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Evaluation of the Efficacy of 99.9% Pure Silver Trilaminate Cups in the Prevention and Treatment of Nipple Pain and Fissures

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Abstract

Breastfeeding is drastically decreasing over time and nipple trauma constitutes one of the most significant reasons for its discontinuation. In this context, this study aimed at evaluating the effectiveness and tolerability of a topical treatment device, namely Silver Cap® (Depofarma S.P.A.), when used to prevent pain and nipple fissure formation. The medical device consists in a silver trilaminate cup to be placed on the nipple, providing physical protection and creating a moist environment. The study involved 187 women: 38 started to apply the device prior to lactation (PL group) and 149 during lactation (DL group). Aiming to collect safety and performance data, both groups were provided with questionnaires during 6 consecutive visits (120 days of follow-up). At last visit, absence of painful symptoms was reported by the 98.8% and the 100% of women in DL and PL groups, respectively. Moreover, no nipple fissures were observed and no adverse events directly correlated to use of the device were reported. According to these findings, it can be concluded that Silver Cap® is a safe and effective device for nipple pain and fissure prevention.

Keywords

Silver Cap, Breastfeeding, Breast Pain, Nipple Fissures

1. Introduction

In the past decades, a substantial amount of evidence has been collected on the beneficial effects that exclusive breastfeeding has on both mothers and children. Just to mention a few, breastfeeding has been associated to the improvement of children survival, health, and development, as well as to the prevention of breast and ovarian cancer and diabetes in mothers [1] [2]. Accordingly, recommendations of World Health Organization state that infants should be exclusively breastfed for the first 6 months of life and thereafter, complementary foods should be introduced while continuing to breastfeed for up to 2 years and beyond [3] [4].

Despite its vital role for children and mothers' health, global target for exclusive breastfeeding remains unmet. Such below-standard rates can be ascribed to multiple factors, spanning from sociocultural to market determinants, which influence mothers' decisions [5]. In addition to these environmental components, several medical reasons might also play a role. Among them, nipple pain and fissures represent some of the leading causes of early breastfeeding cessation [6] [7] [8] [9] [10].

Nipple fissures can be described as a macroscopic cutaneous lesion around the nipple and areola, typically arising during the first post-partum week as ulcerations, oedema, erythema, blisters, and dark spots [11]. Such lesions and the associated pain are experienced by about the 80% - 90% of breastfeeding women [12] [13]. And the main causes of their occurrence have a mechanical, infectious or hormonal origin [2] [14]. Indeed, incorrect latch and positioning of infants can lead to nipple damage, eventually facilitating bacterial infections (usually *Staphylococcus aureus* and *Candida albicans*). Moreover, hormonal changes associated to menstrual cycle can also contribute to nipple soreness [2].

As the surface of the skin is covered by a hydrophilic film which ensures the maintenance of the correct pH and hydration of the stratum corneum, a properly moisturized areola prevents the onset of skin damage, nipple fissures, soreness and mastitis [15]. Accordingly, the prevention and treatment of nipple fissures relies, from one side, on appropriate mothers training regarding the correct positioning and latching of the infant and, from the other side, on the application of topical treatments including hydrogels, warm compresses, collagenase, and dexpanthenol [12] [16] [17]. Lanolin, breast milk and hydrogel dressing are considered valid interventions to create a moist healing environment to prevent and treat nipple fissures and sorenesss [16] [17] [18].

The effects of moisture on epidermal regeneration include enhanced keratinocyte migration, proliferation, and differentiation, as well as increased fibroblast proliferation, collagen synthesis, angiogenesis, and a subsequent faster wound healing process. Nevertheless, the optimal level of moisture has not been clearly defined [19] [20]. Accordingly, occlusive dressings (*i.e.*, gels, films) [17] create a hypoxic environment that improves collagen synthesis and angiogenesis, thus accelerating re-epithelization, and act as a barrier preventing infections that

could delay wound healing [21]. However, adverse events such as burning, itching, and fissure infection have been associated to the use of lanolin [18] [21] and, while safe, breast milk typically requires long times to provide visible results [12] [17] [22]. Some difficulties have also been associated to the use of hydrogel and hydrocolloid dressings. Specifically, hydrogels can cause the maceration of the wound, resulting in bacterial overgrowth, and hydrocolloids removal can be unpleasant due to the exudate and hydrocolloids mix malodor [21].

An alternative approach to create a moist and hypoxic environment is represented by the use of 99.9% pure silver trilaminate cups—marketed as Silver Cap® (Depofarma S.P.A., Mogliano Veneto, Italy)—to be placed on the nipple [23]. Besides providing physical protection as breast shells, such cups create a moist area around the nipple, boosting wound epithelialization [24].

The safety and effectiveness of Silver Cap® device in treating nipple fissures have been already proven in an observational prospective study, providing encouraging results [23]. With the aim of expanding such previous findings, in the current study, the effectiveness and tolerability of Silver Cap® have been investigated from the perspective of preventing nipple fissure formation, focusing on the importance of creating a healthy and elastic nipple tissue to prevent skin damages [25].

For this purpose, Silver Cap® performances were evaluated on healthy women who started to apply the device either prior to start lactating or in the early lactating period.

2. Subjects and Methods

This study involved 38 women who started to apply the Silver Cap® device at 35 weeks of gestation (prior to lactation group, PL) and 149 women whose treatment started within 7 days from childbirth (during lactation group, DL). None of the patients reported nipple fissures at the day of enrollment. In accordance with our institution regulations, ethical approval was not sought since the data were the result of doctors' databases and patient-reported questionnaires, not including subject identifying or sensitive data. Nevertheless, ethical considerations were made with respect to the principles for research on human subjects as outlined in the Declaration of Helsinki.

PL women underwent the first visit (V0) at 35 weeks of gestation, while DL women underwent V0 on the day of delivery. At such first visit, all patients were instructed to use the device correctly.

Both groups were provided with questionnaires during 6 consecutive visits, scheduled at 7, 15, 30, 60, 90, and 120 days after delivery (from now on V7, V15, V30, V60, V90, and V120). Specifically, at each visit women were asked to rate the experienced nipple pain with a 4-point scale (from 0 to 3) of increasing pain levels (no pain, mild, moderate, severe). The questionnaire was designed to collect information also regarding: occurrence of nipple fissure, lactation modality (either exclusively breastfeeding or not), device usage frequency (never, occa-

sionally, always, only in case of painful symptoms), and occurrence of adverse events (frequency and type).

During V7, only women belonging to the PL group were also asked to report on how many hours per day during pregnancy (from week 35 of gestation to week 40) they were accustomed to use the device and to describe possible skin changes around the nipple area (no skin changes, softer, softer and more elastic, harder, thicker, thinner).

Statistical Analysis

Data analyses was conducted using SAS 9.4 (SAS Institute Inc., Cary, NC, USA). At each evaluated timepoint, frequency distribution of categorical variables was evaluated as count and percentage. Continuous variables were analyzed as count, mean, and interquartile range (IQR).

For categorical variables, differences between patient's groups (*i.e.*, PL and DL) were tested for significance using the Fisher's exact test. For each patient's group, categorical variable changes at different timepoints were tested using the McNemar test. Normality test was carried out for continuous variables by means of Shapiro-Wilks test. All tests were two-tailed and considered significant at a 5% level.

3. Results

3.1. Nipple Pain

To perform the statistical evaluations, pain scores reported by patients were pooled in two levels: level "0 - 1" (No pain/Mild) and level "2 - 3" (Moderate/Severe). Frequency distribution of nipple pain level divided by patient group and timepoint of evaluation are reported in Table 1. Overall, all patients reported a decreasing pain level from V7 to V120. As also graphically represented in Figure 1, between treatment groups comparison showed a significant ($p = 0.04$) lower proportion of Moderate/Severe pain in favor of the PL group, both at V7 (26.3% vs 45.6%) and V15 (7.9% vs 22.8%). Conversely, no significant differences in the PL and DL group were reported at V30 and for all the subsequent evaluated timepoints (*i.e.*, V60, V90, and V120).

The analysis of pain level changes at different timepoints showed that 7 out of 10 patients of the PL group with Moderate/Severe pain at V7 switched to a No pain/Mild level of pain at V15 (Table 2). Moreover, none of the 28 patients reporting a No pain/Mild score at V7 switched to the higher pain level ($p = 0.008$). For the PL patients, no further significant pain level changes were observed from V30 to V120 ($p > 0.05$). Concerning the DL group (Table 3), a significant proportion of patients switched to a lower level of pain at V15 (55.9%; $p < 0.001$), V30 (78.8%; $p < 0.001$), and V60 (77.8%; $p = 0.03$).

3.2. Nipple Fissures

All the data regarding the frequency distribution of nipple fissures occurrence

divided by patient group and timepoint of evaluation are reported in Table 4. As also shown in Figure 2, nipple fissures mostly affected DL patients ($p < 0.001$). Indeed, in the PL group, only one patient (2.6%) reported nipple fissures at V7 which resolved within V15. Starting from 30 days on from delivery, the observed proportion of patients reporting fissures were no longer significantly different between patients' groups and, at the last visit, no fissures were observed in none of the examined groups. Focusing on DL patients, nipple fissures significantly ($p < 0.001$) healed within 30 days from delivery (Table 5). Specifically, 27 patients

Table 1. Frequency distribution of nipple pain level divided by patient group and timepoint of evaluation.

		Patient group, N (%)		
Visit	Pain level[a]	PL	DL	p-value
V7	0 - 1	28 (73.7)	81 (54.4)	**0.04**
	2 - 3	10 (26.3)	68 (45.6)	
V15	0 - 1	35 (92.1)	115 (77.2)	**0.04**
	2 - 3	3 (7.9)	34 (22.8)	
V30	0 - 1	36 (97.3)	137 (93.2)	0.70
	2 - 3	1 (2.7)	10 (6.8)	
V60	0 - 1	35 (100)	129 (97.7)	1.00
	2 - 3	0	3 (2.3)	
V90	0 - 1	28 (100)	102 (99.0)	1.00
	2 - 3	0	1 (1.0)	
V120	0 - 1	23 (100)	80 (98.8)	1.00
	2 - 3	0	1 (1.2)	

a. 0 - 1 = No pain/Mild; 2 - 3 = Moderate/Severe.

Table 2. Frequency distribution of pain level changes at different visits in the PL group.

		Pain level[a] at V2, N (%)		
V1, V2	Pain level[a] at V1	0 - 1	2 - 3	p-value
7, 15	0 - 1	28 (100)	0	**0.008**
	2 - 3	7 (70.0)	3 (30.0)	
15, 30	0 - 1	34 (100)	0	0.16
	2 - 3	2 (66.7)	1 (33.3)	
30, 60	0 - 1	34 (100)	0	-
	2 - 3	1 (100)	0	
60, 90	0 - 1	28 (100)	0	-
	2 - 3	0	0	
90, 120	0 - 1	23 (100)	0	-
	2 - 3	0	0	

a. 0 - 1 = No pain/Mild; 2 - 3 = Moderate/Severe.

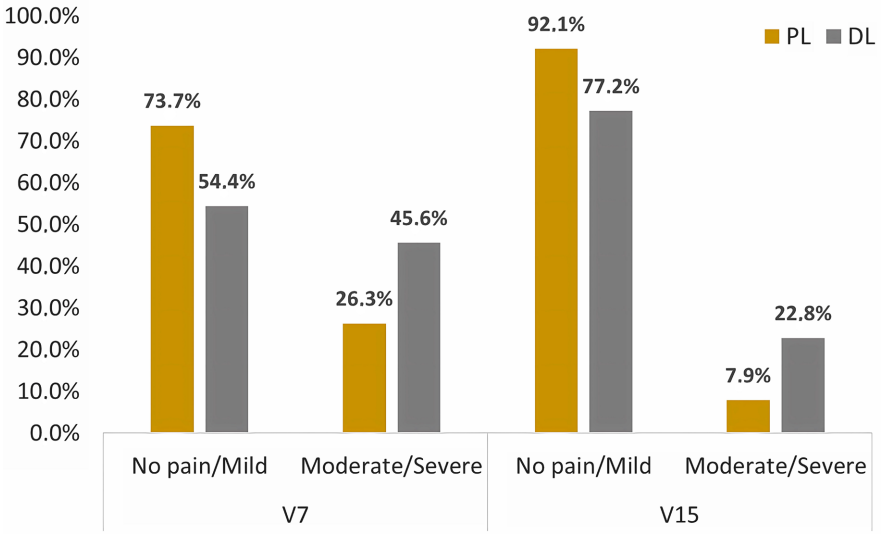

Figure 1. Frequency distribution of nipple pain level divided by patient group at V7 and V15.

Table 3. Frequency distribution of pain level changes at different visits in the DL group.

		Pain level[a] at V2, N (%)		
V1, V2	Pain level[a] at V1	0 - 1	2 - 3	p-value
7, 15	0 - 1	77 (95.1)	4 (4.9)	**<0.001**
	2 - 3	38 (55.9)	30 (44.1)	
15, 30	0 - 1	111 (97.4)	3 (2.6)	**<0.001**
	2 - 3	26 (78.8)	7 (21.2)	
30, 60	0 - 1	121 (99.2)	1 (0.8)	**0.03**
	2 - 3	7 (77.8)	2 (22.2)	
60, 90	0 - 1	101 (100)	0	0.32
	2 - 3	1 (50.0)	1 (50.0)	
90, 120	0 - 1	80 (100)	0	-
	2 - 3	0	1 (100)	

a. 0 - 1 = No pain/Mild; 2 - 3 = Moderate/Severe.

Table 4. Frequency distribution of nipple fissures divided by patient group and timepoint of evaluation.

	Patient group, N (%)		
Visit	PL	DL	p-value
V7	1 (2.6)	43 (28.9)	**<0.001**
V15	0	19 (12.8)	**0.02**
V30	0	6 (4.1)	0.60
V60	0	3 (2.7)	1.00
V90	0	2 (1.9)	1.00
V120	0	0	-

Table 5. Frequency distribution of nipple fissures presence at different timepoints in the DL group.

V1, V2	Fissures at V1	Fissures at V2, N (%)		p-value
		Absent	Present	
7, 15	Absent	103 (97.2)	3 (2.8)	**<0.001**
	Present	27 (62.8)	16 (37.2)	
15, 30	Absent	128 (99.2)	1 (0.8)	**0.001**
	Present	13 (72.3)	5 (27.8)	
30, 60	Absent	125 (99.2)	1 (0.8)	0.18
	Present	4 (66.7)	2 (33.3)	
60, 90	Absent	98 (98.0)	2 (2.0)	0.65
	Present	3 (100)	0	
90, 120	Absent	78 (100)	0	-
	Present	2 (100)	0	

a. 0 - 1 = No pain/Mild; 2 - 3 = Moderate/Severe.

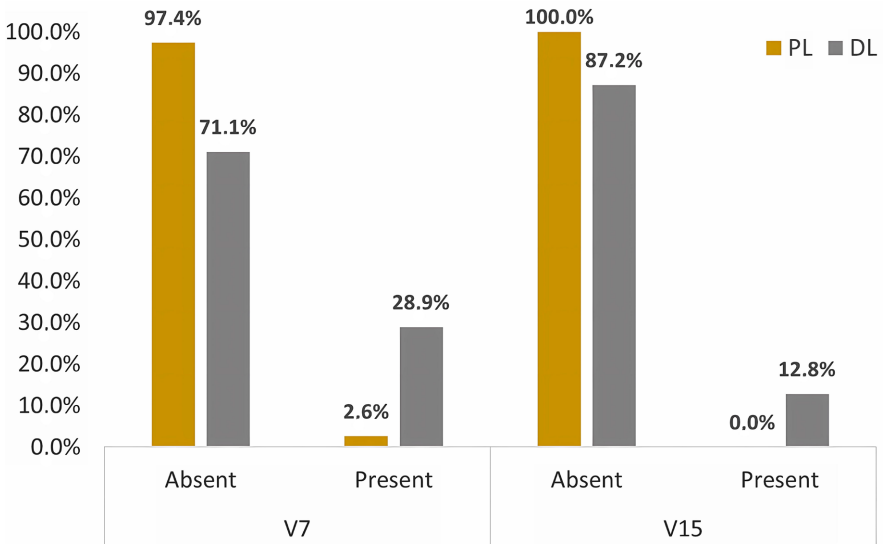

Figure 2. Frequency distribution of nipple fissures divided by patient group at V7 and V15.

(62.8%) healed within V15 and 13 patients (72.3% of the 18 left at V15) healed at V30.

3.3. Lactation Modality

Data regarding lactation modality (either exclusively breastfeeding or not) during treatment are reported in Table 6. On average, the proportion of patients exclusively breastfeeding, slightly decreased from V7 (81.6%, PL group; 85.8%, DL group) to V120 (69.6%, PL group; 76.5%, DL group) in both evaluated groups. Such proportions were not significantly different when comparing the two patients' groups at any evaluated timepoint.

Table 6. Frequency distribution of exclusive breastfeeding divided by treatment arm and timepoint.

	Patient group, N (%)		
Visit	PL	DL	p-value
V7	31 (81.6)	127 (85.8)	0.61
V15	31 (81.6)	123 (82.6)	1.00
V30	31 (81.6)	117 (80.7)	1.00
V60	27 (77.1)	104 (78.2)	1.00
V90	22 (78.6)	83 (79.8)	1.00
V120	16 (69.6)	62 (76.5)	0.59

3.4. Device Usage Frequency

Both patients' groups, were asked to always use the device until V15. Frequency distributions of device usage from V30 on are reported in Table 7 divided by patients' group. From V30 to V90, the majority of patients in both evaluated groups reported to always use the device without statistically significant differences between groups ($p > 0.05$ at V30, V60, and V90). Differently, at V120, there was a significantly ($p = 0.01$) different distribution with most of the PL patients reporting "never" (56.5%) and most of the DL patients (52.5%) reporting "always".

Regarding PL patients, they were also asked to report on device usage during pregnancy (hours/day). PL patients resorted to the use of the device from a mean of 6.0 hours/day (IQR 0.12) at week 35 of gestation to a maximum average of 13.3 hours/day (IQR 7.23) at week 39. Overall, from week 35 of gestation to week 40, PL patients used the device for an average time of 10.3 hours/day (IQR 5.14).

3.5. Skin Changes Associated to the Use of the Device

At V7, patients belonging to the PL group were asked to report on possible nipple skin changes associated to the use of the device during pregnancy (Table 8). The two most prevalent nipple changes were classified as "softer" (52.6%) and "softer and more elastic" (29.0%). In 4 patients (10.5%), no skin changes were observed, while only 1 patient (2.6%) per category reported either "harder", "thicker", or "thinner" skin.

3.6. Adverse Events and Drop-Out Frequency

None of the PL patients reported the occurrence of adverse events (AEs). As regards the DL group, 2 patients reported nipples irritation at V7 which might be ascribed to lactation *per se*. In addition, 4 patients started to suffer from mastitis, event that cannot be directly related to device usage though. Indeed, other factors might have contributed to the occurrence of mastitis: 2 patients concomitantly used topical gels; in 1 patient, mastitis started right after changing lactation

Table 7. Frequency distributions of device usage divided by patient group and timepoint.

Visit		Patient group, N (%)		p-value
		PL	DL	
V30	Never	0	16 (10.7)	0.08
	Occasionally	6 (15.8)	18 (12.1)	
	Always	32 (84.2)	109 (73.2)	
	Only in case of pain	0	6 (4.0)	
V60	Never	6 (17.1)	19 (14.4)	0.56
	Occasionally	3 (8.6)	23 (17.4)	
	Always	24 (68.6)	78 (59.1)	
	Only in case of pain	2 (5.71)	12 (9.1)	
V90	Never	7 (25.0)	24 (23.1)	0.62
	Occasionally	8 (28.6)	22 (21.2)	
	Always	13 (46.4)	52 (50.0)	
	Only in case of pain	0	6 (5.8)	
V120	Never	13 (56.5)	21 (26.3)	**0.01**
	Occasionally	5 (21.7)	12 (15.0)	
	Always	5 (21.7)	42 (52.5)	
	Only in case of pain	0	5 (6.3)	

Table 8. Frequency distribution of nipple skin changes reported by PL patients at V7.

Skin change	N (%)
No skin change	4 (10.5)
Softer	20 (52.6)
Softer and more elastic	11 (29.0)
Harder	1 (2.6)
Thicker	1 (2.6)
Thinner	1 (2.6)

modality (from exclusively breastfeeding to mixed modality); in the last patient, mastitis started after device usage discontinuation.

All the patients underwent all visits until V30. At last follow-up visit (V120), study population consisted of 24 PL patients and 83 DL patients (63.2% and 55.7% of the enrolled patients at V0, respectively).

4. Discussion

As it is well known, breastfeeding gives many advantages for both mother and child [26] [27] [28]. Nevertheless, most of mothers reporting episodes of nipple pain and fissures feel compelled to stop breastfeeding prematurely [16] or delay seeking treatment until substantial damage has already occurred [25].

In this context, our study aimed to collect data regarding nipple soreness and fissures occurrence rate in women using Silver Cap® from the 35th week of pregnancy or starting the treatment during breastfeeding, as a way to understand if the early promotion of nipple hydration might represent an efficient preventive strategy.

Results of the present study suggest that Silver Cap® can be safely and effectively employed as a device to prevent nipple pain and fissure formation in lactating women and that the best clinical outcomes are obtained when an early application of the device (*i.e.*, during the last period of pregnancy) is advised.

The preventive action of the device is supported by the comparison of the occurrence rates observed in the current study with respect to the prevalence data reported in literature regarding both nipple pain (45.6% as the highest percentage observed in the DL group vs 79% - 97% reported in literature) and nipple damage (28.9% as the highest percentage observed in the DL group vs 26.7% - 52.75% reported in literature) [29] [30] [31].

When comparing the DL patients' data to the ones reported in literature is worth noticing that the resulting percentages might have been biased by the fact that women belonging to the DL group started to apply the device within 7 days after delivery and thus, some of them were possibly not benefiting from the application of the device yet. As a consequence, a significant improvement of DL patients' symptoms was clearly observed after 15 days from delivery. Specifically, at V15, the percentage of DL patients reporting pain dropped to 22.8% and nipple fissure were found in the 12.8% of DL patients. Differently, in the PL group, percentages as low as 26.3% and 2.6% of nipple pain and fissures, respectively, were already achieved at V7, after 15 days from delivery none of the PL patients reported nipple fissure and only the 7.9% complained about nipple pain. Therefore, when comparing symptoms' occurrence rate of the two groups, more favorable results were observed in the PL group. However, such comparison should be interpreted within the limitation of having substantially different sample sizes, which might have led to the observation of more favorable results in the smaller group (*i.e.*, PL group).

Overall, all evaluated symptoms decreased along with the weeks of treatment in both groups. At last follow-up (120 days), none of the patients suffered from nipple fissures and only 1 DL patient (1.2%) still reported painful symptoms. Moreover, hinting at the safety of the device, none of the few reported adverse events (occurring in 6 DL patients out of 149 [4.0%]) was undoubtedly correlated to the use of the device.

Taking into account that PL and DL group did not significantly differ neither in term of breastfeeding modality or in frequency of device usage, the better clinical outcomes observed in the PL group with respect to the DL group might be attributed to the nipple skin changes experienced by PL patients. Indeed, the majority of PL patients reported to feel the skin around the nipple as "softer" (52.6%) and "softer and more elastic" (29.0%) after using the device during the pre-partum period. Such skin changes might have played a crucial role in pre-

paring the nipple area to breastfeeding, eventually preventing the occurrence of nipple pain and fissures.

Therefore, together with the findings of a previously conducted study [23], the results herein discussed indicate that Silver Cap® device serves as a safe and effective strategy to treat and prevent nipple pain and fissure formation in lactating women.

Main limitations of the study are represented by the lack of a control group and the small number of patients in the PL group. Moreover, in the interest of sensitive data protection, patients' demographic data were not collected and thus, homogeneity of baseline characteristics between groups was not assessed. As a future perspective, it would be interesting to confirm the encouraging results obtained in the PL group with a larger controlled study.

5. Conclusion

Results of the present study suggest that Silver Cap® is a safe and effective device for the prevention of nipple pain and fissure formation and that the most relevant clinical outcomes are obtained when applying the device during the last period of pregnancy. Indeed, after 120 days of treatment, the absence of painful symptoms was reported by the 100% and the 98.8% of women who started to use the device prior to and during the lactation period, respectively. Notably, no nipple fissures were observed and no adverse events directly correlated to use of the device were reported.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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