• Meta-Analysis •

Comparative efficacy of non-steroidal anti-inflammatory drugs in preventing postoperative macular edema following cataract surgery: a systematic review and Network Meta-analysis

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Abstract

● **AIM:** To assess and rank the efficacy of various non-steroidal anti-inflammatory drugs (NSAIDs) in preventing postoperative macular edema (PME) after cataract surgery.

● **METHODS:** A comprehensive search was conducted across PubMed, Embase, Cochrane Library, and Web of Science databases. Randomized controlled trials (RCTs) comparing different NSAIDs and control treatments for the prevention of PME were included. Data from the studies were synthesized using the "gemtc" package in R. Risk of bias was assessed with the Cochrane RoB 2 tool, and heterogeneity was evaluated using the global I^2 statistic. Surface under the cumulative ranking curve (SUCRA) values were calculated for each treatment.

● **RESULTS:** Of 132 identified records, 9 RCTs met the inclusion criteria. The Network Meta-analysis indicated that nepafenac had the highest efficacy in preventing PME, followed by artificial tear substitute, ketorolac, diclofenac, and bromfenac. The league table comparisons and rankograms corroborated these findings, with nepafenac consistently ranking highest. Heterogeneity analysis yielded high I^2 values, indicating substantial variability across studies.

● **CONCLUSION:** This Network Meta-analysis suggests that nepafenac is the most effective NSAID for preventing PME following cataract surgery. Given the substantial heterogeneity observed, further high-quality RCTs are required to confirm these findings and explore the sources of variability. Clinicians should consider these results when selecting NSAIDs for PME prophylaxis in cataract surgery patients.

● **KEYWORDS:** postoperative macular edema; cataract surgery; non-steroidal anti-inflammatory drugs; Network Meta-analysis; nepafenac

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INTRODUCTION

Cataract surgery is one of the most commonly performed ophthalmic procedures worldwide, delivering substantial improvements in vision and quality of life for millions of patients annually[1-2]. Despite its high success rate, postoperative complications such as macular edema (PME) can significantly impede visual recovery[3]. PME is characterized by the accumulation of fluid in the macula, leading to swelling and impaired vision, and it remains a pressing concern in the postoperative management of cataract patients[4].

The pathophysiology of PME involves inflammation-induced breakdown of the blood-retinal barrier, with subsequent fluid leakage into the retinal layers[5]. Non-steroidal anti-inflammatory drugs (NSAIDs) have been frequently employed to counteract this inflammatory response, providing a pharmacological means to prevent PME[6]. NSAIDs inhibit cyclooxygenase (COX) enzymes, which play a pivotal role in the synthesis of pro-inflammatory prostaglandins[7]. By mitigating the inflammatory cascade, NSAIDs can potentially reduce the incidence and severity of PME, thereby optimizing postoperative visual outcomes[8].

Several NSAIDs, including nepafenac, ketorolac, diclofenac, and bromfenac, are available for ocular use. Numerous randomized controlled trials (RCTs) have explored the efficacy of these agents in preventing PME; however, the comparative effectiveness of these NSAIDs remains inconclusive[9-10]. For instance, while individual studies have suggested

varying degrees of efficacy among the different NSAIDs, a comprehensive synthesis of the available data has been lacking.

Previous systematic reviews and Meta-analyses have attempted to address this gap, yet they often focused on pairwise comparisons or included heterogeneous study designs, complicating the interpretation of their findings[6,11]. Furthermore, these studies did not employ network Meta-analysis (NMA) techniques, which allow for the simultaneous comparison and ranking of multiple treatments[12]. NMA integrates direct and indirect evidence across a network of studies, providing a more robust and comprehensive assessment of comparative efficacy.

Given the clinical importance of selecting the optimal NSAID for PME prophylaxis, our study aims to systematically review the available literature and conduct an NMA to evaluate and rank the efficacy of various NSAIDs in preventing PME following cataract surgery. By leveraging advanced statistical methods and a rigorous methodological approach, we endeavor to provide clinicians with evidence-based guidance for NSAID selection, ultimately enhancing patient care. In this systematic review and NMA, we conducted an exhaustive search across multiple databases, including PubMed, Embase, Cochrane Library, and Web of Science, to identify relevant RCTs. We synthesized data from the included studies using the GeMTC package in R, assessed the risk of bias using the Cochrane Risk of Bias 2 (RoB 2) tool, and evaluated heterogeneity using global I^2 statistics. Surface under the cumulative ranking curve (SUCRA) values were calculated to rank the efficacy of each NSAID. This study aims to contribute to the body of evidence guiding the prophylactic use of NSAIDs in cataract surgery, ultimately improving postoperative outcomes for patients at risk of PME.

MATERIALS AND METHODS

Ethical Approval As this study involved the analysis of previously published data, ethical approval and informed consent were not required. However, the study adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension statement for NMA to ensure transparency and completeness in reporting[13].

Search Strategy A comprehensive and systematic search strategy was employed across four major databases: PubMed, Embase, Cochrane Library (Trials), and Web of Science. The search strategies were tailored to each database in accordance with their specific indexing terms and structure. Search terms included NSAIDs, specific drug names, cataract, and macular edema. Boolean operators, Medical Subject Headings (MeSH), Emtree terms, and free-text terms were combined to maximize the retrieval of relevant studies. Filters were applied to restrict the search to article, humans, English, and RCT. The search was conducted from database inception up to June 27, 2024.

Inclusion and Exclusion Criteria To be included in the systematic review and NMA, studies needed to meet the following criteria: adults undergoing cataract surgery, administration of any NSAID for the prevention of PME, and control treatments including placebo or glucocorticoid. Exclusion criteria were case reports, comments, conference abstracts, editorials, letters, non-English publications, protocols, reviews, systematic reviews, non-RCTs, non-cataract postoperative studies, studies involving combination medications, and data not available in full-text form.

Data Extraction and Management Two independent reviewers screened titles and abstracts for eligibility. Full-text articles of potentially relevant studies were then assessed for inclusion. Discrepancies were resolved through discussion or by consulting a third reviewer. Data extraction was conducted using a predesigned data extraction form, capturing study characteristics, country, disease, surgical procedure, intervention type, frequency, dose, duration, sample size, age, and follow-up duration.

Risk of Bias Assessment The risk of bias in included RCTs was assessed using the Cochrane RoB 2 tool. This tool evaluates five domains: bias arising from the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. Each study received a judgment of “low risk”, “some concerns”, or “high risk” of bias. Two independent reviewers conducted the assessments, and disagreements were resolved by consensus or involving a third reviewer.

Data Synthesis and Statistical Analysis An NMA was performed using the GeMTC package in R (version 4.3.2), which employs a Bayesian framework to compare multiple treatments across a network of studies. Direct and indirect comparisons were synthesized to estimate the relative efficacy of each NSAID in preventing PME. Potential scale reduction factors (PSRFs) were computed to evaluate the convergence of the NMA models. The primary outcome was the incidence of PME.

Heterogeneity and Inconsistency Assessment Heterogeneity across studies was evaluated using the global I^2 statistic, with values interpreted as follows: low (0-25%), moderate (26%-50%), substantial (51%-75%), and considerable (76%-100%). Inconsistency between direct and indirect comparisons within the network was assessed using node-splitting techniques.

Pairwise Comparisons Pairwise comparisons of NSAIDs and control treatments were summarized in a league table. This table presents the odds ratios (ORs) and 95% credible intervals (CIs) for each comparison, with ORs greater than 1 indicating superior efficacy of the column header treatment over the row header treatment.

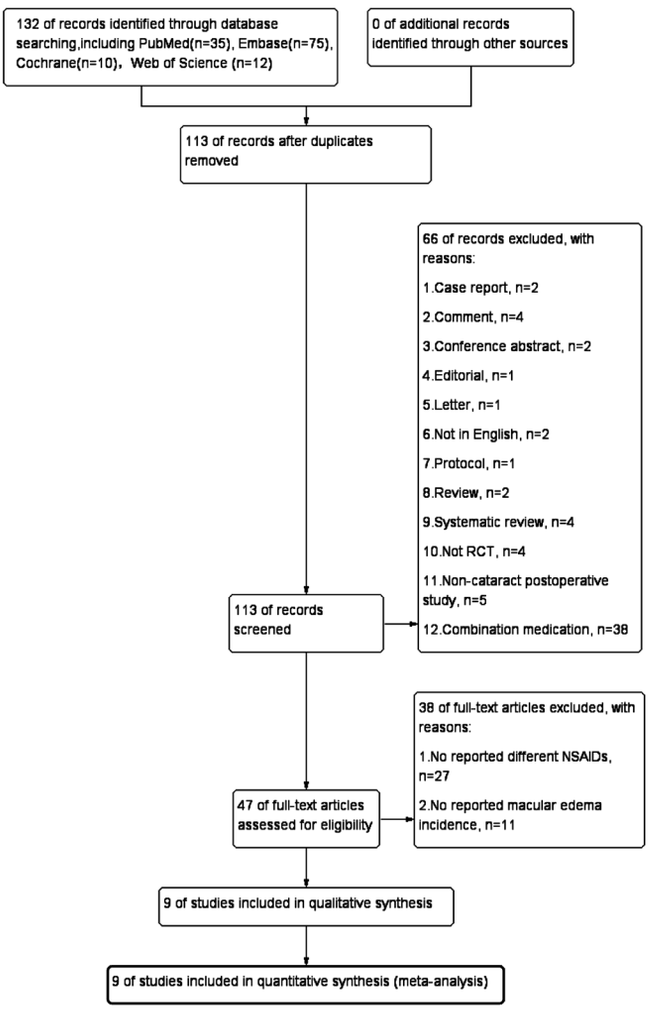

Figure 1 PRISMA flow diagram for study selection process PRISMA flow diagram details the study selection process for the systematic review and Network Meta-analysis on the efficacy of various NSAIDs in preventing postoperative macular edema following cataract surgery. Out of the 132 records identified through database searches, no additional records were identified through other sources. After removing duplicates, 113 records were screened, resulting in the exclusion of 66 records for various reasons. Ultimately, 9 studies were included in both the qualitative and quantitative synthesis (Meta-analysis). PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; NSAIDs: Non-steroidal anti-inflammatory drugs.

Ranking of Treatments The efficacy of each treatment was ranked based on the incidence of macular edema using rankograms and SUCRA values. These metrics provide a probabilistic ranking of each intervention, with higher SUCRA values indicating a higher likelihood of being the most effective treatment.

RESULTS

Study Selection and Characteristics The PRISMA flow diagram illustrates the study selection process (Figure 1). Initially, 132 records were identified, with 19 duplicates removed, leaving 113 records for screening. Ineligible records (n=66) were excluded due to criteria such as being case reports, comments, non-English publications, and studies involving combination medications. Full-text assessment of 47 articles led to the exclusion of 38 further records, mainly due to the absence of different NSAIDs and lack of data regarding macular edema incidence. Ultimately, 9 RCTs were included in the qualitative and quantitative synthesis (Table 1)[14-22].

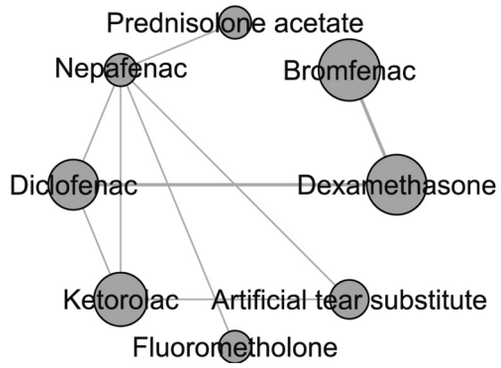

Figure 2 Network plot of comparisons among different NSAIDs and controls The network plot depicts the comparisons among various NSAIDs and control treatments used in the studies included in the Network Meta-analysis. Each node represents an intervention, with the size of the node being proportional to the number of studies involving that particular treatment. The connections (or edges) between the nodes signify direct comparisons made within the included studies. The NSAIDs compared in the network include nepafenac, diclofenac, ketorolac, and bromfenac. Control treatments such as dexamethasone, prednisolone acetate, fluorometholone, and artificial tear substitute are also represented. NSAIDs: Non-steroidal anti-inflammatory drugs.

Evaluation of Bias Bias assessment of the included RCTs was conducted using the Cochrane RoB 2 tool (Table 2). The majority of studies demonstrated a low risk of bias across most domains, although a few studies had some concerns regarding the randomization process and selection of the reported result.

Network Meta-Analysis Structure The network plot displays the structure of the comparisons among various NSAIDs and control treatments included in the analysis (Figure 2). The nodes represent interventions such as nepafenac, diclofenac, ketorolac, and bromfenac, with each node's size being proportional to the number of studies involving the respective treatment. Control treatments included dexamethasone, prednisolone acetate, fluorometholone, and artificial tear substitute. The network highlights direct comparisons between these interventions.

Heterogeneity and Consistency Heterogeneity tests revealed pairwise I^2 values of 90.21% and consistency I^2 values of 80.55% for the outcome of macular edema incidence, indicating substantial heterogeneity among the included studies (Table 3). The consistency assumption was evaluated and supported. Moreover, the convergence of the Bayesian

Table 1 Characteristics of included randomized controlled trials

Study	Country	Disease	Operation	Intervention type	Intervention frequency	Intervention dose	Intervention duration	Sample size	Age (y)	Follow-up time
De Maria, 2020[14]	Italy	Cataract	Phacoemulsification with posterior chamber IOL implantation	Dexamethasone 0.1%	4 times daily	-	2wk	37	70.5±9.3	6mo
				Bromfenac 0.09%	Twice daily	-	2wk	38	70.8±9.5	6mo
Ilveskoski, 2020[15]	Finland	Cataract	Phacoemulsification with IOL implantation	Prednisolone acetate	-	-	-	20	77.0±5.3	3mo
				Nepafenac	-	-	-	20	77.6±6.8	3mo
Maca, 2010[16]	Austria	Cataract	Phacoemulsification with posterior chamber IOL implantation	Preservative-free diclofenac sodium 0.1%	4 times daily	1 drop	4wk	31	66.2±10.4	1mo
				Preserved diclofenac sodium 0.1%	4 times daily	1 drop	4wk	29	68.2±10.4	1mo
				Preserved ketorolac tromethamine 0.5%	4 times daily	1 drop	4wk	33	70.8±9.9	1mo
Medić, 2017[17]	Croatia	Diabetic retinopathy	Phacoemulsification	Dexamethasone	4 times daily	-	7d before to 30d after surgery	20	47-82	90d
				Diclofenac	4 times daily	-	7d before to 30d after surgery	24	59-81	90d
Miyake, 2011[18]	Japan	Cataract	Phacoemulsification with foldable intraocular lens implantation	Nepafenac 0.1%	3 times daily	-	5wk	28	64.3±7.8	5wk
				Fluorometholone 0.1%	3 times daily	-	5wk	27	65.7±12.2	5wk
Tzelikis, 2015[19]	Brazil	Cataract	Phacoemulsification	Artificial tear substitute	4 times daily	1 drop	4wk	40	65.36±7.3	4wk
				Ketorolac 0.4%	4 times daily	1 drop	4wk	45		4wk
				Nepafenac 0.1%	3 times daily	1 drop	4wk	41		4wk
Wielders, 2018[20]	Netherlands	Cataract	Phacoemulsification with posterior chamber IOL implantation	Bromfenac 0.09%	Twice daily	1 drop	2d before to 2wk after surgery	269	69.70±8.94	12wk
				Dexamethasone 0.1%	4 times daily,	1 drop	2d surgery to 2wk after surgery	270	71.23±8.73	12wk
Ylinen, 2018[21]	Finland	Cataract	Phacoemulsification with IOL implantation	Preservative-free Dexamethasone	3 times daily	-	3wk	64	63-96	1mo
				Preservative-free Diclofenac	3 times daily	-	3wk	70	62-88	1mo
Ylinen, 2018[22]	Finland	Cataract	Phacoemulsification	Nepafenac	3 times daily	-	3wk	39	75.6±1.0	3mo
				Diclofenac	3 times daily	-	3wk	34	76.4±0.9	3mo

IOL: Intraocular lens.

Table 2 Evaluation of bias risk in RCTs using the Cochrane RoB 2 tool

Study	D1	D2	D3	D4	D5	Overall
De Maria, 2020[14]	Low risk	Low risk	Low risk	Low risk	Some concerns	Some concerns
Ilveskoski, 2020[15]	Some concerns	Low risk	Low risk	Low risk	Some concerns	Some concerns
Maca, 2010[16]	Low risk	Some concerns	Low risk	Low risk	Some concerns	Some concerns
Medić, 2017[17]	Low risk	Low risk	Low risk	Low risk	Some concerns	Some concerns
Miyake, 2011[18]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Tzelikis, 2015[19]	Low risk	Some concerns	Low risk	Low risk	Some concerns	Some concerns
Wielders, 2018[20]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Ylinen, 2018[21]	Low risk	Low risk	Some concerns	Low risk	Low risk	Some concerns
Ylinen, 2018[22]	Low risk	Some concerns	Low risk	Low risk	Some concerns	Some concerns

D1: Bias arising from the randomisation process; D2: Bias due to deviations from intended interventions; D3: Bias due to missing outcome data; D4: Bias in measurement of the outcome; D5: Bias in selection of the reported result; RCT: Randomized controlled trial; RoB 2: Risk of Bias 2.

Table 3 Heterogeneity tests

Outcome	Global I^2	
	I^2 pair	I^2 cons
Macular edema incidence	90.21213	80.55245

models was verified by calculating PSRFs, which were found to be equal to 1 (Table 4). This indicates that the models fit well without significant discrepancies.

Pairwise Comparisons The league table (Table 5) provides detailed results of pairwise comparisons between NSAIDs and

Table 4 Potential scale reduction factors

Parameters	Point est.	Upper CI	Multivariate PSRF
d.dexamethasone.bromfenac	1	1	1
d.diclofenac.dexamethasone	1	1	1
d.diclofenac.ketorolac	1	1	1
d.diclofenac.nepafenac	1	1	1
d.nepafenac.artificial tear substitute	1	1	1
d.nepafenac.fluorometholone	1	1	1
d.nepafenac.prednisolone acetate	1	1	1
sd.d	1	1	1

d: Log odds ratio; sd.d: Standard deviation of the log odds ratio; PSRF: Potential scale reduction factors; CI: Credible intervals.

Table 5 League table of pairwise comparisons of NSAIDs and control treatments

Dexamethasone	0.12 (0.002, 3.05)	197931.09 (0, <0.0001)	0.02 (0, 11.63)	0.1 (0.001, 2.60)	0.06 (0, 186.90)	0.92 (0, 1742.16)	0.02 (0, 97.72)
8.06 (0.328, 656.14)	**Bromfenac**	2002263.85 (0, <0.0001)	0.249 (0, 428.53)	0.8 (0.004, 171.76)	0.576 (0, 5248.59)	7.84 (0.001, 53524.71)	0.24 (0, 2737.82)
0 (0, <0.0001)	0 (0, <0.0001)	**Prednisolone acetate**	0 (0, <0.0001)	0 (0, <0.0001)	0 (0, <0.0001)	0 (0, <0.0001)	0 (0, <0.0001)
34.09 (0.086, 40001.15)	4.01 (0002, 7721.54)	7531305.03 (0, <0.0001)	**Nepafenac**	3.19 (0.01, 769.50)	2.29 (0.01, 523.76)	31.45 (0.28, 3571.58)	0.99 (0.003, 291.92)
10.02 (0.38, 781.17)	1.25 (0.006, 247.46)	2371287.04 (0, <0.0001)	0.31 (0.001, 51.99)	**Diclofenac**	0.71 (0, 1151.46)	9.78 (0.007, 10395.21)	0.30 (0, 610.97)
14.94 (0.005, 98327.64)	1.73 (0, <16495.77)	3271975.35 (0, <0.0001)	0.43 (0.002, 77.82)	1.40 (0.001, 2489.49)	**Ketorolac**	13.67 (0.01, 15449.52)	0.43 (0.002, 79.93)
1.08 (0.001, 5694.58)	0.127 (0, 962.34)	239267.21 (0, <0.0001)	0.032 (0, 3.49)	0.10 (0, 137.74)	0.07 (0, 93.89)	**Fluorometholone**	0.03 (0, 48.70)
35.40 (0.01, 297802.81)	4.07 (0, 48935.52)	7787571.14 (0, <0.0001)	1.00 (0.003, 301.91)	3.28 (0.002, 8203.34)	2.30 (0.01, 568.69)	31.67 (0.02, 51123.21)	**Artificial tear substitute**

NSAIDs: Non-steroidal anti-inflammatory drugs.

Table 6 The surface under the cumulative ranking curve values

Parameters	SUCRA values
Nepafenac	0.7127063
Artificial tear substitute	0.6761924
Ketorolac	0.5778755
Diclofenac	0.5766126
Bromfenac	0.5555051
Prednisolone acetate	0.3370579
Fluorometholone	0.3043384
Dexamethasone	0.2597119

SUCRA: Surface under the cumulative ranking curve.

control treatments, showing OR and 95%CI. An OR greater than 1 indicates higher efficacy of the row treatment over the column treatment.

Treatment Rankings Nepafenac had the highest probability of being ranked first, followed by artificial tear substitute, ketorolac, and diclofenac. SUCRA values supported these findings, with nepafenac having the highest SUCRA value (0.7127), indicating superior efficacy (Table 6).

The league table summarizes the pairwise comparisons between various NSAIDs and control treatments in terms of their efficacy in preventing postoperative macular edema following cataract surgery. Each cell in the table contains the OR and 95%CI for the comparison between two treatments, with the treatment listed in the column header compared to the treatment listed in the row header. An OR greater than 1 suggests that the treatment in the row header is more effective than the treatment in the column header, while an OR less than 1 indicates the opposite.

DISCUSSION

Our systematic review and NMA aimed to compare the efficacy of various NSAIDs in preventing PME following cataract surgery. The findings provide valuable insights into the relative performance of different NSAIDs, indicating that nepafenac outperforms other agents in PME prevention.

Our results align with several studies that have highlighted the efficacy of nepafenac in managing postoperative inflammation and edema. For example, Ilveskoski *et al*[15] found routine cataract surgery on eyes with pseudoexfoliation syndrome, using NSAIDs alone or in combination with prednisolone acetate, resulted in faster postoperative recovery and reduced incidence of pseudophakic cystoid macular edema compared to using prednisolone acetate alone. Similarly, a study by Miyake *et al*[18] demonstrated that nepafenac proved to be more effective than fluorometholone in preventing angiographic cystoid macular edema and the disruption of the blood-aqueous barrier.

One of the salient features of our analysis was the high heterogeneity (global I^2) observed across studies. Several factors might contribute to this variability, including differences in study populations, variations in surgical techniques, and inconsistent definitions and measurements of PME. Further subgroup analyses could help elucidate these sources of heterogeneity. For example, stratifying studies by patient demographics (age, comorbidities) might offer clearer insights.

The superior ranking of nepafenac suggests that it should be the preferred choice for PME prophylaxis in cataract surgery, especially in high-risk patients. However, given the substantial heterogeneity and the limitations inherent in the existing RCTs, clinicians should exercise caution. Individual patient factors, such as previous ocular history, NSAID tolerability, and corticosteroids for the postoperative management of age-related cataract surgery, should also be taken into account[23].

Interestingly, the artificial tear substitute ranked second, suggesting a potential placebo effect or the impact of adjunctive therapy. This finding warrants further investigation as it may reflect the importance of patient adherence and the supportive role of lubricating agents in postoperative care.

Our analysis underscores the need for more high-quality RCTs to validate these findings and address the identified heterogeneity. Future research should aim for standardized definitions and consistent methodologies to facilitate more accurate comparisons. Additionally, exploring the pharmacokinetics and pharmacodynamics of different NSAIDs in the ocular environment, and the impact on macular oedema and visual outcome after phacoemulsification could offer deeper insights into their mechanisms of action and efficacy profiles[24].

While our study provides robust evidence through an NMA approach, several limitations merit consideration. The relatively small number of included studies (n=9) and the inherent risk of bias in some trials may affect the generalizability of our findings. Moreover, the high heterogeneity suggests that the results should be interpreted with caution.

In summary, our NMA indicates that Nepafenac is the most effective NSAID for preventing PME following cataract surgery. Despite the substantial heterogeneity, these findings offer actionable insights for clinical practice. Future high-quality RCTs are needed to confirm our results and explore the underlying sources of variability. Until then, clinicians should consider these findings in conjunction with patient-specific factors when selecting NSAIDs for PME prophylaxis.

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Authors' Contributions: Lang M, Liu T designed the study. Lang M wrote the original draft. Xuan J, Li X collected raw data. Liu MM, Xu J performed statistical and bioinformatics analyses. Lang M, Liu T supervised the study.

Availability of Data and Materials: The data could be obtained by contacting the corresponding author.

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