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ABSTRACT

Objective To assess leakage caused by the Pedi-Cap.

Methods Bench test I: Pedi-Caps were connected between the Neopuff and a test lung and placed underwater to detect the leak. Bench test II: the disposable Avea VarFlex Flow Transducer measured the leak. Retrospective analysis: recordings of intubations in the delivery room were analysed.

Results The (rippled) male end of the Pedi-Cap is the origin of the leak. In bench test I, 32% of the Pedi-Caps caused inevitable extensive leaks and 34% caused leaks that diminished after sealing the end. In bench test II (n=44) and the retrospective analysis (n=17), the flow transducer measured 22% (18–60) and 39% (8–82) leakage, respectively. Leakage decreased after removal of the Pedi-Cap (before vs after; 17% (7–75) vs 4% (2–10), p=0.004).

Conclusion The Pedi-Cap causes the leak which can compromise respiratory support. We recommend to remove the Pedi-Cap directly after change of colour and to be cautious when using the device as evaluation tool.

What is already known on this topic?

- The Pedi-Cap is primarily used for verifying endotracheal tube positioning.
- The Pedi-Cap is used as evaluation tool for effectiveness of mask ventilation and predictor for lung aeration.
- The Pedi-Cap stays connected in-line with the ventilatory circuit after successful intubation.

What this study adds?

- The Pedi-Caps cause a large variety of leaks coming from the (rippled) male end of the Pedi-Cap.
- In retrospective analysis, leaks diminished after removing the Pedi-Cap.
- Awareness that the Pedi-Cap can cause extensive leaks compromising respiratory support.

INTRODUCTION

Intubation of preterm infants is a challenging procedure and the endotracheal tube is easily positioned incorrectly. To verify successful tube positioning, detection of exhaled carbon dioxide is recommended.[1]

The Nellcor Pedi-Cap (Medtronic, Minneapolis, MN, USA) is a disposable carbon dioxide detector initially designed to guide intubations. It incorporates a pH-sensitive chemical indicator that changes colour when the exhaled carbon dioxide concentration reaches a set concentration (partial pressure of carbon dioxide 15 mm Hg), indicating successful tube positioning. The use of the Pedi-Cap has expanded to evaluation during non-invasive respiratory support to detect airway obstruction and reflect gas exchange.[2 3] To avoid interrupting of respiratory support and as evaluation tool, the Pedi-Cap remains connected in the ventilation circuit during the stabilisation period.

Based on clinical observations we expected the Pedi-Cap to leak from the rippled male end (figure 1). Leakage in the ventilatory circuit using the Pedi-Cap has not been described in literature. The objective of this study was to assess the frequency and degree of the leak caused by the Pedi-Cap.

METHODS

To examine the leak produced by the Pedi-Cap, an observational study was conducted at the Leiden University Medical Center (LUMC) consisting of two bench tests and a retrospective clinical analysis.

Bench test I

The direct Neopuff/Pedi-Cap connection was tested (A) as used in clinic and (B) using a disproportionate force to completely seal the male end of the Pedi-Cap by the Neopuff tubing (figure 1). In both test settings the Pedi-Cap was connected to a test lung (50 mL, 0.66 mL/mbar compliance) (Dräger, Lübeck, Germany) and ventilated with 25 cmH_2O peak inspiratory pressure (PIP) using a flow of 8 L/min. The Pedi-Cap and connecting junctions were placed underwater to detect the bubbles indicating leakage. The extent of the leak was categorised as: (1) no or few bubbles; (2) continuous bubbling which could be diminished by covering the male end of the Pedi-Cap; and (3) excessive leaks that could not be prevented (online supplementary video).

Bench test II

Respiratory function monitoring during the neonatal resuscitation is standard of care at the LUMC. A disposable variable resistance pneumometer sensor (Avea VarFlex Flow Transducer, CareFusion, Yorba Linda, CA, USA) connects the ventilatory circuit with the device (face mask or endotracheal tube) that interfaces with the infant. The sensor does not cover the male end of the Pedi-Cap completely. The sensor measured the flow to and from the test lung. The signals were digitised at 200 Hz using the

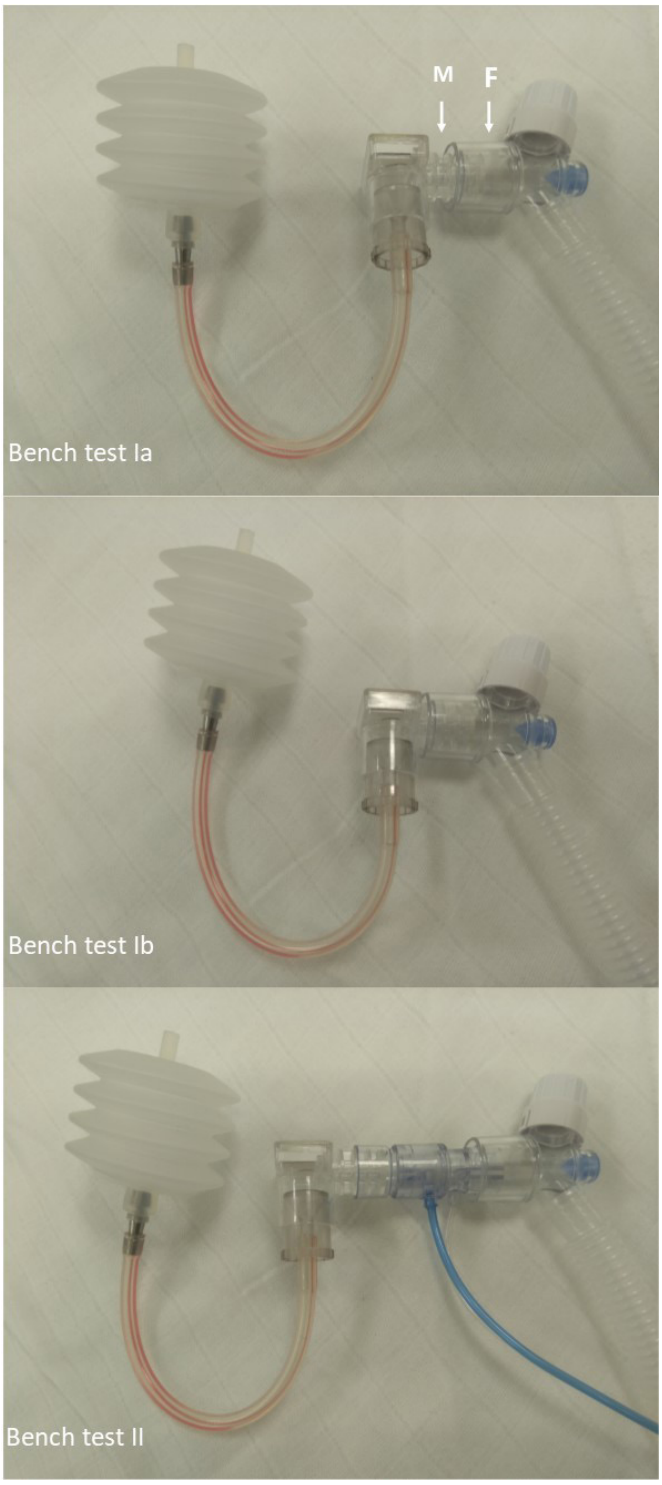

figure 1 Bench test set-up. Test setting (I) direct Neopuff/Pedi-Cap connection using (a) an expected level of force needed to make the connection and (b) a disproportionate level of force needed to completely seal the male end of the Pedi-Cap; and (II) Neopuff/disposable Avea VarFlex Flow Transducer/Pedi-Cap. F, female connector of the Neopuff; M, male end of the Pedi-Cap.

NewLifeBox-R physiological recording system and recorded by the NewLifeBox Neo-RSD computer system (Advanced Life Diagnostics, Weener, Germany) supported by Polybench physiological software (Applied Biosignals, Weener, Germany). Pulmochart software (Applied Biosignals) was used to calculate the degree of the leak as the difference between inspiratory and expiratory tidal volumes in a breath-by-breath analysis.

Clinical situation

Recordings of intubations in the delivery room were analysed if intubation was successful and a Pedi-Cap was used for a minimum of five inflations. Recordings were excluded due to technical errors. The recordings were measured and analysed as in the bench test. The number of inflations that were analysed depended on availability with a maximum of 1 min.

All data were analysed with IBM SPSS Statistics V.23 (IBM Software, 2015). Groups were compared using a paired t-test and presented as % or median (IQR).

RESULTS

Bench test I

Forty-four Pedi-Caps were collected for the bench test. In case of leakage, bubbles appeared surrounding the Neopuff/Pedi-Cap connection. Thirty-four per cent of the Pedi-Caps showed no or few bubbles escaping the ventilatory circuit, 32% had regular, continuous air leaks that could be diminished by covering the male end of the Pedi-Cap and 34% excessive not preventable leakage.

Bench test II

When the flow sensor was connected in-line with the Neopuff and the Pedi-Cap, the median (IQR) leak was 22% (18%–60%).

Clinical situation

The database of our respiratory function monitor recordings included 42 recordings of infants who were intubated in the delivery room. Files were excluded from the analysis due to technical problems (n=16), failed intubation attempts (n=2), constant manipulation of the tube (n=1) and when the Pedi-Cap was used for less than five inflations (n=6). The remaining 17 files were included in the analysis.

The gestational age and birth weight of the included infants was 26^{+1} (24^{+6}–27^{+5}) weeks and included 10 males (59%). Although the Pedi-Cap is registered for use in infants >1 kg, the

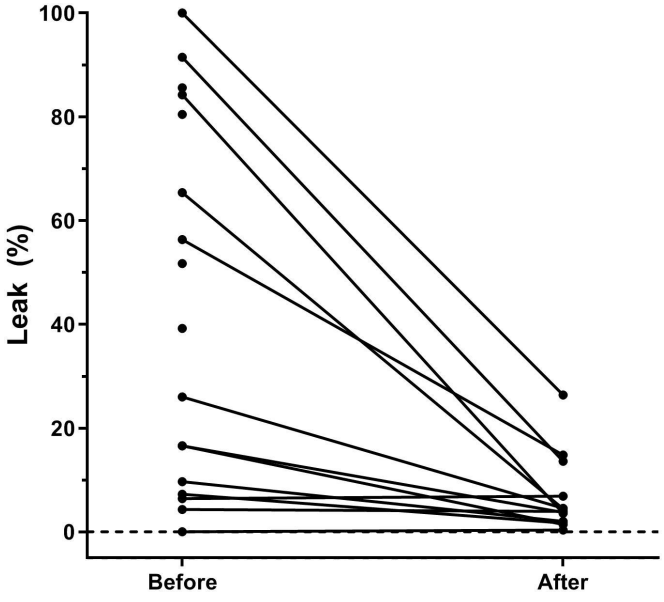

figure 2 Leak caused by the Avea VarFlex Flow Transducer/Pedi-Cap connection in the clinical setting.

device is frequently used in smaller infants and the median birth weight of included infants was 831 (681–1157) g. Clinicians connected the Pedi-Cap after the flow sensor (the following order from proximal to distal: Neopuff/disposable Avea VarFlex Flow Transducer/Pedi-Cap).

The leak of all Pedi-Caps (n=17) was 39% (8%–82%). Four Pedi-Caps stayed connected for the duration of the resuscitation. Of the remaining, 3 (23%) showed no difference (<1%) in leaks after removal of the Pedi-Cap, whereas 10 (77%) had an absolute reduction in leaks of 31% (11%–75%). Overall, the leak was significantly lower after removing the Pedi-Cap from the ventilatory circuit (before vs after; 17% (7–75) vs 4% (2–10), p=0.004) (figure 2).

DISCUSSION

The origin of the leak was the connection between the male rippled end of the Pedi-Cap.

Connecting the Pedi-Cap directly to the Neopuff caused considerable leaks in 66% of the Pedi-Caps. In 32% of the total tested, the leak was substantially reduced by pushing the male end of the Pedi-Cap further into the female connector of the Neopuff tubing. This may seem reassuring, however, the force needed to achieve a complete seal may not be expected, particularly during resuscitations.

Bench test II and the clinical evaluation confirmed the large variety with 22% (18%–60%) and 39% (8%–82%) leakages, respectively. The leak was measured using the disposable Avea VarFlex Flow Transducer, of which the female connector does not cover the entire male end of the Pedi-Cap. While connecting the Avea VarFlex Flow Transducer may increase the degree of the leak, the bench test showed that not all leaks are inevitable by covering the male end of the Pedi-Cap.

The leak caused by the Pedi-Cap may delay colour changes indicating correct tube positioning. If the evaluation time exceeds this delay, clinicians might unnecessarily reposition the tube. Leakage also compromises respiratory support leading to underventilation, which is crucial for physiological unstable infants who require intubation.[4]

The leak caused by the Pedi-Cap is easy to resolve by removing the Pedi-Cap from the ventilatory circuit, preferably directly after change of colour. Especially if a monitor is used, the flow transducer may increase but also display leakage. When the Pedi-Cap is used for monitoring non-invasive mask ventilation, clinicians should be aware of leaks compromising support and added resistance, described by Brown *et al*,[5] which could increase work of breathing.

Medtronic has been contacted; they acknowledged the results while underlining that the degree of leakage might vary between tubing of different resuscitators.

We were unable to measure the degree of leaks by a direct Neopuff/Pedi-Cap connection. Ideally, future studies explore the degree of leaks in this connection and clinical consequences such as requirement of higher pressures.

CONCLUSION

Clinicians should be aware of the leak caused by the Pedi-Cap. There is a large variety in the degree of the leak and excessive leaks could compromise respiratory support. As the Pedi-Cap is a useful evaluation tool for intubation, we recommend to use it while closely observing the leak and to disconnect the Pedi-Cap after successful change of colour.

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Contributors ABP conceptualised and designed the study, was involved in data analysis and interpretation, and reviewed and revised the manuscript. AH and TM contributed to the literature search, data acquisition, analysis and interpretation. TM drafted the manuscript. SJEC, RNGBT and SBH were involved in data interpretation.

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Competing interests None declared.

Patient consent for publication Not required.

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Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.

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