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The accuracy of delivery of target pressures using self-inflating bag manometers in a benchtop study

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Running title: Self-inflating bag manometers to target pressure

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Abstract

Aim: We tested whether operators using manometers attached to self-inflating bags could accurately deliver set targeted peak inspiratory pressures (PIPs) compared to the Neopuff™ T-piece resuscitator (TPR). **Methods:** Participants provided positive pressure ventilation to a leak-free neonatal test lung at a rate of 60 inflations/min and a flow of 8 L/min. Participants used three manometers attached to self-inflating bags and a Neopuff™ TPR to target PIPs of 20, 30, and 40 cmH_2O on each device. Mean PIPs delivered with each manometer were compared to the 'gold-standard' Neopuff™ TPR. **Results:** 13,991 inflations delivered by 20 participants were analysed. At all target PIPs, the mean PIP delivered using the Mercury Medical manometer attached to a Laerdal self-inflating bag was significantly higher by 5 cmH_2O ($P < 0.01$) than the Neopuff™ TPR. The PIP delivered using both the Ambu™ and Parker Healthcare manometers attached to their respective devices was similar to that delivered by the Neopuff™ TPR at all targeted PIPs. **Conclusion:** Accurately targeted PIPs can be achieved when a manometer specifically designed for use on a self-inflating bag is used during manual ventilation. This may be useful in settings where access to a Neopuff™ TPR or a gas flow source is limited.

Key words:

Low-resource, Manometer, Neonate, Resuscitation, Self-inflating bag

Key notes:

- The ability to deliver consistent peak inspiratory pressures (PIPs) with self-inflating bags is challenging, and inconsistency can lead to incorrect lung inflation causing injury.
- We demonstrated that accurately targeted PIPs can be achieved using a manometer designed specifically for use with a self-inflating bag during manual ventilation.

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- This may be useful in settings where access to a Neopuff™ TPR or a gas flow source is limited.

Introduction

Approximately 6 million newborn infants require resuscitation each year (1). The most important aspect of neonatal resuscitation is effective ventilation, which reduces intrapartum-related neonatal death by up to 47% in resource-limited settings (2). According to international guidelines, effective positive pressure ventilation (PPV) may be provided using self-inflating bags and T-piece resuscitators (TPRs) (3). Several manikin studies have shown that TPRs are the 'gold standard' because they deliver accurate and consistent positive airway pressure (PIP), and constant tidal volumes (4, 5). However, self-inflating bags are primarily used in low-resource settings because TPRs are expensive and require a gas flow source to drive the device.

The ability to deliver a consistent PIP varies considerably between self-inflating bags (6). This poses a significant problem because excessive airway pressure (barotrauma) increases the risk of lung injury (7), which may ultimately lead to bronchopulmonary dysplasia (BPD). Some manufacturers produce small spring manometers that can be attached, or are built in, to self-inflating bags to allow operators to target a specific PIP during manual ventilation. Manometers can also be purchased as individual items for attachment to some devices. However, neonatal studies comparing TPRs and self-inflating bags generally do not include manometers on the latter devices (9). Moreover, the value of using a manometer has been questioned in the literature (10) and research investigating whether manometers increase the accuracy of delivered PIP is limited.

The aim of this study was to determine whether operators using three internationally available manometers attached to self-inflating bags could accurately deliver set targeted PIPs compared to the Neopuff™ TPR.

Participants and Methods

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This bench-top study was performed at the Royal Women's Hospital, Melbourne. Neonatal staff (doctors, nurses and clinical researchers) that had not used a self-inflating bag during the past 2 years were invited to participate in the study. We tested three new manometers attached to new self-inflating bags, against the 'gold-standard' Neopuff™ infant resuscitator with built-in manometer and pressure-relief valve (Fischer & Paykel Healthcare, Auckland, New Zealand) (Fig. 1). The manometers tested were: (1) a disposable Mercury Medical manometer (range 0-40 cmH_2O; manufacturer specified accuracy ±5 cmH_2O) attached to a Laerdal infant resuscitator (240 mL capacity and 35 cmH_2O pop-off valve; Laerdal Medical, Stavanger, Norway); (2) a non-disposable Ambu™ manometer (range 0-60 cmH_2O; manufacturer specified accuracy ±2 cmH_2O at PIP 20 and 30, and ±3 cmH_2O at PIP 40) attached to an Ambu™ Mark IV Baby resuscitator (450 mL capacity and 40 cmH_2O pop-off valve; Ambu™ A/S, Ballerup, Denmark); and (3) a disposable Parker Healthcare manometer (range 0-60 cmH_2O; unreported accuracy) built into a Parker Healthcare infant resuscitator (280 mL capacity and 40 cmH_2O pop-off valve; Parker Healthcare, Melbourne, Australia). All manometers used during the study consisted of small and light spring devices attached, or built in, to the patient end of the self-inflating bag (Fig. 1). When pressure is applied to the self-inflating bag, the gas fills the manometer chamber and the spring is compressed (Fig. 1).

A preliminary investigation prior to study commencement compared the PIP delivered with each self-inflating bag with and without a gas flow. Analysis of 5,868 inflations showed that gas flow had no significant affect on delivered PIP. Therefore, to maintain scientific consistency between the self-inflating bags and the Neopuff™, which requires a gas flow for operation, all devices were connected to a gas flow source of 8 L/min. The self-inflating bags had no positive end expiratory pressure (PEEP) valve attached, whereas the Neopuff™ PEEP was set at 5 mmH_2O.

Participants were asked to provide positive pressure ventilation (PPV) to a neonatal test lung (Drager, Lubeck, Germany) attached to each device at a rate of 60 inflations/min. Manual inflations were delivered at a constant rate using a metronome (MetroTimer 3.3.1, ONYX Apps, Sofia, Bulgaria).

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The leak-free neonatal test lung had a compliance of 0.6 mL/cmH_2O and resistance of 85 cmH_2O/L/s. Participants targeted PIPs of 20, 30, and 40 cmH_2O on each device using the manometer attached. The delivered PIP was measured using a calibrated Florian Neonatal Respiratory Monitor (Acutronic Medical Systems, Zug, Switzerland) during PPV for one minute at each PIP level. The pop-off valve was occluded at a targeted PIP of 40 cmH_2O for each of the three self-inflating bags because the pressure threshold at which the valves release are not consistent between brands. The order in which each PIP and device was used was randomised for each participant prior to commencement, and participants rested for one minute between devices to prevent fatigue. Delivered PIP was recorded digitally at 200 Hz using Spectra software (Grove Medical, London, UK). The study system was leak-free.

Data were extracted from Spectra and analysed using Stata/IC version 13.0 (StataCorp LP, Texas, USA). The first and last inflation of each 60-second recording were removed prior to analysis. For each targeted PIP, a single model linear regression was used to compare the PIP delivered by each device to that of the Neopuff™ TPR. In each model, delivered PIP and device were the dependent and independent variables, respectively, and data were clustered by operator. Statistical significance was assumed if $P < 0.05$.

Results

A total of 13,991 inflations delivered by 20 participants were analysed. Pressures delivered by all devices are shown in Table 1 and Fig. 2. At all targeted PIPs, the mean PIP delivered using the Mercury Medical manometer was consistently significantly higher than the Neopuff™ TPR ($P < 0.01$), whereas the PIP delivered when using both the Ambu™ and Parker Healthcare manometers was similar to the Neopuff™ TPR at all target PIPs. However, all self-inflating bags delivered a wider PIP range than the Neopuff™ TPR (Fig. 2).

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Discussion

Previous bench-top studies show that TPRs deliver more consistent target inflation pressures than self-inflating and flow-inflating bags (11, 12). Two of the self-inflating bags used in this study (Laerdal and Ambu™) have previously been shown to deliver excessive PIPs in the absence of a manometer. Use of the Mercury Medical manometer with the Laerdal self-inflating bag generated more consistent PIP but it was almost 5 cmH_2O higher than the targeted PIP. Operators using both the Ambu™ and Parker Healthcare manometers delivered PIPs similar to the Neopuff™ TPR. Although the manometers have a similar design, the pressure level is indicated differently. When pressure is applied to the self-inflating bag, compression of the spring forces the pressure indicator on the Mercury Medical manometer to move in a circular (clockwise) manner, whereas the spring itself indicates the pressure that is delivered in the Ambu™ and Parker Healthcare manometers (Fig. 1). We speculate that these differences in manometer design may explain why the accuracy of the Mercury Medical, and Ambu™ and Parker Healthcare manometers varied.

In neonatal resuscitation training programs clinicians are taught to assess the degree of chest wall movement as a measure of adequate lung inflation (3). However, this method of assessment is a poor proxy for PIP and tidal volume delivery, and may result in under- or over-inflation of the lung (9, 13), causing injury that leads to BPD. Our findings suggest that the use of a manometer attached to a self-inflating bag may assist in the delivery of consistent PIP and thus reduce lung injury. Our results agree with previous studies showing the benefit of using a manometer to target PIP during manual ventilation. Zmora and Merritt demonstrated that operators successfully achieved a PIP of 30 cmH_2O 74% of the time when a manometer was used, compared to only 13% when it was not (14).

TPRs are commonly used and are becoming the device of choice for neonatal resuscitation in many well-resourced settings (15), because of its consistent PIP delivery and the capability of delivering PEEP. However, there is limited evidence to support its use over a self-inflating bag (16), the

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recommended device when a compressed gas source is unavailable (17). To the best of our knowledge, there are only two published neonatal clinical trials comparing these devices for the delivery of PPV in the delivery room (9, 18). Szyld et al compared the use of a Neopuff™ TPR versus an Ambu™ self-inflating bag fitted with a manometer and a pop-off valve, in a large multicentre randomised control trial that included infants ≥26 weeks' gestation (19). They targeted a PIP of 25 cmH_2O and their primary outcome was HR ≥100 bpm at 2 minutes after birth. They found that, although the use of a TPR significantly decreased the intubation rate in the delivery room (17 vs 26%, $P < 0.01$), as well as the maximum PIP provided and its variability (26±1.9 vs 28±4.9 cmH_2O), there was no difference in the primary outcome. Furthermore, there were no differences in secondary clinical outcomes beyond the delivery room (days on respiratory support, use of oxygen, and BPD). Dawson et al compared the use of a TPR versus a self-inflating bag, fitted with a pop-off valve but without a manometer, including infants <29 weeks' gestation born in a large tertiary centre (8). PIP was set at 30 cmH_2O with the TPR but could not be targeted with the self-inflating bag. Primary outcome was SpO_2 at 5 minutes after birth. Respiratory variables measured in 59% of the infants showed that mean PIP delivered with the TPR was similar to the self-inflating bag (30±1.9 vs 31.5±5.6 cmH_2O). Delivered mean expiratory tidal volume was also similar between devices. Finally, they found no significant difference in the primary outcome (SpO_2 61 vs 55%) or any other respiratory intervention in the delivery room (CPAP support, intubation, surfactant administration, oxygen administration) or during NICU admission (oxygen delivery at 28 days after birth or BPD at 36 weeks' corrected age).

O'Donnell et al compared a TPR and a Laerdal self-inflating bag with and without a manometer, showing no significant difference in tidal volume between the three devices (10). They concluded that measuring tidal volume was more important than PIP during ventilation of newborn infants, a conclusion shared by other studies (20-22). PIP is only a single variable influencing tidal volume and others including PEEP, inspiratory time and mean airway pressure may play an important role. Also, for a given PIP, tidal volume may change according to lung compliance and resistance (20).

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Neonatal self-inflating bags are manufactured with a built-in pop-off valve that limits the PIP to 35-40 cm H_2O (23). Further clinical studies are therefore needed to determine whether knowing the PIP improves clinical outcomes following PPV. This is especially important in low-resource settings where a self-inflating bag is the device of choice for neonatal resuscitation (17).

Operator skill level influences PIP delivered during manual bag and mask ventilation in the absence of a manometer (6). However, experience does not affect PIP when using a TPR because target PIP is manually set prior to providing PPV. The variability of PIP delivered with a self-inflating bag decreases when a manometer is used during ventilation regardless of operator level of experience (10). This is also shown in our study, where mean delivered PIP with the Ambu™ and Parker Healthcare manometers was comparable to the Neopuff™ mean PIP despite the limited recent self-inflating bag ventilation experience of our operators.

We recognise that our study was conducted in a controlled environment that may not accurately reflect a clinical setting, where distractions, stress and fatigue may disrupt the administration of consistent PIPs with a self-inflating bag. We noted some limitations of individual devices; we found that the built-in Parker Healthcare manometer was unsuitable for left handed operators due to its position on the device, also the attachment site for the Mercury Medical manometer on the Laerdal device made it difficult to visualise the manometer.

In conclusion, accurate PIPs can be delivered using some small portable manometers designed specifically for use with self-inflating bags. This may be useful in low-resource settings where access to a TPR is limited. Clinical studies are needed to ascertain whether a portable manometer improves clinically important outcomes following PPV in newborn infants. Studies comparing self-inflating bags with and without a manometer are needed in low-resource settings.

Conflict of Interest and funding

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Abbreviations

Positive pressure ventilation (PPV)
Peak inspiratory pressure (PIP)
T-piece resuscitator (TPR)
Positive end expiratory pressure (PEEP)
Continuous positive airway pressure (CPAP)
Neonatal intensive care unit (NICU)

References:

1. Wall SN, Lee AC, Niermeyer S, English M, Keenan WJ, Carlo W, et al. Neonatal resuscitation in low-resource settings: what, who, and how to overcome challenges to scale up? *Int J Gynecol Obstet* 2009; 107:S47-S64
2. Msemo G, Massawe A, Mmbando D, Rusibamayila N, Manji K, Kidanto HL, et al. Newborn mortality and fresh stillbirth rates in Tanzania after helping babies breathe training. *Pediatrics* 2013; 131:e353-e60
3. Kattwinkel J, Perlman JM, Aziz K, Colby C, Fairchild K, Gallagher J, et al. Part 15: neonatal resuscitation 2010 american heart association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation* 2010; 122:S909-S19
4. Roehr CC, Kelm M, Fischer HS, Bührer C, Schmalisch G, Proquitté H. Manual ventilation devices in neonatal resuscitation: tidal volume and positive pressure-provision. *Resuscitation* 2010; 81:202-5

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5. Roehr CC, Kelm M, Proquitté H, Schmalisch G. Equipment and operator training denote manual ventilation performance in neonatal resuscitation. *Am J Perinatol* 2010; 27:753-8
6. Finer NN, Rich W, Craft A, Henderson C. Comparison of methods of bag and mask ventilation for neonatal resuscitation. *Resuscitation* 2001; 49:299-305
7. Ali Attar M, Donn SM. Mechanisms of ventilator-induced lung injury in premature infants. *Semin Neonatol* 2002; 7:353-60
8. Kacmarek RM, Dimas S, Mack CW. Essentials of respiratory care. 4th ed: Elsevier Health Sciences; 2013:545
9. Dawson JA, Schmölzer GM, Kamlin COF, Te Pas AB, O'Donnell CP, Donath SM, et al. Oxygenation with T-piece versus self-inflating bag for ventilation of extremely preterm infants at birth: a randomized controlled trial. *J Pediatr* 2011; 158:912-8
10. O'Donnell CP, Davis PG, Lau R, Dargaville PA, Doyle LW, Morley CJ. Neonatal resuscitation 3: manometer use in a model of face mask ventilation. *Arch Dis Child Fetal Neonatal Ed* 2005; 90:F397-F400
11. Hussey S, Ryan C, Murphy B. Comparison of three manual ventilation devices using an intubated mannequin. *Arch Dis Child Fetal Neonatal Ed* 2004; 89:F490-F3
12. Oddie S, Wyllie J, Scally A. Use of self-inflating bags for neonatal resuscitation. *Resuscitation* 2005; 67:109-12
13. Baskett P, Nolan J, Parr M. Tidal volumes which are perceived to be adequate for resuscitation. *Resuscitation* 1996; 31:231-4
14. Zmora E, Merritt TA. Control of peak inspiratory pressure during manual ventilation: a controlled study. *Am J Dis Child* 1982; 136:46-8
15. Roehr C, Gröbe S, Rüdiger M, Hummler H, Nelle M, Proquitté H, et al. Delivery room management of very low birth weight infants in Germany, Austria and Switzerland-a comparison of protocols. *Eur J Med Res* 2010; 15:493-503
16. Perlman J, Wyllie J, Kattwinkel J, Wyckoff M, Aziz K, Guinsburg R, et al. Part 7: neonatal resuscitation: 2015 international consensus on cardiopulmonary resuscitation and emergency cardiovascular care science with treatment recommendations *Circ J* 2015:S204-41

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17. World Health Organization. Guidelines on basic newborn resuscitation [cited 2015 August 21]. Available from: URL: http://apps.who.int/iris/bitstream/10665/75157/1/9789241503693_eng.pdf2012
18. Szyld EG, Aguilar AM, Musante GA, Vain NE, Guerrero MN, Serra M, et al. Newborn ventilation: comparison between a T-piece resuscitator and self-infating bags in a neonatal preterm simulator. *Arch Argent Pediatr* 2012; 110:106-12
19. Szyld E, Aguilar A, Musante GA, Vain N, Prudent L, Fabres J, et al. Comparison of devices for newborn ventilation in the delivery room. *J Pediatr* 2014; 165:234-9. e3
20. Te Pas AB, Davis PG, Hooper SB, Morley CJ. From liquid to air: breathing after birth. *J Pediatr* 2008; 152:607-11
21. Hillman NH, Moss TJ, Kallapur SG, Bachurski C, Pillow JJ, Polglase GR, et al. Brief, large tidal volume ventilation initiates lung injury and a systemic response in fetal sheep. *Am J Respir Crit Care Med* 2007; 176:575-81
22. Kattwinkel J, Stewart C, Walsh B, Gurka M, Paget-Brown A. Responding to compliance changes in a lung model during manual ventilation: perhaps volume, rather than pressure, should be displayed. *Pediatrics* 2009; 123:e465-e70
23. PATH. Practical selection of neonatal resuscitators, version 3: A field guide [cited 2015 August 21]. Available from: URL: http://www.path.org/publications/files/TS_nnr_field_guide_v3_print.pdf 2006

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Tables

Table 1. Mean (SD) pressure delivered at three target pressures using four different manometers.

	Delivered pressure (cm H_2O)						
Target Pressure	**Neopuff TP**	**Ambu**		**Mercury Medical**		**Parker Healthcare**	
(cm H_2O)	Mean (SD)	Mean (SD)	*P*-value	Mean (SD)	*P*-value	Mean (SD)	*P*-value
20	20 (3)	20 (1)	0.49	25 (1)	<0.01	19 (4)	0.20
30	30 (3)	30 (2)	0.73	33 (1)	<0.01	29 (3)	0.08
40	39 (3)	40 (3)	0.06	45 (3)	<0.01	40 (3)	0.42

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Figure legends

Figure 1. Operator (A) and close-up (B) views of three self-inflating bag manometers displaying pressures of 0 and 30 cmH_2O (MM = Mercury Medical; AM = Ambu; PH = Parker Healthcare).

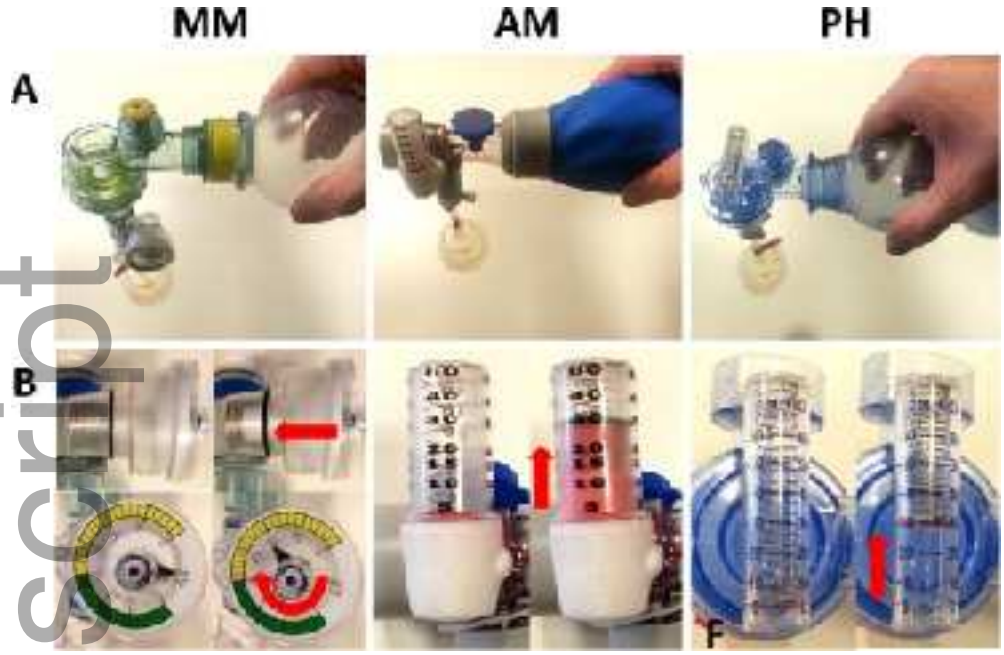
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Figure 2. Median and interquartile range of pressures delivered at 3 target pressures using 4 different manometers (NP = Neopuff t-piece resuscitator; MM = Mercury Medical; AM = Ambu; PH = Parker Healthcare).

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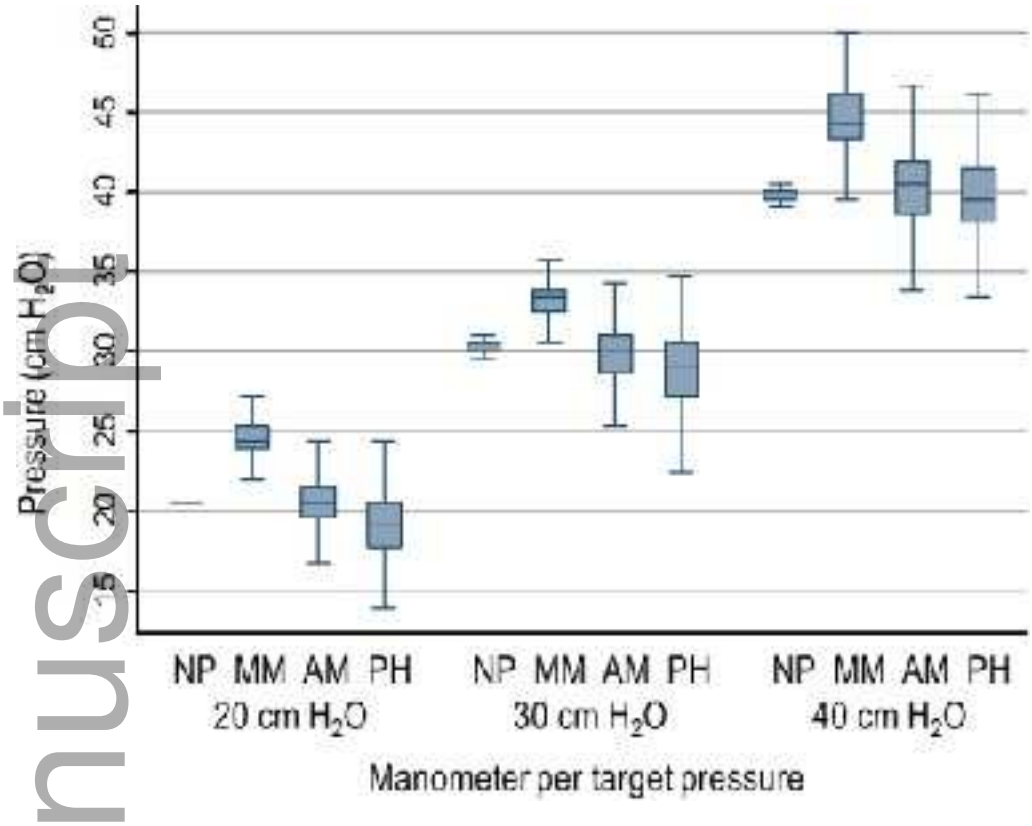
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