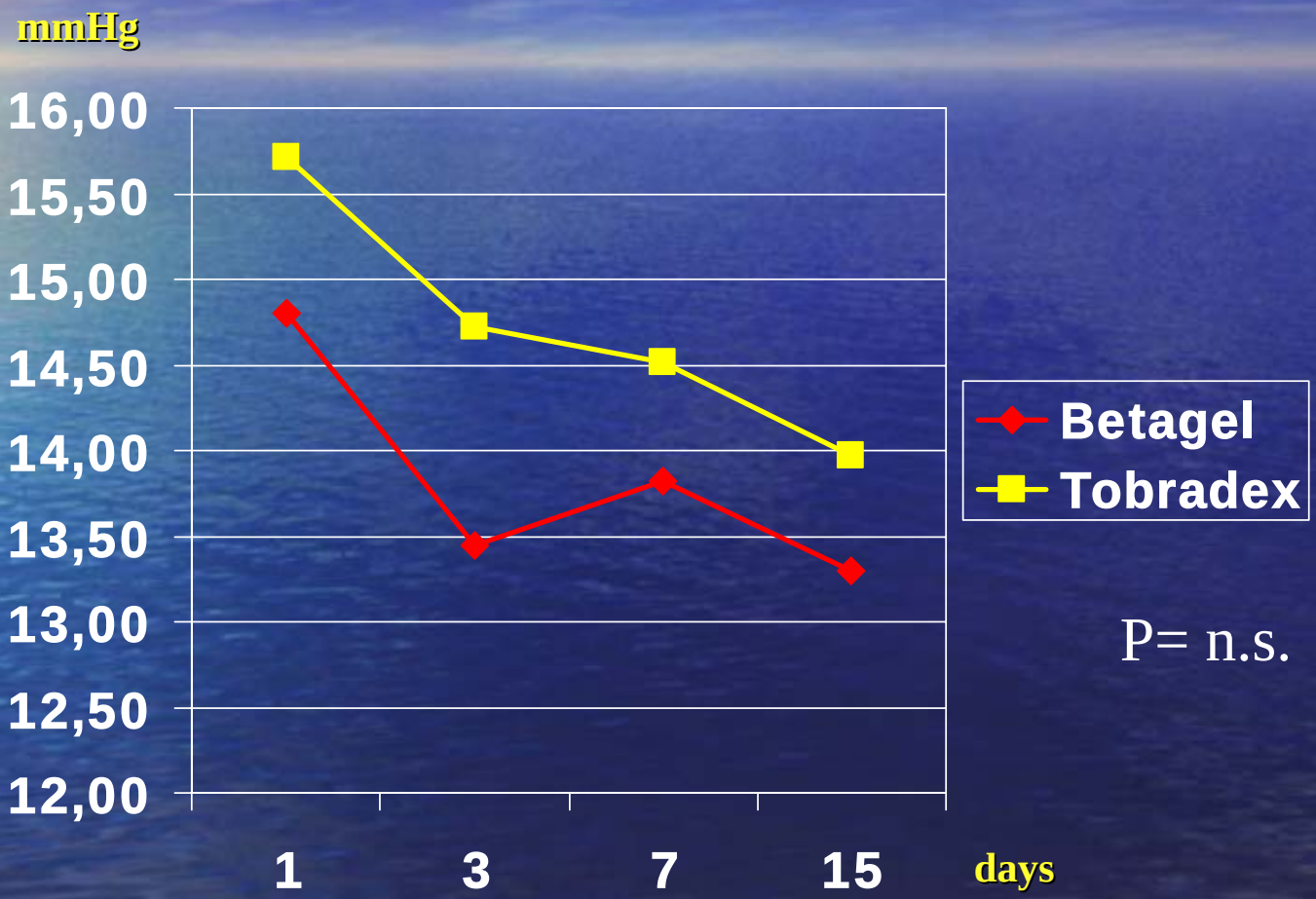
Duration of Surgery

	First Eye	Second Eye
	cases	cases
< 15 min	80	99
between 15 and 20 min	46	23
> 20 min	0	0
Total	142	142

Intraoperative Complications

Complication	Number of cases	%
Insufficient Midriasis	11	3.85
Anterior chamber unstability	4	1.40
Iris prolapse	1	0.35
Difficult IOL insertion	9	3.15
Iris chafe	0	0
Posterior capsule break	0	0
Vitrectomy	0	0
Corneal wound suture	0	0

Postoperative Data
IOP

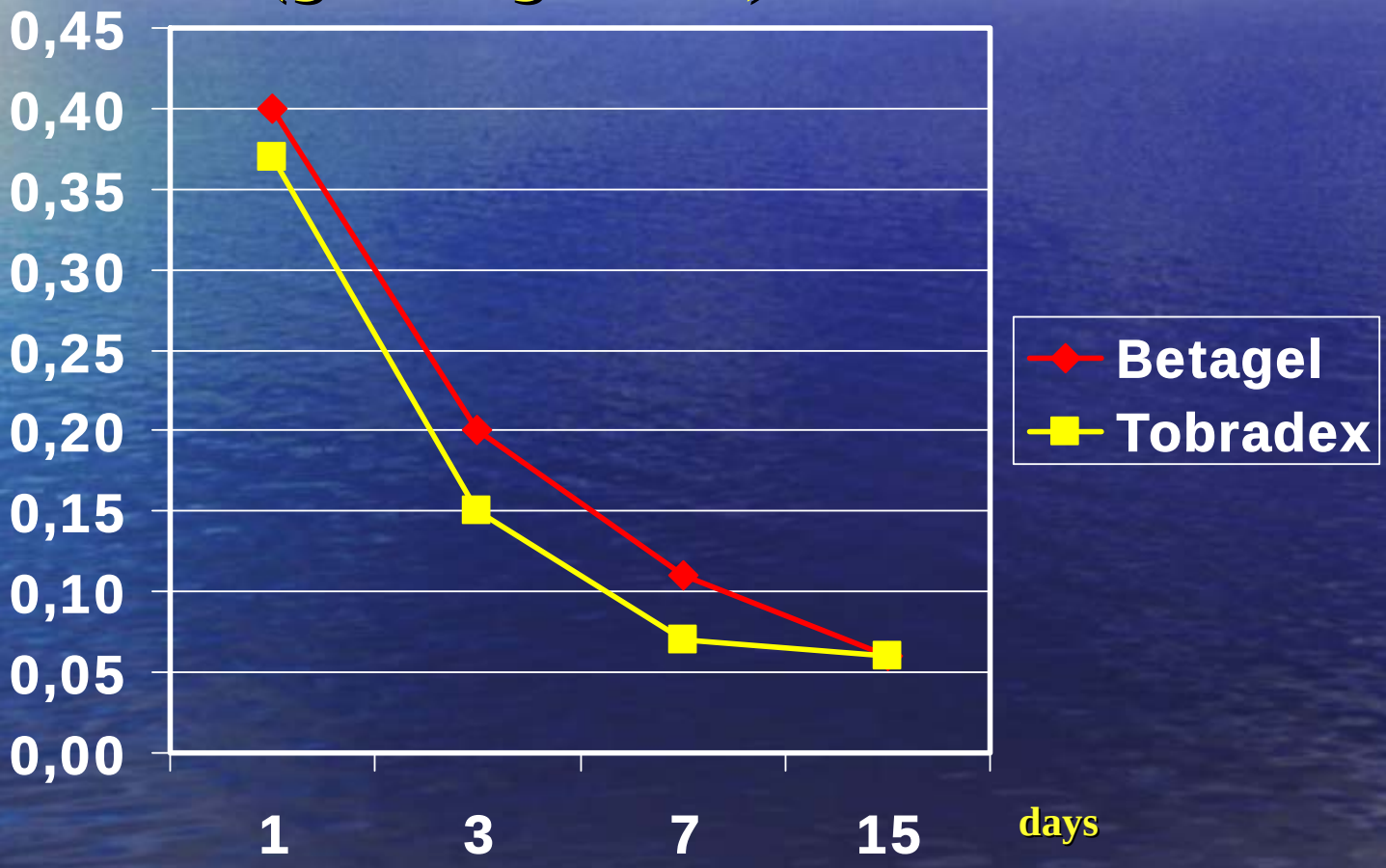


P= n.s.

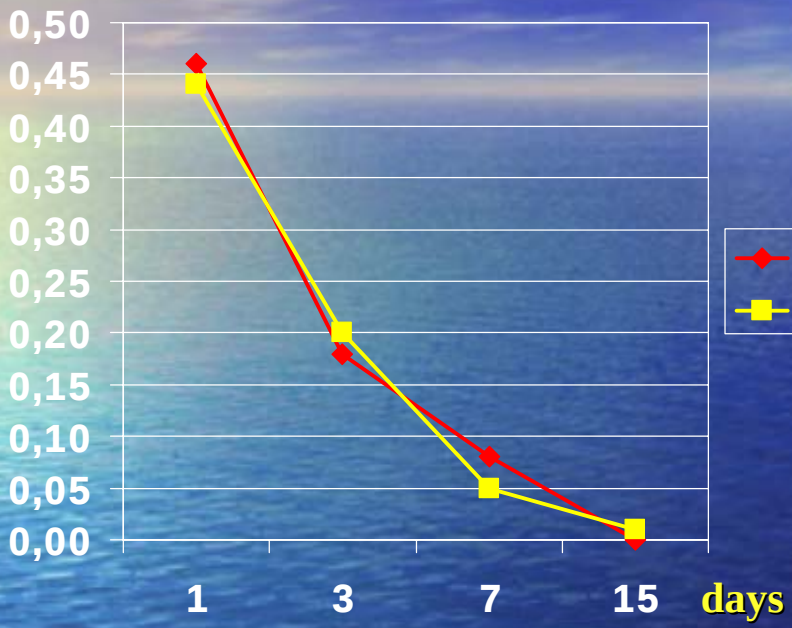
Postoperative Data

Tyndall

(grading: 1 - 4)

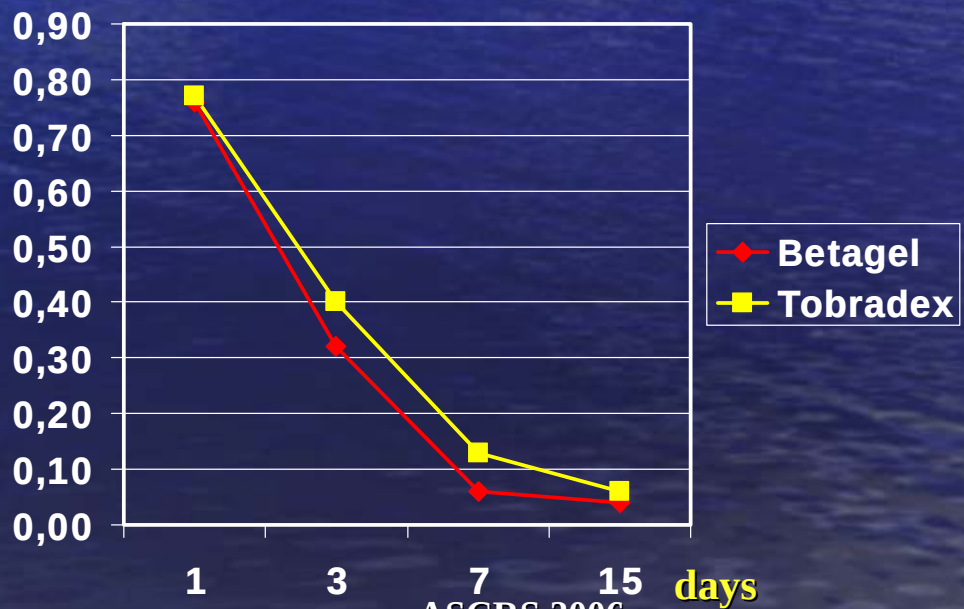


Postoperative Data
(grading: 1 - 4)

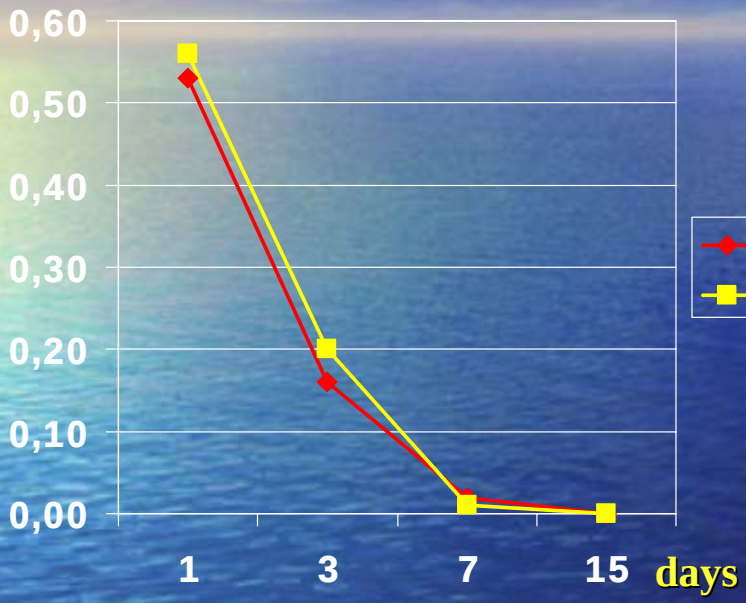


Lid and/or Conjuctival Edema

Lid and/or Conjuctival Congestion

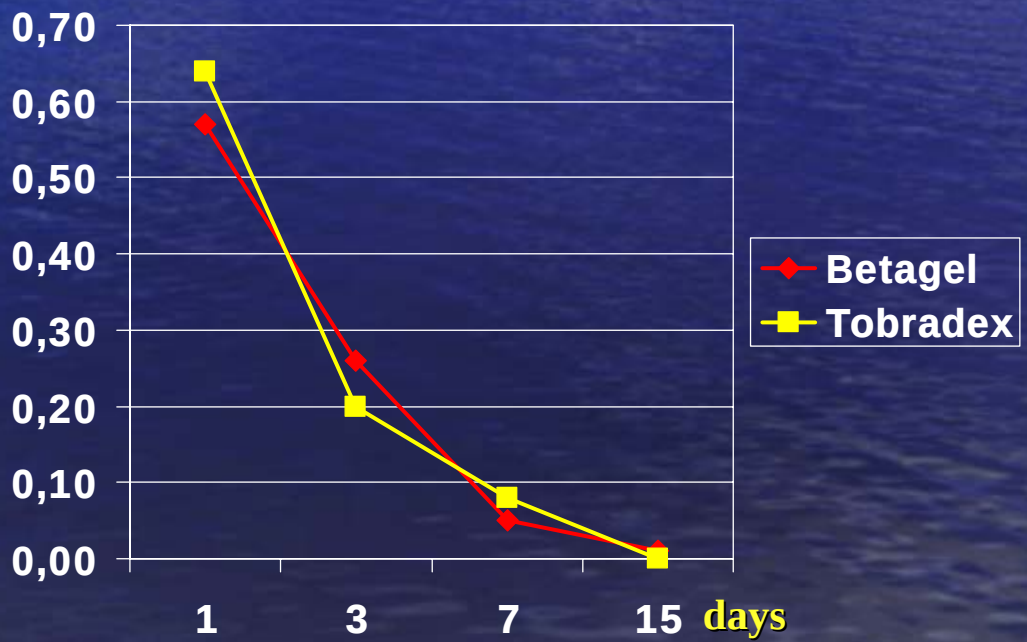


Postoperative Data
(grading: 1 - 4)



Reduced Corneal Transparency

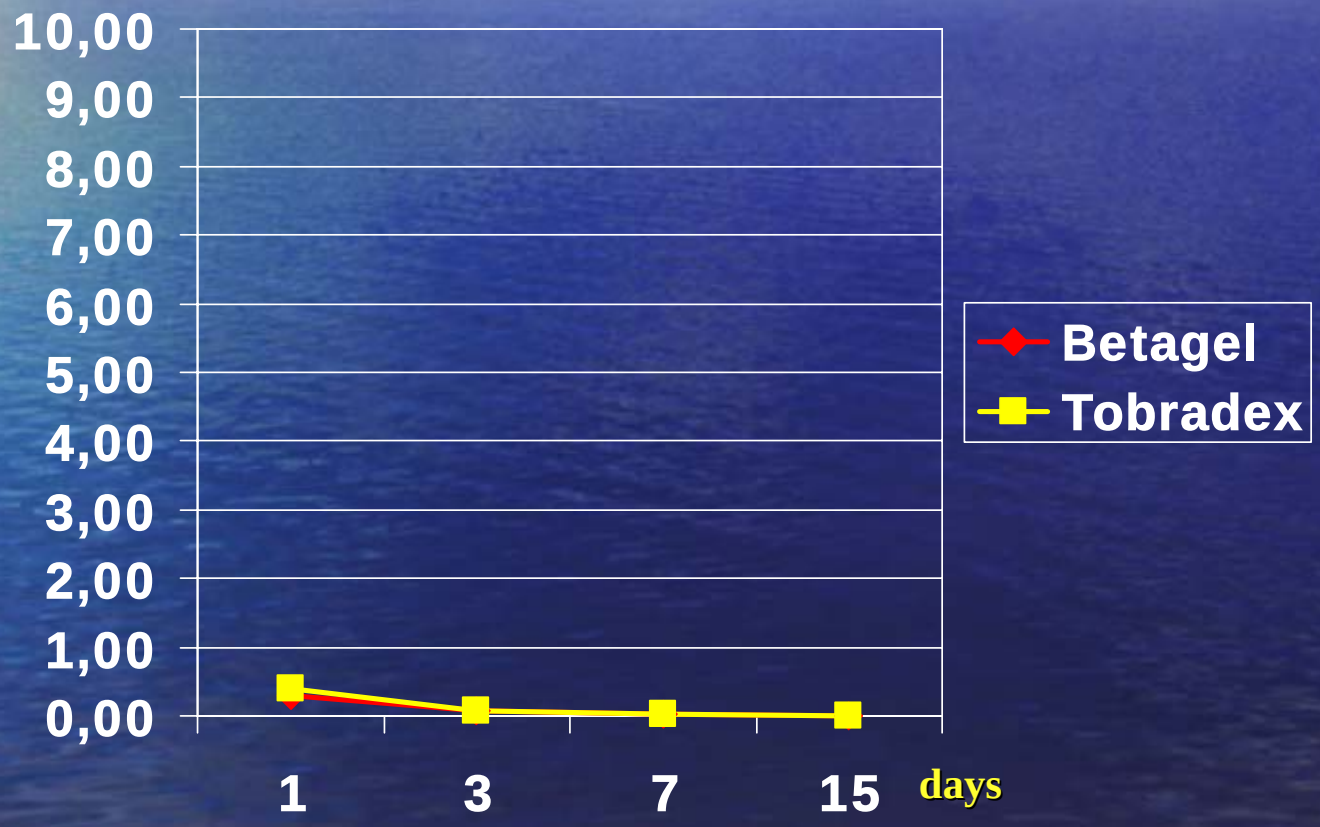
Corneal Edema



Subjective Data

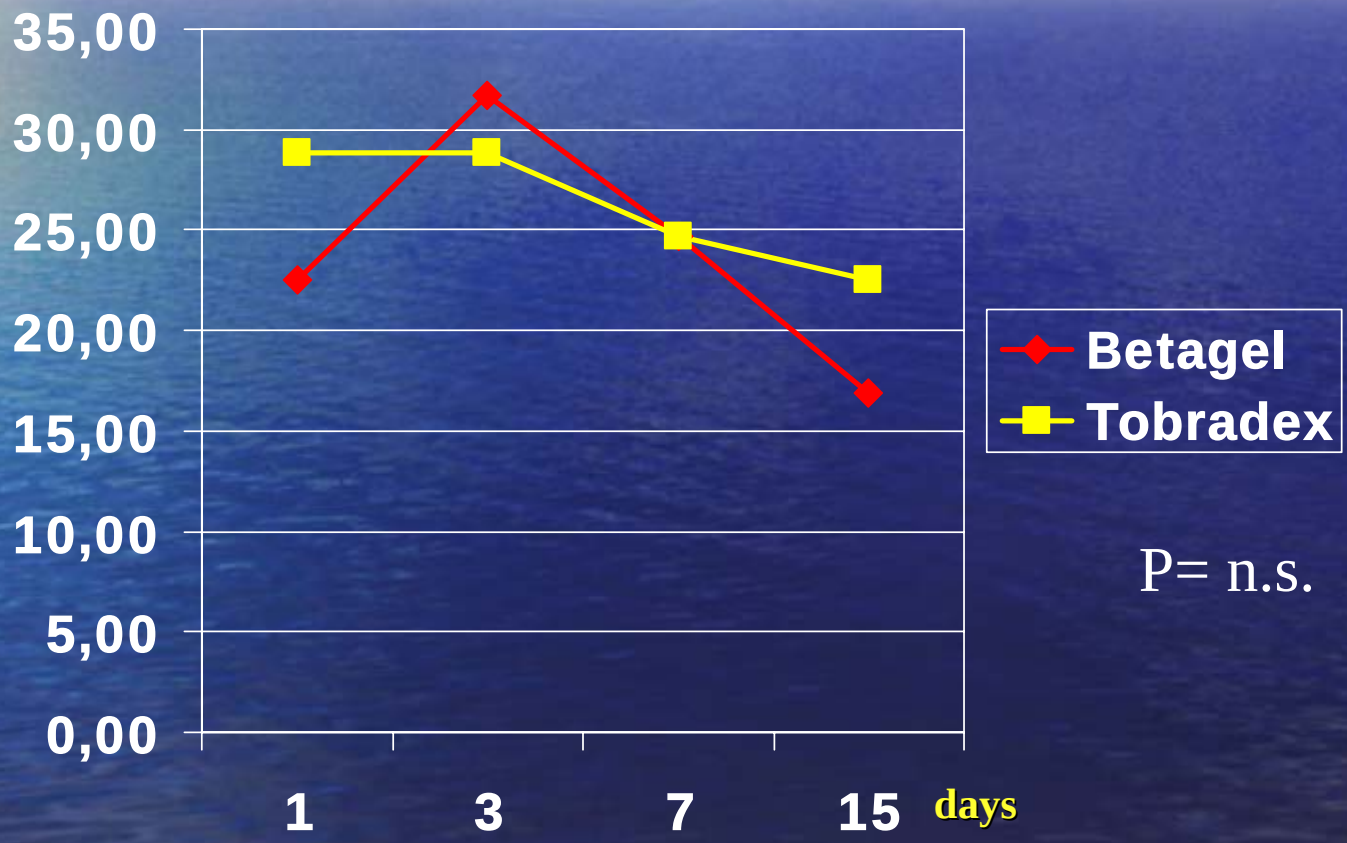
Pain

(Grading 0-10)



Subjective Data

Dry Eye (%)



P= n.s.

Subjective Data
Sensation After Instillation

		No change %	Unpleasant %	Pleasant %
Sensation change after instillation	**Betagel**	23.24	2.11	74.65
	Tobradex	27.46	7.75	64.79
p		.04		

Conclusions – Post-Cataract Surgery Therapy

- Steroid/antibiotic association: diffuse and well accepted use
- Chloramphenicol features good intraocular penetration, antibacterial spectrum adequate for common pathogens
- betamethasone and dexamethasone have similar potency and duration of action

Leaming DV, J Cataract Refract Surg 2004; 30:892-900
Lum F, Ophthalmology 2000; 107:691-7

Conclusions

- Two completely comparable Groups
- Bias factors: minimized
- Evaluation of all parameters related to postoperative treatment

Conclusions

- Postoperative pain: no significant difference
- Gel preparation was subjectively more pleasant (p= .04)
- Identical clinical results with gel TRID vs. eyedrops QUID
- No allergic reaction or side effect

Conclusions

- Chloramphenicol 0.25% - betamethasone 0.13% gel association proved to have similar efficacy and tolerance but better patient acceptance than tobramycin 0.3% – dexamethasone 0.1% association in acqueous solution.


Thank You For Your Attention !