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Evaluation and comparative studies of the dissolution profiles of gummi armeniacae and PVP-containing Acetaminophen tablets

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ABSTRACT

Background: Prunus armeniaca gum is a functional food ingredient with beneficial antioxidant properties. As a natural polymer, like different gums, it possesses high binding capacity as well as other pleasing properties like preservatives, fillers, and sustained release. The usage of apricot gum as a food and pharmacy formulation additive provides a more economical option than synthetic polymers like polyvinylpyrrolidone (PVP). Gummi Armeniacae, similar to Gummi Arabica, is widely used as an excipient in the pharmaceutical and food industries.

Objectives: This study aimed to formulate 50 mg acetaminophen tablets using either Gummi Armeniacae or PVP as a binder and compare their dissolution profiles in different media.

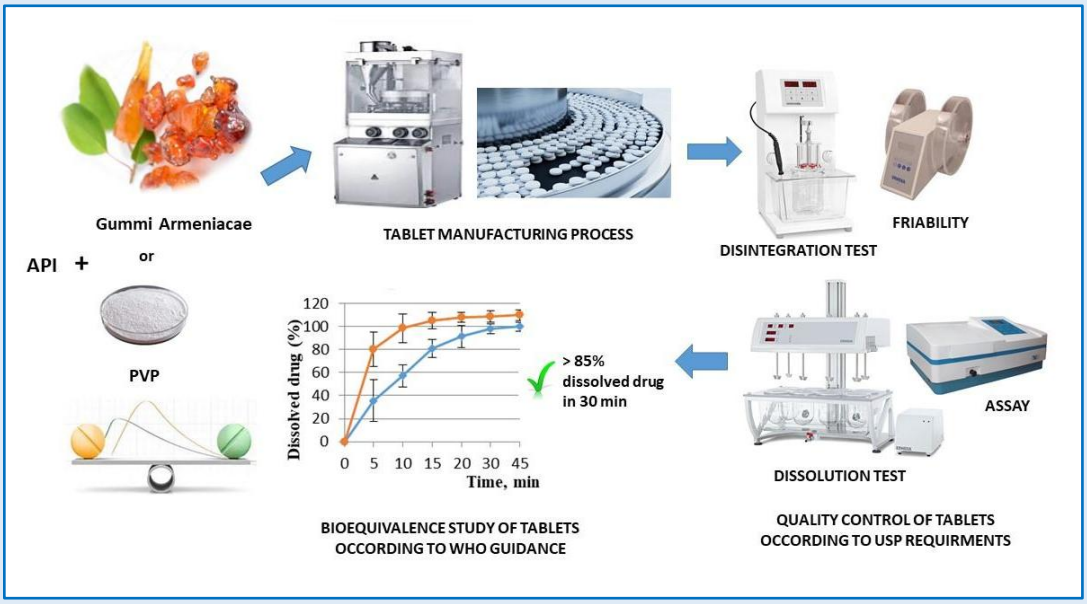
Methods: For research purposes, the purified and standardized Gummi Armeniaca collected from the Arzni region was used. Acetaminophen 50 mg, and the PVP or Gummi Armeniacae as a binder, containing tablets, were produced at the "Arpimed" Pharmaceutical LLC. The characterization of the obtained tablets was conducted according to the tablet's USP quality requirements. The dissolution profiles of Acetaminophen 50 mg tablets were carried out according to WHO Guidance (the paddle speed was 75 rpm, the temperature was 37±0.5°C, and the dissolution media volume was 900 mL) in three dissolution media with pH 1.2, 4.5, and 6.8.

Results: At Arpimed Pharmaceutical Company, two series of 50 mg Acetaminophen tablets with two different compositions were produced (PVP K30 and standardized powder of Gummi Armeniacae). The results of general tablet

quality testing procedures, including average mass, uniformity of mass, thickness, diameter, assay, friability, and disintegration time, corresponded to USP requirements. PVP and Gummi Armeniacae containing Acetaminophen 50 mg tablets exhibited high solubility in three different (pH 1.2, 4.5, 6.8) dissolution media (≥85% of the labeled amount of drug in 30 minutes). Furthermore, the comparative dissolution profile study indicates that tablets containing Gummi Armeniacae dissolve rapidly in hydrochloric acid media at pH 1.2. Moreover, the rate of acetaminophen dissolution from this formulation decreases as the pH shifts from 1.2 to 6.8.

Conclusions: Tablets containing Gummi Armeniacae as a binder possess pH-dependent drug substance release from tablets. Further studies could recommend it as a bonding excipient for the tablet manufacturing process.

Keywords: Gummi Armeniacae, Acetaminophen tablets, Binder, Dissolution profile, PVP



Graphical Abstract:

INTRODUCTION

The correct and effective choice of excipients is crucial in developing drugs with the necessary biopharmaceutical properties and assurance of high drug quality requirements. The excipients considerably affect drug release and absorption speed. They should not only provide the necessary biopharmaceutical properties of drugs but also speed and the necessary degree of release of drug substance, as well as be chemically and pharmaceutically inert, and economically admissible Figure 1[1–3]. The role of excipients is also important for providing drug stability.

Thus, although a wide variety of excipients have been utilized in the pharmaceutical industry, the search for new excipients remains a current challenge.

The binders are an important group of excipients, such as those used in the technology of manufacturing tablets, which provide the necessary strength of tablet hardness and the speed of drug substance release from solid oral dosage form. In recent years, plant-based

polymers have shown significant interest due to their varied pharmaceutical applications, including usage as diluents, binders, and disintegrants in tablet formulation [4, 5, 6]. Natural binders such as different types of gums not only possess binding capabilities, but also offer additional benefits like disintegration, filling, and sustained release. These natural polymers are safer and cost-effective compared to synthetic polymers like polyvinylpyrrolidone (PVP) [7, 8, 9]. These polymers, such as natural gums, have several advantages over synthetic analogues and are often preferred over both semi-synthetic and synthetic excipients [10]. These materials offer a variety of beneficial properties that render them highly valuable. They are biocompatible and readily available, ensuring ease of access for various applications. Their chemical inertness and non-toxic nature further enhance their safety, while their affordability promotes widespread use. Additionally, their soothing properties and non-irritant traits contribute to a positive experience for users [1, 4, 8, 10-12].

Gums are natural hydrophilic polymers, and they are useful as tablet binders, disintegrants, emulsifiers, suspending agents, gelling agents, stabilizing agents, thickening agents, protective colloids in suspension, and sustaining agents in tablets. They show adhesive properties and impart cohesiveness to the powder mass and convert it into granules, which are further compressed into tablets. The gums show the ability to absorb water and swell, and can also be used as disintegrants in tablets [4].

Thus, Gummi Armeniacae is recognized as one of the most promising sources of natural excipients. It forms viscous solutions with excellent emulsifying and enveloping properties [13]. It can be used as a natural additive in many foods, improving stability and shelf life, and potentially replacing more costly ingredients like gum Arabic [14, 15]. The chemical composition and applications of Gummi Armeniacae are comparable to those of Gummi Arabica, which is widely used as an excipient in both the pharmaceutical and food industries. Despite the beneficial properties of Gummi Armeniacae as a natural binder, its usage in the pharmacy industry nowadays is limited due to a lack of investigation.

Given this, our study aimed to design as a binder agent Gummi Armeniacae or synthetic origin PVP (polyvinylpyrrolidone) containing acetaminophen (Paracetamol) 50 mg tablets, perform their USP quality requirements approval, and study their dissolution profiles in different pH media according to WHO Guidance.

MATERIALS AND METHODS

Materials: Acetaminophen (98% of purity), Acetaminophen standard (99.9% of purity, USP), Polyvinylpyrrolidone K30 (manufactured by Shanghay Yuking), Gummi Armeniacae (collected from the Arzni region, RA), Lactose, Starch, Magnesium stearate (Sigma Aldrich), Talc.

METHODS

Collection and purification of Gummi Armeniacae: Gummi Armeniacae was collected from apricot trees, purified by removing the bark, and dried, after washing with warm distilled water, and dried again. After that, the dried gum was sorted into light and dark-colored grades. Selected light-colored gum was crushed. The raw material of gums was sterilized by nebulizing hydrogen peroxide 3% and dried at 36-40°C [16].

Standardization of Gummi Armeniacae: The standardization of apricot gum was carried out according to the following indicators: description of appearance, description of aqueous solution (1:20), determination of pH of aqueous solution, determination of purity, determination of Ca presence, and microscopic analysis.

Starch and dextrins should be absent from the raw material. To confirm this, 10 ml of an aqueous solution of

apricot gum with a ratio of 1:20 was prepared, and 1-2 drops of iodine solution were added to it.

Ammonium oxalate was added to the aqueous solution of gum (1:20) to confirm the presence of Ca ions in the raw material.

Microscopic analysis - pre-crushed small gum crystals were selected, and a powder preparation was made from them in an aqueous medium [17].

Evaluation of tablets: The tablet manufacturing process includes the following stages: weighing ingredients, crushing, sieving, wet granulation, drying, sieving, fattening, pressing, and primary packaging.

Ingredients for tablet manufacturing are represented in Table 1 and were weighed, and if necessary, were crushed and sieved to obtain a uniform powder. After that, wet granulation was done, and the granules were dried at 45-55 °C, and sieved again to obtain uniform granules with a diameter of about 1 mm. The granules were consecrated and pressed to obtain tablets under 5 Tons pressure by an Adept rotor pump (ADR B-B-35 GMP) at the "Arpimed" LLC.

Table 1. The composition of PVP or Gummi Armeniacae containing Acetaminophen 50 mg tablets.

Ingredients	PVP containing Acetaminophen tablets (F1)	Gummi Armeniacae containing Acetaminophen tablets (F2)
Acetaminophen	50 mg	50 mg
Lactose	25 mg	25 mg
PVP	7 mg	-
Gummi Armeniacae	-	7 mg
Starch	15 mg	15 mg
Talc	1.5 mg	1.5 mg
Magnesium stearate	1.5 mg	1.5 mg

Characterization of tablets: The average mass, uniformity of mass, thickness, disintegration time, friability, and dissolution of the obtained tablet were carried out according to the USP, the International Pharmacopoeia, WHO, and RPh methods [18-21]. The equivalence study of tablets was performed by comparing the dissolution profiles of tablets by the WHO.

Average mass determination: To determine the average mass, 20 tablets of each formulation were weighed with ±0.001 precision and the average weight.

Uniformity of mass: To study the uniformity of mass, 20 tablets of each formulation were weighed individually, and the mass variation was calculated from the average mass of each tablet.

Thickness and diameter: Thickness and diameter determination were randomly selected for 10 tablets for each formulation, and the average value was calculated.

Identification and assay of formulated Acetaminophen tablets: 20 tablets were randomly selected and crushed. Then, 0.17 g of crushed tablet powder was accurately weighed and placed into a 200 mL volumetric flask. Then, 100 mL of 0.1 *M* sodium hydroxide solution was added and shaken for 10 minutes, made up to the mark with water, and filtered. A 1 mL aliquot of the filtrate was transferred to a 100 mL volumetric flask, 10 mL of 0.1 M sodium hydroxide solution was added, and the mixture was then mixed. The volume was subsequently brought up to the mark with water. The optical density of the solution was measured with a spectrophotometer UV-VIS Unicam 8635 at a wavelength of 257 nm and a cuvette layer thickness of 10 mm. In parallel, the optical density of the paracetamol standard working solution was measured. A 0.01 M sodium hydroxide solution was used as a blank [22, 23].

Friability testing: The friability of each formulation (Gummi Armeniacae (F2)- and PVP (F1)- containing) was detected by the friability tester Erweka ZA. Samples of each formulation of 10 tablets were weighed and placed into the drum. The drum rotates at a speed of 20 rpm for 5 minutes. After that, the tablets were degraded and reweighed. The % friability (%F) was calculated using the following formula (1)

$$\%F = \frac{W1-W2}{W1} \times 100\% \quad (1)$$

where -W1 is the weight of tablets before the test (mg)

W2 is the weight of tablets after the test (mg).

Disintegration Time: The disintegration time of each formulation tablet (Gummi Armeniacae- and PVP-containing) was detected by the Erweka ZT 41 apparatus according to the USP 30 method. Six tablets were randomly selected from two formulations and placed one by one in each of the six tubes of the basket. The temperature of the medium was 37±0.5°C. The disintegration time of each tablet was recorded in minutes, and the average disintegration time was then determined.

Dissolution rates profile study: The dissolution rate study of Acetaminophen 50 mg tablets containing Gummi Armeniacae or PVP as a binder was carried out according to WHO Guidance (the paddle speed was 75 rpm, the temperature was 37±0.5°C, and the dissolution media volume was 900 mL) [18]. Three dissolution media solutions, 0.1 N hydrochloric acid solution (pH 1.2), acetate buffer solution (pH 4.5), and phosphate buffer solution (pH 6.8), were used [19]. If necessary pH of buffers has been corrected with 0.1 M HCl or 0.1 M NaOH solutions. The buffer's pH has been detected by a pH meter (pH/mV Bench Meter Hanna, Germany). The solubility test was performed by Erweka DT 60 (Germany) Dissolution "paddle" Apparatus (USP Apparatus 2).

For the dissolution profiles study in each vessel has been placed one tablet of Acetaminophen 50mg (containing Gummi Armeniacae or PVP). The sampling was carried out at 5, 10, 15, 20, 30 and 45 minutes. The samples were cooled at room temperature and then filtered with a "blue ribbon" filter paper. 0.5 mL filtered samples were transferred to the measuring vessel, and the corresponding buffer volume was added to 5 mL for dilution. Quantitative detection was performed using a spectrophotometric method at 243 nm using a 10 mm thickness cuvette. In parallel, the optical density of a 0.005 mg · mL^{-1} concentration of Acetaminophen working standard (USP Reference standard) solution was measured and prepared using the same dissolution media. The appropriate dissolution media have been used as a blank.

Twelve tablets of each composition were studied to obtain statistically significant results.

For the study equivalence of dissolution profiles, factor similarity (f_2), presented by Moor and Flamer (formula 2), was calculated.

$$f_2 = 50\ log\ log\ \{[1 + \frac{1}{n}\sum_{n-1}^{n} (R_t - T_t)^2]^{-0.5} * 100\} \quad (2)$$

where f_2 is the similarity factor, n is the number of observations,

R_t - the average percentage of drug dissolved from the reference formulation and

T_t - the average percentage of drug dissolved from the test formulation.

Generally, an average of twelve observations is used for calculating f_2 [24].

Statistical Analysis: Statistical analysis was carried out using Microsoft Excel 2019 software. All results are represented as M±RSD.

RESULTS AND DISCUSSION

The raw material of Gummi Armeniacae collected from the Arzni region, RA, was prepared and standardized according to Russian Pharmacopeia requirements [25]. The results and the Pharmacopeia requirement for quality assessment are represented in Table 2. As shown in Table 2, all points of quality correspond to allowed limits.

Table 2. The results of the pharmacopeial analysis of Gummi Armeniacae according to the RPh XIII

	INDICATORS	PHARMACOPEIA REQUIREMENTS	RESULTS
1.	Appearance	Colorless, pale yellow or yellow, transparent, solid lumps	Yellow, yellow-orange firm lumps
2.	Description of aqueous solution (1:20)	Clear, slightly opalescent, colorless, or yellowish viscous liquid.	Corresponded
3.	pH of an aqueous solution	Weakly acidic (5.5-6.5)	6.0
4.	Purity determination	10 mL aqueous solution of gum (1:20) does not turn red or blue in the presence of iodine solution (starch, dextrin)	Corresponded, which means the solution lacks starch and dextrin.
5.	Determination of the presence of Ca ions	An aqueous solution of gum in the presence of ammonium oxalate produces a turbidity that is insoluble in acetic acid but soluble in dilute nitric acid.	Corresponded
6.	Microscopic analysis (1:10) of gum powder	A gum powder preparation in an aqueous medium under microscopic visualization lacks swollen, deformed cell membranes and starch granules.	Polygonal, light yellowish-gray pigmented crystals are present, indicative of the irregular crystalline structure of the gummy polysaccharide. Swollen, deformed cell membranes and starch granules are absent.

At Arpimed Pharmaceutical Company, a series of 50 mg Acetaminophen tablets with two different compositions presented in Table 1 were produced (F1 and F2 formulations). F1 formulation was prepared using the most commonly used tablet production binder, PVP K30, while F2 utilized the standardized powder of Gummi Armeniacae. The quality assessment of the obtained tablets with two different compositions was carried out according to the USP requirements.

The results of general tablet quality testing procedures, including average mass, uniformity of mass, thickness, diameter, assay, friability, and disintegration time are presented in Table 3. Thus, the friability of PVP and Gummi Armeniacae-containing tablets didn't exceed 3%, and disintegration didn't exceed 15 min [25, 26], which fulfilled the USP requirements. The average disintegration time of PVP containing 50 mg Acetaminophen tablets was 2 min 67 seconds, and the Gummi Armeniacae containing tablets was 4 min 59 seconds. The friability (%) was accordingly 2.94% and 2.83%. The uniformity of mass for the two formulations fulfilled the International Pharmacopoeias and WHO requirements [20, 26].

Table 3. Quality control parameters of PVP and Gummi Armeniacae containing 50 mg Acetaminophen tablets.

	Average mass (g)	Uniformity of mass	Thickness (mm)	Diameter (mm)	Assay (%)	Friability, %	Disintegration Time (min)
PVP-containing 50mg Acetaminophen tablets (F1)	0.104	+5.769% -3.846%	1.34± 0.052	6.11±0.032	100	2.94	2min67sec
Gummi Armeniacae containing 50mg Acetaminophen tablets (F2)	0.1075	+2.325% -6.977%	1.35± 0.053	6.11±0.032	104	2.83	4min59sec

The dissolution study results indicate that the F1 and F2 formulations demonstrate high solubility in all three-dissolution media (pH 1.2, 4.5, and 6.8) (≥85% of the labeled amount of drug in 30 minutes) [18, 27]. The dissolution test results of the F1 and F2 formulations in all dissolution media are presented in Table 4.

Table 4. Dissolution Test Results for PVP and Gummi Armeniacae containing Acetaminophen tablets at different dissolution media

Formulation	PVP containing Acetaminophen 50 mg tablets (F1)		Gummi containing Acetaminophen 50 mg tablets (F2)		PVP containing Acetaminophen 50 mg tablets (F1)		Gummi containing Acetaminophen 50 mg tablets (F2)		PVP containing Acetaminophen 50 mg tablets (F1)		Gummi containing Acetaminophen 50 mg tablets (F2)	
Sampling	pH=1.2				pH=4.5				pH=6.8			
Time	%	RSD	%	RSD	%	RSD	%	RSD	%	RSD	%	RSD
Time (min)	% dissolve	% RSD	% dissolve	% RSD	% dissolve	% RSD	% dissolve	% RSD	% dissolve	% RSD	% dissolve	% RSD
5	35.61	18.04	80.12	15.12	39.69	16.46	71.77	16.14	39.11	15.45	33.41	12.73
10	57.19	9.62	98.53	12.4	73.5	13.16	94.53	12.09	72.0	7.65	57.18	6.21
15	80.7	7.86	101.15	6.94	85.32	6.19	98.54	9.16	95.45	9.44	76.14	8.17
20	91.32	9.75	107.98	4.4	91.34	8.3	101.18	7.61	104.63	5.45	89.15	6.62
30	97.93	4.12	108.37	5.06	94.18	7.96	102.79	8.15	109.61	4.58	102.77	5.12
45	99.76	3.71	109.64	4.7	94.43	7.58	103.57	7.32	113.145	3.61	110.75	4.49

The relative standard deviation (RSD, %) was calculated for all time points. The RSD values should be ≤20% for 10 minutes and ≤10% for the remaining time points, which indicates the reliability of the data [27]. The dissolution kinetic profiles of tablets in three dissolution media are presented in Figure 1.

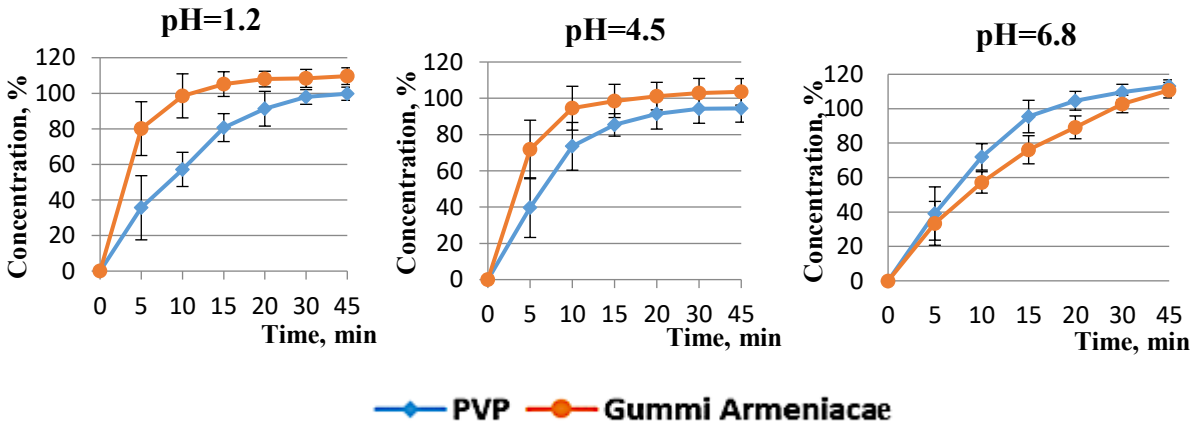


Figure 1. PVP and Gummi Armeniacae containing Acetaminophen 50 mg tablets, active substance release rate in different dissolution media.

The calculated values of the similarity factor (f_2) for the two formulations indicate that dissolution profiles are not similar. Thus, the values of the mentioned factor in the conditions of three solubility pH (at pH1.2 was 27.47, pH4.5 was 37.45, and pH6.8 was 45.36) are smaller than 50. Therefore, curves of solubility kinetics are not similar, as they are considered similar when f2≥50 [27-29].

At the same time, Gummi Armeniacae and PVP-containing tablets exhibit high solubility in three dissolution media. Gummi Armeniacae-containing tablets have very rapid solubility at pH 1.2 and 4.5. However, the solubility of Gummi Armeniacae-containing

tablets at pH 1.2 and 4.5 exceeds the solubility of the PVP-containing tablets after 45 minutes. The absence of similarity of the solubility curves is also due to the different solubility of Gummi Armeniacae and PVP-containing tablets depending on media acidity. Tablets containing Gummi Armeniacae dissolve rapidly in hydrochloric acid at pH 1.2, whereas those containing PVP dissolve at pH 6.8. So, the rate of solubility of Gummi Armeniacae-containing tablets decreases from pH 1.2 to 6.8. This is explained by the chemical structure of the polysaccharides of the Gummi Armeniacae, which was evaluated previously [30]. This finding can serve as a basis for using Gummi Armeniacae as an excipient in future evaluations of modified-release tablets. Further studies are needed to investigate the preservative properties of Gummi Armeniacae, which could enhance its significance as an excipient.

CONCLUSION

The formulations of acetaminophen 50 mg tablets containing PVP and Gummi Armeniacae were developed. The quality assessment data indicate that the Gummi Armeniacae-containing Acetaminophen evaluated tablets meet all requirements set by the Pharmacopeias for tablets. Both formulations dissolved rapidly, with at least 85% of the labeled drug amount dissolving within 30 minutes in all three-dissolution media. The percent of relative standard deviation (% RSD) for all time points meets the WHO requirements (≤20% for 5 minutes and ≤10% for other time points), confirming the validity of the results.

Additionally, the calculation of the similarity factor (f2) revealed that the dissolution profiles of tablets containing PVP and those containing Gummi Armeniacae are not similar. Furthermore, the tablets with Gummi Armeniacae display pH-dependent drug release, showing higher solubility than the PVP-containing tablets at pH levels of 1.2 and 4.5. In this context, Gummi Armeniacae could be recommended for further investigation as a promising natural binding excipient in tablet formulation. Its favorable physicochemical properties, such as high binding capacity, stability, and compatibility with a range of active ingredients, make it suitable for formulating different tablets. Incorporating Gummi Armeniacae could enable the development of products that combine nutritional benefits with enhanced stability, controlled release of bioactives, and improved consumer acceptability.

Abbreviations: API-active pharmaceutical ingredient; WHO-World Health Organization; PVP-polyvinylpyrrolidone; USP-United States Pharmacopeia; RPh-Russian Pharmacopeia; RSD-relative standard deviation.

Conflicts of interest statement: There are no conflicts of interest.

Author contributions: L.P. and A.Zh. designed the research. L.P., B.Y., H.Gh. provided tablets evaluation, A.Zh., L.P., F.S. performed analysis. L.P., A.Zh. performed statistical analyses and wrote the manuscript. B.Y. and A.Zh. edit the article. All authors read and approved the final version of the manuscript.

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