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ORIGINAL ARTICLE

Comparison of methods to estimate the affected body surface area and the dosage of topical treatments in psoriasis and atopic dermatitis: the advantage of a picture-based tool

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Abstract

Background The accurate determination of the dosage of topical treatments is important given its repercussions on patient adherence and therapeutic efficacy. Up till now, the fingertip unit calculated by the rule of hands is considered the gold standard, although its use is associated with several drawbacks.

Objective To compare different methods to estimate the affected body surface area (BSA) and dosage of topical treatments in atopic dermatitis and psoriasis and investigate its reliability, user-friendliness and timing.

Methods In this study, we compared the reliability of three different methods: (i) the fingertip unit calculated by the 1% hand rule; (ii) a picture-based tool [termed Cutaneous Inflammatory Disease Extent Score (CIDES)]; and (iii) a digital drawing tool. Eleven observers scored 40 patients with psoriasis and eczema to assess the inter-rater and intrarater reliability. Timing was automatically recorded, and user-friendliness was investigated by a questionnaire.

Results An excellent intraclass correlation (ICC) was found for both inter-rater agreement and intrarater agreement for the picture-based tool (ICC = 0.92 and ICC = 0.96, respectively). The ICCs for drawing the area of involvement on a silhouette were 0.89 and 0.93, respectively. Finally, the rule of hands was associated with an increased inter-rater variability although an excellent intrarater agreement was found (ICC = 0.79 and 0.95, respectively). Automated calculation of the amount of topical treatment improved reliability, and CIDES was associated with the least variation. CIDES was considered the preferred method by all observers and was fast to perform (median: 30 s).

Conclusion A picture-based method offered the most advantages (in terms of reliability, speed and user-friendliness) to estimate the affected BSA and calculate the dosage of topical treatments.

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Conflict of interest

None reported.

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Introduction

Estimating the dosage of topical treatments and explaining this information in a reliable way to patients is a long-standing problem in dermatology. In 1989, the 'fingertip unit' (FTU) was developed as a method to clarify the amount of ointment that should be used.[1] Global charts were developed explaining how much FTUs are needed to cover entire body parts. However, as skin diseases are rarely confined to anatomical borders, the FTU was combined with the rule of hands.[2] This method assumes that for each affected skin area of two palms (=2%), the patient should use the amount of ointment covering one tip of the index finger if dispensed in a straight line from a tube with a 5-mm nozzle (=1 FTU). This quantity approximates a weight of 0.5 g. The FTU strictly only applies to corticosteroid ointments. Unfortunately, the method is often used for other substances (e.g. retinoids, moisturizers, sunscreens) in different topical vehicle formulations (e.g. creams, gels, foams), where other dosage regimens may be more appropriate. In daily practice,

dermatologists use this method only in a small minority of patients, and despite the fact that many patient websites mention the FTU, only a minority of patients is familiar with this method. This illustrates the inherent problems of this technique in a real-life situation. Physicians often rely on their own professional experience to estimate the dosage resulting in a high variability.[3]

The use of the rule of hands to estimate the affected body surface area (BSA) in skin disorders has been a topic of debate. First, the assumption that 1 hand corresponds to 1% of the BSA has been challenged as planimetric measurements showed it represents approximately 0.78% of the BSA.[4] Although this method has advantages as it requires no additional material/software and gives a rough estimate, it feels inaccurate in clinical practice due to the scattered distribution pattern of most inflammatory skin diseases. Especially in patients with extensive disease, a reliable estimate is challenging. Despite its long-time use, data on the inter-rater and intrarater reliability of the rule of hands are limited for common skin diseases such as psoriasis and eczema.

On the other hand, digital imaging systems are time-consuming and fail to evaluate the palmoplantar, genital and hair covered sites.[5] In addition, their introduction and widespread availability are difficult to attain. The need for new standardized (digital) easy-to-use tools has therefore been emphasized in the literature.[3]

This study is the first step in the development of a new digital tool to calculate the dosage of topical treatments. Three different methods to estimate the extent of psoriasis and atopic dermatitis were compared and investigated for reliability, timing and user-friendliness.

Methods

Scoring sessions

Eleven observers with different degrees of medical experience [three students (6th-year medical school), one physician (non-dermatologist), three dermatologists with limited years of experience (<3 years) and four experienced dermatologists scored pictures of 40 patients (20 psoriasis patients and 20 patients with atopic dermatitis) using three methods (rule of hands, picture-based instrument and the drawing tool). Before the first scoring session, a short introduction during 3–5 min was given to explain the three scoring tools. The aim (='comparison of different methods') was explained to the raters. For each patient, a fixed time period (range 0.5–12 months) was given, explaining the duration for which the topical treatment had to be prescribed. The raters were asked how much ointment they would advise during this period and how much (=percentage of prescribed amount) they considered the patient should have used for optimal efficacy (='current practice') following the existing guidelines. This was compared to an automated calculation based on the affected BSA using the rule of hands, the picture-guided instrument and the drawing tool. For the automated calculation, a standard total BSA for men (1.9 m^2) and women (1.6 m^2) was used. The optimal amount of ointment was calculated following the rules of the FTU.[1] The reliability of the three methods regarding determination of the affected BSA and the estimation of the appropriate amount of ointment over a given time period was investigated. The inter-rater and intrarater agreement, timing and user-friendliness were assessed. Eight observers repeated the scoring after a minimal interval of 1 week to calculate the intrarater agreement. This study was approved by the local ethics committee and was performed according to the Declaration of Helsinki. The COSMIN checklist was used for designing the protocol and reporting the results.

For calculation of ICC's in reliability studies, a minimum sample size of at least 30 cases involving at least three raters has been proposed.[6] As no general consensus exists on the optimal sample size to study inter-rater and intrarater reliability in physician performed scoring tools, we ensured that the number of patients and raters exceeded most comparable studies and performed a sample size calculation based on the predefined statistical analyses.

Rule of hands combined with the fingertip unit (=method 1)

The method assumes that on an affected skin area corresponding with the surface area of 2 hands (=2% BSA), 1 FTU of ointment should be applied.[2]

'Pattern tool' (=method 2)

A new instrument was developed consisting of six main (extent) categories (2.5%, 10%, 25%, 50%, 75%, 100%), which are illustrated by a series of pictures, mimicking the most common distribution patterns in psoriasis and eczema (Fig. 1). All categories can be scored separately for 24 different body parts [head (front + back), trunk (front + back), arms (left + right, front + back), hands (left + right, front + back), genital area (front + back), legs (left + right, front + back), feet (left + right, front + back), armpits (left + right)]. Combined with the possibility to score 'in between' categories (0%, 6.25%, 17.5%, 37.5%, 87.5%), a huge amount of different outcomes (11 categories for 24 body parts) can be generated, resulting in an almost continuous scale.

Design of the 'drawing tool' (=method 3)

A human silhouette (front and back) was drawn with separate representations of the armpits and palmar sides of the feet. During the scoring sessions, the raters could mark the involved areas using a pencil drawing tool in ImageJ software, National Institute of Health, Bethesda, Maryland, USA. The percentage of involvement was automatically calculated for each body part.

Timing and user-friendliness

The time required to score each patient was automatically recorded using Excel, Microsoft, Redmond, Washington, USA. At the end of the first session, the observers filled out a questionnaire to rate the user-friendliness, timing, accuracy and effort to

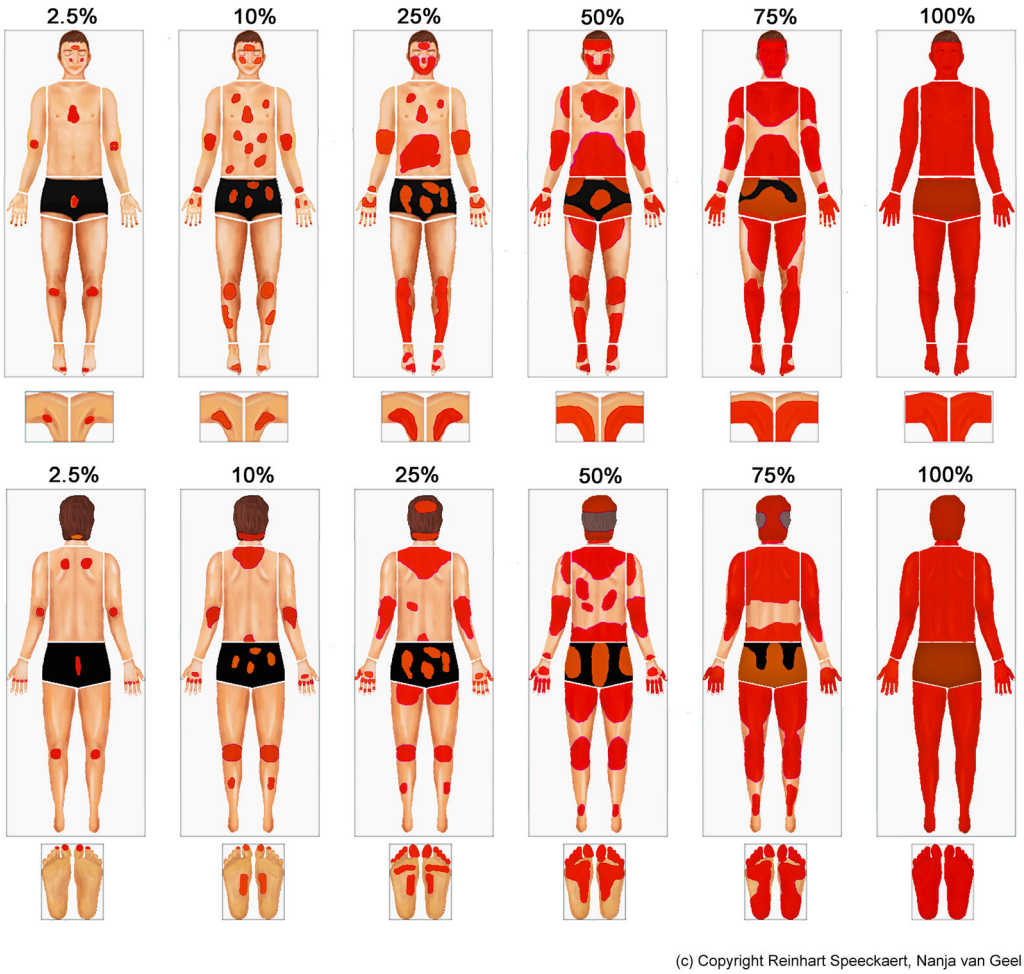

Figure 1 Template of the Cutaneous Inflammatory Disease Extent Score (CIDES). All 24 body parts can be scored separately. Scoring can be done on the pictures (2.5%, 10%, 25%, 50%, 75%, 100%) combined with the possibility to score 'in between' categories (0%, 6.25%, 17.5%, 37.5%, 87.5%).

complete the score for each method on a visual analogue scale (0–10). The raters were asked to choose a preferred method if physicians or patients would use the instrument.

Statistical analysis

The inter-rater agreement and intrarater agreement were determined using the intraclass correlation coefficient (ICC) in a two-way random model with absolute agreement and reported as single measures. In case the assumption of normality was not met, log transformation was carried out before calculating the ICC. Comparison between methods was performed using the Mann–Whitney *U*-test. Pearson correlation was used to assess the relation between different continuous variables. Bland–Altman plots were generated to compare the results of the different measuring techniques. All analyses were done using Medcalc 18.5 (Medcalc Software bvba, Ostend, Belgium) and SPSS 23.0 (SPSS Science, Chicago, IL, USA).

Results

Body surface area estimation

The mean BSA estimates using the rule of hands showed a very high correlation with the picture-based instrument and the drawing tool ($r = 0.98$ and $r = 0.94$, respectively; both $P < 0.001$; Fig. 2). Similarly, the picture-guided instrument was strongly correlated with the drawing tool ($r = 0.93$, $P < 0.001$). Mean BSA values were not significantly different between the first and the second methods. In contrast, the rule of hands showed higher percentages compared to the drawing tool ($P = 0.035$; Fig. 2d).

Bland–Altman plots displayed a significant slope in the regression line between the rule of hands and the other two scoring tools ($P < 0.001$ and $P < 0.001$, respectively; Fig. 3). This was due to higher BSA estimations in patients with advanced disease using the rule of hands compared to the other two methods. In both situations, a proportional error was evident showing an increased difference in patients with high BSA involvement. In contrast, a Bland–Altman plot between the picture-based instrument and the drawing tool showed no obvious differences.

Inter-rater and intrarater agreement

The inter-rater agreement was excellent for the picture-based instrument [ICC = 0.92 (95% CI: 0.88–0.95)], which was followed by the drawing tool [(ICC = 0.89 (0.83–0.94)] and finally the rule of hands [ICC = 0.79 (95% CI: 0.66–0.88)]. The standard deviation between the scores of the raters was significantly lower for the picture-based tool and the drawing tool compared to the rule of hands ($P < 0.001$ and $P < 0.001$, respectively; Fig. 4). The results were very consistent among raters with different grades of experience.

The overall intrarater agreement was very high for all methods. An ICC of 0.95 (95% CI: 0.94–0.96) was observed for the rule of hands, 0.96 (95% CI: 0.95–0.97) for the picture-based instrument and 0.93 (95% CI: 0.92–0.95) for the 'drawing' tool. The standard deviations between the first score and second score were increased for the 1% hand rule compared to the other two methods ($P = 0.003$ and $P = 0.003$, respectively).

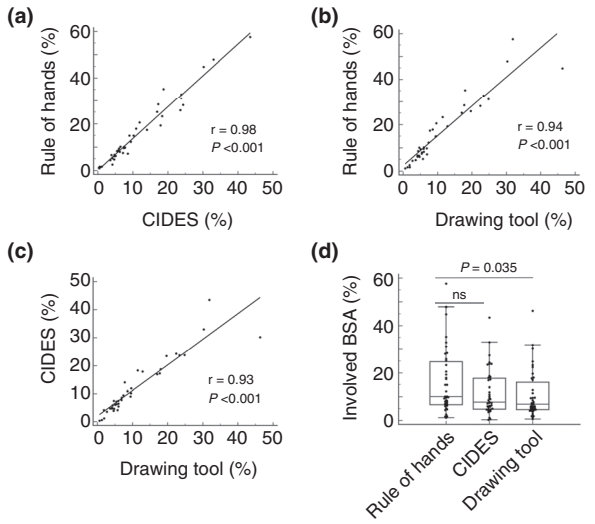

Figure 2 The rule of hands was highly correlated with the picture-based tool (CIDES) (a) and the drawing tool (b). Similarly, CIDES was strongly correlated with the drawing tool (c). The rule of hands resulted in the highest values, which was not significantly different from CIDES, although significantly higher than the drawing tool (d).

Estimation of the amount of topical treatment

The estimation of the amount of ointment (grams) that should be used during a fixed time period in order to achieve an optimal response proved very difficult without additional aids. Despite an excellent correlation ($r = 0.95$), non-automated estimation resulted in higher mean values (of amount of cream) compared to the automated calculation (Fig. 4). The inter-rater ICC of the estimation without automated calculation was only 0.65 (0.48–0.78). Nonetheless, this is the most widely used standard practice. Automated calculation improved the ICC drastically. The picture-guided instrument resulted in the best ICC (ICC = 0.94 (95% CI: 0.90–0.96)], followed by the drawing tool [ICC = 0.91 (95% CI: 0.86–0.95)] and the rule of hands [ICC = 0.82 (95% CI: 0.71–0.89)]. As expected from this result, the SD between raters was significantly smaller for the picture-based instrument and the drawing tool compared to the other methods (Fig. 4e). Similarly, intrarater reliability estimation without automated calculation showed an ICC of 0.64 (95% CI: 0.48–0.74), which was clearly lower compared to automated calculation using the rule of hands [ICC = 0.95 (95% CI: 0.94–0.96)], Cutaneous Inflammatory Disease Extent Score [CIDES; ICC = 0.96 (95% CI: 0.95–0.97)] and the drawing tool [ICC = 0.96 (95% CI: 0.95–0.97)]. Due to the increased variability in patients needing a high amount of cream, the picture-based instrument and the drawing tool displayed a decreased SD (between the first and second scores of all raters) compared to the rule of hands and the estimation without automated calculation (Fig. 4).

User-friendliness and timing

User-friendliness was scored in favour of the picture-based tool (8.5/10), followed by the drawing tool (6.4/10) and the rule of hands (5.3/10). The feeling of accuracy (8.3/10, 6.6/10 and 4/10, respectively) and effort to complete the tool (3.6/10, 5.8/10, 6.8/10, respectively) showed similar results. This all supports the superior properties of a picture-based tool in daily practice compared to the rule of hands. The mean duration of a score was 57 s (median 50 s; IQR: 40–64 s) for the rule of hands (+estimation of the amount of product to prescribe) compared to 42 s (median: 30 s; IQR: 16–44 s) for CIDES and 89 s (median: 80 s; IQR: 59–116 s) for the drawing tool (both with automated calculation of the amount of prescribed product). All observers considered the pattern tool as the most appropriate tool for physicians. 63.6% of raters found this instrument most appropriate for patients while 36.4% considered the 'drawing' tool to be more suited for this purpose.

Discussion

Topical treatment remains the gold standard of care for mild-to-moderate psoriasis and atopic dermatitis. In extensive cases, the combination of systemic therapy with topicals is common practice.[7] However, adherence to topical treatments is low in skin

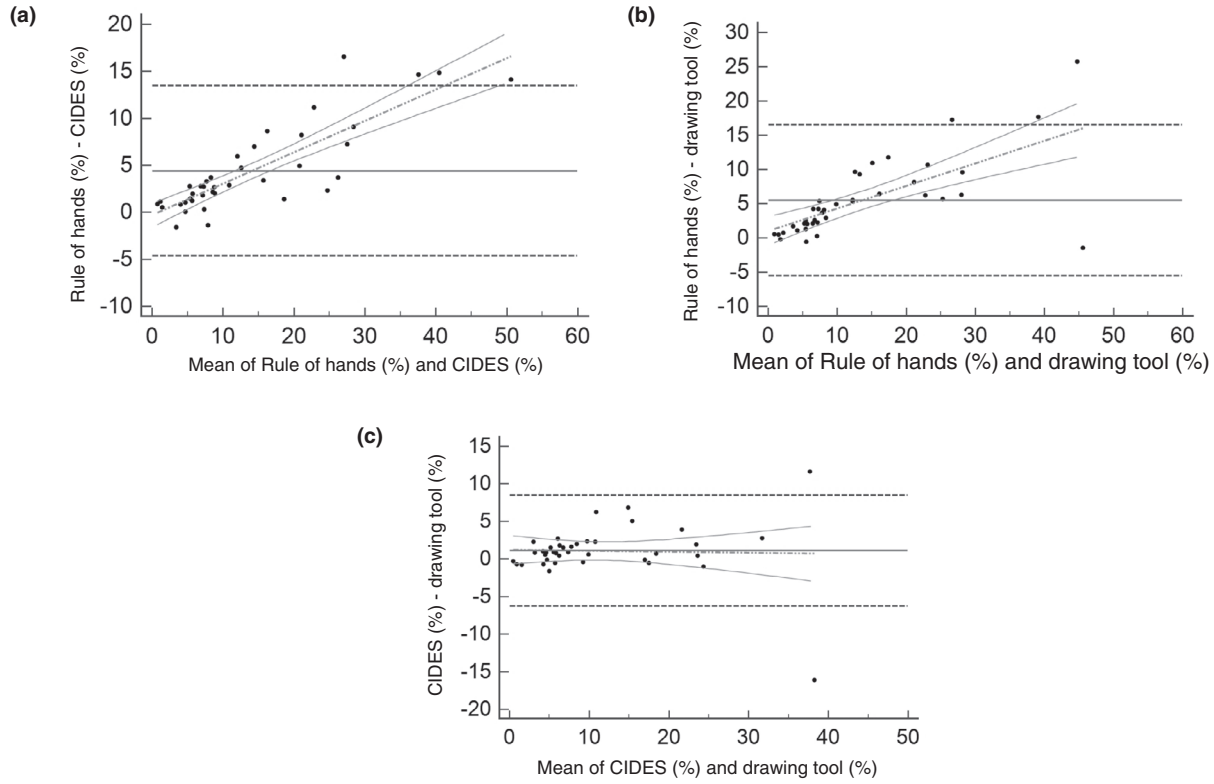

Figure 3 Bland–Altman plots showed proportional error between the rule of hands and both the picture-guided instrument (CIDES) (a) and the drawing tool (b), indicating that the rule of hands displays increased differences with both methods in patients with advanced body surface involvement. No clear difference was found between picture-based instrument and the drawing tool.

diseases and varies in clinical trials between 55% and 100%. In a real-life situation, this is likely to be even less. A systematic review found four studies which investigated the quantity of topicals that patients actually applied and discovered that the amount was 35–72% of the recommended dosage. The authors therefore advised an increased use of clear user instructions.[8] Recent studies in atopic dermatitis found that only 20.9–26.5% of patients used the correct amount of tacrolimus and that treatment efficacy significantly increased according to the applied quantity.[9,10] Interventions clarifying the correct use of topicals have shown dramatic (89%) decreases in the severity of inadequately controlled childhood eczema.[11] Additionally, a study confirmed that 95% of psoriasis patients under dose their topical treatment with current standard practice.[12] The physician seems – at least partly – to blame as almost two-thirds of topical prescriptions for psoriasis do not include enough information for patients to manage their disease properly.[3] Moreover, the number of prescriptions has been documented to be insufficient in one-fourth of cases with widespread eczema. It has been shown that these patients are reluctant to ask additional prescriptions out of fear for possible side-effects.[13]

In this article, we compared different methods to estimate the body surface extent and calculate the dosage of topical treatment for the most common inflammatory skin disorders: psoriasis and atopic dermatitis. A new tool based on patterns called 'CIDES' shows excellent inter-rater agreement and intrarater agreement to estimate the affected BSA and amount of topical treatment that should be used. This method (=CIDES) outperformed the reliability of the FTU combined with the rule of hands. CIDES was created based on our previous experience with a comparable method to measure the body surface involvement of vitiligo named the Vitiligo Extent Score.[14] During several validation studies, its superior user-friendliness and accuracy were shown over methods using the rule of hands. Even in cases when the pattern of the disease did not seem to correspond to the template, no decreased reliability was observed. This led us to develop a comparable tool for psoriasis and eczema, which now shows to exhibit the same excellent results regarding inter-rater and intrarater reliability and user-friendliness. The 'drawing' tool showed also excellent inter-rater and intrarater reliability but required substantially more time (more than double) and

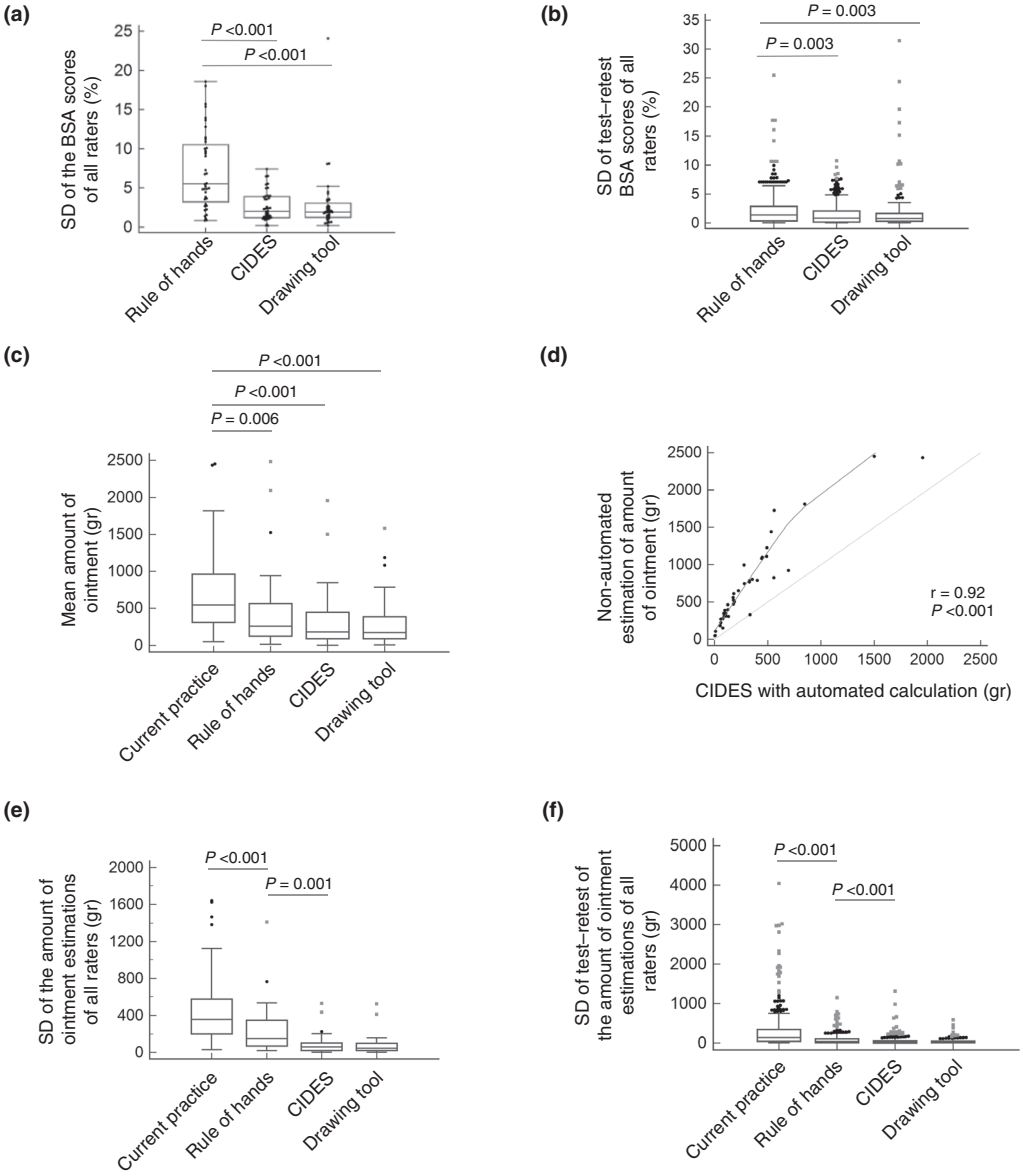

Figure 4 The standard deviation of the body surface area estimations (between raters) was higher using the rule of hands compared to the other methods (a). Similarly, the standard deviation of the test–retest scores was highest using the role of hands followed by the drawing tool and the picture-guided instrument (CIDES) (b). Estimation without an automated calculation resulted in higher weights of ointment (c) displaying higher differences with increasing amounts (d). The standard deviation of the amount of treatment (grams) during a fixed time period was highest using the method without automated calculation (='current practice') and was also higher using the rule of hands compared to CIDES and the 'drawing tool' (e). Test–retest evaluations showed similar results (f).

effort to complete and was not considered to be a practical approach in clinical practice.

This study is the first phase of the development of a new digital easy-to-use application to calculate the dosage of topical treatments and offer patients accurate user information. The picture-based method (CIDES) was faster and even slightly more reliable compared to a 'drawing tool'. It required very little instructions and was easily understood by all participants. As the extent of body surface involvement can change rapidly during treatment, patients should themselves be capable to adjust the dosage (benefiting the cost-effectiveness of the initiated therapy). Future studies will show if this tool can also be used by patients,

which will allow them to calculate independently their affected BSA and adapt the dosage if the extent of their skin disease changes over time. A limitation of this study was that all patients were Caucasian. A multicultural international validation study will be planned including more raters with different levels of experience. For practical and analytical reasons, the study was conducted on pictures instead of live evaluation of patients. In the future, the value of using separate patterns for atopic dermatitis and psoriasis in CIDES will be investigated.

In conclusion, this validation study shows that a picture-guided tool outperforms the current gold standard (FTU based on the rule of hands) in terms of inter-rater reliability and user-friendliness. Given these superior characteristics, this instrument can be used to calculate the affected BSA in inflammatory skin disorders and will be integrated in a new digital tool to determine the dosage of topical treatments.

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