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ORIGINAL RESEARCH ARTICLE

# KECORT Study: An International e-Delphi Study on the Treatment of KEloids Using Intralesional CORTicosteroids in Clinical Practice

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## Abstract

**Background** Intralesional corticosteroid administration (ICA) is a first-line keloid treatment. However, it faces significant variability in current clinical and scientific practice, which hinders comparability of treatment results.

**Objectives** The aim of the study was to reach consensus on different aspects of ICA using hypodermic needles in keloids among an international group of dermatologists and plastic surgeons specialized in keloid treatment to provide consensus-based clinical treatment recommendations for all physicians treating keloids.

**Methods** The keloid expert panel of 12 dermatologists and 11 plastic surgeons rated 30 statements. Two online e-Delphi rounds were held, both with a response rate of 100%. Fifteen (65%) keloid experts participated in the final consensus meetings. Consensus was defined as ≥ 75% of the participants choosing agree or strongly agree on a 7-point Likert scale.

**Results** Consensus was reached on treatment goals, indication for ICA, triamcinolone acetonide (TAC) 40 mg/mL as the preferred corticosteroid administered at a maximum of 80 mg per month and at intervals of 4 weeks, minimizing pain during ICA, the use of 1 mL syringes and 25 or 27 Gauge needles, blanching as endpoint of successful infiltration, caution of not injecting subcutaneously, and the option of making multiple passes in very firm keloids prior to infiltration. Consensus could not be reached on TAC dosing, methods of prior local anesthesia, and location of injection.

**Conclusions** This e-Delphi study provides important clinical treatment recommendations on essential aspects of ICA in keloids. By implementing these recommendations, uniformity of ICA in keloid treatment will increase and better treatment results may be achieved.

**Key Points**

This consensus statement provides clinical treatment recommendations on essential aspects of intralesional corticosteroid administration in keloids, which is currently administered very differently even though it is a first-line keloid treatment.

By implementing these recommendations, uniformity of intralesional corticosteroid administration in keloid treatment will increase and better comparison of treatment results can be made.

## 1 Introduction

Intralesional corticosteroid administration (ICA) using hypodermic needles is a first-line treatment for keloids [1, 2]. Nevertheless, the reported results of this treatment are highly variable and often suboptimal [3, 4]. Treatment results may be influenced by various operator-dependent factors, such as the type, volume, and concentration of the corticosteroid; the number and the interval of treatment sessions; the size of needle and syringe; and the manual injection techniques. Currently, there is substantial heterogeneity and incomplete reporting on many aspects of ICA in randomized controlled trials (RCTs), as demonstrated in a recent scoping review [5]. Additionally, a recent survey reveals a large variation of ICA in clinical practice [6]. Uniform global treatment guidelines for this first-line treatment for keloids are needed to ensure consistent and comparable results. While

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evidence-based treatment recommendations cannot be made on the basis of the current studies lacking long-term follow-up, opinions of keloid experts worldwide are valuable in achieving uniformity in ICA for keloids globally. The aim of the study was to reach consensus on different aspects of ICA using hypodermic needles in keloids among an international group of dermatologists and plastic surgeons specialized in keloid treatment to provide consensus-based treatment recommendations for all physicians treating keloids.

## 2 Methods

Prior to starting the e-Delphi rounds the study protocol was sent to all participants for their critical appraisal (Supplementary file 1). All participants involved in the study were informed that data collection would be identifiable and agreed that collected data would be used for publication. Additionally, all participants gave consent for recording the consensus meeting so that a detailed version of the minutes could be produced afterwards. All results were presented anonymously.

### 2.1 Selection of Participants

The keloid expert panel was assembled by the founding committee (Q.Y., A.W., O.L., F.N., P.Z.). Eligible participants fulfilled three criteria: the participant (1) is a dermatologist or plastic surgeon, (2) has $\geq 5$ years of clinical experience in keloid treatment, and (3) has $\geq 5$ publications or ongoing research projects related to keloids or corticosteroid administration. Recruitment was based on (1) a search of keloid-related publications in PubMed in the past 10 years and (2) the list of speakers on the 2022 Annual International Keloid Symposium. We assembled a group with participants from different countries, with a fair balance of dermatologists and plastic surgeons. Even though patients are frequently involved in consensus studies, it was considered not to be relevant for this study, which predominantly focuses on detailed technical aspects of a specific treatment modality aiming to increase uniformity and enhance clinical practice.

### 2.2 Design of the Statements for the e-Delphi Study

A total of 30 statements were included in the e-Delphi study. The statements were designed by Q.Y. and K.Q. on the basis of a recent scoping review [5], a survey round among the participants using the questionnaire from a recent survey study [6], and related scientific evidence found with the broad systematic search used for the scoping review [5]. In total, three plastic surgeons (O.L., F.N., and P.Z.) and one dermatologist (AW) experienced in keloid treatment critically evaluated the clarity of each statement, the comprehensiveness, and potential (technical) problems. All statements with supporting scientific evidence are provided in Supplementary file 2. The statements of the e-Delphi rounds with the supporting scientific evidence were presented using a secured online survey software platform (Alchemer, USA).

### 2.3 Rating of Statements

For each statement, the participants rated their level of agreement on a 7-point Likert scale: (1) strongly disagree, (2) disagree, (3) slightly disagree, (4) neutral, (5) slightly agree, (6) agree, and (7) strongly agree. Additionally, "not applicable" could be chosen if a statement would not apply in any way to the participant. For both the e-Delphi rounds and the final consensus meeting, consensus was defined as $\geq 75\%$ of the participants choosing "agree" or "strongly agree" on the 7-point Likert scale. This threshold was chosen on the basis of a systematic review on methodologic criteria for reporting of Delphi studies, stating that 75% is the median threshold to define consensus [7]. Statements that came close to consensus and statements that did not achieve consensus were defined as 60–75% and $< 60\%$ of the participants choosing "agree" or "strongly agree" on the 7-point Likert scale, respectively.

### 2.4 e-Delphi Rounds

Two online e-Delphi rounds were held, followed by a final consensus meeting. Voting in the e-Delphi rounds took place anonymously. Controlled feedback to the participants was provided in a structured manner after each e-Delphi round. The participants could adjust their initial ratings on the basis of this feedback in the subsequent round. Moreover, the participants could add statements or suggest amendments to the statements, which could be included in the subsequent round. All proposed changes were discussed by the founding committee, and the statements were rephrased accordingly. Both original and amended statements were presented in the second round and consensus meeting. The final online consensus meetings were held on Teams (Microsoft, USA). To accommodate participants in wide-ranging time zones, two sessions of the final consensus meeting were held. All 30 statements of the e-Delphi study were presented. Discussion and additional voting took place for each statement that came close to consensus (60–75%). Remaining statements could be discussed and rerated if needed. Anonymity was not attempted during the consensus meetings to accommodate an open discussion. Following the final consensus meetings, the minutes and results of the pooled voting were sent to all participants of the keloid expert panel for approval.

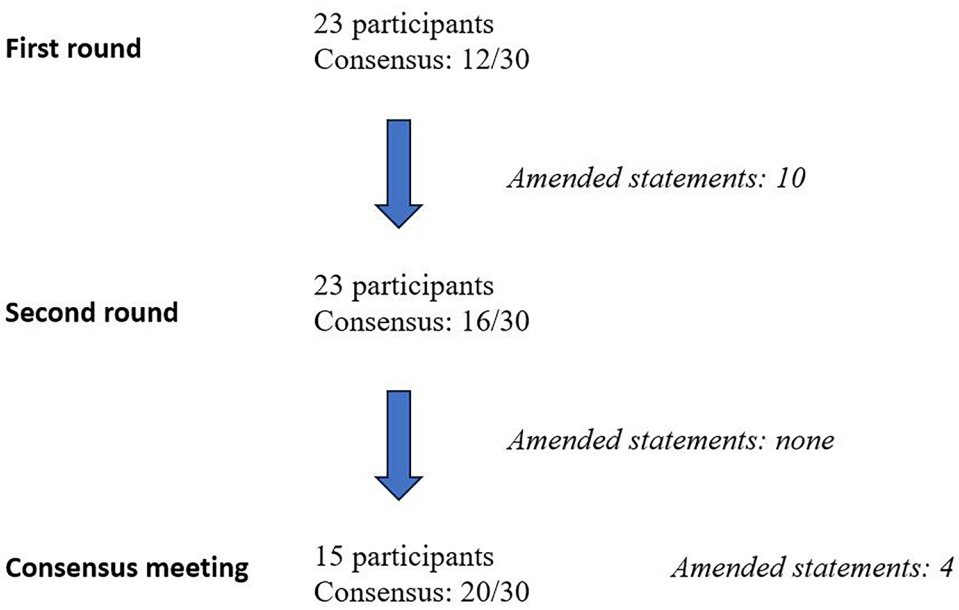


**Fig. 1** Flowchart of number of participants, statements that reached consensus, and amended statements per round

### 2.5 Data analysis

Data collection and analysis was performed by one member of the founding committee (Q.Y.) who did not participate in the keloid expert panel. Data analysis was performed using SPSS (IBM SPSS Statistics 26, USA). Frequency distributions were created for all response variables. Open-ended answers were collected separately.

## 3 Results

Data was collected between 20 October 2022 and 22 December 2022. A total of 28 keloid experts (14 dermatologists, 14 plastic surgeons) were sent an invitation, of which 3 invitees did not respond and 2 invitees did not complete the first e-Delphi round. Twelve dermatologists and 11 plastic surgeons completed the first e-Delphi round and were subsequently included in the e-Delphi study (Fig. 1). The response rate of both e-Delphi rounds was 100%. Fifteen participants (65%) participated in the final consensus meetings. Consensus (> 75%) was reached on 12 of the 30 statements in the first e-Delphi round, on 4 of the 30 statements in the second e-Delphi round, and on 4 of the 30 statements in the final consensus meetings (Fig. 1). Ratings of the e-Delphi rounds and the voting results of the final consensus meetings for each statement are presented in Table 1. Collected comments on the first and second e-Delphi round and the minutes of the final consensus meetings are presented in Supplementary file 3. Ten statements were adjusted following the first e-Delphi round, no statements were adjusted in the second e-Delphi round, and four statements were adjusted in the consensus meetings (Fig 1.). No new statements were introduced. All amended statements are presented in Supplementary file 4.

### 3.1 Treatment Goals and Indication for ICA

Consensus was reached on discussing the following treatment goals with the patient prior to keloid treatment: pain reduction (87%), itch reduction (87%), prevention or treatment of functional impairment (83%), and maintaining a cosmetically acceptable appearance (100%). Consensus was reached that ICA with or without additional modalities is generally the first-line treatment for keloids smaller than 10 $cm^2$, with an elevation between 0.3 and 1 cm (87%).

### 3.2 Type of Corticosteroid, Dosing Interval, and Equipment for ICA

Triamcinolone acetonide (TAC) (Kenalog, Kenacort) is the preferred corticosteroid for ICA in keloids (87%). Consensus was reached that 40 mg/mL is generally the preferred TAC concentration for treatment of non-facial keloids (78%). The participants agreed that if the required cumulative dose exceeds 80 mg of TAC per session for large or multiple keloids, (combining) other treatment options should be considered to prevent systemic adverse effects (96%). Consensus was reached on the suggested interval of 4 weeks between treatment sessions with TAC. Consensus was reached that a syringe with a small inner diameter, generally 1 mL syringes, should be used for ICA in keloids (78%). Moreover, the participants agreed that 25 gauge (orange, inner diameter 0.26 mm) or 27 gauge (medium grey, inner diameter 0.21 mm) needles are suggested for corticosteroid injection in keloids, but larger or

**Table 1** Ratings of the e-Delphi rounds and the voting results of the final consensus meetings for each statement

| Statements | First | Second | Meeting |
|---|---|---|---|
| **Treatment goals** | | | |
| *Pain reduction as treatment goal should be discussed with the patient prior to keloid treatment.* [17, 18] | 87 | – | – |
| *Itch reduction as treatment goal should be discussed with the patient prior to keloid treatment.* [17, 18] | 87 | – | – |
| *Prevention or treatment of functional impairment as treatment goal should be discussed with the patient prior to keloid treatment.* [17, 18] | 83 | – | – |
| *Maintaining a cosmetically acceptable appearance as treatment goal should be discussed with the patient prior to keloid treatment.* [17, 18] | 100 | – | – |
| **Drugs and dosing** | | | |
| *Intralesional corticosteroid administration with or without additional modalities is generally the first-line treatment for keloids smaller than 10 $cm^2$ (e.g. 5 × 2 cm), with an elevation between 0.3 and 1 cm.* [1, 2] | 87 | – | – |
| *Triamcinolone acetonide (TAC) (Kenalog, Kenacort) is the preferred option for the intralesional corticosteroid administration in keloid treatment, based on its favorable pharmacokinetic properties and the evidently larger available (clinical) literature compared to other available intralesional corticosteroids.* [19–36] | 87 | – | – |
| *40 mg/mL is generally the preferred concentration of TAC for treatment of a non-facial keloid.* | 78 | – | – |
| 10 mg/mL is generally the preferred concentration of TAC for treatment of a facial keloid with a thickness < 5 mm. | 39 | 52 | – |
| Generally, it is recommended to inject 4–12 mg TAC per $cm^{(2/3)}$ in a non-facial keloid.[a] [5] | 61 | 74 | 53 |
| *It is preferred to limit the dose of TAC to 40 mg per month for adults. However, in larger keloids TAC doses may be increased up to 80 mg.* [32–34, 37, 38] | 65 | 83 | – |
| *If a higher dose than 80 mg of TAC per session is required for large keloids (e.g., larger than 20 $cm^2$, i.e., 10 × 2 cm or 5 × 4 cm) or multiple keloids, consider (combining) other treatment options in order to prevent systemic adverse events.* | 74 | 96 | – |
| Alternatively, consider 10 mg/mL as concentration of TAC for the treatment of large keloids (e.g., larger than 20 $cm^2$, i.e., 10 × 2 cm or 5 × 4 cm) or multiple keloids. | 61 | 74 | 60 |
| *Dose reduction according to weight is recommended in children.* [38] | 83 | – | – |
| *The suggested interval between treatment sessions with TAC is 4 weeks. Shorter intervals may be indicated, but increase the risk of side effects.*[a] [39–41] | 83 | – | – |
| *Minimizing pain during intralesional corticosteroid administration in keloids should be aimed for, as the treatment is often painful.* [42–47] | 83 | – | – |
| Field block anesthesia prior to intralesional corticosteroid administration in keloids is an adequate option for local anesthesia.[a] [48–50] | 52 | 61 | 73 |
| Local skin cooling prior to intralesional corticosteroid administration in keloids is an adequate option for local anesthesia.[a] [8, 51–53] | 48 | 52 | – |
| *Topical anesthetics such as lidocaine/prilocaine (EMLA) cream prior to intralesional corticosteroid administration in keloids is an adequate option for reducing needle puncture pain.*[a] [54] | 48 | 61 | 87 |
| Lidocaine/prilocaine (EMLA) cream should preferably be applied 1–2 h prior to intralesional corticosteroid administration in keloids.[a] [55] | 44 | 57 | – |
| *Diluting the intralesional corticosteroid with a local anesthetic is not recommended for pain reduction.* [54] | 65 | 91 | – |
| *The speed of corticosteroid injection should be taken into consideration for pain reduction.* [56, 57] | 78 | – | – |
| **Equipment** | | | |
| *A syringe with a small inner diameter, generally 1 mL syringes, should be used for corticosteroid injection in keloids.* [58] | 74 | 78 | – |
| *25 Gauge (orange, inner diameter 0.26 mm) or 27 Gauge (medium grey, inner diameter 0.21 mm) needles are suggested for corticosteroid injection in keloids. Larger or smaller gauge needles can be considered on the basis of the scar pliability and the use of any adjunctive measures including laser pre-treatment.*[a] [20, 23, 50, 58] | 74 | 70 | 100 |
| **Manual injection techniques** | | | |
| I recommend injecting in the superficial part of the keloid.[a] [11, 12] | 44 | – | – |
| I recommend injecting in the margin of the keloid.[a] [2, 11, 12] | 48 | – | – |
| I recommend injecting in the central part of the keloid.[a] [2] | 39 | – | – |
| I recommend injecting in the deep part of the keloid.[a] [2] | 43 | – | – |
| *Care should be taken not to inject subcutaneously, as it increases the risk of subcutaneous atrophy.* [59] | 100 | – | – |
| *Observation of blanching determines the endpoint of infiltration when injecting directly into keloidal tissue. However, this is less noticeable in Fitzpatrick skin type 5–6.*[a] | 74 | 70 | 93 |
| *For very firm keloids, making multiple longitudinal or cross-sectional passes with a needle through the keloid, allowing for significant deposition of the corticosteroid within the needle tracts, can be considered.*[a] [50] | 61 | 70 | 80 |

Statements presented in Italics are statements on which final consensus has been reached

[a]Statement was amended after the e-Delphi rounds or after the first consensus meeting (Supplementary file 4)

smaller gauge needles can be considered on the basis of scar pliability and the use of any adjunctive measures such as laser pre-treatment.

### 3.3 Local Anesthesia

Consensus was reached that minimizing pain during ICA in keloids should be aimed for, as the treatment is often painful (83%). Participants agreed that the speed of corticosteroid needle injection should be taken into consideration in pain reduction (78%), and that topical anesthetics such as lidocaine/prilocaine (EMLA) cream prior to ICA in keloids are an adequate option for reducing needle puncture pain (87%), but that mixing the intralesional corticosteroid with a local anesthetic is not recommended for pain reduction (91%). No agreement was reached on the use of local skin cooling prior to ICA (52%), nor field block anesthesia prior to ICA (73%) for pain reduction.

### 3.4 Manual Injection Techniques

Consensus was reached that observation of blanching determines the endpoint of infiltration when injecting directly into keloid tissue, although it is less noticeable in Fitzpatrick skin types V–VI. Moreover, participants agreed that for very firm keloids, multiple longitudinal or cross-sectional passes with a needle through the keloid could be considered (80%), allowing for better deposition of the corticosteroid within the needle tracts. Notably, all participants agreed that care should be taken not to inject subcutaneously, as this increases the risk of fat atrophy (100%). However, consensus could not be reached on the location of injection. In the first e-Delphi round, the choice of "strongly agree" or "agree" was < 60% among the participants for injecting the superficial part (43%), central part (39%), deep part (43%), and margin (48%) of the keloid. After adjusting the statement in the second e-Delphi round, the majority (56.5%) opted for not always injecting in the same part(s) of the keloid.

## 4 Discussion

This e-Delphi consensus study provides important clinical treatment recommendations for ICA in keloids with hypodermic needles for all physicians treating keloids. This marks a pivotal step toward making treatment results of keloids more comparable. Consensus was achieved on essential variables of ICA in keloids, including treatment goals, indication for ICA, triamcinolone acetonide 40 mg/mL as preferred corticosteroid at a maximum of 80 mg TAC per month to prevent systemic adverse events, minimizing pain during ICA, 4 weeks as suggested treatment interval, the general use of 1 mL syringes and 25 or 27 gauge needles, blanching as the endpoint of infiltration, caution for not injecting subcutaneously, and the option of making multiple passes in very firm keloids prior to infiltration, allowing for better deposition of the corticosteroid within the needle tracts.

Consensus could not be reached on the dosing per specific area or volume of keloid, as no uniformity in the measurement of keloid size could be determined in terms of length, area, or volume, which makes dose comparison unreliable. Although ultrasound may be useful for determining keloid size in research practice, it was not considered to be practical in the clinical setting. Discussion in the final consensus meeting focused on recommending a maximum dosage of TAC per session, which may be distributed in all keloids. Consensus was reached on a maximum dose of 40 mg preferably, and if necessary 80 mg per month, to prevent systemic adverse effects. Discussion in the final consensus meeting also focused on a maximum dosage of TAC aiming to prevent local adverse effects. However, a uniform recommendation applicable for all cases could not be formed, as various factors such as the level of injection, keloid characteristics (e.g., location and thickness), and previous treatments are important determinants. Nevertheless, consensus was reached that observation of blanching determines the endpoint of infiltration, as a useful parameter in the clinical setting.

Consensus was reached on that minimizing pain during ICA in keloids should be aimed for (83%). Adequate methods of local anesthesia may include local skin cooling and field block anesthesia. As local skin cooling was not further specified in the statement, participants considered this method differently, varying from cold air cooling to contact cooling using ice packs. Both methods of local skin cooling have been proven to be effective in pain reduction [8, 9]. However, no consensus was reached on local skin cooling prior to ICA in keloids as an adequate method for local anesthesia. No peer-reviewed evidence exists regarding the effects of pain reduction following field block anesthesia prior to ICA in keloids; and consensus was not reached on this method. Future studies comparing different methods of local anesthesia are needed to further determine adequate methods of local anesthesia prior to ICA in keloids. Additionally, an individual approach based on the patient's pain perception, age, keloid size, and keloid density is needed.

The location of ICA varied among the keloid experts. A reason given for superficial injections is the increased epidermal thickness and abnormal epidermal differentiation of keloids compared with normal skin, normotrophic scars, and hypertrophic scars [10]. While many participants preferred

central injections, these injections may be too difficult and painful in very firm keloids [2]. Alternatively, injecting the deepest part of the keloid may be easier and less painful, because of its looser tissue. However, deep injections increase the risk of fat atrophy. Injections in the keloid margin may be preferred due to the increased activity of the aberrant fibroblasts at the margin of the keloid [11, 12]. No agreement could be reached on the location of ICA, which may be due to the lack of studies on the effect of ICA in different locations of the keloid. Additionally, discussion in the final consensus meeting highlighted that the location of injections should also depend on various keloid characteristics, including keloid size and morphology.

Making multiple passes prior to corticosteroid infiltration is an injection technique that has been described. Consensus was reached that for very firm keloids it can be considered to first make multiple passes using needles to facilitate corticosteroid infiltration. During the consensus meeting alternative methods such as a fractional $CO_2$ laser were raised as a way to enhance the distribution of the corticosteroid. However, according to critics of the 'multiple passes' technique, there is increased trauma and a risk of spreading keloid fibroblasts into normal tissue, ultimately resulting in larger keloids. Studies on the distribution of intralesional corticosteroids in keloids using this technique are currently being conducted and may provide further insight as to the effectiveness of this technique.

A strength of this e-Delphi study is the clear representation of current collective judgments among an international panel of keloid experts on the ICA in keloids. Additionally, the study highlights important questions for future research. Recommendations of this e-Delphi study are based on expert opinion instead of strong scientific evidence, but are nonetheless important, as lack of scientific evidence and large variety exists in scientific practice on the basis of the broad search strategy of the recent scoping review [5].

There are some limitations to this study. Firstly, there were no participants from Africa and South America. This may limit the generalizability of the findings of this e-Delphi study. As keloids are more prevalent in skin types V and VI, physicians in Africa and South America may generally be experienced in treating keloids in this patient population, which may be different compared with patients with lighter skin types. However, most participating physicians also treat keloids in patients with skin types V and VI. Secondly, consensus agreements are based on a group of 23 keloid experts, of whom only 65% participated in the consensus meeting. However, this is similar or higher compared with other e-Delphi studies [13, 14]. In addition, four members of the founding committee were also part of the keloid expert panel, which may lead to bias, although all members of the keloid panel could add new statements or suggest changes throughout the e-Delphi rounds and in the consensus meetings. Furthermore, the consensus-based recommendations do not specifically involve keloids in children, besides indicating that dose reduction is recommended according to the weight. Additionally, there are some elements of ICA that could have been further specified in this consensus study, such as the use of a luer lock system, the use of an insulin syringe, specific methods of field block anesthesia such as the translesional local anesthesia method (Mirmovich et al., 2012) [15], and the number of treatment sessions before changing to another treatment modality. Considering the latter, we expect that the management will be variable between physicians and keloids. Finally, it should be noted that treatment response of ICA in keloids is also dependent on other factors than solely operator dependent factors. These factors may be related to the different characteristics of patients and keloids. For instance, there is some evidence that suggests that genetic variations are responsible for drug response in keloids [16]. This may be a reason that combining ICA with other treatments such as 5-fluorouracil, cryotherapy, and lasers may result in better treatment responses in some patients.

## 5 Conclusions

This e-Delphi consensus study provides consensus-based clinical treatment recommendations on essential aspects of ICA in keloids for all physicians treating keloids, including treatment goals, indication for ICA, type of corticosteroid, dosing, treatment interval, syringe and needle size, the use of local anesthesia, and manual injection techniques. By implementing these recommendations, uniformity of ICA in keloid treatment will increase and treatment results will become more comparable. Additionally, better treatment results may be achieved.

**Supplementary Information** The online version contains supplementary material available at https://doi.org/10.1007/s40257-024-00888-7.

## Declarations

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**Conflict of interest** The authors have no conflicts of interest.

**Author contributions** A.W., P.Z., F.N., O.L., Q.Y., and K.Q. made substantial contributions to the conception or design of the work. The acquisition, analysis, and interpretation of data were performed by Q.Y., K.Q., A.W., P.Z., F.N., and O.L. Q.Y. and K.Q. drafted the article. All authors revised the article critically and approved the final version of the article.

**Ethics approval** Not applicable.

**Consent to participate/publish** All participants participated voluntarily in the study and agreed that collected data would be identifiable and be used for publication.

**Data availability** The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Code availability** Not applicable.

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