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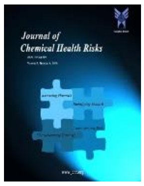

Reassessing Gentian Violet Application on the Umbilical Cord: Ally or Adversary?

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KEYWORDS

Umbilical cord care, Gentian violet, Dry cord care, Cord separation, Omphalitis

ABSTRACT:

Background: Gentian violet, a traditional antiseptic, has been widely used for umbilical cord care due to its antimicrobial properties.

Objective: To evaluate the impact of gentian violet paint application on the umbilical cord in term institutional deliveries, specifically assessing its influence on cord separation time, the incidence of umbilical granuloma, and the occurrence of umbilical infections, in comparison to the dry cord care practice recommended in institutional settings.

Methods: This case-control study was conducted between January 2015 and December 2016 in four maternity centers in Karaikal, comprising two government institutions and two private institutions among 178 term healthy newborns (liquid gentian violet was applied to the umbilical cord) and 211 gestation-matched healthy newborns (practicing dry cord care).

Results: The mean (SD) birth weight of the newborns was 3.1 (0.30) kg, and the mean (SD) gestational age was 37.6 (1.5) weeks. All parameters were statistically comparable between the groups, except for the selection criteria related to gentian violet application. The results indicate a statistically significant higher rate of umbilical granuloma in the gentian violet application group compared to the dry cord care group. Additionally, the cord separation time was significantly prolonged in the study subjects compared to the controls, with mean values of 28.7 (11.6) days (p=0.015) and 15.6 (0.24) days (p=0.022), respectively. However, the incidence of umbilical infections between the two groups was not statistically significant, with a mean (SD) value of 1.6 (0.2) and a p-value of 1.612. Binary logistic regression analysis revealed an odds ratio of less than 1 for covariates, indicating that these factors were not significant in influencing cord separation time or the formation of umbilical granuloma.

Conclusion: The application of gentian violet paint in term institutional deliveries appears to be more detrimental than beneficial, as it significantly delays cord separation, increases the risk of umbilical granuloma formation, and does not provide substantial protection against omphalitis.

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Introduction

Neonatal mortality, defined as the death of a newborn within the first 28 days of life, accounts for a significant proportion of under-five mortality globally. In India, the Neonatal Mortality Rate (NMR) was reported as 31 per 1000 live births in 2011, declining to 28 per 1000 live births in 2013.(1) This decline reflects progress, but it remains a matter of concern, particularly in states like Odisha, which recorded the highest NMR, in contrast to Kerala, with the lowest. Reducing neonatal mortality is a priority under the National Health Mission and aligns with the Sustainable Development Goals (SDGs) to end preventable deaths of newborns and children under five.(2)

One critical area of focus in neonatal care is umbilical cord management. The Ministry of Health and Family Welfare (MoHFW) in India advocates for the practice of “dry cord care” for both institutional and home deliveries. This practice involves keeping the umbilical cord stump clean and dry without the application of substances, aiming to minimize the risk of infection.(3) Complementing national guidelines, the World Health Organization (WHO) recommends a targeted approach based on neonatal mortality levels. In regions with high neonatal mortality (30 or more deaths per 1000 live births), WHO advises the daily application of 7.1% chlorhexidine digluconate aqueous solution or gel delivering 4% chlorhexidine to the umbilical cord stump during the first week of life. Conversely, for regions with lower neonatal mortality, clean and dry cord care is recommended, with chlorhexidine use limited to replacing harmful traditional substances when necessary.(4)

Despite these evidence-based recommendations, cultural practices regarding umbilical cord care vary widely across different regions of India and the world. In many areas, traditional substances are applied to the umbilical cord stump, some of which are harmful, while others are deemed harmless. Harmful practices include the application of ash, cow dung, or soil, which pose a high risk of introducing infections such as neonatal tetanus.(5-7) Conversely, practices involving substances like coconut oil, breast milk, or herbal remedies are often perceived as benign, though their efficacy and safety remain under-researched.(8-10)

Gentian violet, a triphenylmethane dye with antimicrobial and antifungal properties, is one such substance used in traditional umbilical cord care in certain regions. Historically, gentian violet has been employed in various medical applications, including treating fungal infections and wounds.(11) However, its use in neonatal care, specifically umbilical cord management, is less studied and remains controversial. The practice is particularly prevalent in coastal regions of Karaikal in the Union Territory of Puducherry, where gentian violet is applied to the umbilical stump as part of local neonatal care customs.

The application of gentian violet on the umbilical cord is hypothesized to influence several outcomes related to cord health. One critical concern is the timing of umbilical stump separation. While delayed stump separation may not always indicate pathology, it can be associated with underlying infections or other complications.(12) Additionally, the development of umbilical granulomas – small, benign overgrowths of tissue at the umbilical stump – is a common condition that may be influenced by cord care practices. Finally, the risk of umbilical infections, including omphalitis, a potentially life-threatening condition characterized by redness, swelling, and purulent discharge around the umbilical stump, warrants careful evaluation in the context of gentian violet use.(13)

Several studies have explored the efficacy of chlorhexidine and other interventions in reducing neonatal mortality and cord-related infections.(14) However, data on gentian violet's role in umbilical cord care are sparse. While its antimicrobial properties may offer some benefits, potential risks, including cytotoxicity and delayed wound healing, cannot be overlooked. This study aims to address these gaps in knowledge by investigating the impact of gentian violet application on key neonatal outcomes related to umbilical cord care. Specifically, the study will compare the incidence of delayed umbilical stump separation, the occurrence of umbilical granulomas, and the risk of umbilical infections among newborns subjected to gentian violet application versus those managed with dry cord care.

Materials and Methods

This case-control study was conducted between January 2015 and December 2016 in four maternity centers in

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Karaikal, comprising two government institutions and two private institutions. Approval from the institutional ethics committee was obtained prior to the commencement of the study. A total of 178 term healthy newborns delivered at the two private institutions, where liquid gentian violet was applied to the umbilical cord from birth to ten days of life and beyond, were enrolled as study subjects. Parental consent was obtained for all participants. Simultaneously, 211 gestation-matched healthy newborns from the two government institutions, practicing dry cord care, were included as controls. Exclusion criteria for the study group included newborns with simultaneous application of other substances, premature births, prolonged rupture of membranes, maternal fever, urinary tract infections, and chorioamnionitis. For the control group, any newborn with even a single application of any substance on the umbilical cord was excluded.

Baseline antenatal, birth, and neonatal parameters were recorded for all participants. The primary outcomes assessed included the timing of umbilical cord separation, the incidence of persistent umbilical granuloma beyond three weeks of cord separation, and the occurrence of umbilical infection, assessed by positive culture from the umbilical base on day 3 and day 10 and/or the presence of frank umbilical sepsis. The sample size was calculated with 80% power and 95% confidence to detect a difference of 12 days in cord separation time between the study and control groups.

Double blinding was implemented to ensure unbiased data collection. The hospital staff conducting deliveries and the trained medical personnel filling out the proforma and collecting umbilical swabs were blinded to the study objectives. The study subjects unintentionally received liquid gentian violet applications, the composition of which was not standardized. The application was performed from the tip to the base of the cord stump once daily from birth to at least ten days of life, including during hospital stays and at home. Sponge baths were given to all newborns up to 15 days of life, after which daily baths were initiated. Among the cases, 86 newborns began everyday baths from day 16 of life, and 92 newborns began from day 40 of life, irrespective of the timing of cord separation.

Both study and control groups were followed up in the community for a total of six weeks. Follow-up was ensured through postal addresses, mobile numbers, and records maintained by local health nurses. Umbilical swabs for culture and gram staining were processed at Thyrocare, Navi Mumbai, using Blood Agar and MacConkey agar media. The timing of cord separation and the occurrence of raw, friable granulomas with bleeding points were recorded.

Data analysis was performed using SPSS version 16. The timing of cord separation and the occurrence of granulomas between the study and control groups were compared using the Mann-Whitney U test. The t-test was employed to assess the significance of umbilical infections between the groups. Binary logistic regression analysis was conducted to identify risk factors for delayed cord separation, umbilical granuloma, and infections. Covariates included sex of the baby (male/female), infections, mode of delivery (normal vaginal, assisted, LSCS), type of cord tie (thread, plastic clamp), length of the cord (≤2.5 cm, >2.5 cm), umbilical vasculature (triple vessel, single umbilical artery), timing of the first bath (before cord separation, after cord separation), and frequency of bathing (>3 times/week, ≤3 times/week). A p-value of <0.05 was considered statistically significant.

Results

A total of 178 term newborns who received gentian violet application on the umbilical stump and 211 term newborns who underwent dry cord care participated in the study. The mean (SD) birth weight of the newborns was 3.1 (0.30) kg, and the mean (SD) gestational age was 37.6 (1.5) weeks. Baseline data of the study subjects and controls are presented in Table 1. All parameters were statistically comparable between the groups, except for the selection criteria related to gentian violet application.

Table 2 provides a comparison of the occurrence of umbilical granuloma, umbilical infections, and cord separation time between the study subjects and controls. The results indicate a statistically significant higher rate of umbilical granuloma in the gentian violet application group compared to the dry cord care group. Additionally, the cord separation time was significantly prolonged in the study subjects compared to the controls, with mean values of 28.7 (11.6) days

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(p=0.015) and 15.6 (0.24) days (p=0.022), respectively. However, the incidence of umbilical infections between the two groups was not statistically significant, with a mean (SD) value of 1.6 (0.2) and a p-value of 1.612.

Binary logistic regression analysis revealed an odds ratio of less than 1 for covariates, indicating that these factors were not significant in influencing cord separation time or the formation of umbilical granuloma.

Discussion

Gentian violet (GV), also known as crystal violet, is a triphenyl methane dye with a broad spectrum of antimicrobial properties, including antibacterial, antifungal, anti-helminthic, anti-trypanosomal, anti-angiogenic, and anti-tumor activities.(15) Traditionally, gentian violet was an integral component of "triple dye," a mixture of brilliant green, gentian violet, and proflavine hemisulfate, used as an umbilical antiseptic.(16) However, the exact mechanism of GV's antimicrobial effects remains unclear despite multiple hypotheses, including the inhibition of reduced NADPH oxidases, formation of free radicals, creation of unionized complexes with bacteria, inhibition of protein synthesis and glutamine synthesis, uncoupling of oxidative phosphorylation, or the inhibition of bacterial cell wall formation.(17-19)

The gentian violet preparation used today differs from the original United States Pharmacopeia (USP) formulation of hexamethyl pararosaniline. Modern formulations are often a mixture of hexamethyl rosaniline, pentamethyl rosaniline, and tetramethyl pararosaniline. This variability in composition may influence its antimicrobial activity and safety profile, warranting cautious consideration in its application.(20)

Gentian violet has been widely used in the prevention of bacterial colonization of the umbilical stump following delivery.(21) It is generally considered safe, with the reported toxicity in humans limited to isolated case reports. Moreover, clinical trials involving GV have typically demonstrated mild or no adverse effects, and the FDA continues to allow its over-the-counter sale. However, the broader adoption of hygienic delivery practices, such as clean delivery chains, rooming-in with the mother, and limiting personnel in postnatal wards, has significantly reduced umbilical colonization rates, often outperforming the use of topical antiseptics.(22-24)

A key concern associated with antimicrobial treatments for umbilical cord care is the prolonged cord separation time, which can distress parents and physicians. The present study corroborates existing evidence that gentian violet application delays cord separation significantly compared to dry cord care. In our study, the mean cord separation time was 9 days with dry cord care and 21 days with gentian violet application, reflecting a prolongation of approximately two weeks. This finding aligns with earlier studies, such as Oudesley et al.,(25) who reported a mean separation time of 7 days with dry cord care and 15 days with triple dye, and Wilson et al.,(26) who noted that 10% of cords treated with triple dye did not fall off even after three weeks.

The delayed cord separation with GV is hypothesized to result from reduced bacterial colonization of the umbilical stump, which diminishes leukocyte infiltration and the subsequent digestion of the cord tissue by leukocytes.(27) While this antimicrobial effect of GV may serve to reduce infection rates, its role in prolonging cord separation raises questions about its routine use in neonates, particularly when alternative practices like dry cord care achieve comparable or superior outcomes in cord healing and separation time.

Umbilical granuloma is one of the most common umbilical masses in newborns, requiring clinical management if it persists beyond three weeks of cord separation. While granuloma formation due to gentian violet application has not been previously reported, theories suggest that subclinical infection and low-grade inflammation may play a role in its etiology.(28) The present study observed a significantly higher incidence of umbilical granulomas in newborns treated with gentian violet compared to those who underwent dry cord care.

A potential explanation for this finding is the non-standardized composition of commercially available gentian violet, which includes pentamethyl pararosaniline chloride and tetramethyl pararosaniline dyes as adulterants. These compounds may trigger a low-grade inflammatory response, contributing to granuloma formation. Additionally, improper application techniques, such as applying GV from the

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tip to the base of the cord stump, may exacerbate this inflammatory reaction.

Our study highlights the need to critically evaluate the practice of gentian violet application in umbilical cord care, particularly in light of its potential to prolong cord separation time and increase the incidence of umbilical granulomas. While its antimicrobial properties are well-established, the unintended consequences observed in this study call for a balanced approach that considers both the benefits and potential risks of gentian violet. Future studies are warranted to explore the mechanisms underlying these outcomes, as well as to assess alternative approaches to umbilical cord care that prioritize safety, effectiveness, and cultural acceptability.

Conclusion

The application of gentian violet paint in term institutional deliveries appears to be more detrimental than beneficial, as it significantly delays cord separation, increases the risk of umbilical granuloma formation, and does not provide substantial protection against omphalitis compared to the "Five Cleans" protocol followed in institutional deliveries.

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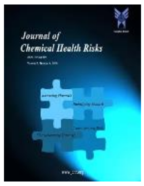

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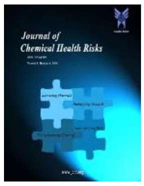
Table 1: Baseline characteristics of study group

	Study subjects N=178	**Control N=211**
Birth weight (in kg)	3.4 (0.36)	52.8(0.37)
Gestational age (in weeks)	37.3(1.1)	37.9 (1.4)
Sex of baby (male), N (%)	84 (47.2)	102(48.3)
Mode of birth (LSCS), N (%)	98 (55.0)	85(40.2)
Day of initiating GV paint application (birth), N (%)	178 (100)	0(0)



Total duration of GV paint (in days)	15 (0.41)	0(0)
Timing of first bath ≤Day 40, N (%)	139 (78.0)	144(68.2)
Frequency of bathing ≤3/ week, N (%)	133 (74.7)	159 (75.3)

Table 2: Comparison of complications following topical application of gentian violet with dry cord

	Gentian violet application (N=178)	**Dry cord (N=211)**
Timing of cord separation	21.6 (0.18)	9.7 (0.22)
Umbilical granuloma	38.2 (11.4)	11.3 (9.7)
Umbilical infection	1.5 (0.1)	0.8 (0.09)

Table 3: Binary logistic regression analysis

	Odds ratio (95% CI)
Sex	0.7 (131.0-144.9)
Mode of delivery	0.6 (94.5-107.1)
Type of cord tie	0.4 (119.1-125.6)
Length of cord	0.6 (62.0-89.2)
Umbilical vasculature	0.5 (100.0 to 144.7)
Timing of first bath	0.8 (166.8-180.9)
Frequency of bathing	0.7 (184.9-132.0)