Diplomarbeit

“Sucking pattern of bottom-vented feeding bottles”

Comparison of bottom-vented- and conventional feeding bottles for newborns

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Zusammenfassung

Baby-Trinkflaschen werden sehr häufig für die Ernährung von Säuglingen benutzt, doch manche Neugeborenen können damit Schwierigkeiten haben. Das Saugen und gleichzeitige Schlucken beeinflusst bei der Verwendung von Flaschen zum Beispiel die Atmung, in der Folge ist auch die Sauerstoffsättigung im Blut niedriger. Um diese Probleme zu lindern wurden viele verschiedene Arten von Flaschen entwickelt. In dieser Studie wurde das Saugmuster an einer bodenbelüfteten Trinkflasche untersucht.

An der Abteilung für Kinder- und Jugendheilkunde des LKH Leoben wurden 11 Neugeborene ausgewählt und nach Einverständniserklärung der Eltern untersucht. Zum Füttern wurde sowohl eine bodenbelüftete-, als auch eine konventionelle Flasche ohne Ventil, verwendet. Jedes Neugeborene wurde zweimal untersucht, wobei die Auswahl der Flasche randomisiert war. Zur Druckmessung wurde ein Absaugkatheter im Sauger der Flaschen platziert, um den intraoralen Druck zu messen. Zusätzlich wurden die Vitalparameter durch Aufzeichnung von O_2-Sättigung und Herzfrequenz erfasst.

Die Ergebnisse für den mittleren Saugdruck, sowie die mittlere Saugfrequenz unterschieden sich bei den verschiedenen Flaschen in einem nicht statistisch signifikanten Niveau. Dennoch konnten im Saugmuster der konventionellen Flasche kurze, abrupte Abfälle des Saugdruckes aufgezeichnet werden. Diese könnten die Möglichkeit bieten, Luft in die Flasche zu lassen, um das entstandene Vakuum auszugleichen. Die Vitalparameter wichen nicht relevant voneinander ab, jedoch zeigte sich im Korrelationsvergleich von O_2-Sättigung und Herzfrequenz ein Unterschied.

In dieser Studie wurde gezeigt, dass sich das Saugmuster beider Flaschen unterscheidet. Sie soll die Grundlage bieten für weiterführende Untersuchungen von bodenbelüfteten Trinkflaschen.

Abstract

Bottle feeding is a very common type of artificial infant feeding, however certain difficulties for newborns can emerge. Sucking and swallowing can interfere with breathing for example, furthermore oxygen-saturation levels are generally lower. Therefore different types of feeding bottles exist in order to alleviate these disadvantages. The sucking pattern of a bottom-vented feeding bottle was the main subject of this study.

11 newborns were elected at the Children's Hospital of Leoben and parents agreed for participation. A bottom-vented bottle and a conventional bottle were provided for feeding. Each newborn was fed two times and the order of the bottle was randomized. An intraoral pressure catheter was placed in the teat, furthermore O_2-saturation as well as heart rate were monitored. The resulting sucking patterns were examined and evaluated.

The results did not show any significant difference between the two bottles in terms of mean sucking pressure as well as mean sucking frequency. However the sucking pattern of the conventional bottle showed quick shifts in sucking pressure, which were interpreted as the opportunities to let air enter the bottle. Furthermore, vital parameters did not differ significantly, whereas the regression correlation of O_2-saturation and heart rate were different.

This study has shown distinctive differences among two feeding bottles in terms of the sucking pattern and shall serve as the basis for further research, concerning bottom-vented feeding bottles.

Glossary and abbreviations

alpha-trace digitalSLEEP record™	B.E.S.T. Medical Systems, Vienna, Austria
AntiColic™	MAM Babyartikel GmbH., Scheeßel, Germany
bpm	beats per minute
cga	corrected gestational age
e.g.	for example
ecg	electro cardiogram
hr	heart rate
i.e.	that is
mBar	1/1000 Bar
Microsoft Excel™	Microsoft Corporation, Redmond, WA, United States
NICU	Neonatal Intensive Care Unit
O_2-sat. (saturation)	oxygen- saturation
pca	post conceptional age
S1	System 1 = conventional bottle
S2	System 2 = AntiColic™ bottle
Silk Teat™	MAM Babyartikel GmbH., Scheeßel, Germany
vlbw	very-low-birth-weight

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Introduction

It is well known that breast feeding is a very beneficial way of infant feeding. However, it is not always possible and therefore bottle feeding represents an alternative option. There is a huge market for different feeding bottles, but the choice of which system to use should not be based on good advertisement. Is there a difference among the variety of feeding bottles for newborns available in stores? Even more important is the question which newborns need help and more sophisticated feeding systems. Especially preterm infants often need intense care during feeding and a lot of aid in order to acquire mature feeding abilities (1-3). In recent years ventilated bottles were introduced and advertised as the new choice of infant feeding. Thus companies try to link every aspect of natural "breast-like" feeding experience to their systems. The question remains if the suggested benefits can be taken for granted. Since only few studies really compare the different feeding bottles (e.g. (4)) in a randomized, controlled clinical trial, it is about time to do so.

Physiology of infant feeding

Infant feeding, especially for newborns and preterm infants, is a very complex process and has to serve different needs. It has to be efficient, preserve energy and provide the newborn enough calories to grow. Furthermore, it has to be guaranteed that oxygen is sufficiently available during all times. As the infant pharynx is the cross-way of air and liquid it has to be of complex anatomic structure as well as of precise functionality. A meticulous regulation of every single muscle assures intermittent swallowing and continuous breathing (1, 5). A highly complex pattern as well as coordination is needed to be developed to minimize the duration of airflow interruption during feeding. The newborn has to provide sufficient oral feeding skills to manage this effort. In nutritive sucking, the infant ingests its nourishment primarily due to changes in pressure as well as secondarily due to expression and compression of the nipple. To produce this pressure differences the oral cavity has to be sealed at first. The tongue is the key player of this closure. It seals the oral cavity anterior together with the buccal mucosa as well as posterior towards the soft palate. After this, the jaw and tongue move down to enlarge the oral cavity, create suction and provide a cavern for the intake of nutrition. Furthermore, the tongue also has to compress the nipple and press it against the hard palate to draw the fluid out of the breast. Indeed the compression/expression provides

an ancillary part in sucking, but for newborns with a mature sucking ability it only has small consequences (1). After the nourishment is sucked into the oral cavity the tongue plays a major role in the further transportation of the nutrition. It stabilizes the lower jaw and brings the bolus backwards due to the coordinated, wave-like movement of the tongue, which creates “standing waves”. If the bolus reaches the pharyngeal region swallowing is evoked (1, 6). The pharyngeal reflex is a very complex chain of brain activities. Swallowing is dependent on a certain amount of fluid gathered in the valleculae at the root of the tongue.

Furthermore during maturation of the newborn its neural system can more and more modify the sequence autonomously. The larynx and pharynx own a variety of chemo-, as well as stretch-, pressure- and thermo-receptors to do so (6). This alteration of the swallowing rhythm is necessary, if a closer look is put on the airway interruption during feeding. As the newborn commonly swallows about 60 times per minute with an average airway closure of about 530 ms, only approximately 30 seconds per minute remain for breathing. To provide sufficient oxygen-saturation levels the central nervous system is looking out for “windows of opportunity” for swallowing (7). Bu’Lock et al. (1) conclude their ultrasound study of newborns with the fact that the optimum sucking and swallowing ratio of 1:1 is already being reached partly by term newborns as early as 3 to 4 days after birth. If the breathing activity is also taken into account the most successful pattern for early newborns is sucking, swallowing and breathing in a ratio 1:1:1. This ratio positively correlates with maturity represented in gestational age.

Developmental stages of the feeding pattern

Preterm evolution

The overall feeding pattern is being developed in certain stages. Swallowing in fetuses has been described as early as 12 to 14 weeks gestational age. Real sucking, as defined by a posterior anterior movement of the tongue, begins at 18 to 24 weeks of postconceptional age. By week 34 most healthy fetuses are able to be fully fed orally, if born at that early age (6). Of course, the interaction of both sucking and swallowing with breathing can only be evaluated after birth. The rhythm of the pattern follows certain developmental stages. The maturation seems to positively correlate with the post conceptional age rather than with the postnatal age. A description by Gewolb et al. (8) revealed further details of the

congenital sucking pattern. Full term newborns at 40 weeks postconceptional age show a sucking frequency of about 65 per minute, whereas immature newborns at 32 weeks only suck 55 times per minute. Furthermore, the study shows that in the sucking pattern so called “sucking runs” appear over time. A sucking run in this study was defined as “more than 3 sucks within 2 seconds time”. Not only the occurrence of these sucking bursts, but also the duration correlate directly with the post conceptional age. The swallowing rhythm on the other hand did not show significant differences in the two age groups investigated. A stable swallowing rhythm seems to be developed earlier. From this point of view the behavior during feeding is rather congenital than acquired (6, 8-9).

Maturation during the first month of life

After birth the coordination of sucking, swallowing and breathing continues to develop. Within the first month of life after full-term birth two main changes can be noticed: on the one hand an increase of sucking frequency, and on the other hand an augmentation in swallowing rates. The suckling frequency increases up to 70 per minute at the end of the first month of life. Furthermore, efficiency of feeding is increasing, i.e. volumes of nutrient per suck and per swallow. It is interesting that concerning sucking pattern preterm infants can reach a fully matured stage earlier than term newborns when corrected for post conceptional age, but the rate of transfer of the liquid is significantly lower (2). Furthermore the 1:1 ratio of sucking and swallowing, which is most efficient for early newborns, yields a 2:1 as well as a 3:1 distribution over time (6).

During the first month of life normal infants gain consequently the ability to regulate the feeding process within certain borders. The feedback system is based on the amount of flow (i.e. liquid per second), temperature as well as taste of the nutrition, in order to optimize the newborn’s feeding efficiency (10). Furthermore fatigue as well as satiety reach higher significance during maturation in this time frame (5, 11).

The two dogmata: Breast- versus bottle-feeding

The exact differences of breast feeding and bottle feeding of newborns are a highly discussed topic. In this study the benefit of breast milk versus formula nutrition shall be disregarded as the main focus of attention will be set on the feeding physiology. It has been exactly investigated why babies benefit if breast milk is provided by breast, rather than applied by bottle. These benefits are miscellaneous, but the most powerful argument for breast feeding is a significant higher oxygen-saturation, not only during, but even after feeding (4). Furthermore, breast feeding has been discussed in terms of decreasing gastric stress and prolonged fussing and crying after feeding (4). To gain more knowledge about this topic, many studies try to demonstrate the differences of bottle- and breast-feeding.

It is important to know that the kind of teat used on the bottle highly influences the feeding success. The human breast nipple is compliant to the tongue movements of the newborn, perfectly seals the oral cavity and furthermore has a certain rough texture (1, 5). Usual artificial nipples are completely different. Even if the teat mimics certain characteristics, which are claimed for being beneficial, additional factors influence the feeding outcome. The bottle itself has certain disadvantages and therefore differs totally from the function of the human breast. A hydrostatic pressure caused by the weight and mass of the nourishment as well as by the position of the bottle influences the flow during feeding. Moreover, a vacuum buildup due to sucking is generated within the bottle and induces resistance for the newborn. Vacuum does not occur during breast-feeding and therefore is not physiological (5). As mentioned above the feeding skills of term newborns maturate after birth rapidly and therefore allow the infant to handle bottle feeding (2), however preterm infants can face difficulties. Especially in very-low-birth-weight infants the adaption to conventional feeding bottles can be prolonged. “In this case specially designed feeding methods can lead to sufficient oral feeding”, is claimed by Lau et Al. (12). Due to the complex setup of this study the fluid characteristics of the human lactation were simulated. The result was a significant higher rate of “successful oral feeding” than in the control group, fed by standard bottle.

The sucking pattern: comparison of breast- and bottle-feeding

Goldfield et al. (4) demonstrated a certain difference among both types of infant feeding. Via the pattern of breast-fed infants it was shown that swallowing is distributed non-randomly in the sucking cycle and breathing is not influenced. During bottle-feeding with standard, hard-walled bottles, swallowing occurs randomly and produces interference with breathing. This leads to lower oxygen-saturation during feeding. Furthermore, it causes gastric upset and burping, therefore even after feeding lower oxygen levels have been measured.

For a thorough understanding more aspects of the differences among natural and artificial infant feeding have to be taken into consideration. Moral et al. (11) investigated newborns, exclusively bottle-fed as well as exclusively breast-fed and a mixed-fed group. The main interest was put on the sucking pattern during feeding. The study demonstrated that newborns quickly get used to the type of feeding provided. It is astonishing that this is the only study comparing two widespread types of feeding in a longitudinal, cross-over design. To clarify the results and under consideration of the maturation of the sucking pattern over time (10) the participants have been investigated at two different ages. It is shown that exclusively breast-fed newborns show a significant higher sucking frequency than exclusively bottle-fed babies. A closer look at the sucking pauses per minute revealed more differences. Not the total number of pauses but its duration increased among the bottle-fed babies. In the mixed-fed group of newborns a mixture of the sucking characteristics is shown. It was interpreted, that newborns adapt their sucking pattern to the method of feeding (11).

The different methods of artificial feeding

It is important to observe two parameters during oral feeding: at first “safety”, which is a maturated coordination of sucking, swallowing and breathing in order to minimize the risk of aspiration or oxygen-desaturation, as well as “success”, which is a sufficient intake of calories over a certain time period (13). This classification is important by looking at the flow rates of an artificial feeding device. On the one hand it has to be assured that enough liquid can be brought into the infant’s mouth to guarantee short feeding times and on the other hand that the flow is limited to a safe level, which prevents infants from choking and guarantees proper ventilation. This led to the development of a “self-paced”

feeding device, which only provides sufficient flow, if the infant is suckling (described above) (13). Unfortunately such a setup is very complex and cannot be simulated in everyday situation. In a standard bottle the flow cannot be regulated precisely, because different forces are involved. The internal hydrostatic pressure of the liquid increases the flow, but its strength depends on the amount and type of nutrition. Therefore the flow changes permanently during the feeding progress. Another key part is the vacuum buildup which is inevitable, because the oral cavity is sealed during suckling (1, 5, 12). This vacuum buildup augments the retention of the liquid in the bottle. Hence the flow in standard bottles can only be regulated by the size of the teat's hole or the sucking characteristics of the infant. The size of the nipple hole is available in coarse steps, so it depends on the infant to adapt to the device. Lau et Al. (12) eliminated in their system both the hydrostatic pressure as well as the vacuum buildup and compared the resulting sucking pattern of very-low-birth-weight infants in different bottle systems. Significant benefits were revealed in terms of feeding safety as well as "success" for the complex device.

Regarding the market for different feeding bottles, many companies advertise their feeding products as the best and most breast-like. In fact, studies have shown validated benefits for certain bottles. It is proven that in terms of oxygen-saturation as well as sucking, swallowing and breathing coordination, some feeding systems really seem to imitate the function of the breast (4, 12). The standard hard-walled bottle with standard latex teat has lost more than once the comparison. Goldfield et al. (4) have investigated a specific feeding bottle and described a breast-feeding-like sucking pattern which characteristic's was a nonrandom distribution of breathing and swallowing, proofing that the neural system is waiting for "windows of opportunity" to induce the swallowing. This behavior is common during breast-feeding. The result was an almost continuous breathing pattern during the whole feeding process. The clue of the system was the special design of the nipple, which was elastic and ripped like the human breast. In addition the bottle was soft walled and contained a valve at its top that allowed a reduction of the vacuum buildup at the inside. Both led to a better compliance during ingestion and resulted in a breast-like feeding success. Other studies cited above surrogate even more complex feeding systems best for very-low-birth-weight infants (12-

13). In these cases a complex setup eliminated both, the hydrostatic pressure of the liquid and the vacuum buildup within the bottle during sucking. In combination with a breast-like nipple as described above, even VLBW infants were able to be fully fed orally. The control group babies, fed with a conventional feeding bottle, however, were dependent on gastric feeding tubes much longer.

Hence different bottles provide different benefits. But what kind of advantage will a bottom-vented feeding bottle have? Many studies showed huge differences between feeding devices (4, 11-13), however, not many studies exist, investigating bottom-vented feeding bottles (e.g. (4)). Under this aspect a basic investigation is needed to reveal possible differences. In consideration of the flow issue obtained above as well as of studies, that already claimed vacuum-free bottles as being beneficial (4), the bottom-vented feeding bottle has been selected for this trial.

The coherence of bottle feeding and extended infant crying

Another highly discussed topic is the increased infant crying and "colic behavior" after bottle-feeding. Studies show significant differences in terms of crying and fussing, comparing breast-feeding to bottle-feeding. It is shown that two different peaks of prolonged crying exist. Breast-feeding drastically reduces the time of "crying and fussing" at the age of two weeks in contrast to bottle-feeding. At two weeks of age, there seems to be the peak for crying for bottle-fed infants, whereas at the age of six weeks, the time of crying and fussing significantly decreases. For breast-fed infants the charts trend is vice versa (14).

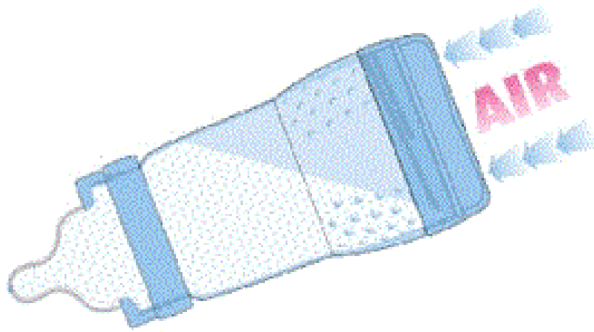
The term "colic behavior" has not been sufficiently defined, but Lucas et al. (14) used the appropriate phrase "bouts of intense, unsoothable crying and other behavior, perhaps due to stomach- or bowel pain". The actual reason why these "colic behavior"-peaks appear at two different ages among certain feeding techniques remains concealed. Furthermore, it is unidentified if the swallowing of air could jointly cause this problem. Goldfield et al. (4) however showed a link between the random swallowing distribution of bottle fed babies and the swallowing of air. Anyway, they could only link oxygen-desaturation events to the swallowed air but neither gastric stress nor "colic behavior". If

putting an eye on the possible reasons for the swallowing of air, both the high hydrostatic pressure as well as the vacuum buildup within the bottle could jointly cause this problem. As said above, the type of feeding leads to the evolution of a basically different sucking habit (11). During bottle-feeding, newborns need to suck the liquid out of their bottles and have to insert breaks into their sucking pattern (11, 13). Furthermore, standard bottles cause difficulties for newborns to regulate flow. This creates additional breathing interruptions due to longer swallowing time (4, 11).
Another reason for augmented crying and fussing could be the foaming of liquid inside the bottle. It is caused by air, which is balancing the negative pressure within the bottle during the sucking pauses, and furthermore depends on the kind of nourishment being used (15). Some bottles are unvented at all, thus the air needs to take the way throughout the nipple hole backwards into the bottle and foams up the liquid. The vented teats of certain bottles lead to the same result (12) as they are also located under the level of the liquid, if the bottle is used correctly.

Bottom-vented feeding bottles

Recently, bottles with bottom ventilation are introduced. As described above, a reduction of the vacuum buildup may be beneficial for infant feeding in many ways (4, 12) and additionally could be a reason for the reduction of infant crying (14).

Now the valve of this specific feeding bottle needs to fit certain criteria (*picture 1*). If it would open up immediately, it would lead to a dripping of liquid out of the bottle, probably causing choking. That again would limit the newborn's ability to regulate flow. So it has to be designed in a way to neutralize the hydrostatic pressure in order to retain the liquid within the bottle. Furthermore, it has to open if the newborn is performing continuous suckling to provide proper flow, but without the buildup of a massive vacuum. This vacuum within the bottle is suspected to produce a non physiological sucking pattern (4, 12). The approximate pressure level for valve opening is kept at about -30 mBar (companie's data from Mam Babyartikel GmbH, Scheeßel, Germany).



Picture 1: schematic of the function of the bottom valve

Picture 2: SilkTeat™

In order to fully gain the possible potential of this bottle it has to be combined with a teat that provides the same beneficial characteristics as the human breast's nipple. It has to have a certain shape in combination with a high elasticity (described above). Furthermore it is important that it is not napless and provides a perfect closure in the baby's mouth (1). The Silk Teat™ used in this study is shown in *picture 2*.

Can newborns really be in need of bottom-vented feeding bottles?

Far more difficult is the selection of participants, who could benefit from such a device. In fact term newborns that have not yet got used neither to any bottle system nor breast-feeding would conform best for a clinical trial. (11). As the recruiting process took place at the newborn ward of the Children's Hospital of Leoben, certain variations (e.g. premature infants) and limitations had to be accepted, but this guarantees external validity. It was considered best to start with newborns, because studies show that babies change their feeding techniques quickly and may adapt to different systems (10-11). As the tested bottle also includes a silicone teat that tries to mimic the elasticity, shape and consistence of the breast, newborns that are used to breast-feeding would probably lead to adulterated results. Therefore exclusively bottle-fed infants conformed best.

The AntiColic™ system was tested against a standard bottle with ordinary latex teat which is commonly used for newborns. To reduce the risk of a selection bias, recruiting process started right after birth, under consideration of the four days stabilization of the sucking performance described above (1). Furthermore, the ability to be fully fed orally as well as exclusive bottle-feeding by then was taken for granted. If there should be a difference between the two devices, the panel of this study will best reveal potential benefits.

Hypothesis of this study

It was investigated, if a clinical difference of bottom-vented feeding bottles in comparison with standard models can be found. Furthermore, it was intended to clarify what kind of distinction this could be and which benefits can be drawn out of it. In prior studies the pressure within the bottle and the oral cavity were registered for different teats (3). Thus it was considered best to use the intraoral sucking pressure as the main variable of this study. It is an objective parameter and can be measured easily. The bottom-vented bottle can be compared to a standard, hard walled system with an ordinary nipple. This system was considered to allow a higher vacuum buildup. Although sucking is not the most important parameter to regulate milk flow during breast feeding (production of standing waves with continuous tongue movements regulates the flow (16)) it is well developed anyway for bottle-fed infants (13) and therefore may be used to appropriately compare the two systems. In this study design a bottle-teat combination was tested, therefore it was not possible to deduce eventual differences in the pressure levels to the bottle or the teat alone. The tested device competed against the most widespread type of artificial feeding system, which is the standard bottle with the standard nipple. Because the study's data was based on two systems available in stores, it will have external validity.

Main and additional variables of this study

The main variable in this study is based on the observation of the intraoral sucking pressure and its distribution in sucking pattern. To expand the significance of this study, it was of interest to collect the vital parameters as well. The main argument against bottle-feeding of early newborns is a lower oxygen-saturation. It is proven that breast-feeding leads to higher oxygen-saturation levels during and after the feeding process (4, 12). Therefore the collection of additional vital parameters, namely oxygen-saturation and heart rate, was considered as essential.

If there is a significant difference in the two feeding systems, a sucking pattern with overall less negative pressure buildup in the bottom-vented system should be expected. If newborns instinctively compensate the vacuum within unvented bottles by letting air backwards into the bottle, these peak-like changes in pressure should be visible. It was another point of interest which changes could be found in terms of sucking frequency. Since the vital parameters were represented in my design, the effort during feeding could be deduced (5, 17). In this term better oxygen-saturation levels should be registered during feeding with the vented bottle. A trend towards lower heart rate levels is expected to be accessorily seen in the recordings of the AntiColic™ system. Therefore my hypothesis was the following:

“It is more exhausting for newborns to continuously suckle against a vacuum; furthermore, periodic breaks for ventilation should occur during the sucking pattern of a conventional feeding bottle.”

Methods

Participants criteria

The recruiting process took place at the Neonatal Ward and Neonatal Intensive Care Unit (NICU) of the hospital of Leoben. In May 2009, all healthy newborns with at least 32 weeks of post conceptional age, birth weight greater than 1390 g and the ability to be fully and only bottle fed were considered as suitable for this study. As exclusion criteria any functional and physical birth malformations, especially those that limit the ability of bottle-feeding, severe health deficits namely necrotizing enterocolitis, bronchopulmonary dysplasia and congenital heart defects, as well as severe birth disabilities were considered. Furthermore, respect was given to the wish of the parents to breast-feed completely. All parents of eligible newborns were given the option of voluntary participation in the study. For all participating newborns parents were given verbal and written information and participation was approved by written informed consent. The prospective, randomized and open study design has been licensed by the Ethics Committee of the Medical University of Graz. As far as possible the same number of male and female newborns was chosen and there was no discrimination in terms of ethnicity or family background.

All participants were made anonymous by giving them identification codes. The exact physical data of all eleven participating newborns are shown in *table 1*. The final goal of this self-control study is to reveal a possible difference in terms of intraoral sucking pressure between two bottle systems. The first system (S1) is a standard hard wall 160 ml bottle, the other system is the AntiColic™ bottom-ventilated bottle (S2), both from MAM Babyartikel GmbH, Scheeßel, Germany.

Table 1: Descriptive characteristics of the study's population

Total number	11
Male newborns	8
Female newborns	3
Weight at the day of examination in grams	3214 (1210)
CGA* in weeks	41 (5)
Age at the day of examination in days	39 (36)
PCA** in weeks	35 (4)
Birth weight in grams	2333 (885)
Birth length in centimeters	45 (5)
Birth head circumference in centimeters	31 (3)

Mean values and standard deviation in (); *CGA – corrected gestational age; **PCA – post conceptional age

Setup and equipment

All measurements took place at the sleep laboratory of the Children's Hospital of Leoben. As all newborns at the ward have standard cardiac monitoring, electrodes simply were connected to the alpha-trace digitalSLEEP record™ system (B.E.S.T. Medical Systems, Vienna, Austria). An additional palm O_2-saturation detector was placed for cardiopulmonary surveillance. The pressure detector of the alpha-trace digitalSLEEP record™ system was plugged to a 3.0 mm suction catheter. The nipples of the two systems were prepared with a piercer, hole-size 1 mm smaller then the exterior diameter of the suction catheter. The first teat was a standard latex one, size 1 (suitable for newborns), the second was the soft silicone Silk Teat™ size 1 (*picture 2*) specially designed for the AntiColic™ bottle (*picture 1*) (Both systems from MAM Babyartikel GmbH, Scheeßel, Germany, except the standard latex teat available from numerous suppliers). Because of this construction, no additional tape was needed to fix the tube. The cut was placed next to the suction hole of the nipple and the catheter ended approximately 5 mm within the oral cavity. This setup allowed a registration of the intraoral pressure over a specific sucking period. All collected data were registered with the alpha-trace digitalSLEEP record™. The same program was used for detailed analysis of the recorded parameters, before exporting to Microsoft Excel™ (Microsoft Corporation, Redmond, WA, United States) for further statistical evaluation. All catheters were single used, bottles and nipples were sterilized after every setup. Every recording was video-taped for documentation.

Timetable of research

After acceptance of participation, all measurements took place on the following day. The newborns were taken, if procurable, at their two morning feeding times, at approximately 8 am and 11 am, whereas the two bottle systems were taken in random order. The newborns were fed, if possible, by their parents and otherwise by nursing personal. Eight babies received breast-milk, whereas the others were fed formula. For the quality of the statistical evaluation it was important that the difference in the sucking pattern to be based only upon the two bottle systems. For that reason the type of nourishment, its amount as well as the feeding-temperature each newborn was used to, were maintained. The different fluid characteristics of either meal were assumed to be negligible. Recording started with providing of the bottle and continued until the end of feeding. It was not taken into account whether the bottle was finished completely or not. The procedure remained the same for both bottle systems, and it was possible to collect all necessary data from one newborn at the same day.

Recorded parameters

All parameters to be analyzed have been clearly defined in advance and are the following:

I.) Intraoral sucking pressure

II.) O_2-saturation

III.) Heart rate and ECG

The primary parameter is the intraoral sucking pressure and its characteristics during bottle-feeding. The heart rate and the O_2-saturation levels are taken in order to receive an objective impression of the physical effort of the newborns during the feeding process. All parameters have been recorded during the whole feeding process, lasting up to 20 minutes maximum. Analyzing the pressure levels in the oral cavity revealed, that during the feeding process liquid filled the small catheters, which lead to an augmenting inaccuracy of the pressure registration with time. To get validated patterns, only the first 20 seconds of continuous sucking were taken separately for statistical evaluation. Accessorily, if available, the whole collected data was taken into another account. To deduce the effort while feeding the levels of heart rate and O_2-saturation were analyzed.

Statistical tools

Statistical analysis was conducted using Microsoft Excel™ in order to get results for the following main aspects: comparison of the two feeding systems in respect to intraoral pressure levels; variation of variables that reflect the physical effort of feeding; creation of a compared sucking pattern; and the correlation between the variables. The paired samples t-test was used for comparison and linear regression, whereas ANOVA was undertaken to find correlations between variables.

Results

For the results, ten participants were taken into account, because one newborn did not create any sucking pattern for the conventional bottle. The data collection is based on direct comparison of the two feeding systems. For comparison of pressure recordings, this infant was excluded from further evaluation. However, since the newborn could be regularly fed and the vital parameter recordings were correct, these data were used for comparison of physiological parameters.

The sucking pattern and its characteristics

A typical sample sucking pattern is shown in *figure 1*. In this sequence the regular sucking pattern can be found for the AntiColic™ system (blue). In the pattern of the conventional system (green) an interruption is shown. At this point a sucking break could be evoked to let air via the nipple into the bottle.

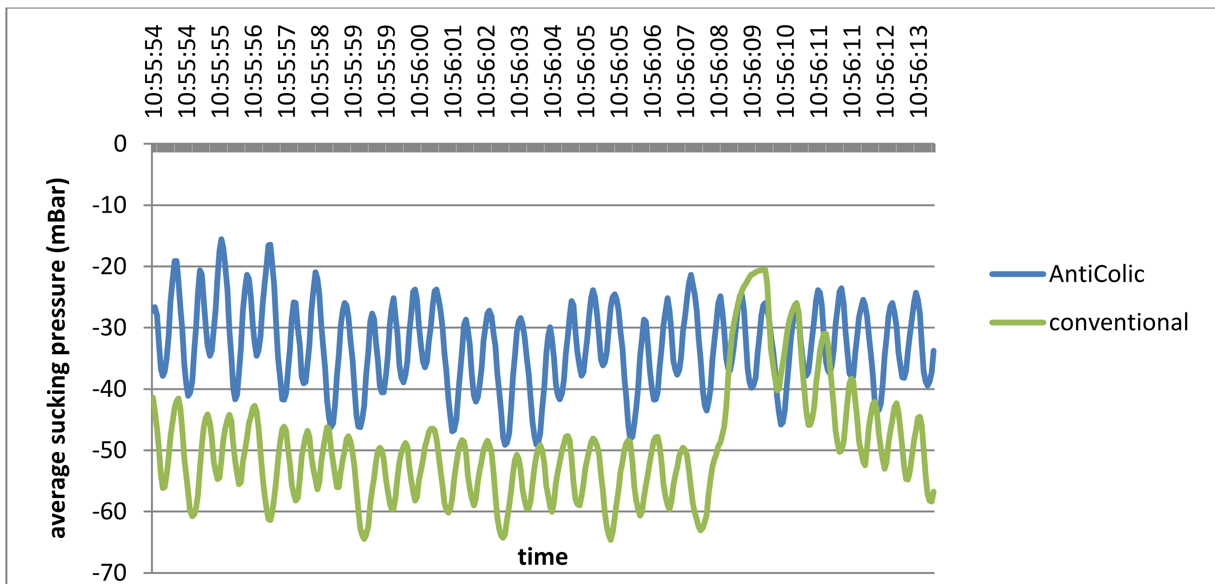


Figure 1: The conventional sucking pattern shows an interruption break at 10:56:09

In order to get an idea of the distribution of these sucking breaks, their number was counted manually within all the 20 seconds recordings. As this method does not show a statistical relevance, only a descriptive result can be published. These sucking breaks appear almost three times more often in the unvented standard bottle. (mean values: 0,4 times / 20 seconds as well as 1,1 times / 20 seconds in the AntiColic™- versus the standard bottle respectively). A break was defined as an abrupt up-shift of the mean pressure level of more than 10 mBar within a time frame of continuous sucking.

Sucking pressure and frequency analysis

The sucking pattern was evaluated separately for two time periods. Due to the varying recording quality of the measurements, it was decided best to take only 20 seconds of every participant's pattern to get comparable results. For further comparison the first 20 seconds of continuous sucking were taken into account. The main endpoint was the intraoral sucking pressure during feeding. During the first 20 seconds the mean sucking pressure for the AntiColic™ system was -33,34 mBar (SD: 11,95 mBar) and -32,60 mBar (SD: 19,25 mBar) for the conventional, unvented bottle. The next analyzed parameter was the most negative sucking pressure. It was located at -50,92 mBar (SD: 9,48 mBar) for the AntiColic™ system and at -51,45 mBar (SD: 15,88) for the conventional system. The results showed no significant difference in the paired samples t-test. For the determination of the sucking frequency, the number of peaks was counted within the first 20 seconds pattern and multiplied by 3. A slightly higher sucking frequency could be found for the AntiColic™ system (p=0,15) as shown in *table 2*. However, also this difference was not statistically significant.

	AntiColic™	*conventional*
average	81,2	78,3
standard deviation	12,53	9,32
observations (n)	10	10
Pearson correlation	0,730	
degrees of freedom (df)	9	
t-statistic	1,070	
one tailed p-value	0,156	

Table 2: sucking frequency (1/min) in paired sample t-test; α=0,05

Analysis of the main variables for the whole collected data

After intense studying of the recorded data, it was clear that the overall sucking pattern followed certain variations in pressure levels. I first wanted to find a standardized way to compare the pattern, which was only possible by defining the first 20 seconds of recordings. In fact, more than one minute of evaluable sucking data of each test was recorded via pressure detector. The pattern was only interrupted by odd sucking breaks. By checking the video material, it could be seen that these pauses were produced mainly due to loose suction catheters, leading to a non physiological high flow, causing choking. After the catheters were replaced and fixed, the sucking pattern could be recorded without further interruptions. Due to the non significant results of the first 20 seconds it was considered in a second step to use all available data of the sucking period. For this purpose, each continuous sucking pattern longer than 10 seconds and showing a frequency between 60 and 110 per minute (the estimated frequency levels for all data) was considered suitable and taken into further evaluation.

In these results, there was a shift in sucking pressure leading to a mean value of -32,70 mBar (SD: 11,63 mBar) for the AntiColic™ system and -33,46 mBar (SD: 18,37 mBar) for the conventional system. The maximum vacuum buildup in the oral cavity was at -52,22 mBar (SD: 8,70 mBar) for the vented bottle and at -53,56 mBar (SD: 15,15 mBar) for system 1. For the frequency analysis of sucking bursts, I used the same method of counting manually, but this time I used all available sequences of the sucking pattern, leading to a more accurate result. In these longer sequences it can be seen that the frequency is slowing down during sucking. For achieving results, I used mean levels of all countable recordings. For the AntiColic™ system the frequency was 76,81 /min (SD: 13,67) and for the conventional system 76,02 /min (SD: 9,06). All values are statistically not different in paired samples t-test, but they are showing a slight trend toward lower pressure levels in the AntiColic™ system.

Regression correlation of sucking pressure and sucking frequency

Due to the high variation of the sucking pattern over time and the low significance of the 20 seconds results, it was assumed best to use only the longer evaluation periods for further statistical analysis. In a regression analysis of the sucking frequency as well as the mean sucking pressure following results could be found:

the higher the sucking frequency, the more negative the sucking pressure drops;

comparing both feeding systems in the regression analysis the gradient for the AntiColic™ bottle is significantly higher (*figure 2; 3*);

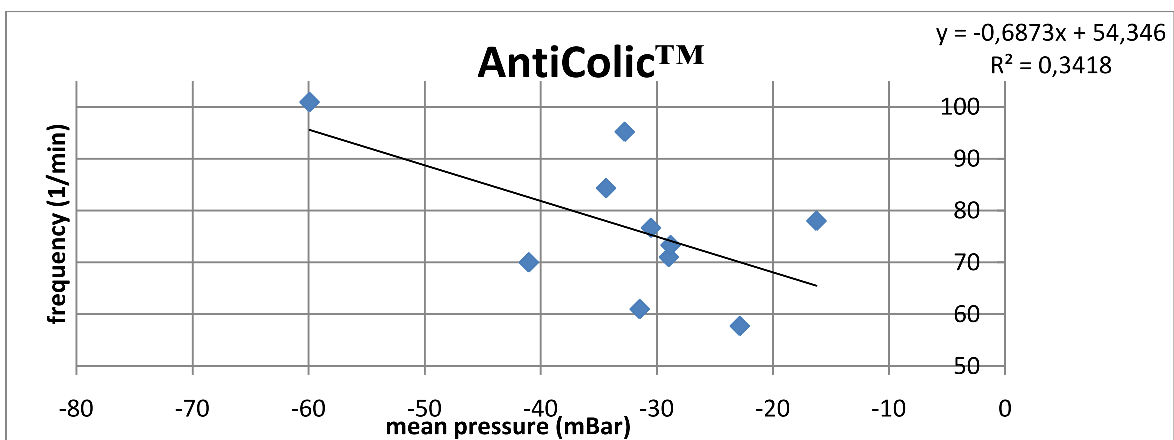


Figure 2: regression analysis of sucking frequency and average sucking pressure, k=-0,69, R^2=0,34;

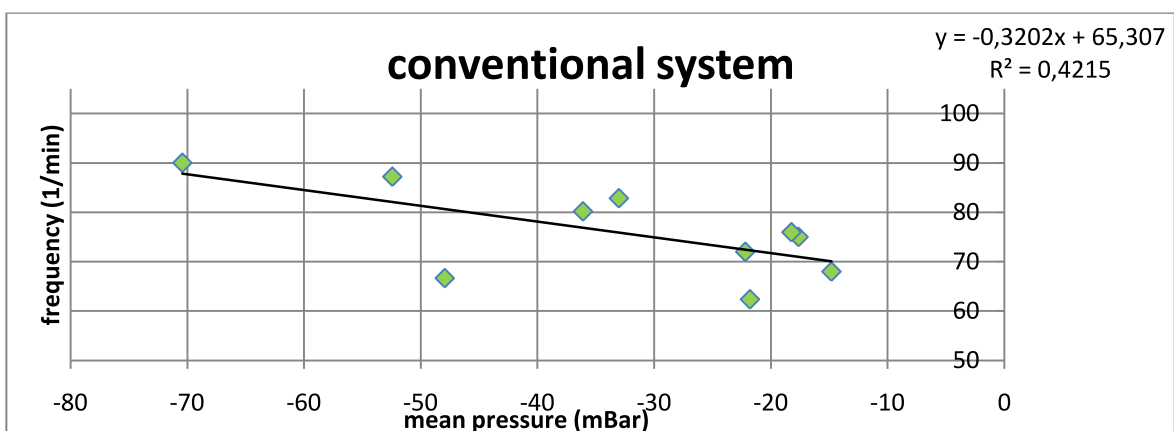


Figure 3: k=-0,32, R^2=0,42; in the conventional system diagram, the regression gradient is half the size of the AntiColic™ system

Vital parameter evaluation

The next point of interest was the investigation of the monitored physiological parameters. I took records of both, O_2-saturation and heart rate during the whole feeding period. Especially newborns regulate these parameters quickly. Therefore I used the same evaluation principle as for the sucking pattern. The collected data again were analyzed separately, at first for 20 seconds and in a second step for the whole feeding period. It was considered best to maintain this approach, because it could be assured that few as possible external influence adulterated the vital parameters during the first 20 seconds.

The results for the data taken synchronously with the first 20 seconds of the sucking-pattern are the following:

Mean O_2-saturation level for the AntiColic™ system was 94,78 % (SD: 2,35 %), compared to 95,62 % (SD: 2,36 %) for the conventional system. Mean heart rate values were 155,13 bpm (SD: 22,66) versus 159,14 bpm (SD: 16,54) for the AntiColic™ system compared to system 1 respectively. The results again did not show any significant p-values in the paired samples t-test. In a regression analysis, no correlation of heart rate and O_2-saturation was found.

Assuming that O_2-saturation levels, as well as may heart rate, are reflecting effort during feeding time, lower heart rate and higher O_2-saturation represent less effort (5, 17-18). To gain validity I analyzed the whole feeding process regarding vital parameters. All feedings were completed with the desired amount of nutrition. The average duration of the collected data was approximately 15 minutes each.

The values of vital parameters for the whole feeding period are resumed in *table 3*.

n = 11	*AntiColic™*		*conventional*	
	O_2-sat.	**HR**	**O_2-sat.**	**HR**
mean value	94,20	154,50	95,26	153,72
standard deviation	3,34	16,40	2,59	13,19

Table 3: O2-sat. (%); heart rate (bpm); n= number of measurements for each system; p-values outside significance levels

Regression analysis

Comparing the regression analysis of the vital parameters of both feeding systems a positive correlation of heart rate and O_2-saturation could be found. It is shown in *figure 4* that the higher the heart rate, the higher the O_2-saturation level increases.

In *figure 5*, representing the conventional feeding system, the correlation is opposite. It shows a negative correlation, i.e. a higher heart rate goes along with lower O_2-saturation level.

This correlation is demonstrable in the measurements of the whole feeding time. As the paired samples t-test shows no significant difference, neither in the mean heart rate levels, nor the O_2-saturation levels, further discussion is needed to determine the reason for this correlation shift.

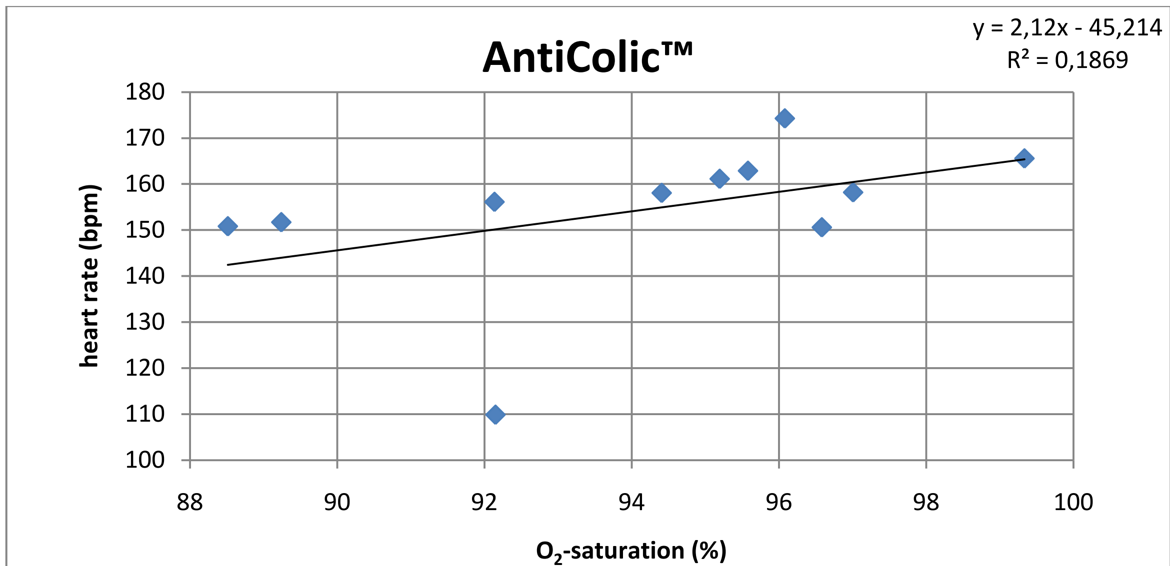


Figure 4: correlation of hr and O2-saturation for the AntiColic™ system, positive correlation: k=2,12;

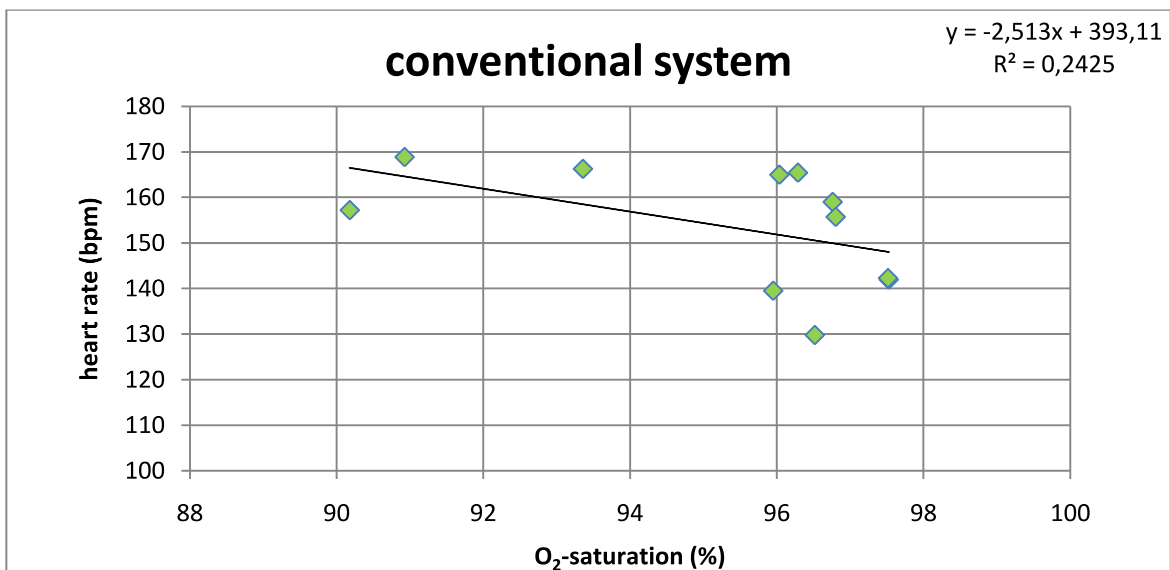


Figure 5: correlation of hr and O2-saturation for the conventional system, negative correlation: k=-2,51;

Discussion

This was the first study to systematically investigate possible differences of bottom-vented feeding bottles. Although mean pressure levels did not differ significantly, certain variations of the sucking pattern could be found. For the trial two commercial available bottles for newborns were tested against each other. Therefore, an objective gaugeable parameter was chosen to find differences between the feeding systems. The sucking pressure as the main variable was recorded in the oral cavity. As recording of the pressure within the bottle would not accurately show the actual sucking physiology this approach was abandoned. Although the main variable did not show statistically significant differences of mean levels, this does not imply that the resulting sucking pattern of the two bottles is identical. Tests with the conventional bottle indicated sudden shifts in pressure levels. Their origin and physiology shall be discussed here.

For the evaluation of the newborn's sucking patterns, two different approaches were needed. This was due to the sucking sequences which were only continuous for about one minute at a maximum. Also in existing literature this behavior is common (10, 19-20). As the shortest continuous sucking period within all data was approximately 20 seconds, this time frame of each sequence was further investigated. In order to find a standardized way of comparing as well as to avoid other influences these recordings were the basis for closer evaluation.

On the other hand it would have been regretful, if the rest of the overall recordings had been ignored. Therefore a second evaluation was created, in which every sucking movement of a certain length, unaffected of the pauses in between, was taken into another account.

Definition of the hypothesis

A pressure detector within the bottle would not allow an estimation on sucking physiology, because the valve of the AntiColic™ systems opens at a pressure of about -30 mBar (manufacturer's information), whereas unvented systems allow higher negative pressure within the bottle. It was hypothesized that the valve should not only limit the vacuum buildup within the bottle, but furthermore should allow the newborn to decrease the sucking pressure during feeding. In the present study this assumption could however not be confirmed.

In addition, the sucking patterns of the two different bottle systems were investigated. Not only the intraoral pressure and its rhythm as well as mean levels were evaluated, but also quick shifts in pressure and peak-like characteristics were counted. The statistical p-values are not significant, however a trend can be shown. This trend was characterized by a more continuous sucking pattern and slightly lower pressure levels for the AntiColic™ system. This fact allows to infer on the hypothesis that there are indeed certain differences of the two sucking patterns.

The actual differences of the sucking pattern

Only regression correlation shows certain differences among both systems

The analysis of the sucking frequency of the whole data corresponded well with the results of prior studies (6, 10), thus indicating a correct setup of the examination. Concerning the newborn's various characteristics, a mean sucking frequency of 76 per minute found during the investigation is common standard for newborns at that age (10). A significant difference of the sucking pattern by use of the two feeding bottles could not be seen. Apparently, sucking rhythm is rather congenital than by predisposed a consequence of the feeding device (9).

After the first parameters were evaluated apart, a combined point of view was used next. The regression correlation of mean sucking pressure and sucking frequency was analyzed and showed explicit coherence (*figure 2, 3*). A higher sucking frequency correlates in both feeding system with a higher sucking pressure. During the maturational changes of the sucking pattern within the first month after birth, the sucking frequency rapidly rises.

During this maturational process the volumes per suck and per swallow almost double (10). This confirms well with the results of my study. In addition, the gradient of the regression line for the AntiColic™ bottle is steeper than for the conventional system *(figure 2).* A simple explanation could be the higher vacuum buildup within the conventional feeding bottle, which may hamper high effective sucking pressure during high sucking frequencies. In bottles with vented bottom higher sucking pressure during high sucking frequencies seems to be possible, maybe because the counterforce of the vacuum decreases, and thus possibly enabling higher volumes per time. As I neither did record the pressure within the bottle nor the flow of nutrition, only speculations in this direction can be made. However, due to this distribution of pressure and frequency for the AntiColic™ bottle, higher flow rates could be possible. As I did not find signs for choking or severe oxygen-saturation decline during all my recordings high sucking pressure in combination with high sucking frequencies is possible. The setup of a future study will have to record flow rates and overall transferred volumes and to investigate if this distribution of sucking parameters allows higher flow rates and safe feeding.

The different characteristics of the sucking patterns

Even if the first part of my hypothesis "it is more exhausting for newborns to continuously suckle against a vacuum" could not be confirmed, the claim "breaks for ventilation will occur during the sucking pattern of a conventional feeding bottle" can be discussed.

Nutritive sucking of newborns is never continuous, actually it contains a lot of physiological interruptions. The distribution and manifestation of these breaks change during maturation of the newborn. Furthermore the type of nourishment, its temperature, amount, as well as feeding method have an influence. Not at least the newborns themselves regulate the sucking pattern depending on fatigue, hunger as well as satiety and day time (5, 10-11).

During standard bottle-feeding a cumulative appearance of sudden shifts in pressure levels was found in this study. The sucking pattern was observed closely and it was tried to find certain interruptions of the pressure levels within a continuous sucking period. In the results it was adhered to the fact that a break was an abrupt up-shift of the mean pressure level of more than 10 mBar. In my study it is shown that these interruptions occur more often if using the conventional bottle system, thus their origin has to be

discussed. An obvious cause could be an opening of the infant's mouth to interrupt sealing of the teat. This would allow air to enter the oral cavity and make sense, because the unvented bottle does not allow another entry of air during sucking. Therefore newborns just have to shortly give up the sealing of the teat to equilibrate the negative pressure.

Still the exact characteristic of the vacuum within the standard bottle is unclear. If no air would be let in the bottle, at a point effective sucking would in terms of fluid intake not be possible anymore. In the standard bottle, there is only one way out, therefore the air has to take the same way like the nourishment does, which is the hole of the teat.

Concerning the interruptions in pressure levels, it is obvious that these are the opportunities to let the air flow. Since they are very short it is unlikely that the vacuum can be balanced but still can be reduced. Regarding the flow characteristics of an unvented bottle as well as the physiology of infant feeding, this reduction however could lead to easier suckling. Nevertheless, these interruptions have been recorded only within the oral cavity, and for further research the results have to be pulled together with transfer rates of the nourishment and feeding success.

What's about the foaming of the milk?

If an eye is put on the thesis that a foaming of the milk during an air inflow interruption via the teat occurs, this could cause augmented swallowing of air. However this could not be observed in my study. The setup did not allow a standardized observation of the bottle's content. As it is manifest that foamed milk could lead to augmented swallowing of air, further investigations have to be made. In addition it is yet unclear if a coherence of air-swallowing and gastric upset can be found at all. Concerning only the observations of this study (the AntiColic™ bottle shows fewer interruptions and is bottom-vented) it could be possible that foaming of the milk simply does not occur and in addition fewer air is swallowed during feeding. If a link between foaming milk and gastric upset can be found, this system could be beneficial in terms of reduced infant crying from colics. As this is a notional thesis further research is needed in this direction.

The vacuum in vented bottles

Since the discovered interruptions also appear in the AntiColic™ bottle, their origin cannot exclusively be explained by the vacuum buildup within standard bottles. Of course the bottom-vented bottle allows a low vacuum buildup as well, however it should not increase to more than -30mBar inside the bottle. Pressure recordings were taken within the oral cavity and the described sucking interruptions exclusively concern the sucking pressure. It could not be revealed within this study's design if during these slight decreases of suction air could enter the bottle. Additionally pressure recordings have to be installed within the bottle, in order to bring the pressure levels together. In future studies it will be essential to additionally register flow rates to reveal the exact coherence of a vacuum buildup and the actual fluid characteristics.

It will be furthermore important, regarding this observation, to look for similar interruptions in the sucking pattern during breast-feeding as well. It will help to specify the origin of these events as it is yet unclear if they only appear during artificial feeding, or if they are a physiological event during suckling.

Monitoring data and the effort during feeding

The monitoring data were defined as additional parameters for this study, but in fact they are probably the most important objective values for safe and successful infant feeding. Since fortunately no severe oxygen-saturation declines occurred during all feedings, both bottle systems in use seem to be well accepted by newborns. If a general look is put on the results of the monitoring data it is shown that no statistical difference exists. Apparently the AntiColic™ bottle does not differ from the conventional feeding system in terms of vital parameters at all.

However, if a closer look is put on the results of this study some interesting correlations were seen. In the regression correlation of oxygen-saturation and heart rate, which are the expected indicators for the effort during feeding (5, 18), distinctive differences could be found within the two bottle systems *(figure 4, 5)*.

Is there an explainable reason for the opposite alignment of the regression lines? It is shown for the AntiColic™ bottle that higher heart rate positively correlates with higher oxygen-saturation. And what is the reason for the alignment of the regression line in the conventional bottle system? In this case low oxygen-saturation levels are combined with higher heart rates.

Basically the correlation changes of heart rate and oxygen-saturation can be explained in two steps. At first apnea causes a vagal stimulus and therefore heart rate decreases. Secondly if the apnea's duration increases the oxygen-saturation level drops and causes a strong stimulus to fasten the heart rate (17). This physiological mechanism of the body guarantees sufficient oxygen as well as substrates during high effort (e.g. during feeding (5)). Of course this reflex is only triggered, if breathing is interrupted, no matter if physically or physiologically (e.g. during swallowing). Many studies have claimed that oxygen-desaturation events during feeding are first of all more common in very-low-birth-weight infants and secondly happen more often, if newborns are fed by bottle and especially by their parents (18). Furthermore, oxygen-desaturation could be a mismatch of swallowing and breathing, but during maturation of the newborns the frequency of these mismatches decreases. Apart of that could the use of conventional feeding bottles lead to worse oxygen-saturation levels as well (4).

In other studies it is claimed that bottle feeding sometimes causes “gastric upset“ or “colic behavior” (14). These two behavioral conditions are caused on the one hand by an uncoordinated swallowing pattern and on the other hand probably by foaming of the milk inside the bottle. Therefore this could lead to a higher amount of air that is being swallowed during feeding and causes augmented stress. As this thesis is not yet confirmed by a controlled clinical trial, further studies have to be conducted.

As the differences among the two bottles are very small and furthermore not statistically relevant, it cannot be explained within this study in which way the AntiColic™ system influences the vital parameters regressions correlation. Nevertheless in this term it differs from the conventional feeding bottle. Companies claim better fluid characteristics as well as minor foaming of the nourishment for bottle vented feeding bottles, which both could be beneficial for the gastro intestinal system as well as for uninterrupted breathing.

However, in this study this argumentation could not be verified. Furthermore it is inexplicit if the vented bottle, in combination with its special teat, can produce a genuine breast-like sucking pattern with all its benefits.

A study design like Goldfield et al. (4) , in which two bottle systems were compared to breast-feeding could reveal further details. The regression correlation for the vital parameters will have to be analyzed for breast-feeding as well and compared to the bottle-feeding results. After that one of the different correlations could be linked to the physiological pattern and therefore determine the more “breast-like” feeding system.

Conclusion

There are certain differences between bottom-vented and conventional feeding bottles. The sucking pattern of conventional bottles shows sudden shifts in pressure levels and the vital parameters are distributed oppositely in a regression analysis. However it is not shown that a bottom-vented bottle causes less effort during feeding.

The goal was to determine if two feeding systems differ at all. For that purpose a small collective was investigated. This study may be the authorization for closer investigations concerning bottom-vented feeding bottles. It will be essential for further research to expand the study’s participants to a control group of breast-fed newborns. Furthermore, repeated measurements at different ages shall uncover, if babies benefit during different maturational stages. It will be useful if flow characteristics are additionally monitored. This will guarantee a more detailed view on the certain differences among the feeding bottles that have been found within this study. Finally under consideration of these aspects a bigger and more homogenous collective has to be recruited to draw statistical significant conclusions.

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Notes