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Semipermeable membranes and hypernatremic dehydration in preterms. A randomized-controlled trial

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ABSTRACT

Background: Hypernatremic dehydration is a complication of preterm infants with reportedly high morbility. In preterm infants, this happens due to a combination of low fluid intake, transepidermal water loss (TEWL), and immaturity of kidney function. Semipermeable membranes are self-adhesive membranes that can be applied as an artificial skin to reduce TEWL.

Aims: To test the hypothesis that early application of a semipermeable membrane (Tegaderm™) in preterm infants ≤30 weeks could result in a significant reduction of hypernatremia (serum Na > 145 mEq/l) during the first 15 days of life.

Study design: Randomized controlled trial (UMIN000010515).

Subjects: 164 consecutive newborns with gestational age ≤ 30 weeks, absence of congenital skin defects, and duration of admission ≥ 15 days. Patients were randomized to receive semipermeable membrane (n = 82) or no membrane (n = 82) for the first 15 days of life.

Outcome measures: The primary endpoint of the study was the incidence reduction of hypernatremia (Na > 145 mEq/l). Secondary endpoints included: postnatal weight loss (WL) and time to birth weight (BW) recovery.

Results: Incidence of hypernatremia in the control and semipermeable membrane group was 59.7% and 41.6%, respectively (p = 0.030). Postnatal WL was larger in the control group (13.9 ± 5.6% *vs* 11.1 ± 3.4%, p = 0.005) and occurred later than the semipermeable membrane group (5.4 ± 2.3 *vs* 4.5 ± 1.4 days, p = 0.005). Time to BW recovery was also longer for control group (13.5 ± 4.3 *vs* 11.9 ± 3.2 days, p = 0.016).

Conclusions: Early application of skin semipermeable membrane to ≤30 week preterm is associated with decreased incidence of hypernatremia, decreased %WL, and earlier BW recovery. No complications were observed with membrane application.

1. Introduction

Hypernatremic dehydration is a severe complication of preterm newborn with a reportedly high morbidity [1,2]. Neonatal hypernatremia is defined as a serum sodium concentration > 145 mEq/l. Up to 40% of preterm infants with gestational age (GA) < 28 weeks and birth weight (BW) < 1250 g develop hypernatremia; similarly, incidence in newborn with GA < 27 weeks increases to 69.7% [1]. Hypernatremic dehydration occurs when body water is lost in excess of sodium. In preterm infants, this happens due to a combination of low fluid intake, transepidermal water loss (TEWL), and immaturity of kidney function. The high body area to weight ratio and incomplete keratinization of the stratum corneum determine larger insensible water losses (IWL) [3]. Keratinization of the stratum corneum is still incomplete at 26 weeks, and complete skin barrier maturation only occurs in the first 2 to 4 weeks of postnatal age in preterm infants. Other factors, such as the presence of iatrogenic skin lesions or skin defects (*e.g.* omphalocele, or gastroschisis), phototherapy, radiant heat, and a non-humidified environment can also increase TEWL [4].

Treatment of hypernatremic dehydration consists of high-volume fluid replacement therapy [5]. Prevention of hypernatremia includes late supplemental administration of sodium, nursing in a high-humidity

Abbreviations: GA, gestational age; BW, birth weight; TEWL, trans-epidermal water loss; IWL, insensible water loss; ELBW, extremely low birth weight; IG, interventional group; CG, control group; IVH, intraventricular hemorrhage; PDA, patent ductus arteriosus; BPD, bronchopulmonary dysplasia; NEC, necrotizing enterocolitis; CPAP, continuous positive airway pressure; NICU, neonatal intensive care unit; SGA, small for gestational age

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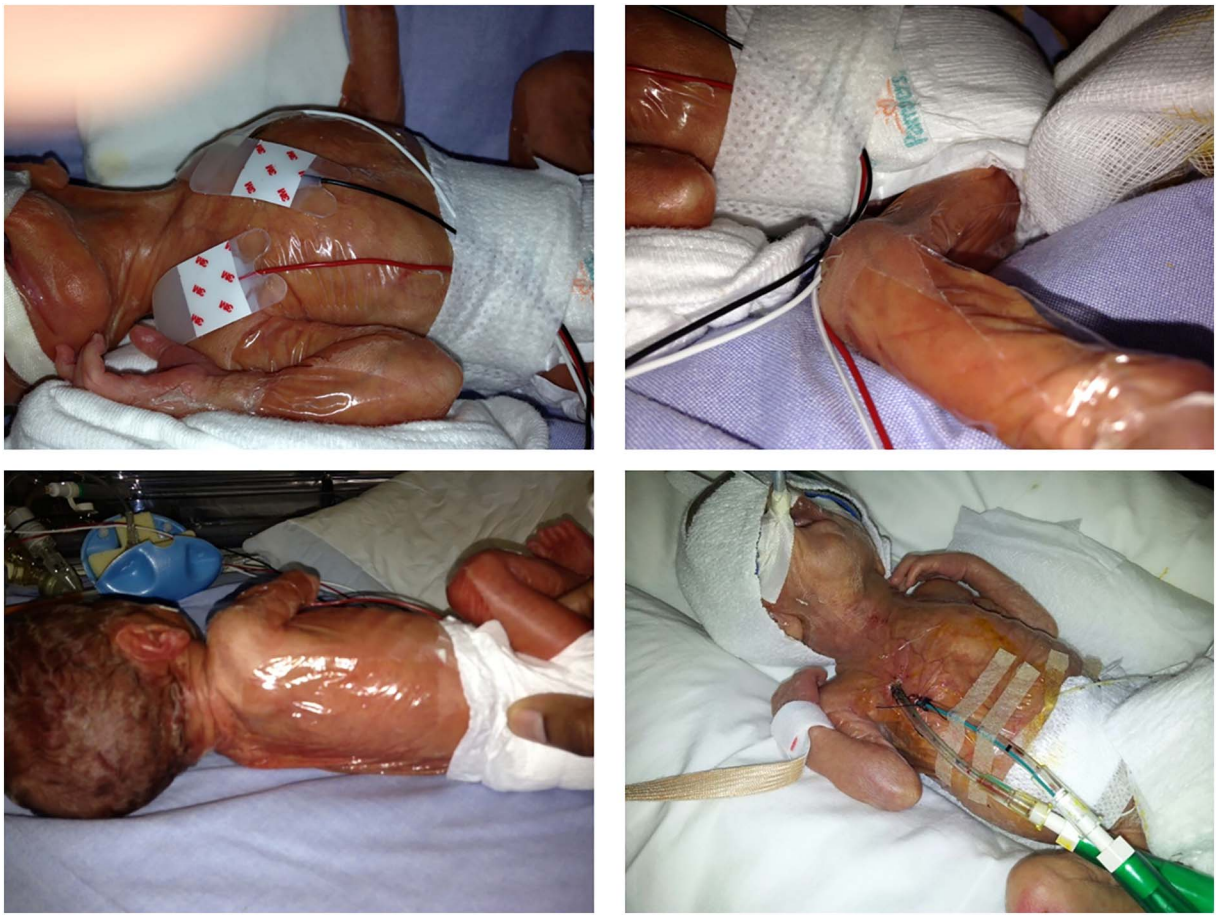

Fig. 1. The picture shows the feasibility of Tegaderm™ membrane application to neonatal chest (top-left panel), limbs (top-right panel), dorsum (bottom-left panel), and chest with chest tubes and invasive lines in place (bottom-right panel).

(60–80%) environment, and daily monitoring of body weight and electrolytes. Particular attention should be paid to the volume and composition of all i.v. solutions used (*e.g.* flushes, drugs, colloids, *etc.*). Semipermeable membranes are thin, self-adhesive membranes used to cover and protect newborn skin. When applied to extremely-low birth weight (ELBW) infants as an artificial skin, they have been shown to significantly reduce TEWL without interfering with skin integrity and development [6,7]. Although semipermeable membranes have been in use since late 1980s, there is been a resurgence of interest in their use for prevention of hypernatremic dehydration in preterm newborns [6,8]. More recent studies have also shown that semipermeable membranes can be a valid barrier against external pathogens and may help reduce the incidence of infections resulting from the use of probes and patches [9].

The aim of this study was to investigate the efficacy of semipermeable polyurethane membranes in reducing the incidence of hypernatremic dehydration in preterm newborn ≤ 30 weeks. We hypothesized that the early application of a semipermeable membrane would result in a significant reduction of the incidence of hypernatremia in preterms.

2. Materials and methods

2.1. Study design and participants

This study was approved by our institutional review board (IRB) and was registered with the UMIN Clinical Trials Registry (ID UMIN000010515). This was a prospective, randomized clinical trial designed to determine the efficacy of a semipermeable skin membrane (Tegaderm™, 3M, St. Paul, MN, USA) in reducing the incidence of hypernatremia in preterm newborns. The study was conducted at an academic, tertiary referral centre. The studied population consisted of 164 preterm newborns consecutively admitted to our Neonatal Intensive Care Unit (NICU) and enrolled for the study from September 2013 to January 2016. Inclusion criteria of the study were: gestational age ≤ 30 weeks, absence of congenital skin defects (*e.g.* gastroschisis, meningomyelocele, omphalocele) or obstetric trauma, duration of admission to the NICU of at least 15 days. The exclusion criteria included: chromosomal syndromes, major malformations, and congenital infectious cutaneous diseases. Patients were randomized in a 1:1 ratio to receive the membrane (*i.e.* interventional group, IG) or no skin membrane (*i.e.* control group, CG). Randomization was performed according to a computer-generated list of random numbers and treatments were allocated in blocks of variable size. Study investigators were blind to the allocation sequence of the infants. Written informed parental consent was obtained before enrolment and randomization.

2.2. Application of semipermeable membrane and care protocol

The semipermeable membrane was applied to the IG infants' chest, abdomen, back, and extremities within the first 6 h of life and left in place for at least 2 weeks and until it started to self-detach from the skin (Fig. 1). In all infants, the membrane was applied by nurses who received a dedicated training. No membrane was applied for the babies in the CG. Fluid supplementation in all babies in the study was managed in accordance with our departmental protocols. Briefly, during the first week of life fluid intake was progressively increased from 60 to 150 ml/Kg/day in infants with GA > 26 weeks, and from 70 to 150 ml/Kg/day