A RANDOMISED FEASBILITY TRIAL AND IN-VITRO PERFORMANCE OF

A NEW SYSTEM FOR RESPIRATORY SUPPORT DURING INITIAL STABILISATION OF PRETERM INFANTS

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Results:

Simulations: Imposed work of breathing for the New System was reduced compared to the T-piece systems (Fig. 1). At 4 cm H2O the reduction was 93% (mask) and 84% (medium prongs) compared to Neopuff ($p<0.05$).

Feasibility trial: Informed consent was obtained from 45 patients, 39 were randomised and 36 needed support. Randomization resulted in imbalance: The New System infants (n=24) had lower GA and birth weight compared to the T-piece resuscitator group (n=12) ($p<0.05$). One infant supported with the new system needed delivery room intubation. There were no problems with the equipment or safety. The clinical feedback was that stabilisation with prongs was easier than with a facemask. The results are presented in Table 1

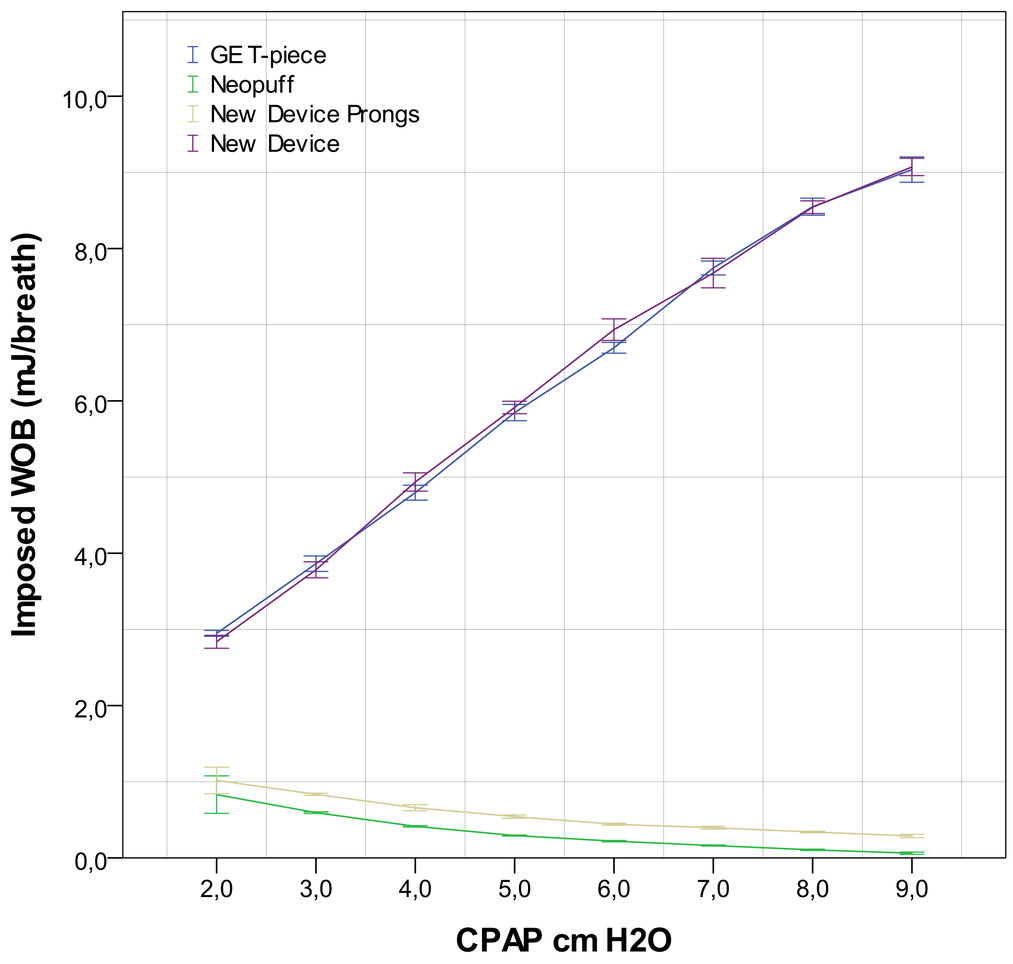

Figure 1: Imposed work of breathing comparing T-piece with the New System in simulated breathing at differnt levels of CPAP (mean with 95% CI).

	Neopuff	New device	
	Face Mask	Face Mask	Prongs
n	12	12	12
Gestational Age (w)	33+0	32+4	30+5
Weight (gr.)	2109	1581	1663
F/M	6/6	6/6	5/7
Vaginal delivery	5/12	4/12	2/12
Steroids complete	7	3	7
PPV	5	6	2
Intubated DR	0/12	0/12	1/12
APGAR 1 min	8,3	7,5	8,2
APGAR 5 min	8,2	8,3	8,9
APGAR 10 min	9,3	9,7	9,9
Time to regular breathing	2,6	2,5	1,0
Time to SpO2 90%	7,8	7,9[A]	6,4
Recived surfactant <72h	2/12	0/12	5/12
Pneumothorax	0/12	0/12	2/12[B]

Table 1: Summary of the three treatment groups. A) Two missing (n=10), B) CPAP 4cmH2O, no PPV. At 12h resp 48h of age

Conclusions

Compared to the T-piece system the New System had a marked reduction in the imposed work of breathing during bench tests. The feasibility trial did not reveal problems with usability or safety. The possible effect on intubation rates by using systems with prongs and low imposed work of breathing needs to be investigated in a large randomised trial.

Future: RCT starting 2015

Academic multicenter RCT comparing new device with prongs and T-piece.

Trial start November 2015 with a total enrolment of 250 patients <28 w GA.

Primary outcome DR intubation.

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