Comparison between dispersive hidroxypropylmethylcellulose and sodium hyaluronate in phacoemulsification: a systematic review and meta-analysis

Comparação entre hidroxipropilmetilcelulose e hialuronato de sódio dispersivos na facoemulsificação: uma revisão sistemática e meta-análise

Francisco Victor Carvalho Barroso[1], Dillan Cunha Amaral[2], Samuel Montenegro Pereira[3], David Rocha Lucena[4], Ricardo Noguera Louzada[2]

[1] Serviço Oftalmológico de Pernambuco, Recife, PE, Brazil.
[2] Faculdade de Medicina, Universidade Federal do Rio de Janeiro, Rio de Janeiro, RJ, Brazil.
[3] Hospital Waldemar Alcantara, Fortaleza, CE, Brazil.
[4] Centro Avançado de Oftalmologia, Fortaleza, CE, Brazil.

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Corresponding author:
Ricardo Noguera Louzada
Instituto de Olhos São Sebastião
Largo do Machado, 54, room 1208
Zip code: 22221-020 – Rio de Janeiro, RJ, Brazil
E-mail: louzadaricardo@gmail.com

Institution:
Faculdade de Medicina, Universidade Federal do Rio de Janeiro, Rio de Janeiro, RJ, Brazil.

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Ricardo Augusto Paletta Guedes
Universidade Federal de Juiz de Fora, Juiz de Fora, MG, Brasil
https://orcid.org/0000-0002-9451-738X

ABSTRACT

Background: There is a debate regarding the differences in intraocular pressure values between different types of dispersive ophthalmic viscosurgical devices in patients after phacoemulsification for cataracts.

Objectives: We aim to evaluate the differences between hydroxypropyl methylcellulose and sodium hyaluronate alone or combined with chondroitin sulfate as ophthalmic viscosurgical devices after phacoemulsification in selected patients related to intraocular pressure.

Methods: We conducted a systematic review and meta-analysis of randomized clinical trial data comparing only dispersive hydroxypropyl methylcellulose with sodium hyaluronate and hydroxypropyl methylcellulose with sodium hyaluronate combined with chondroitin sulfate in intraocular pressure operative day outcomes. Mean differences were calculated for continuous outcomes. We used Review Manager 5.3 (Cochrane Centre, The Cochrane Collaboration, Denmark) for statistical analysis.

Results: Six studies, including 489 eyes undergoing senile phacoemulsification, were analyzed; 246 eyes (50.3%) received hydroxypropyl methylcellulose 2% and 3%; 149 eyes (29.44%) received sodium hyaluronate 1%, and 99 eyes (20.24%) received sodium hyaluronate 1.6% and/or 3% sodium hyaluronate combined with chondroitin sulfate 4%. Overall, there were no significant differences between groups on the seventh post-operative day in hydroxypropyl methylcellulose *versus* sodium hyaluronate (MD 0.00 mmHg; 95%CI -0.50-0.49; I2 =0%) and hydroxypropyl methylcellulose *versus* sodium hyaluronate combined with chondroitin sulfate (MD -0.25 mmHg; 95%CI -1.05-0.54; I2 = 0%). But a significant statistically difference was found on the first post-operative day in hydroxypropyl methylcellulose *versus* sodium hyaluronate (MD-0.93 mmHg; 95%CI -1.66-0.19; I2 = 87%).

Conclusion: This meta-analysis compared only the following dispersive hydroxypropyl methylcellulose to sodium hyaluronate and sodium hyaluronate combined with chondroitin sulfate in over 400 eyes that underwent phacoemulsification. The findings suggest that in the context of phacoemulsification in cataracts, hydroxypropyl methylcellulose showed similar changes in intraocular pressure from baseline compared to sodium hyaluronate and sodium hyaluronate combined with chondroitin sulfate.

PROSPERO Registry - CRD42024563452.

RESUMO

Histórico: Debate-se sobre as diferenças nos valores da pressão intraocular entre diferentes tipos de dispositivos viscocirúrgicos oftálmicos dispersivos em pacientes após facoemulsificação para catarata.

Objetivos: Nosso objetivo é avaliar as diferenças entre a hidroxipropilmetilcelulose e o hialuronato de sódio, isolados ou combinados com sulfato de condroitina, como dispositivos viscocirúrgicos oftálmicos após a facoemulsificação em pacientes selecionados, em relação à pressão intraocular.

Métodos: Realizamos uma revisão sistemática e meta-análise de dados de ensaios clínicos randomizados comparando apenas hidroxipropilmetilcelulose dispersiva com hialuronato de sódio e hidroxipropilmetilcelulose com hialuronato de sódio combinado com sulfato de condroitina nos resultados da pressão intraocular no dia da cirurgia. As diferenças médias foram calculadas para resultados contínuos. Utilizamos o Review Manager 5.3 (Cochrane Centre, The Cochrane Collaboration, Dinamarca) para a análise estatística.

Resultados: Seis estudos, incluindo 489 olhos submetidos a facoemulsificação senil, foram analisados; 246 olhos (50,3%) receberam hidroxipropilmetilcelulose 2% e 3%; 149 olhos (29,44%) receberam hialuronato de sódio a 1% e 99 olhos (20,24%) receberam hialuronato de sódio a 1,6% e/ou 3% de hialuronato de sódio combinado com sulfato de condroitina a 4%. No geral, não houve diferenças significativas entre os grupos no sétimo dia pós-operatório em hidroxipropilmetilcelulose *versus*

hialuronato de sódio (DM 0,00 mmHg; IC 95% -0,50-0,49; I2 = 0%) e hidroxipropilmetilcelulose *versus* hialuronato de sódio combinado com sulfato de condroitina (DM -0,25 mmHg; IC 95% -1,05-0,54; I2 = 0%). No entanto, foi encontrada uma diferença estatisticamente significativa no primeiro dia pós-operatório entre a hidroxipropilmetilcelulose e o hialuronato de sódio (DM -0,93 mmHg; IC 95% -1,66-0,19; I2 = 87%).

Conclusão: Esta meta-análise comparou apenas a seguinte hidroxipropilmetilcelulose dispersiva com hialuronato de sódio e hialuronato de sódio combinado com sulfato de condroitina em mais de 400 olhos submetidos a facoemulsificação. Os resultados sugerem que, no contexto da facoemulsificação na catarata, a hidroxipropilmetilcelulose apresentou alterações semelhantes na pressão intraocular em relação ao valor basal, em comparação com o hialuronato de sódio e o hialuronato de sódio combinado com sulfato de condroitina.

PROSPERO Registry - CRD42024563452.

INTRODUCTION

Since their introduction in 1972,[1] viscoelastic materials have become increasingly vital in ophthalmic surgery, one of the most frequently performed surgical procedures globally.[2] Specifically, ophthalmic viscosurgical devices (OVDs) are crucial in cataract surgery. They provide a protective coating for the endothelium and implant, effectively preventing compression and shearing during the procedure. [3] Moreover, these materials can mitigate potential changes in corneal thickness, intraoperative pressure values, and the corneal endothelial cell layer resulting from the mechanical trauma of cataract surgery instruments and intraocular lens (IOL) implantation.[4, 5]

A wide range of viscoelastic substances is available for cataract surgery, each offering unique physical and chemical properties. Hydroxypropyl methylcellulose (HPMC), sodium hyaluronate (NaHa), and sodium hyaluronate – chondroitin sulfate (NaHa-CS) are among the most popular choices for OVDs today, known for their efficient dispersion.[6]

The 2.0% HPMC provides low zero-shear viscosity and effective dispersive characteristics. However, it has the drawback of poor spacing and occasional removal difficulties.[7] Moreover, the NaHa-CS represents a groundbreaking combination of highly viscous and dispersive OVD behaviors. As the first viscoelastic with viscous and dispersive properties, NaHa-CS facilitates space maintenance and protects tissue.[7] Furthermore, the 1% hyaluronic acid is a reliable dispersive OVD is used to maintain the anterior chamber during phacoemulsification.[8]

Ophthalmic viscosurgical devices are critical components of contemporary cataract surgery.[6,9,10] Since phacoemulsification has been one of the most frequently performed eye surgeries worldwide,[11] they are crucial in preserving space, inserting the IOL, and protecting the corneal endothelium throughout the surgery.[12,13] There are four primary types of OVDs: cohesive, dispersive, viscoadaptive, and combined agents/dual viscoelastic systems.[10] Cohesive OVDs effectively establish and maintain space and pressure and are easily removed. In contrast, dispersive OVDs excel at coating and protecting intraocular structures while breaking them apart during removal. The choice of OVD, firmly guided by the specific anatomy of the patient, their pre-existing conditions, and the surgeon's preferences and techniques, is crucial for optimizing the success of the surgery, the postoperative outcomes, and patient satisfaction.[10,14,15]

Understanding the behavior of OVDs within the eye and their removal process is crucial during cataract surgery.[16] Due to their viscous nature, OVDs obstruct the trabecular meshwork and Schlemm's canal.[14] A small number of cases show significant increases in intraocular pressure (IOP) following uncomplicated cataract surgery. [16] Such IOP spikes rarely exceed 30 mmHg in eyes without glaucoma and are generally temporary. Earlier meta-analyses have examined the variation in IOP before and after phacoemulsification within the same groups of OVDs and the differences in central corneal thickness and endothelial cell density.[17]

Current randomized controlled trials (RCTs) show inconsistent results regarding changes in IOP. For example, Rainer et al.[18] did not find a significant increase in IOP between HPMC and NaHa at 5 to 6 hours post-operation. However, other researchers have reported the highest average IOP in patients using HPMC during the same time frame. [4,16]

Given these differing results, we undertook a systematic review and meta-analysis to evaluate the effectiveness of dispersive HPMC versus dispersive NaHa and NaHa-CS in cataract surgery patients, specifically looking at changes in IOP.

METHODS

This systematic review and meta-analysis followed the guidelines of the Cochrane Collaboration and adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement, implementing protocol CRD42024563452.

Eligibility criteria

Eligibility for this meta-analysis was limited to studies that met all the following inclusion criteria: RCTs; age-related cataracts comparing HPMC with NaHa and HPMC with NaHa-CS; patients who underwent phacoemulsification were registered; and studies must have a follow-up period of at least one month, as previously reported by several RCTs. Furthermore, studies were included only if they reported changes in IOP. The studies that were excluded considered the absence of a control group; extracapsular cataract extraction (ECCE); glaucoma patients; intraoperative complications; traumatic or subluxated cataracts; and coexisting corneal endothelial disease.

Search strategy and data extraction

We conducted a thorough search of PubMed®, Embase, and the Cochrane Central Register of Controlled Trials from their inception until June 2024, using specific search phrases: ("phaco" OR "phacoemulsification") AND ("methylcellulose" OR "hydroxypropylmethylcellulose") AND ("sodium hyaluronate" OR "ophthalmic viscosurgical devices" OR "chondroitin sulfate" OR "hyaluronic acid" OR "OVDs") AND ("IOP" OR "intraocular pressure"). Two authors extracted the data independently based on predefined criteria for searching and quality assessment. Additionally, we performed a manual search through the references of all included studies as well as previous systematic reviews and meta-analyses to identify any further studies.

Endpoints and subanalysis

Efficacy outcomes included IOP. Predefined subanalysis focused on limited data: by 24 hours and 7 days follow-up.

Quality assessment

The quality of RCTs was evaluated using the Cochrane Collaboration's bias risk tool for randomized trials categorizes studies into high, low, or unclear risk of bias across five dimensions: selection bias, performance bias, detection bias, attrition bias, and reporting bias.[4]

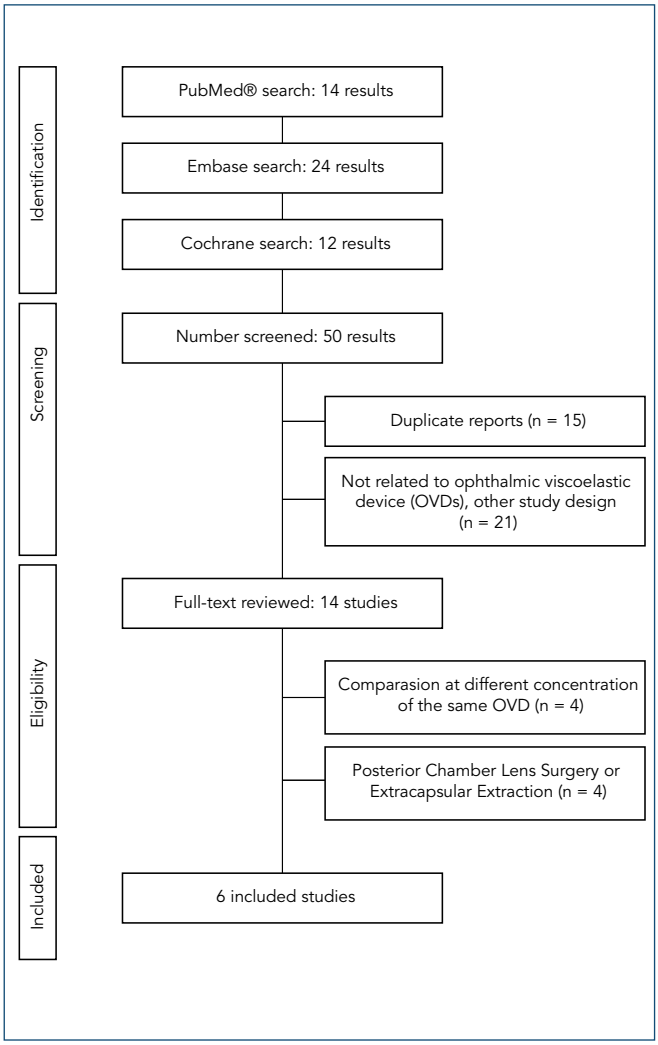
Statistical analysis

Mean differences (MD) and 95% confidence intervals (CI) were used to compare predictive effects for continuous outcomes. Heterogeneity was assessed using the Cochran Q test and I^2 statistics, with p-values below 0.10 and I^2 greater than 25% considered significant indicators of heterogeneity; at the same time, p-values below 0.05 were regarded as statistically significant. A random effects model was utilized for results displaying low heterogeneity (I2 < 25%). The statistical analysis was conducted using Review Manager 5.3 software developed by the Cochrane Centre, part of The Cochrane Collaboration in Denmark.

RESULTS

Study selection and characteristics

Figure 1 shows that the initial search resulted in 50 entries. After filtering out duplicates and studies that did not meet the eligibility criteria, 35 studies remained for a detailed review based on predefined inclusion criteria. The participants in these studies had an average age of 72.6 years. Among these, there were six RCTs involving a total of 489 eyes. Out of these, 246 eyes (50.3%) received HPMC 2% and 3%, 149 eyes (29.44%) received NaHa 1%, and 99 eyes (20.24%) received NaHa 1.6% or 3% - CS 4%. The specifics of these studies are detailed in table 1.



OVD: ophthalmic viscosurgical devices.

Figure 1. Study selection process.

Table 1. Baseline characteristics of included studies

Study	Country	Cataract grade	OVDs	Washout time OVD (min)	Amount of OVD used (mL)	No (eyes)	Age (years)	Female (%)
Holzer et al.[8]	Germany	NA	HPMC 2%	NA	NA	30	71.2 ± 7.8	NA
Espíndola et al.[16]	Brazil	1-3 (LOCS III)	HPMC 2%	0.22 ± 0.09	1.35 ± 0.20	78	71.5 ± 7.9	67
			NaHa 1.6% -CS 4.0%	0.17 ± 0.06	0.89 ± 0.11	78	71.5 ± 7.9	67
			NaHa 3% -CS 4%		NA	20	71.2 ± 7.8	NA
Ray-Chaudhuri et al [4]	United Kingdom	NA	HPMC 2%	NA	An attempt was made to use similar amounts of OVD	52	NA	NA
Rainer et al.[18]	Austria	NA	HPMC 2%	NA	NA	80	75.1 ± 8.0	78
Rainer et al.[23]	Austria	NA	HPMC 2%	NA	NA	80	75.9 ± 9.3	68
			NaHa 3% -CS 4%	NA	NA	80	75.9 ± 9.3	68
			NaHa 1%		NA	80	75.1 ± 8.0	78
			NaHa 1%	NA		58	NA	NA
Waseem et al.[24]	Pakistan	NA	HPMC 2%	NA	NA	45	52-75*	42
			NaHa 1%	NA	NA	46	57-77*	46

* Age spectrum.
Results expressed as mean ± standard deviation, if not mentioned another way.
OVD: ophthalmic viscosurgical devices; NA: not available; HPMC: hydroxypropyl methylcellulose; LOCS: Lens Opacities Classification System; NaHa CS: sodium hyaluronate – chondroitin sulfate.

Analysis of first post-operative day outcomes

A notable difference was observed in the change in IOP from baseline one day post-surgery with HPMC and NaHa (MD -0.93 mmHg; 95%CI -1.66 to -0.19; p < 0.005; I^2 = 87%; Figure 2A).

First post-operative day, there was no difference between the groups using HPMC and NaHa-CS (MD 0.01 mmHg; 95%CI -1.06 to 1.08; p = 0.98, I^2 = 0%, Figure 3A).

Analysis of long-term outcomes

No significant differences were found in the IOP changes from the baseline between the HPMC and NaHa groups (MD -0.00 mmHg; 95%CI -0.50 to 0.49; p = 0.83, I^2 = 0%, Figure 2B). The same was found in 7 days post-operative between HPMC and NaHa-CS (MD -0.25 mmHg; 95%CI -1.05 to 0.54; p = 0.53, I^2=0%, Figure 3B).

Quality assessment

The quality assessment includes six randomized studies in which the intervention and control groups were matched based on their initial characteristics. The analysis showed no evidence of publication bias, as indicated by a symmetrical funnel plot demonstrating that studies of similar size converged on the cumulative effect size of the treatment as their weights increased.

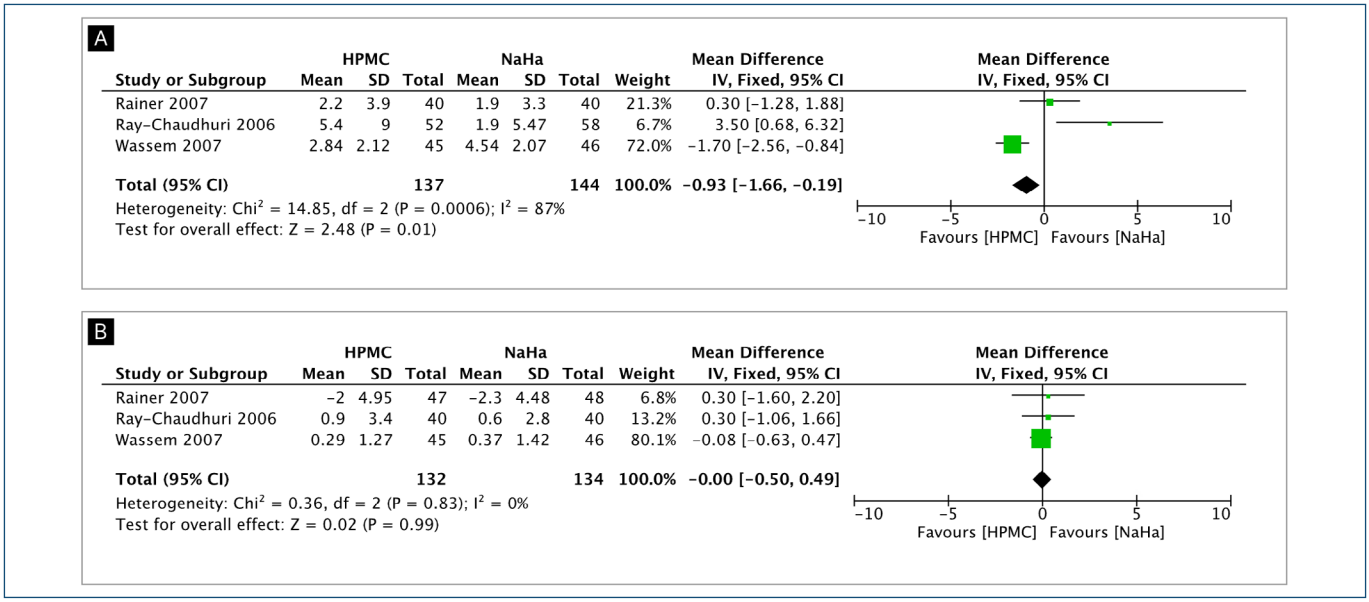


Figure 2. (A) Change of intraocular pressure (mmHg) one day post-surgery from baseline hydroxypropyl methylcellulose versus sodium hyaluronate. (B) Change of intraocular pressure (mmHg) from baseline in 7 days between hydroxypropyl methylcellulose versus sodium hyaluronate.(B) Change of intraocular pressure (mmHg) from baseline in 1 day between hydroxypropyl methylcellulose *versus* sodium hyaluronate.

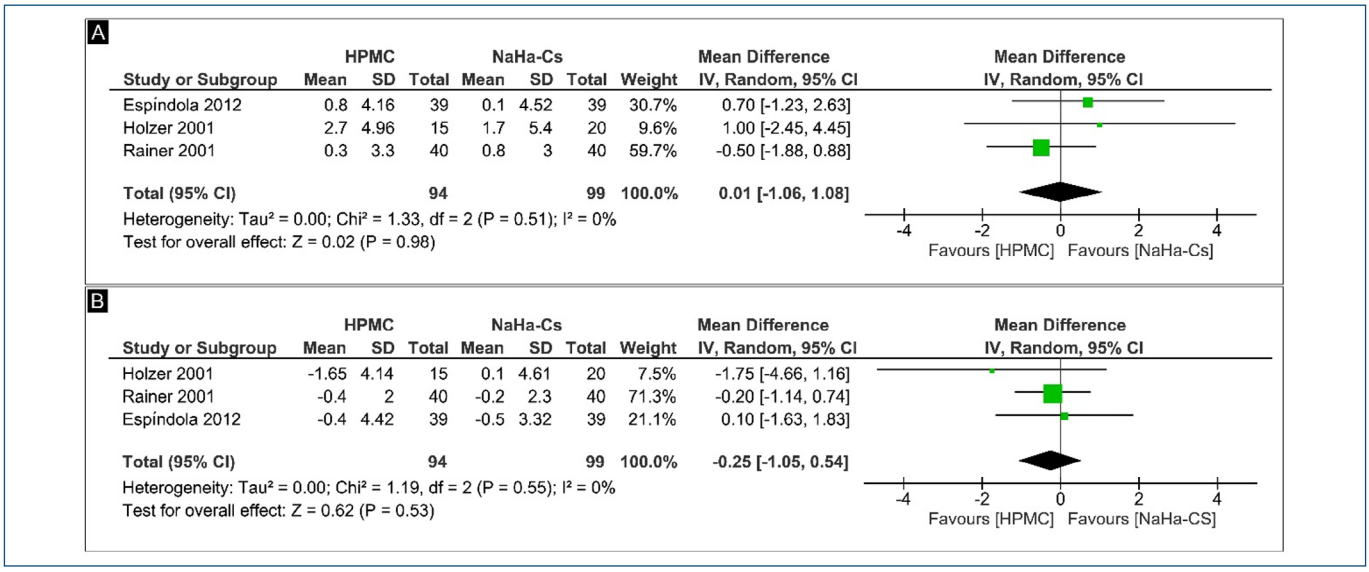


Figure 3. (A) Change of intraocular pressure (mmHg) one day post-surgery from baseline hydroxypropyl methylcellulose versus sodium hyaluronate – chondroitin sulfate. (B) Change of intraocular pressure (mmHg) from Baseline in 7 days between hydroxypropyl methylcellulose *versus* sodium hyaluronate – chondroitin sulfate.

The funnel plot displayed a symmetrical distribution of studies with similar weights, converging toward the pooled prognostic effect size as the weights increased. [19]

DISCUSSION

This systematic review and meta-analysis of six studies involving 489 eyes compared dispersive OVDs, HPMC, with NaHa and NaHa-CS following phacoemulsification. The main findings indicate that there are no significant differences in IOP during both short-term and long-term follow-ups.

To reduce the incidence and severity of post-operative IOP elevation, various surgical techniques for the complete removal of OVDs have been described.[6, 20] An increase in IOP during the first day of the post-operative period has become a significant concern since many cataract surgeries are outpatient.[21] The issue of post-operative IOP spikes associated with OVD use in cataracts has long been contentious, with many conflicting reports and only a few conclusive studies. Rainer et al. showed that HPMC has fewer IOP spikes than NaHa OVD in eyes that underwent phacoemulsification. Espíndola et al.[16] found no statistically significant difference between HPMC and (NaHa-CS) in IOP at any point time post-surgery.

In contrast, Ray-Chaudhuri et al.[4] found that IOP was significantly lower in the NaHa at one day post-operatively, while no significant difference was found between the two groups seven days post-operatively.

Our information serves to resolve the discrepancies found in earlier research findings. [4, 8, 16, 18, 21-24] We showed no differences between HPMC and NaHa and NaHa-CS in the seventh post-operative day follow-up. Accordingly, due to the lack of clinical benefit with HPMC previous studies,[4] we performed two subanalyses of studies restricted to one day post-operatively and seven post-operatively found significant differences between HPMC and NaHa, but not in the HPMC and NaHa-CS comparison. But that significant difference is not enough to provide a high level of recommendation due to high heterogeneity and because our baseline characteristic consists of non-glaucomatous patients. Furthermore, on the seven post-operative day in the same group this difference disappears.

We must note that we analyzed IOP changes as secondary outcomes after phacoemulsification. To more effectively determine the advantages of using HPMC over NaHa and NaHa-CS, it is essential to measure primary outcomes such as endothelial cell density and central corneal, since the most critical role of those OVDs is to avoid mechanical trauma from phacoemulsification energy in endothelial cells. [9] A previous meta-analysis revealed a significantly lower percentage (%) decrease in endothelial cell density for NaHa-CS compared to HPMC (MD -6.47%; 95%CI -10.41—2.52; p = 0.001) and still needed more studies to clarify the primary effectiveness between the OVDs.

The meta-analysis above[9] compared the changes in IOP before and after phacoemulsification using groups with the same OVDS. The results demonstrated a significant increase in post-operative IOP one day after surgery with Healon® (SMD = 0.37; CI 0.07-0.67), Viscoat® (SMD = 0.29; CI 0.13-0.45]), and ProVisc® (SMD = 0.46; CI 0.17-0.76). Conversely, the study indicated that there was no

significant difference in post-operative IOP with Healon GV (SMD = 0.07; CI -0.28-0.41), Healons (SMD = 0.15; CI -0.33-0.64), 2% HPMC (SMD = 0.32; CI -0.0-0.64), and OcuCoat (SMD = 0.26; CI -0.37-0.9).

Our study has limitations. First and foremost, it is important to recognize that our research did not include patients with glaucoma, which means our conclusions may not apply to them. Additionally, our analysis was based on a limited dataset of only six RCTs. Therefore, we emphasize the need for more comprehensive RCTs in the future that should compare the effectiveness of HPMC with NaHa and the combination of NaHa with NaHa-CS in post-phacoemulsification cataract patients. Despite these limitations, the heterogeneity of our long-term results was notably low.

CONCLUSION

This meta-analysis compared hydroxypropyl methylcellulose with sodium hyaluronate and sodium hyaluronate – chondroitin sulfate in over 400 eyes that underwent phacoemulsification. Our study indicates that hydroxypropyl methylcellulose may experience changes in intraocular pressure from baseline similarly to sodium hyaluronate and sodium hyaluronate – chondroitin sulfate in patients who underwent cataract surgery within seven post-operative days.

Authors' contribution

All authors made substantial contributions to the conception and design, data acquisition, or analysis and interpretation of the data; took part in drafting the article or critically revising it for important intellectual content; gave final approval of the version to published; agreed on the journal to which the article has been submitted; and agreed to be accountable for all aspects of the work.

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