

# A randomised control trial of clingfilm for prevention of hypothermia in term infants during phototherapy

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## ABSTRACT

**Introduction:** This study aimed to compare the core, abdominal wall, and plantar temperatures of well jaundiced term infants undergoing phototherapy with or without clingfilm covering the lower two-thirds of the upper end of their bassinets.

**Methods:** This was a randomised controlled trial carried out in a tertiary university hospital on normal healthy term infants undergoing phototherapy. 106 eligible infants were randomised to receive phototherapy with (n=52) or without (n=54) the use of clingfilm during a two-hour period. Subsequently, after nappy change and feeding, they were crossed over to receive phototherapy without or with the clingfilm in place, respectively. Their body temperatures were measured at zero and two hours after phototherapy.

**Results:** There was no significant difference in their core, abdominal wall and plantar temperatures at baseline and after two hours of phototherapy (p-value is greater than 0.05) between infants with and without the use of clingfilm. Irrespective of the use of clingfilm, there was significant (p-value is less than 0.001) increase in core body temperatures after two hours of continuous phototherapy, with resultant hyperthermia (greater than 37.5 degree Celsius) in 42 percent of infants when under clingfilm and 35.8 percent when without clingfilm. A few (2.8 percent) infants, though statistically not significant, became mildly hypothermic after two hours of phototherapy when clingfilm was not used (p-value is greater than 0.05).

**Conclusion:** Hyperthermia was common during phototherapy, irrespective of the use of clingfilm. Hypothermia was rare and the preventive role of clingfilm is not certain.

**Keywords:** clingfilm, hypothermia, neonatal hypothermia, phototherapy

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## INTRODUCTION

In term infants with clinically significant hyperbilirubinaemia, phototherapy is usually carried out in bassinets. To ensure the efficiency of phototherapy, the trunks of these infants are exposed. In air-conditioned neonatal intensive care units (NICUs) or nurseries where environmental temperature is maintained at around 25°C or lower, there is concern that infants undergoing phototherapy may develop hypothermia. Even in nurseries with ambient temperature between 26 and 30°C, hypothermia has been reported<sup>(1)</sup>. In an attempt to prevent neonatal hypothermia in infants undergoing phototherapy, some NICUs place clingfilm over the lower two-thirds of the upper edge of their bassinets. Unlike infant incubators, a piece of clingfilm costs very little, is easy to apply, allows ease of nursing and is readily disposable after use or when soiled. It is speculated that the clingfilm so placed may decrease heat loss due to radiation and convection. On the other hand, as heat is emitted from phototherapy lights, the latter may be sufficient to keep the infants warm during phototherapy without the use of clingfilm. Review of medical literature published via MEDLINE between 1966 and 2002 shows that no published studies have been reported on the effectiveness of clingfilm for the prevention of hypothermia in term infants undergoing phototherapy.

The objectives of the present study were to compare the core body temperature, abdominal skin temperature, plantar temperature, core-plantar temperature gap, and abdominal-plantar temperature gap of well jaundiced term infants undergoing phototherapy with or without clingfilm placed over the lower two-thirds of the upper end of their bassinets. The ultimate objective was to determine whether placing a piece of clingfilm

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in such a manner would reduce the incidence and severity of hypothermia in healthy term infants undergoing phototherapy. We hypothesised that there would be no significant difference in the proportion of infants with hypothermia (defined as a core temperature of  $<36.5^{\circ}\text{C}$ ) between infants undergoing phototherapy with and without the use of clingfilm.

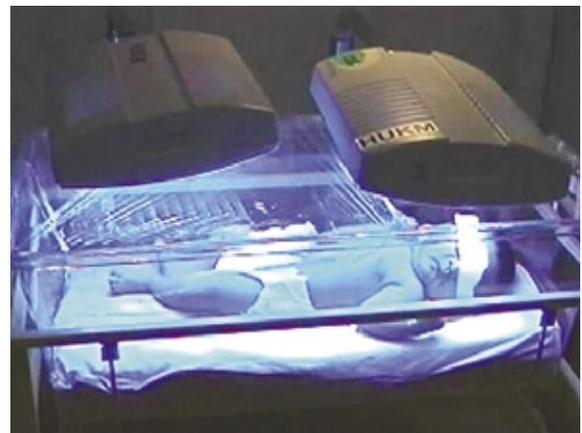
## METHODS

This was a randomised controlled study carried out over a four-month period between January 30, 2005 and May 30, 2005 in the NICU and postnatal wards of Hospital Universiti Kebangsaan Malaysia. Approval from our institutional scientific and ethics committees was obtained prior to the commencement of this study. Written parental consent was obtained prior to recruitment of cases. The inclusion criterion was healthy term infants admitted to the NICU or postnatal wards for phototherapy. The exclusion criteria were: preterm infants of gestation less than 37 completed weeks, congenital abnormalities, or unwell infants. Eligible infants with severe hyperbilirubinaemia were recruited only after their serum bilirubin had decreased to  $<300\ \mu\text{mol/L}$ .

Upon recruitment, an infant was first fed to satiate its hunger. Its clothing was then removed except for its nappy secured below its umbilical cord. Phototherapy was carried out with the infant nursed in a bassinet. A phototherapy light panel (Madelo AG, Medical Technology, Baar, Switzerland) was placed at a standard distance of 25 cm above the infant. The irradiance of phototherapy lights was maintained at a constant level. The core temperature of the infant was measured using an infrared tympanic membrane thermometer (Braun ThermoScan IRT, 3020, Braun GmbH, Kronberg, Germany) with its probe covered by a disposable plastic cover and placed in the infant's external ear canal at zero and two hours during each of the two study phases. Core temperature was measured within one second of placement of the probe in the external ear canal, as indicated by the sound of a beep emitted by the thermometer that displayed temperature readings on its screen.

Abdominal skin temperature was measured using a thermistor temperature probe (Yellow Springs Instrument Co, Yellow Springs, OH, USA) of 5-mm diameter placed on the infant's right hypochondrial region at 3 cm above and away from its umbilicus. This site was chosen to prevent the temperature probe from being sandwiched between the infant's skin and the mattress of its bassinet. Falsely-high abdominal skin temperature reading might be caused by heat

generated from rubbing of the probe by an infant's trunk pressed against the mattress when nursed in the prone position. A second (peripheral) temperature probe was placed on the plantar aspect of the infant's forefoot. Both temperature probes were secured and each covered with a disposable cover (Kendall Argyle Care Covers™, Ludlow Company LP, Chicopee, Canada) with adhesive hydrogel. Temperatures at both sites were measured continuously and displayed on a monitor (SpaceLab Medical Inc, Redmond, WA, USA). Readings at zero, one, and two hours during each study phase were recorded. Because of the variable intervals at which infants needed their next feeds (between two and three hourly), the end-point of each of the two phases of the study was set at two hours.



**Fig. 1** Photograph of an infant under phototherapy with a piece of clingfilm placed over the lower two-thirds of its bassinet.

The clingfilm used was from a single manufacturer (PE Stretch Film, Sepadukinetik, Kuala Lumpur, Malaysia). It was 0.02 mm thick and 500 mm wide, and was placed on the open end of infant's bassinet, such that the lower two-thirds of the body of an infant (from the level of its neck to its feet) was under the clingfilm (Fig. 1). Infants were randomised to receive phototherapy with or without clingfilm during Phase I, based on information contained in sequentially-numbered sealed envelopes. The envelopes were prepared beforehand, shuffled randomly and then numbered serially. During the second phase of the study, infants who previously received phototherapy under clingfilm were given phototherapy without clingfilm, and vice versa. When clingfilm was in use, a notice was placed on the edge of an infant's bassinet, reminding staff and visitors not to remove the clingfilm during the two-hour period. At the end of Phase I of the study, infants were removed from their

**Table I. Comparison of basic data of infants undergoing phototherapy with or without clingfilm during Phase I of study.**

Variable	With clingfilm (n=52)	Without clingfilm (n=54)	95% CI of difference between means	p-value
Male (%)	28 (53.8)	32 (59.3)	-	0.8
Malays (%)	32 (61.5)	33 (61.1)	-	1.0
Admitted to NICU (%)	24 (46.2)	29 (53.7)	-	0.4
Mean birth weight in g (SD)	3,015 (366)	3,068 (433)	-208, 102	0.5
Mean gestation in weeks (SD)	39.0 (1.1)	38.7 (1.1)	-0.1, 0.7	0.2
Median age at recruitment in days (IQR)	4.0 (2.0)	4.0 (3.0)	-	0.3#
Median total serum bilirubin at recruitment in $\mu\text{mol/L}$ (IQR)	253 (58)	262 (50)	-	0.6#
Mean environmental temperature at recruitment in $^{\circ}\text{C}$ (SD)	26.0 (3.1)	25.9 (3.3)	-1.1, 1.3	0.9
Two phototherapy lights in use (%)	18 (34.6)	18 (33.3)	-	0.9
Phototherapy under an electric fan (%)	26 (50.0)	24 (44.4)	-	0.6

CI: confidence intervals; NICU: neonatal intensive care unit; SD: standard deviation; IQR: interquartile range; #: Mann-Whitney U test.

bassinets, covered with a piece of linen and blanket, and fed on demand. After nappy change and feeding, phototherapy was resumed. Before commencement of Phase II of study, the skin temperature probes were checked to ensure secured placement.

Based on the World Health Organisation (WHO) recommendations, normothermia was defined as a core temperature of between  $36.5^{\circ}\text{C}$  and  $37.5^{\circ}\text{C}$ <sup>(1,2)</sup>. Hypothermia was defined as a core temperature of  $<36.5^{\circ}\text{C}$ . Hypothermia was categorised as mild when the core temperature was between  $36.0$  and  $36.4^{\circ}\text{C}$  or the skin temperature was between  $35.5$  and  $35.9^{\circ}\text{C}$ , moderate when the core temperature was between  $32$  and  $35.9^{\circ}\text{C}$  or the skin temperature was between  $31.5$  and  $35.4^{\circ}\text{C}$ , and severe when the core temperature was  $<32^{\circ}\text{C}$  or the skin temperature was  $<31.5^{\circ}\text{C}$ <sup>(2)</sup>. Hyperthermia was defined as a core temperature of  $>37.5^{\circ}\text{C}$  or skin temperature was  $\geq 38.0^{\circ}\text{C}$ . In a previous pilot study carried out in this NICU using abdominal skin temperature probes, the incidences of hypothermia in infants undergoing phototherapy with or without clingfilm in place were 30% and 55%, respectively. In order to detect a 25% difference in the incidence of hypothermia when infants were given phototherapy with or without the use of clingfilm (with a power of 80% (two-tailed) and an alpha value of 0.05), a sample size of at least 47 infants was required in each group.

The Statistical Package for Social Sciences (SPSS) version 10.1 (Chicago, IL, USA) was used for analysis of data. Basic data (gender, ethnic groups, birth weight, gestation, age of phototherapy,

and baseline body temperatures) between the two groups of infants randomised to receive phototherapy with or without clingfilm during Phase I were compared. The chi-square test (or Fisher exact test for expected value of less than five) was used for comparison of categorical variables between groups. For comparison of continuous variables between groups, the Student's t-test was used for normally distributed data and Mann-Whitney U test for data with skewed distribution. Paired Student's t-test was used for within-group analysis of normally distributed continuous variables and Wilcoxon signed rank test for variables with skewed distribution. All tests were two-tailed. A p-value of less than 0.05 was considered to be statistically significant.

## RESULTS

During the study period, 114 healthy term infants were admitted for phototherapy. Parental consent was obtained from 108 infants. Eight infants were excluded from the study for the following reasons: no parental consent (n=6), and phototherapy was terminated prior to recruitment (n=2). The remaining 106 infants were recruited, of which 52 were randomised to undergo phototherapy with clingfilm and 54 infants without clingfilm during Phase I of the study.

The basic data between these two groups of infants were compared (Table I). There was no significant difference in their gender distribution, ethnic distribution, proportion of infants admitted to the NICU or postnatal wards, mean birth weight,

**Table II. Comparison of core, abdominal wall and plantar temperatures of infants with or without use of clingfilm during the two-hour phototherapy period of Phase I.**

Body temperature	Time interval (hours)	With clingfilm (n=52)	Without clingfilm (n=54)	95% CI of difference between means	p-value
Core (ear drum)	0	36.8 (0.5)	37.0 (0.4)	-0.4, 0.01	0.06
	2	37.5 (0.5)	37.5 (0.5)	-0.2, 0.2	0.9
Abdominal wall	0	35.5 (0.7)	35.4 (0.9)	-0.2, 0.4	0.5
	1	36.5 (0.7)	36.3 (0.8)	-0.1, 0.5	0.2
	2	36.8 (0.6)	36.7 (0.6)	-0.1, 0.3	0.3
Plantar	0	31.3 (2.4)	31.2 (2.5)	-0.8, 1.0	0.8
	1	32.6 (4.8)#	31.9 (5.6)#	-	0.09
	2	33.8 (2.4)	32.9 (2.9)	-0.06, 2.0	0.07
Abdominal wall-plantar temperature gap	0	4.2 (2.0)	4.2 (2.2)	-0.8, 0.8	1.0
	1	3.8 (2.2)	4.5 (2.7)	-1.7, 0.2	0.1
	2	2.2 (2.7)#	2.7 (4.4)#	-	0.07
Core-plantar temperature gap	0	5.5 (2.2)	5.7 (2.4)	-1.1, 0.6	0.6
	2	2.8 (2.6)#	3.5 (4.6)#	-	0.048*

All temperatures measured in °C are expressed as mean (standard deviation) except those denoted by # which are expressed as median (interquartile range); \* denotes statistical significance.

mean gestational age, median age at recruitment, mean environmental temperature, median total serum bilirubin levels, proportion of infants under two phototherapy lights and proportion of infants under an electric fan. Neither was there any significant difference in the baseline core temperature, abdominal wall temperature, plantar temperature, abdominal wall-plantar temperature gap, and core-plantar temperature gap between the two groups at recruitment (Table II).

At the end of two hours of phototherapy in Phase I, there was significant increase in the core ( $p < 0.0001$ ,  $p < 0.0001$ ), abdominal wall ( $p < 0.0001$ ,  $p < 0.0001$ ) and plantar temperatures ( $p < 0.0001$ ,  $p < 0.001$ ) of all infants, irrespective of the use of clingfilm (Table II). When compared between infants with and without use of clingfilm, there was no significant difference in their core temperature, abdominal wall temperature, and plantar temperature after two hours of phototherapy ( $p > 0.05$ ). Although the abdominal wall-plantar temperature gap was narrower in infants under clingfilm, the difference was not statistically significant. However, the core-plantar temperature gap of infants under clingfilm was significantly narrower than infants not under clingfilm ( $p < 0.05$ ).

The core, abdominal wall and plantar temperatures of infants undergoing phototherapy with or without clingfilm during Phase II of the

study were compared (Table III). After crossing over, there was no significant difference in the core and plantar temperatures between the two groups, both at the beginning and at the end of this phase ( $p > 0.05$ ). However, infants receiving phototherapy under clingfilm had significantly higher abdominal wall temperature after one and two hours of phototherapy than those without use of clingfilm ( $p < 0.05$ ). There was no significant difference in the abdominal wall-plantar temperature gap or core-plantar temperature gap between the two groups. Similar to the findings observed in Phase I, there was a significant increase in their core ( $p < 0.001$ ,  $p < 0.001$ ), abdominal wall ( $p < 0.001$ ,  $p < 0.001$ ) and plantar temperatures ( $p < 0.001$ ,  $p < 0.01$ ) during the two hour-period of Phase II in each group of infants, irrespective of the use of clingfilm (Table III).

There was no significant difference in the proportions of infants with hypothermia (core temperature  $< 36.5^{\circ}\text{C}$ ), normothermia ( $36.5\text{--}37.5^{\circ}\text{C}$ ) and hyperthermia ( $> 37.5^{\circ}\text{C}$ ) at zero ( $p = 0.8$ ) and two hours ( $p = 0.2$ ) after phototherapy between the two groups (Table IV). After two hours of phototherapy under clingfilm, no infants were hypothermic, with their core temperatures ranging from  $36.5^{\circ}\text{C}$  to  $38.8^{\circ}\text{C}$ . Without clingfilm, three infants were mildly hypothermic at the end of two hours of phototherapy, with their core temperature ranging from  $36.1^{\circ}\text{C}$  to

**Table III. Comparison of core, abdominal wall and plantar temperatures of infants with or without clingfilm during the two-hour phototherapy period of Phase II.**

Body temperature	Time interval (hours)	With clingfilm (n=52)	Without clingfilm (n=54)	95% CI of difference between mean	p-value
Core	0	36.9 (0.4)	36.8 (0.6)	-0.1, 0.2	0.5
	2	37.5 (0.5)	37.4 (0.6)	-0.05, 0.3	0.2
Abdominal wall	0	35.9 (0.6)	35.8 (0.6)	-0.1, 0.4	0.2
	1	36.7 (0.6)	36.4 (0.7)	0.08, 0.6	0.01*
	2	36.9 (0.5)	36.6 (0.6)	0.1, 0.5	0.003*
Plantar	0	31.7 (2.4)	32.3 (2.4)	-1.5, 0.4	0.2
	1	33.1 (2.6)	32.4 (3.0)	-0.3, 1.9	0.2
	2	33.9 (2.4)	32.9 (3.0)	-0.04, 2.1	0.06
Abdominal wall-plantar temperature gap	0	4.2 (2.1)	3.5 (2.2)	-0.1, 1.6	0.09
	1	3.5 (2.4)	4 (2.9)	-1.5, 0.6	0.4
	2	2.0 (2.8)#	2.9 (4.5)	-	0.3
Core-plantar temperature gap	0	5.2 (2.3)	4.5 (2.2)	-0.2, 1.5	0.1
	2	2.8 (2.9)#	3.7 (4.4)#	-	0.1

All temperature measurements in °C are expressed as mean (standard deviation) except those marked by # which are expressed as median (interquartile range); CI: confidence intervals; \* denotes statistical significance.

**Table IV. Relationship between core temperature of infants and use of clingfilm before and after two hours of phototherapy.**

Core temperature at 0 hour	Core temperature after two hours of phototherapy	With clingfilm (n=106) (%)	No clingfilm (n=106) (%)	p-value
<36.5°C	<36.5°C	0 (0)	1 (5.6)	0.5
	36.5-37.5°C	17 (81.0)	14 (77.8)	
	>37.5°C	4 (19)	3 (16.7)	
36.5-37.5°C	<36.5°C	0 (0)	2 (2.5)	0.1
	36.5-37.5°C	42 (52.5)	50 (61.7)	
	>37.5°C	38 (47.5)	29 (35.8)	
>37.5°C	36.5-37.5°C	2 (40.0)	1 (14.3)	0.5
	>37.5°C	3 (60)	6 (85.7)	

38.7°C. Irrespective of the use of clingfilm, more than a third of infants in each group developed hyperthermia (clingfilm: 42.5%; no clingfilm: 35.8%) after two hours of phototherapy.

## DISCUSSION

In a previous pilot study, we used abdominal skin probes to monitor the temperature of infants undergoing phototherapy and found the incidence of hypothermia to be rather high. To confirm this,

measurement of core temperature was included in the present study. Tympanic membrane temperature was chosen as a reflection of the core body temperature in this study because the tympanic membrane has a similar blood supply, via the internal carotid artery, with the hypothalamus functioning as the body's internal thermostat. Technically, it was found to be very easy to measure the tympanic membrane temperature with minimal disturbance of the infants. In addition, studies have shown that in well infants,

tympanic membrane temperature is a reliable measurement of core body temperature<sup>(3-5)</sup>.

Although the environment temperature of the NICU and postnatal wards during the study was at times much lower than the 25°C as recommended by WHO<sup>(1)</sup>, and hypothermia was common in the infants at the onset of phototherapy, very few infants remained (n=1) or became (n=2) hypothermic during phototherapy. Furthermore, the degree of hypothermia was very mild. Irrespective of the use of clingfilm, continuous phototherapy of a two-hour duration resulted in a significant rise of core, abdominal wall and plantar temperatures of all term infants, as well as a narrowing of their core-plantar and abdominal wall-plantar temperature gaps. On the other hand, hyperthermia was common, affecting more than a third of the infants after two hours of phototherapy. However, none of them developed clinically significant severe hyperthermia of  $\geq 42^{\circ}\text{C}$  as defined by WHO<sup>(1)</sup>. Nevertheless, as hyperthermia can cause dehydration and discomfort in the infants, it is imperative that the core temperature of infants undergoing phototherapy be closely monitored and appropriate remedial actions taken when indicated.

When compared with those infants undergoing phototherapy without clingfilm, the use of clingfilm was not associated with significantly greater increases in body temperature. Although not statistically significant, a small proportion of infants (n=2) receiving phototherapy without clingfilm did become mildly hypothermic after two hours of phototherapy. On the other hand, no infants developed hypothermia when receiving phototherapy under clingfilm, suggesting that the use of clingfilm may help prevent hypothermia in a very cold environment. The lack of statistical significance could be due to the small sample size recruited for this study.

The findings of this study confirm the importance of monitoring the body temperature of infants during phototherapy. Based on the results of this study, the use

of clingfilm is not necessary to prevent hypothermia during phototherapy of healthy normothermic term infants when their mean environmental temperature is around 26.0°C. However, if they are hypothermic at the onset of phototherapy, the use of clingfilm may help to raise their body temperature more quickly during phototherapy. In temperate climates where the environmental temperature of the nursery is lower, there may be a role for the use of clingfilm on bassinets of healthy term infants undergoing phototherapy. This can obviate the need for an incubator which is more expensive to purchase and costly to maintain. As the incidence of hypothermia is not common during this study, a further study should be carried out with a much larger sample size of hypothermic term infants recruited to determine whether the use of clingfilm could significantly reduce the incidence by hypothermia during phototherapy in this subset of infants.

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