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OCIMUM BASILICUM L. STARCH BASED HYDROGELS IN *IN-VITRO* DRUG DELIVERY OF DICLOFENAC SODIUM

Shubhangi Pandey[1], Anmol Kumar[1], Krishna Kumar[2], S. Krishnamoorthi[3], Kranthikumar Tungala[1*]

1. Department of Chemistry, Ewing Christian College, University of Allahabad, Prayagraj, Uttar Pradesh-211003, India.
2. Department of Chemistry, School of Basic & Applied Science, Harcourt Butler Technical University, Kanpur, Uttar Pradesh-208002, India.
3. Department of Chemistry, Centre of Advanced Studies, Institute of Science, Banaras Hindu University, Varanasi-221005, U.P., India.

ABSTRACT: In the present work, starch-based hydrogels derived from *Ocimum basilicum* L. starch (OBS) were explored as pH-responsive carriers for controlled drug delivery. Building on previously reported synthesis and characterization, this article highlights the *in-vitro* performance of three hydrogel grades (OBS-g-(PAM-co-PAA)-1 to OBS-g-(PAM-co-PAA)-3), fabricated by copolymerizing acrylamide and acrylic acid onto the backbone of OBS, in delivering an anti-inflammatory drug, diclofenac sodium. The hydrogels demonstrated efficient drug loading capacity and exhibited distinct release kinetics under varying pH conditions, confirming their sensitivity to gastrointestinal environments. Comparative release profiles revealed tunable drug release behavior dependent on hydrogel composition, underscoring their potential as adaptable drug vehicles. These findings establish OBS-based graft copolymer hydrogels as promising cargos for controlled oral drug delivery systems, combining natural polysaccharide biocompatibility with responsive synthetic polymer networks.

Keywords: *Ocimum basilicum* L. starch, hydrogel, diclofenac sodium, pH responsive.

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Corresponding Author: Dr. Kranthikumar Tungala* Ph.D.

Department of Chemistry, Ewing Christian College, University of Allahabad, Prayagraj, U.P., -211003, India. Email Address: kktungala@ecc.ac.in

1. INTRODUCTION

The development of eco-friendly, bio-compatible, and stimuli-responsive materials has become central to modern drug delivery research. Hydrogels, which are three-dimensional hydrophilic polymer networks, are particularly attractive because of their ability to retain large amounts of water, mimic the physical characteristics of biological tissues, and undergo structural transitions in response to external conditions [1,2]. Their elasticity, transparency, and ease of chemical modification further enhance their applicability in biomedical systems. In drug delivery applications, such responsiveness allows hydrogels to regulate the controlled, sustained, and on-demand release of therapeutic molecules in accordance with physiological triggers such as pH, temperature, or metabolic variations [3,4,5]. Among the various smart hydrogel systems, pH-sensitive hydrogels have been widely explored because they can exploit the natural pH variations across the gastrointestinal tract, bloodstream, or pathological tissues. Incorporation of ionizable monomers during copolymerization enhances this pH-adaptive behavior, making them suitable for targeted drug delivery applications [6,7,8]. Polyacrylic acid (PAA) is one such monomer that has been extensively used to impart pH-responsiveness due to its dissociable carboxyl groups [9,10,11]. Polyacrylamide (PAM), on the other hand, contributes high water-absorption capacity and temperature-sensitive swelling behavior because of its amide functionalities [12]. The complementary nature of acrylic acid (AA) and acrylamide (AM) enables their copolymerization to produce hydrogels with improved hydration, hydrogen-bonding potential, tunable swelling, and enhanced environmental sensitivity [13,14]. When coupled with natural polymers like starch, such systems gain additional advantages of biodegradability, biocompatibility, and sustainability [15,16]. Basil seeds (*Ocimum basilicum* L.) also offer an interesting natural polymer source. The seeds, traditionally used in foods and reported for various medicinal properties including alleviation of diarrhoea, ulcerative symptoms, and digestive discomfort, possess an outer mucilaginous polysaccharide layer known as basil seed gum (BSG) [17,18,19]. When hydrated, this polysaccharide rapidly swells to form a viscous gel-like matrix [20]. Such natural hydrocolloids, when combined with synthetic monomers, can form hybrid hydrogels with enhanced mechanical strength, water absorption, and responsiveness suitable for drug delivery [21]. Previous studies have demonstrated that grafting synthetic monomers onto natural polysaccharide backbones can significantly improve hydrogel performance. For example, Musa et al. synthesized potato starch hydrogel by grafting polyacrylamide onto starch and studied drug delivery of promethazine drug, hydrogel have lower absorption ability at lower pH when compared to the higher pH [22]. Chang synthesized pH sensitive hydrogel based on potato starch with PAA and studied its drug delivery ability by making microbeads by introducing sodium alginate in the hydrogels [23]. In hydrogel-based drug release study, diffusion of drug takes place because of the polymer which entraps it, this process in general known as controlled drug release study. Body fluids, mainly water, flow into the

hydrogel because of which its matrix swells up and dissolution of drug followed by diffusion leads in an easiest way [24,25]. In the present work, diclofenac sodium (DS), has been used as a model drug in *in-vitro* drug release study. As DS exhibits antipyretic efficacy, anti-inflammatory and analgesic biocompatible properties in it, meanwhile it is non-steroidal drug which makes it useful in the semi-permanent treatment of degenerative joint diseases which are of rheumatic and non-rheumatic in origin, such as ankylosing spondylitis, rheumatoid arthritis, and osteoarthritis [26]. It has limited water solubility, especially in gastric juices and is precarious in aqueous solution [27,28]. Study of controlled release rate of DS has been investigated by using our initially synthesized hydrogels [29].

2. MATERIALS AND METHODS

2.1. Materials

N-(hydroxymethyl)acrylamide (>98.0%), acrylamide (98.5%), acrylic acid (98%), potassium persulphate (98%), NaOH pellets, hydrochloric acid, were purchased from Loba chemie, Mumbai, India. Ethanol (99.9%) was purchased from MSB Chemical Limited, Mumbai, India. Diclofenac sodium (≥98%) was procured from Alfa Aesar, India. Sodium phosphate monobasic dihydrate was procured from Rankem Avantor Performance Materials India Limited, India. Sodium dihydrogen phosphate monohydrate was purchased from Merck Specialities Private Limited, India. All chemicals were used as received.

2.2. Synthesis of *Ocimum basilicum* L. starch-based hydrogels [OBS-g-(PAM-co-PAA)]

Fabrication of three different grades of OBS-g-(PAM-co-PAA) hydrogel was done as reported in literature [29] which is briefed as: 0.5 g of starch was dispersed in 40 mL of distilled water at 80 °C and continuously stirred at 500 rpm for 30 minutes. After obtaining a homogenous solution, addition of comonomers viz., 0.375 g of AM and 0.356 mL of AA was done. Cross-linker N-(hydroxymethyl)acrylamide was added in varied amounts, in order to prepare three different grades of the hydrogel (OBS-g-(PAM-co-PAA)-1, OBS-g-(PAM-co-PAA)-2 and OBS-g-(PAM-co-PAA)-3) in which the amount of crosslinker was increased gradually from grade 1 to 3. Afterwards 20 mg of potassium persulphate was added to initiate the polymerization. For inert environment, nitrogen gas was continuously purged throughout the entire procedure. The reaction mixture was allowed to stir for one hour and then cooled down to room temperature while adjusting the pH to 8 by the addition of 1 N NaOH solution. Then the viscous mixture was poured into 200 mL of ethanol and kept for 24 hours. Thus, obtained hydrogel was vacuum filtered, dried at 70 ℃ in hot air vacuum oven and then stored in an air-tight container.

2.3. *In-vitro* drug load and release study

100 mg each of OBS-g-(PAM-co-PAA)-1, OBS-g-(PAM-co-PAA)-2 and OBS-g-(PAM-co-PAA)-3 hydrogel grades were dispersed in 20 mL aqueous solution of 10 mg of diclofenac sodium drug at 25 ℃. After 72 hours of soaking, the swollen hydrogels were filtered and vacuum-dried in an oven

at 37 °C to yield drug-loaded hydrogels, designated as OBS-g-(PAM-co-PAA)-DS-1 to OBS-g-(PAM-co-PAA)-DS-3, corresponding respectively to the original hydrogels OBS-g-(PAM-co-PAA)-1 to OBS-g-(PAM-co-PAA)-3 [30]. For the construction of the calibration curve, 1 mg/mL stock solution of DS drug was prepared in distilled water. Dilutions of 0.5, 0.25, 0.125, 0.06, 0.03, 0.015 mg/mL were done using this stock solution, and the corresponding absorbance was measured at 276.8 nm using a UV-Visible Spectrophotometer (Systronics PC Based Double Beam Spectrophotometer 2206, bandwidth: 1.0 nm). Finally, a calibration graph was plotted between concentration and absorbance. By using the calibration curve, the drug content loaded on the hydrogels was estimated. Further, the drug encapsulation efficiency percentage (DEE%) for each grade was calculated by using the equation **(1)**.

DEE (%) = [Experimentally calculated drug content /Theoretical drug content] x 100 …….**(1)**

To study the release of the drug, dried samples of drug loaded hydrogel were kept immersed in three different PBSs of pH 2, 4 and 7 at room temperature, separately. At specific time intervals, i.e., 0.50, 1, 2, 3, 4, 6, 8, 10, 12, 24, 36 and 48 h, 3 mL of drug released buffer solution was withdrawn and replaced with 3 mL of fresh buffer solutions. Then, these withdrawn samples were analysed through UV-vis spectrophotometer where blank PBS of particular pH was used as reference in reference cell.

3. RESULTS AND DISCUSSION

3.1. Drug encapsulation efficiency of hydrogels

The DEE and pH-dependent release behavior of diclofenac sodium from OBS-g-(PAM-co-PAA) hydrogels of grades 1, 2, and 3 were evaluated to understand their potential as pH-responsive drug delivery systems. A pictorial representation of diclofenac sodium loaded in OBS-g-(PAM-co-PAA) is shown in (Figure 1). The DEE values viz., 77.20% (Grade 1), 95% (Grade 2), and 82.47% (Grade 3), demonstrate efficient drug loading, with Grade 2 exhibiting the highest encapsulation capability, likely due to optimal crosslinking density and interaction between polymeric chains and DS.

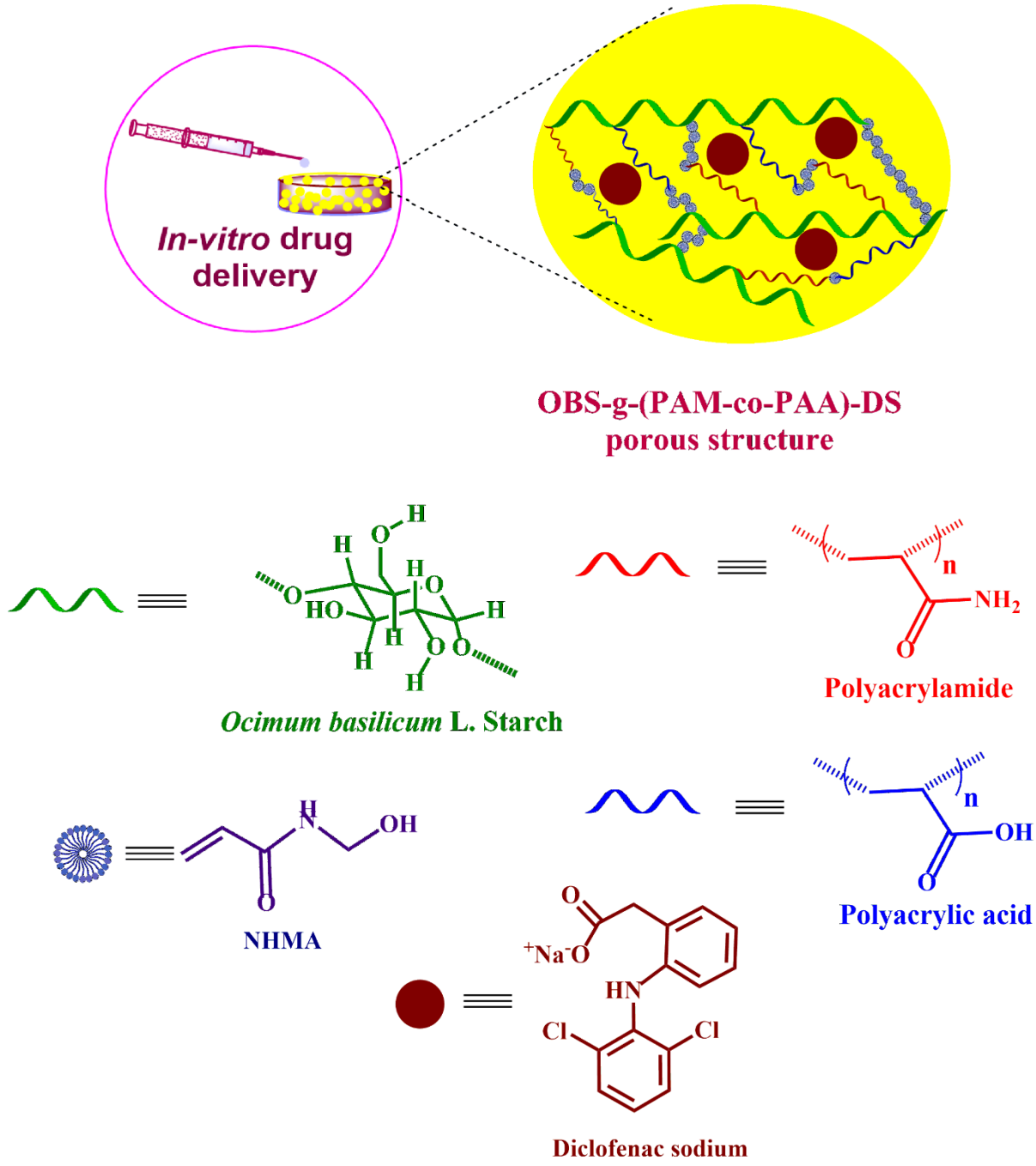

Figure 1. Pictorial representation of diclofenac sodium drug entrapping in OBS-g-(PAM-co-PAA)

3.2. Drug release profiles of drug loaded hydrogels

The drug release profiles, as illustrated in (Figure 2), confirm a pronounced pH-responsive behavior of the hydrogel OBS-g-(PAM-co-PAA)-DS-1. At pH 2, drug loaded hydrogel of Grade 1 showed significant drug release within 10 hours i.e., of 97%, while in pH 4 and 7 significant drug release was achieved within 6 hours of 97% this shows that in acidic medium drug release was slower than slightly acidic and neutral pH.

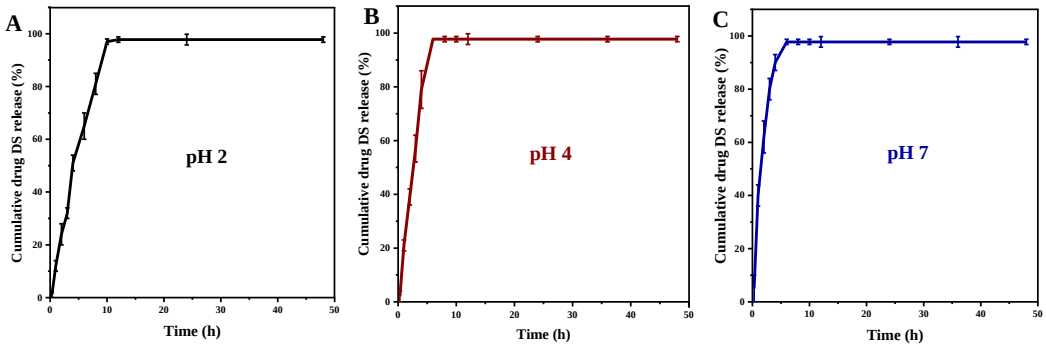

Figure. 2. Cumulative drug (DS) release (%) profiles of OBS-g-(PAM-co-PAA)-DS-1 at pH **(A)** 2 **(B)** 4 and **(C)** 7.

An explicit pH-responsive behavior of the hydrogel OBS-g-(PAM-co-PAA)-DS-2 is illustrated by the drug release profiles (Figure 3). At pH 2, drug loaded hydrogel of Grade 2 showed significant complete drug release within 24 hours i.e., of 94%, while in pH 4 significant drug release was achieved within 48 hours of 53% whereas in pH 7 significant drug release was achieved within 6 hours of 97% this shows that this grade can perform drug release slightly slower in slight acidic areas than more acidic and neutral pH.

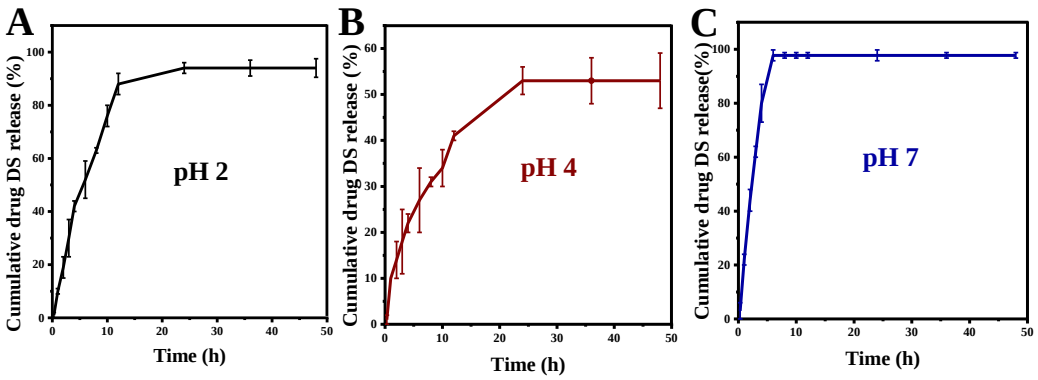

Figure. 3. Cumulative drug release (%) profiles of OBS-g-(PAM-co-PAA)-DS-2 at pH **(A)** 2 **(B)** 4 and **(C)** 7.

Hydrogel OBS-g-(PAM-co-PAA)-DS-3 shown distinct pH-responsive behavior, which is depicted in the drug release profiles, shown in figure below (Figure 4). At pH 2, drug loaded hydrogel of Grade 3 showed significant complete drug release within 8 hours i.e., of 97%, while in pH 4 significant drug release was achieved within 6 hours of 99% whereas in pH 7 significant drug release was achieved within 24 hours of 97% this shows that this grade can perform drug release better in acidic and slight acidic areas than neutral pH.

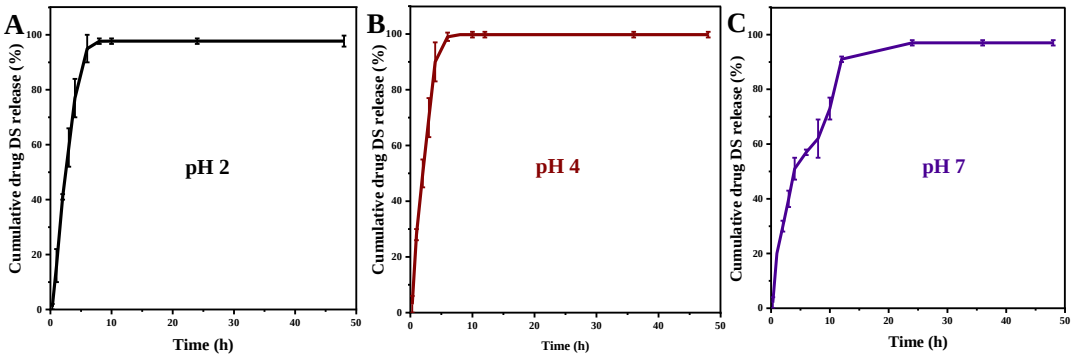

Figure. 4. Cumulative drug release (%) profiles of OBS-g-(PAM-co-PAA)-DS-3 at pH **(A)** 2 **(B)** 4 and **(C)** 7.

From the above results it could be seen clearly that the drug release profiles, as illustrated in above figures, confirm a pronounced pH-responsive behavior of the hydrogels. At neutral pH, hydrogels of Grade 1and 2 showed significantly accelerated drug release, with complete release achieved within 6 hours. This can be attributed to the ionization of carboxylic acid groups in PAM-co-PAA chains, leading to increased electrostatic repulsion, enhanced swelling, and thus faster diffusion of DS. In contrast, Grade 3 hydrogel exhibited a delayed release at pH 7, requiring up to 48 hours for complete release, which may indicate a higher crosslink density or reduced porosity impeding drug diffusion. Interestingly, at pH 4, a moderately acidic condition, Grade 1 and Grade 3 hydrogels released DS rapidly (within 6 hours), while Grade 2 showed a markedly slower release, reaching only 53% even after 48 hours. This suggests that the matrix of Grade 2 may be more compact or less swellable at this pH, limiting drug diffusion. Conversely, Grade 3, which showed slower release at pH 7, was more responsive at pH 4, highlighting the influence of network composition and swelling characteristics on drug release kinetics. Under strongly acidic conditions (pH 2), drug release was generally slower across all hydrogel types. Grade 3 released the maximum amount of drug within 8 hours, while Grade 1 took 12 hours for complete release. Grade 2 again exhibited a sustained release profile, with approximately 94% of the drug released over 48 hours. The reduced drug release rate at low pH is attributable to the protonation of anionic functional groups (e.g., $–COO^-$ to –COOH), reducing the electrostatic repulsion within the network and leading to matrix shrinkage due to stronger hydrogen bonding. This shrinkage restricts water uptake and drug diffusion.

Overall, the findings confirm that the chemically crosslinked starch-based OBS-g-(PAM-co-PAA) hydrogels exhibit pH-sensitive behavior, where swelling and drug release are significantly influenced by environmental pH. The enhanced release at pH 4 and 7 compared to pH 2 suggests that these hydrogels are suitable for targeted drug delivery in neutral to mildly acidic environments, such as the intestinal region, where pH-responsive swelling can be exploited for controlled drug release. The variation in release patterns among the three grades also underscores the importance of

polymer composition and crosslinking density in tailoring drug delivery performance

4. CONCLUSION

In this research, OBS starch based pH-responsive hydrogels which were prepared by free radical graft copolymerization are employed in *in-vitro* drug delivery in three different pH environment i.e., 2, 4 and 7. The pH-responsive OBS-g-(PAM-co-PAA) hydrogels demonstrated strong potential as oral drug-delivery carriers due to their ability to modulate drug release according to gastrointestinal pH conditions. The formulations exhibited enhanced diclofenac sodium release at pH 4 and pH 7, indicating suitability for both gastric and intestinal delivery windows. Their responsiveness to physiologically relevant acidic and neutral environments support controlled and site-specific release behavior, making these hydrogels promising candidates for gastro-intestinal drug-delivery applications. Overall, the findings confirm that OBS-g-(PAM-co-PAA) hydrogels can serve as an effective platform for pH-triggered oral drug administration, enabling improved therapeutic efficiency and better management of drugs requiring targeted release along the GI tract.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

HUMAN AND ANIMAL RIGHTS

No animals or humans were used for the studies that are based on this research.

CONSENT FOR PUBLICATION

Not applicable.

FUNDING

None.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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