

LETTERS TO THE EDITOR

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NEEDLING SENSATION: EXPLANATION OF INCONGRUENT CONCLUSION DRAWN FROM ACUPUNCTURE fMRI STUDY

Dear Editor:

Whether or not acupuncture intervention involves neurologic effects has recently been explored via functional magnetic resonance imaging (fMRI) experiments commonly consisting of multiple experimental blocks with ON- and OFF-condition alternations. Such fMRI experiments normally employed a block interval of more than a minute.^{1–3} However, the psychophysical response to acupuncture, a needling (or *de qi*) sensation (a sensation including sourness, numbness, heaviness, and distension surrounding the area of needle insertion), introduced by the acupuncture stimulus conducted in one current trial can be carried over to the next trial. This carryover effect might alter the baseline condition of the following trials and thus affect data analyses, possibly resulting in incongruent conclusions. Here, we demonstrate the carryover effect with a psychophysical test using a single block of acupuncture needling.⁴

Subjective psychophysical responses were obtained from 16 subjects (6 females and 10 males, 27 ± 2.7 years old). The subjects received acupuncture at the acupoint of left ST42 (Chong Yang). In this experiment, the needle was inserted and twisted clockwise and counterclockwise at a frequency of 1–2 Hz to produce a needling sensation. The subjects were requested to continually report this needling sensation verbally every 10 seconds, for up to 1 hour. The needling sensation was scored from 0 (no *de qi* at all) to 10 (the strongest *de qi* sensation a subject can endure).

The result showed that the initial *de qi* was the strongest reaction, which then reached its plateau at 20 seconds and started to drop at 2 minutes (Fig. 1). This strongly suggests that if the block duration is less than 2 minutes in a multi-block fMRI experiment, the evoked brain responses registered to the current acupuncture stimulus would be prolonged enough to perturb the baseline of the subsequent trial(s). This can further affect the ON/OFF contrasting in the statistical analysis. In other words, a multiblock design with its OFF-condition lasting longer than 2 minutes for each block or a single-block design will be more suitable for conducting an fMRI acupuncture study. In the future, we will

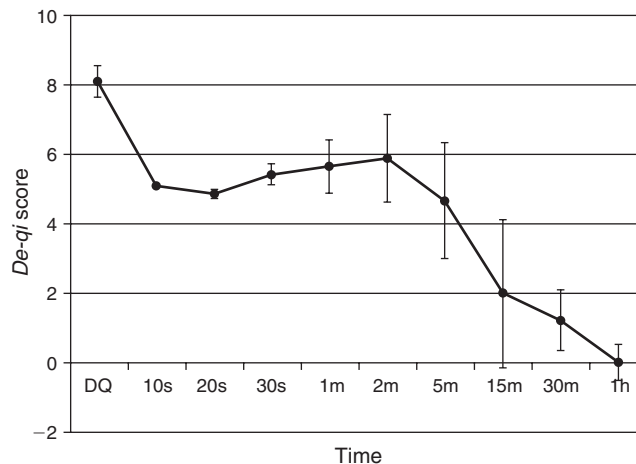


FIG. 1. Changes of *de qi* sensation conducted in a psychophysical test ($n = 16$). DQ indicates the timing of *de qi* sensation produced (time zero as plotted).

demonstrate empirically the influence of carryover effects on an fMRI study involving acupuncture stimulation with a larger sample size and compare the result from multiple- and single-block experimental designs.

REFERENCES

1. Cho ZH, Chung SC, Jones JP, et al. New findings of the correlation between acupuncture points and corresponding brain cortices using functional MRI. *Proc Natl Acad Sci U S A* 1998;95:2670–2673.
2. Cho ZH, Oleson TD, Alimi D, Niemtzw RC. Acupuncture: The search for biologic evidence with functional magnetic resonance imaging and positron emission tomography techniques. *J Altern Complement Med* 2002;8:399–401.
3. Gareus IK, Lacour M, Schulte AC, Hennig J. Is there a BOLD response of the visual cortex on stimulation of the visual-related acupuncture point GB37? *J Magn Reson Imaging* 2002;15:227–232.
4. Stux G, Pomeranz B. *Basics of Acupuncture*, 4th ed. Berlin: Springer-Verlag, 1998.

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MINISCALPEL-NEEDLE VERSUS TRIGGER- POINT INJECTION FOR CERVICAL MYOFASCIAL PAIN SYNDROME: A RANDOMIZED COMPARATIVE TRIAL

Dear Editor:

Cervical myofascial pain syndrome (CMPs), which frequently involves the superior trapezius muscle, is one of the most common causes of musculoskeletal pain originating from one or more muscles with their fasciae. A wide range of treatments including drugs, physiotherapy, manual treatments, acupuncture, and so on, are proposed, whether some of above treatments such as acupuncture are in question.¹ A new instrument called miniscalpel-needle (MSN, shown in Fig. 1) based on acupuncture has been developed in china. The aim of this study is to evaluate the therapeutic effects of MSN on CMPs.

In this study approved by the hospital's ethical committee and allowed by the patients, 72 patients who had CMPs of the superior trapezius muscle were randomly divided into two groups. Patients in group 1 ($n = 36$) received MSN treatment. The patient lay in prone position with a high pillow under the breast, so the fully stretched neck was exposed. After the trigger points were located, marked, and sterilized, an aseptic hole-towel was spread. The MSN was inserted into the TP (Trigger Point) vertically for 30 seconds. The direction of the insertions was paralleled to the nerves, blood vessels, and muscle fibers. Thereafter, the MSN was withdrawn, and the small hole caused by MSN was pressed for a while until the bleeding stopped. Then the hole was covered with a simple adhesive bandage. In the same posture, patients in group 2 ($n = 36$) received the in-

jection of a mixture of 0.5 mL 1% lidocaine and 1.5 mL saline into the TP of the trapezius muscle by using a 25-gauge needle.

After the treatment was finished, all patients were observed for 30 minutes to avoid any adverse reaction. In order to simplify the study and assessment, the treatment was performed only one time, and only the most painful TP was treated.

The time points observed included the day before treatment (T0, baseline), and half a month (T1), 2 months (T2), and 3 months (T3) after the treatment. We measured the subjective intensity of pain through the visual analogue scale (VAS),² the neck pain and disability visual analogue scale (NPDVAS),³ the evaluation of the TPs (ETP)⁴ by manual palpation and the range of movement of the cervical spine⁵: contralateral bending (Cb), ipsilateral bending and contralateral rotation (Cr), and ipsilateral rotation (Ir).

Statistical analyses were performed using nonparametric tests. If $p < 0.05$, the difference is considered statistically significant. Of the original 72 patients, 31 from group 1 (G1) and 33 from group 2 completed the study and the follow-up. No severe adverse events were observed.

Results showed that age, education, duration of illness, and the number of the TPs were not significantly different. G1 showed a significant improvement in the parameters (VAS, NPDVAS, ETP, Cb, and Ir) after the treatment ($p < 0.05$) (shown in Fig. 2A–C, E, and F). Group 2 (G2) did show the significant improvement of VAS at T0 versus T1 ($p < 0.05$) (shown in Fig. 2A); however, no significant improvements in

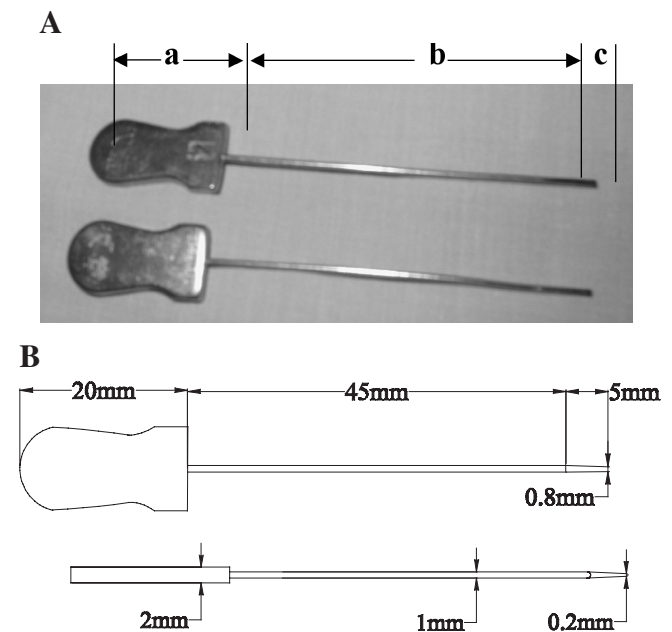


FIG. 1. (A) Photograph of miniscalpel-needle. (B) Illustration of the miniscalpel-needle: (a) The calabash-like flat handle is about 2 mm thick; (b) The columniform body with 1-mm diameter is 4.5 cm long; (c) The flat subuliform blade is 0.5 cm long, 0.8 mm wide, and 0.2 mm thick.

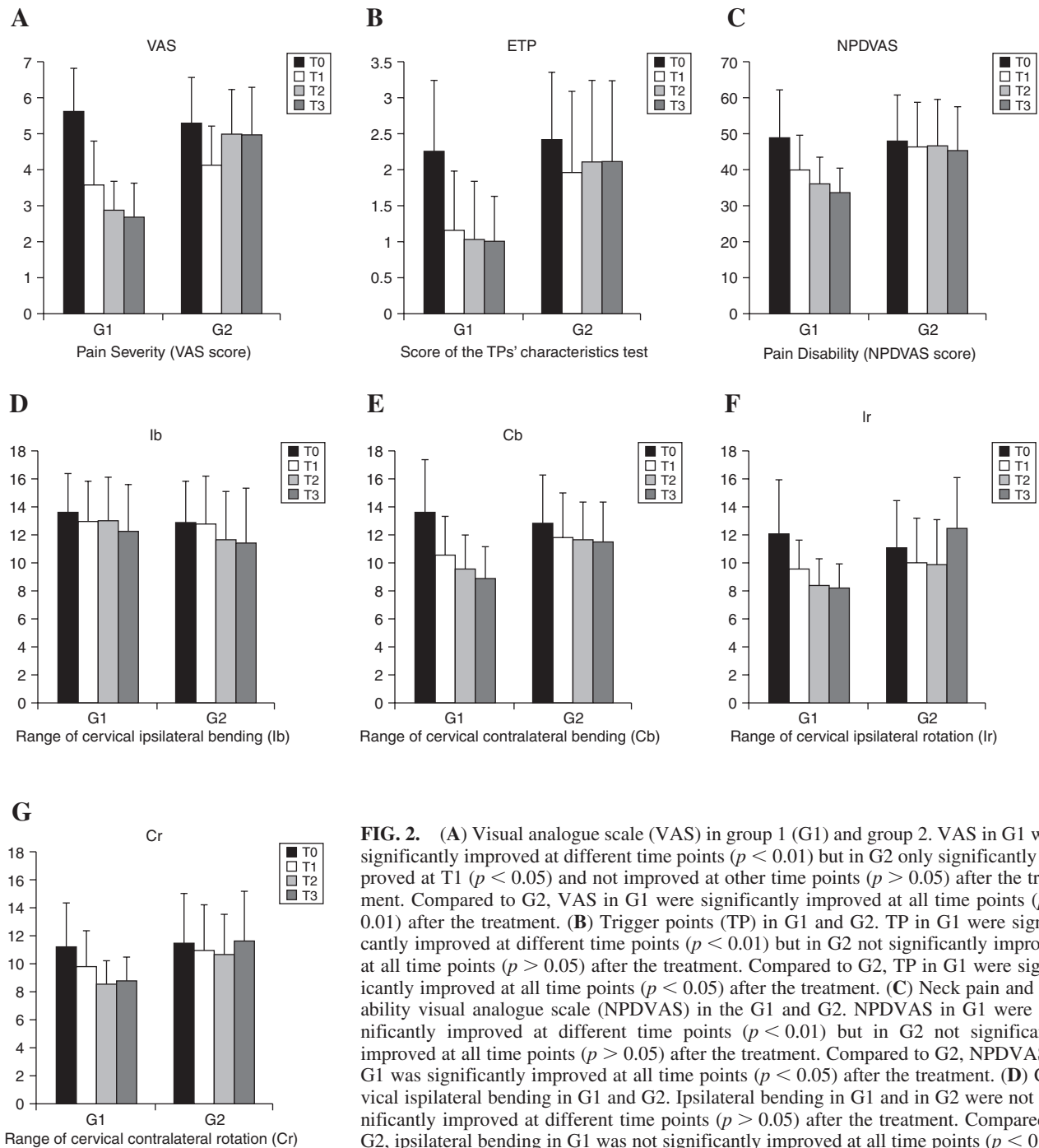


FIG. 2. (A) Visual analogue scale (VAS) in group 1 (G1) and group 2. VAS in G1 were significantly improved at different time points ($p < 0.01$) but in G2 only significantly improved at T1 ($p < 0.05$) and not improved at other time points ($p > 0.05$) after the treatment. Compared to G2, VAS in G1 were significantly improved at all time points ($p < 0.01$) after the treatment. (B) Trigger points (TP) in G1 and G2. TP in G1 were significantly improved at different time points ($p < 0.01$) but in G2 not significantly improved at all time points ($p > 0.05$) after the treatment. Compared to G2, TP in G1 were significantly improved at all time points ($p < 0.05$) after the treatment. (C) Neck pain and disability visual analogue scale (NPDVAS) in the G1 and G2. NPDVAS in G1 were significantly improved at different time points ($p < 0.01$) but in G2 not significantly improved at all time points ($p > 0.05$) after the treatment. Compared to G2, NPDVAS in G1 was significantly improved at all time points ($p < 0.05$) after the treatment. (D) Cervical ipsilateral bending in G1 and G2. Ipsilateral bending in G1 and in G2 were not significantly improved at different time points ($p > 0.05$) after the treatment. Compared to G2, ipsilateral bending in G1 was not significantly improved at all time points ($p < 0.05$) after the treatment. (E) Cervical contralateral bending in G1 and G2. Contralateral bending in G1 was significantly improved at different time points ($p < 0.01$) but in G2 not significantly improved at all time points ($p > 0.05$) after the treatment. Compared to G2, contralateral bending in G1 was significantly improved at all time points ($p < 0.01$) after the treatment. (F) Cervical ipsilateral rotation in G1 and G2. Ipsilateral rotation in G1 was significantly improved at different time points ($p < 0.01$) but in G2 not significantly improved at all time points ($p > 0.05$) after the treatment. Compared to G2, ipsilateral rotation in G1 was significantly improved at T2 and T3 time points ($p < 0.05$), but not significantly improved at T1 time point ($p > 0.05$) after the treatment. (G) Cervical contralateral rotation in G1 and G2. Contralateral rotation in G1 was significantly improved at T2 and T3 time points ($p < 0.05$) but not significantly improved at T1 time points ($p > 0.05$) after the treatment. Compared to G2, contralateral rotation in G1 was significantly improved at T2 and T3 time points ($p < 0.05$), but not significantly improved at T1 timepoint ($p > 0.05$).

all the above parameters in the follow-up were observed ($p > 0.05$) (shown in Fig. 2A–G). The comparisons between the effects of two group confirmed TP, NPDVAS, VAS, and Cb tests in G1 were improved more effectively at all timepoints ($p < 0.01$) than in G2 after the treatment (shown in Fig. 2A–C, E). The MSN technique combines the therapeutic role of acupuncture and microinvasive operation. The effect of acupuncture includes stimulation of vessel and nerve bundles, restoration of the mechanical dynamic equilibrium, improvement of local microcirculation, elimination of muscular spasm and tension, enhanced metabolism, and promotion of eliminating inflammatory substance.^{6,7} Therefore, it relieves spasm and pain. On the other hand, the MSN is a microinvasive operation. This operation can cut and detach the adhesive, cicatricial, and contracted abnormal tissues; therefore, it can relax the compressed blood vessels and slapped nerves at the primary and second foci.⁸

Our study showed that the group receiving MSN treatment had significantly improved VAS, NPDVAS, and ETP. These effects lasted at least 3 months and had a tendency toward progressive improvement over time. The rotation and contralateral bending of cervical range of motion (ROM) were also significantly improved, but other cervical ROM did not benefit much from the treatment. It is not surprising, because the trapezius muscle is only anatomically responsible for the rotation and contralateral bending of cervical ROM but no other cervical ROM.⁹ The group receiving 0.25% lidocaine treatment did have a better VAS at T1 but not any significant improvement in all other parameters above at any other time points.

In conclusion, the effect of the MSN for CMPs is superior to that of the 0.25% lidocaine TP injection.

This procedure requires strict disinfection. During the operation, one should avoid damaging the important blood vessels, nerves, and organs. The contraindications of this procedure include severe cardiovascular, hepatic, renal, and pulmonary diseases.

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REFERENCES

- Ramsay DJ, Bowman MA, Greenman PE, et al. Acupuncture: NIH Consensus Development Panel on Acupuncture. *JAMA* 1998;280:1518–1524.
- Carlsson AM. Assessment of chronic pain. *Pain* 1983;16: 87–101.
- Wheeler AH, Goolkasias P, Gretz SS. A randomized, double-blind, prospective pilot study of botulinum toxin injection for refractory, unilateral, cervicothoracic, paraspinal, myofascial pain syndrome. *Spine* 1998;23:1662–1667.
- Gam AN, Warming S, Larsen LH, et al. Treatment of myofascial trigger points with ultrasound combined with massage and exercise—a randomized controlled trial. *Pain* 1998;77:73–79.
- Clarkson HM, Gilewich GB. *Musculoskeletal Assessment: Joint Range of Motion and Manual Muscle Strength*. Baltimore: Williams & Wilkins, 1989.
- Pomeranz B, Chiu D. Naloxone blockade of acupuncture analgesia: Endorphin implicated. *Life Sci* 1976;19:1757–1760.
- Ghia JN, Mao W, Toomey TC, Gregg JM. Acupuncture and chronic pain mechanisms. *Pain* 1976;2:285–299.
- Zhu KC. Small needle scalpel treating HEEL pain. *Chinese J Rehabil* 2003;7:3656–3657.
- Esenyel M, Caglar N, Aldemir T. Treatment of myofascial pain. *Am J Phys Med Rehabil* 2000;79:48–52.

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EFFICACY AND SAFETY OF TWO BABY CREAMS IN CHILDREN WITH DIAPER DERMATITIS: RESULTS OF A POSTMARKETING SURVEILLANCE STUDY

Dear Editor:

Although not a life-threatening disease, diaper dermatitis (diaper rash) is a common cause of aggravation for parents. Occlusion and urinary wetness increase skin friction, skin pH, and transdermal permeability. With the protective stratum corneum breached, micro-organisms such as yeast or bacteria invade the skin, causing painful inflammation. Suitable treatment for uncomplicated cases are mild disinfecting and anti-inflammatory ointments (e.g., baby creams containing zinc oxide).^{1–3}

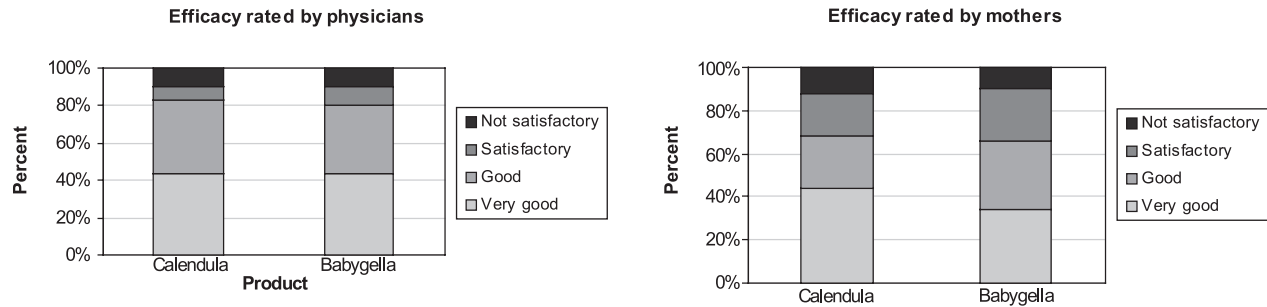


FIG. 1. Efficacy rated by physicians and mothers. Calendula Baby Cream was manufactured by Weleda, Arlesheim, Switzerland. Babygella was manufactured by Rottapharm, Monza, Italy.

A postmarketing surveillance study was approved by an independent institutional review board and performed by pediatricians at the SS Pietro e Paolo Hospital in Borgosesia, Italy. Eighty-two (82) infants, between 3 days old and 48 months old, with uncomplicated dermatitis were enrolled and randomly assigned to treatment with either Calendula Baby Cream (Weleda, Arlesheim, Switzerland) (C) or Babygella (Rottapharm, Monza, Italy) (B). Children with suspected atopic dermatitis, candida infection, and so on were excluded from the study. The active ingredient in Babygella is zinc oxide (4%). Calendula Baby Cream contains, among other ingredients, more zinc oxide (16%), and anti-inflammatory herbal extracts (*Calendula officinalis*, *Chamomilla recutita*).⁴⁻⁸ Both creams were obtained by the investigators.

The parents were asked to use the creams as necessary and document their administration and their own assessments of efficacy, safety, and satisfaction in a diary. Another efficacy, safety, and satisfaction rating was done for each child by the treating pediatrician after treatment end.

The descriptive statistical analysis after cross-tabulation for qualitative variables was performed using SAS software, release 9.13 (SAS Software, Inc., Chicago, IL).

Gender distribution was equal in both study groups. The children in the B group were somewhat older (mean age:

5.9 ± 7.7 months versus 3.6 ± 3.3 months). C was in most cases applied three times per day (58.5%), and B was administered twice daily (92.7%). Both C and B were usually applied for up to 7 days, being the only medication used.

The efficacy rating was favorable for both creams, without statistically significant differences between both preparations (Table 1). About 80% of physicians judged both creams as “very good” or “good.” Mothers were somewhat less convinced, especially for Babygella, preferring the term “satisfactorily” more often than physicians did. Only four persons were not satisfied with treatment efficacy in each group (Fig. 1).

The safety of C was rated slightly better compared to B by both physicians and mothers. Adverse events were noted only for 3 of 81 infants (2 C, 1 B). However, these being “not improved” and “not healed” rather points to insufficient efficacy rather than actual adverse events. In 11 cases (13.4%; 4 C, 7 B), irritations and/or reddening were observed, which could be basic symptoms or adverse events (hypersensitivity reactions to the calendula extract).

Customer satisfaction was good: in 78.0% of cases the physician would prescribe C again, in 65.9% B, respectively.

TABLE 1. RESULTS: EFFICACY RATING OF PRODUCTS BY PHYSICIANS AND MOTHERS

| Efficacy rating | Calendula Baby Cream | | | | Babygella | | | |
|------------------|----------------------|-------|---------|-------|------------|-------|---------|-------|
| | Physicians | | Mothers | | Physicians | | Mothers | |
| | N | % | N | % | N | % | N | % |
| Very good | 18 | 43.9 | 18 | 43.9 | 18 | 43.9 | 14 | 34.1 |
| Good | 16 | 39.0 | 10 | 24.4 | 15 | 36.6 | 13 | 31.7 |
| Satisfactory | 3 | 7.3 | 8 | 19.5 | 4 | 9.8 | 10 | 24.4 |
| Not satisfactory | 4 | 9.8 | 5 | 12.2 | 4 | 9.8 | 4 | 9.8 |
| Total | 41 | 100.0 | 41 | 100.0 | 41 | 100.0 | 41 | 100.0 |

Note: Calendula Baby Cream was manufactured by Weleda, Arlesheim, Switzerland. Babygella was manufactured by Rottapharm, Monza, Italy.

Considering the good efficacy and safety, both products can be recommended for treatment of diaper dermatitis in children up to 2 years of age.

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REFERENCES

1. Agren MS, Chvapil M, Franzen L. Enhancement of re-epithelization with topical zinc oxide in porcine partial-thickness wounds. *J Surg Res* 1991;50:101–105.
2. Akiyama H, Yamasaki O, Kanzaki H, et al. Effects of zinc oxide on the attachment of *Staphylococcus aureus* strains. *J Derm Sci* 1998;17:67–74.
3. Baldwin S, Odio MR, Haines SL, et al. Skin benefits from continuous topical administration of a zinc oxide/petrolatum formulation by a novel disposable diaper. *J Eur Acad Dermatol Venereol* 2001;15(suppl 1):5–11.
4. Cordova CA, Siqueira IR, Netto CA, et al. Protective properties of butanolic extract of the *Calendula officinalis* L. (marigold) against lipid peroxidation of rat liver microsomes and action as free radical scavenger. *Redox Rep* 2002;7:95–102.
5. Klouček-Popova E, Popov A, Pavlova N, Krá-steva S. Influence of the physiological regeneration and epithelialization using fractions isolated from *Calendula officinalis*. *Acta Physiol Pharmacol Bulg* 1982;8:63–67.
6. No authors listed. Final report on the safety assessment of *Calendula officinalis* extract and *Calendula officinalis*. *Int J Toxicol* 2001;20(suppl 2):13–20.
7. Shipochliev T, Dimitrov A, Aleksandrova E. Anti-inflammatory action of a group of plant extracts. *Vet Med Nauki* 1981;18:87–94.
8. Wagner H, Proksch A, Riess-Maurer I, et al. Immunostimulant action of polysaccharides (heteroglycans) from higher plants. Preliminary communication. *Arzneimittelforschung* 1984;34:659–661.

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