The Patient Hazards of Not Maintaining Proper Cuff Pressure of Air Inflated Endotracheal Tubes

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The following is a compilation of clinical research articles centered around safe airway management. These articles provide insight on how constantly managing cuff pressure can help avoid complications such as Ventilator Associated Events (VAE), Tracheal stenosis, post-operative sore throat, bleeding and cough. Each summary statement will reference the abstract/full article submission. The summary also references a newer prescription device (CuffSentry™) that has entered the market and is designed to measure and regulate intracuff pressures of endotracheal and tracheostomy tubes.
A Clinical Summary:

- Air filled endotracheal tube (ETT) cuffs are often underinflated and overinflated. CuffSentry is designed to maintain the user set Pcuff for ETT.

- Optimal endotracheal tube cuff pressures are recommended between 20-30 cmH₂O. CuffSentry is user adjustable within and beyond the recommended ranges.

- Microaspiration occurs when ETT cuffs are underinflated. CuffSentry maintains a constant Pcuff therefore minimizes microaspiration.

- ETT cuff over inflation results in ischemia and tracheal wall damage. Underinflated ETT cuffs contribute to ventilator-associated pneumonia. CuffSentry continuously displays applied Pcuff increasing clinician awareness.

- Commonly used techniques to manage Pcuff cause loss of air in the cuff, therefore under inflation. The minimal leak technique and minimal occlusive volume are examples that result in low Pcuff. Devices for cuff pressure management that require the use of a syringe and manometer to inflate cause loss of Pcuff. CuffSentry ensures continuous Pcuff and remains at the clinically set value.

- Use of a pneumatic device or device that continuously controls Pcuff aids in reducing incidences of over and under inflation in ETT cuffs versus intermittent cuff technique. CuffSentry continuously controls Pcuff without the need for intermittent cuff checks.

Note: The corresponding numbers for the statements above refer to article abstracts found in this publication. Look for the number next to each statement to locate the referenced abstract. All abstracts were obtained from http://www.pubmed.gov (unless noted otherwise). Links to the abstracts and full articles are included.
Continuous control of tracheal cuff pressure and microaspiration of gastric contents in critically ill patients.

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Abstract

RATIONALE:
Underinflation of the tracheal cuff frequently occurs in critically ill patients and represents a risk factor for microaspiration of contaminated oropharyngeal secretions and gastric contents that plays a major role in the pathogenesis of ventilator-associated pneumonia (VAP).

OBJECTIVES:
To determine the impact of continuous control of tracheal cuff pressure (P(cuff)) on microaspiration of gastric contents.

METHODS:
Prospective randomized controlled trial performed in a single medical intensive care unit. A total of 122 patients expected to receive mechanical ventilation for at least 48 hours through a tracheal tube were randomized to receive continuous control of P(cuff) using a pneumatic device (intervention group, n = 61) or routine care of P(cuff) (control group, n = 61).

MEASUREMENTS AND MAIN RESULTS:
The primary outcome was microaspiration of gastric contents as defined by the presence of pepsin at a significant level in tracheal secretions collected during the 48 hours after randomization. Secondary outcomes included incidence of VAP, tracheobronchial bacterial concentration, and tracheal ischemic lesions. The pneumatic device was efficient in controlling P(cuff). Pepsin was measured in 1,205 tracheal aspirates. Percentage of patients with abundant microaspiration (18 vs. 46%; P = 0.002; OR [95% confidence interval], 0.25 [0.11-0.59]), bacterial concentration in tracheal aspirates (mean ± SD 1.6 ± 2.4 vs. 3.1 ± 3.7 log(10) cfu/ml, P = 0.014), and VAP rate (9.8 vs. 26.2%; P = 0.032; 0.30 [0.11-0.84]) were significantly lower in the intervention group compared with the control group. However, no significant difference was found in tracheal ischemia score between the two groups.

CONCLUSIONS:
Continuous control of P(cuff) is associated with significantly decreased microaspiration of gastric contents in critically ill patients.

Abstract Link: http://tinyurl.com/kjss39f
Full Article Link: http://tinyurl.com/l5272ky
Variations in endotracheal cuff pressure in intubated critically ill patients: prevalence and risk factors.

Nseir S\textsuperscript{1}, Brisson H, Marquette CH, Chaud P, Di Pompeo C, Diarra M, Durocher A.

Abstract

BACKGROUND AND OBJECTIVE:
An endotracheal cuff pressure of 20-30 cmH(2)O is recommended. Underinflation and overinflation are associated with complications such as aspiration and tracheal wall damage. The aim of this study was to identify prevalence of, and risk factors for, endotracheal cuff underinflation and overinflation.

METHODS:
Prospective observational cohort study. All critically ill patients intubated with a high-volume low-pressure endotracheal tube were eligible. After manual adjustment of cuff pressure at 25 cmH(2)O, continuous recording of cuff pressure and airway pressure was performed for 8 h. Underinflation and overinflation of the endotracheal cuff were defined as cuff pressure less than 20 cmH(2)O and more than 30 cmH(2)O, respectively. In all patients, the time spent with normal cuff pressure or with underinflation or overinflation of the endotracheal cuff was measured. Univariate and multivariate analyses were used to determine risk factors for cuff underinflation and overinflation.

RESULTS:
Eight hundred and eight hours of cuff pressure recordings were analysed in 101 patients. Eighteen per cent of study patients spent 100% of recording time with normal (20-30 cmH(2)O) cuff pressure. Fifty-four per cent of study patients developed cuff underinflation, 73% developed cuff overinflation, and 44% developed both. Thirty-three per cent of study patients developed underinflation or overinflation for more than 30 min. Absence of sedation [odds ratio (95% confidence interval)=2.51 (1-6), \(P=0.03\)] and duration of prior intubation [1.16 (1.04-1.29), \(P<0.01\)] were independently associated with cuff underinflation. No risk factor for overinflation could be determined. The percentage of time spent with underinflation significantly increased during the recording period.

CONCLUSION:
Variations in endotracheal cuff pressure are common in ICU patients. Duration of prior intubation and absence of sedation are independently associated with increased risk for cuff underinflation.

Abstract Link: \texttt{http://tinyurl.com/ow4hszy}
Bench study of a new device to display and maintain stable artificial airway cuff pressure.

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Abstract

BACKGROUND:
Artificial airway cuff pressure should be maintained within a narrow range. Excessive cuff pressure presents a risk of tracheal damage and stenosis. Insufficient cuff pressure adds the risk of secretion leak past the cuff, tidal-volume leakage, and accidental extubation. The available cuff-inflation devices do not address these problems.

OBJECTIVE:
In the laboratory I developed and evaluated a new cuff-inflation device that continuously displays the cuff pressure and maintains stable cuff pressure.

METHODS:
The cuff-inflation device evaluation included: test the manometer accuracy; compare the displayed pressure to the pressure delivered to the pilot balloon; determine the device’s response to cuff-pressure changes with the addition of 5 mL or 10 mL of air after achieving a 30 cm H(2)O baseline; measure the V(T) leak in an intubated artificial trachea by comparing the device results to benchmark measurements; and determine the stability of baseline cuff pressure during routine cuff checks.

RESULTS:
The mean ± SD bias and precision of device’s display, compared to the calibration analyzer, was 1.3 ± 2.6 cm H(2)O. The pressure delivered by the cuff-inflation device’s gas-sampling line to the pilot balloon was equal to the pressure displayed by the cuff-inflation device. With the cuff-inflation device the cuff pressure was unchanged, compared to baseline, after adding 5 mL or 10 mL of air. With 2 current cuff methods, cuff pressure increased to means exceeding 160 cm H(2)O and 300 cm H(2)O, respectively. Compared to the benchmark, the difference in exhaled V(T) mean ± SD bias and precision were: cuff-inflation device 1.4 ± 4.8 mL, and syringe-inflation method 2.4 ± 6.2 mL. Representing a single cuff pressure check, disconnecting the endotracheal-tube pilot balloon from the cuff-inflation device’s gas-sampling line and then reconnecting it had no effect on baseline cuff pressure at 2 seconds or 60 seconds.

CONCLUSIONS:
The cuff-inflation device demonstrated possible improvements over available cuff-inflation devices and cuff-pressure-control methods.

Abstract Link: http://tinyurl.com/pzmw9gx
Full Article Link: http://tinyurl.com/ouohvza
Laboratory evaluation of 4 brands of endotracheal tube cuff inflator.

Blanch PB.

Abstract

INTRODUCTION:
Routine measurement of endotracheal tube (ETT) cuff pressure is a standard in respiratory care, and several devices are available for measuring ETT cuff pressure. Yet an informed choice in the buying process is hindered by the present paucity of unbiased, comparative data.

METHODS:
Four brands of cuff inflator were tested: Posey Cufflator, DHD Cuff-Mate 2, RüschEndotest, and SIMS-Portex Cuff Pressure Indicator. Ten randomly selected 8.0-mm-inner-diameter ETTs were modified and tested in a trachea model. The cuffs were gradually inflated and deflated. After each sequential change in cuff volume, cuff pressure measurements were simultaneously recorded with the cuff inflator and with a calibration analyzer. These data were compared using limits-of-agreement analysis. Then, with each of the 10 ETTs, each cuff inflator was used to measure 3 known (ie, measured with the calibration analyzer) cuff pressures: 20, 40, and 60 cm H(2)O. Cuff pressure measurements were averaged, by brand, and compared to the respective baseline cuff pressure. Finally, using the 10 ETTs and trachea model, the ETT cuffs were inflated, in 0.25-mL increments, using only a syringe and the calibration analyzer. The cuff pressure and cuff volume data from that procedure were plotted and the best-fit regression line was determined.

RESULTS:
There were differences in bias and precision among the tested cuff inflators. The Cuff-Mate 2 had the smallest bias and best precision. None of the cuff inflator brands accurately measured cuff pressure. In each case the Cuff-Mate 2 measured cuff pressures closest to actual. The Cuff-Mate 2 contains about half the compressible volume of that in the Endotest and Cufflator and < 20% of that in the Cuff Pressure Indicator. Regarding the relationship between cuff pressure and intracuff volume, the best-fit linear regression equation was: cuff volume = 0.05 x CP - 0.39 (r(2) = 0.96).

CONCLUSIONS:
The 4 cuff inflators tested differ in bias and precision and none of the devices accurately measure cuff pressure. Cuff inflator manufacturers should design an accurate yet reasonably priced device to inflate ETT cuffs, and ideally that device should allow cuff-pressure checks without decreasing cuff pressure. In the meanwhile clinicians may opt to use my proposed cuff-pressure measurement technique, which minimizes the loss of cuff pressure during cuff-pressure checks and provides more accurate cuff-pressure measurements.

Abstract Link: [http://tinyurl.com/n7l5gqo](http://tinyurl.com/n7l5gqo)
Full Article Link: [http://tinyurl.com/jwwf4mu](http://tinyurl.com/jwwf4mu)
Continuous endotracheal tube cuff pressure control system protects against ventilator-associated pneumonia.

Lorente L, Lecuona M, Jiménez A, Lorenzo L, Roca I, Cabrera J, Llanos C, Mora ML.

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Abstract

INTRODUCTION:
The use of a system for continuous control of endotracheal tube cuff pressure reduced the incidence of ventilator-associated pneumonia (VAP) in one randomized controlled trial (RCT) with 112 patients but not in another RCT with 142 patients. In several guidelines on the prevention of VAP, the use of a system for continuous or intermittent control of endotracheal cuff pressure is not reviewed. The objective of this study was to compare the incidence of VAP in a large sample of patients (n = 284) treated with either continuous or intermittent control of endotracheal tube cuff pressure.

METHODS:
We performed a prospective observational study of patients undergoing mechanical ventilation during more than 48 hours in an intensive care unit (ICU) using either continuous or intermittent endotracheal tube cuff pressure control. Multivariate logistic regression analysis (MLRA) and Cox proportional hazard regression analysis were used to predict VAP. The magnitude of the effect was expressed as odds ratio (OR) or hazard ratio (HR), respectively, and 95% confidence interval (CI).

RESULTS:
We found a lower incidence of VAP with the continuous (n = 150) than with the intermittent (n = 134) pressure control system (22.0% versus 11.2%; p = 0.02). MLRA showed that the continuous pressure control system (OR = 0.45; 95% CI = 0.22-0.89; p = 0.02) and the use of an endotracheal tube incorporating a lumen for subglottic secretion drainage (SSD) (OR = 0.39; 95% CI = 0.19-0.84; p = 0.02) were protective factors against VAP. Cox regression analysis showed that the continuous pressure control system (HR = 0.45; 95% CI = 0.24-0.84; p = 0.01) and the use of an endotracheal tube incorporating a lumen for SSD (HR = 0.29; 95% CI = 0.15-0.56; p < 0.001) were protective factors against VAP. However, the interaction between type of endotracheal cuff pressure control system (continuous or intermittent) and endotracheal tube (with or without SSD) was not statistically significant in MLRA (OR = 0.41; 95% CI = 0.07-2.37; p = 0.32) or in Cox analysis (HR = 0.35; 95% CI = 0.06-1.84; p = 0.21).

CONCLUSIONS:
The use of a continuous endotracheal cuff pressure control system and/or an endotracheal tube with a lumen for SSD could help to prevent VAP in patients requiring more than 48 hours of mechanical ventilation.

Abstract Link: http://tinyurl.com/lg5l5xm
Full Article Link: http://tinyurl.com/oecguo2
Efficiency of a pneumatic device in controlling cuff pressure of polyurethane-cuffed tracheal tubes: a randomized controlled study.

Jaillette E, Zerimech F, De Jonckheere J, Makris D, Balduyck M, Durocher A, Duhamel A, Nseir S.

Abstract

BACKGROUND:
The primary objective of this study was to determine the efficiency of a pneumatic device in controlling cuff pressure (Pcuff) in patients intubated with polyurethane-cuffed tracheal tubes. Secondary objectives were to determine the impact of continuous control of Pcuff, and cuff shape on microaspiration of gastric contents.

METHODS:
Prospective randomized controlled study. All patients requiring intubation and mechanical ventilation ≥48 h were eligible. The first 32 patients were intubated with tapered polyurethane-cuffed, and the 32 following patients were intubated with cylindrical polyurethane-cuffed tracheal tubes. Patients randomly received 24 h of continuous control of Pcuff using a pneumatic device (Nosten®), and 24 h of routine care of Pcuff using a manometer. Target Pcuff was 25 cmH₂O. Pcuff was continuously recorded, and pepsin was quantitatively measured in all tracheal aspirates during these periods.

RESULTS:
The pneumatic device was efficient in controlling Pcuff (med [IQ] 26 [24, 28] vs 22 [20, 28] cmH₂O, during continuous control of Pcuff and routine care, respectively; p = 0.017). In addition, percentage of patients with underinflation (31% vs 68%) or overinflation (53% vs 100%) of tracheal cuff, and percentage of time spent with underinflation (0.9 [0, 17] vs 14% [4, 30]) or overinflation (0 [0, 2] vs 32% [9, 54]) were significantly (p < 0.001) reduced during continuous control of Pcuff compared with routine care. No significant difference was found in microaspiration of gastric content between continuous control of Pcuff compared with routine care, or between patients intubated with tapered compared with cylindrical polyurethane-cuffed tracheal tubes.

CONCLUSION:
The pneumatic device was efficient in controlling Pcuff in critically ill patients intubated with polyurethane-cuffed tracheal tubes.
Evaluation of an intervention to maintain endotracheal tube cuff pressure within therapeutic range.

Sole ML¹, Su X, Talbert S, Penoyer DA, Kalita S, Jimenez E, Ludy JE, Bennett M.

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Abstract

BACKGROUND:
Endotracheal tube cuff pressure must be kept within an optimal range that ensures ventilation and prevents aspiration while maintaining tracheal perfusion.

OBJECTIVES:
To test the effect of an intervention (adding or removing air) on the proportion of time that cuff pressure was between 20 and 30 cm H(2)O and to evaluate changes in cuff pressure over time.

METHODS:
A repeated-measure crossover design was used to study 32 orally intubated patients receiving mechanical ventilation for two 12-hour shifts (randomized control and intervention conditions). Continuous cuff pressure monitoring was initiated, and the pressure was adjusted to a minimum of 22 cm H(2)O. Caregivers were blinded to cuff pressure data, and usual care was provided during the control condition. During the intervention condition, cuff pressure alarm or clinical triggers guided the intervention.

RESULTS:
Most patients were men (mean age, 61.6 years). During the control condition, 51.7% of cuff pressure values were out of range compared with 11.1% during the intervention condition (P < .001). During the intervention, a mean of 8 adjustments were required, mostly to add air to the endotracheal tube cuff (mean 0.28 [SD, 0.13] mL). During the control condition, cuff pressure decreased over time (P < .001).

CONCLUSIONS:
The intervention was effective in maintaining cuff pressure within an optimal range, and cuff pressure decreased over time without intervention. The effect of the intervention on outcomes such as ventilator-associated pneumonia and tracheal damage requires further study.

Abstract Link: http://tinyurl.com/oh67woc
Full Article Link: http://tinyurl.com/n9dgqr8
Optimal care and design of the tracheal cuff in the critically ill patient.

Jaillette E, Martin-Loeches I, Artigas A, Nseir S.

Abstract

Despite the increasing use of non-invasive ventilation and high-flow nasal-oxygen therapy, intubation is still performed in a large proportion of critically ill patients. The aim of this narrative review is to discuss recent data on long-term intubation-related complications, such as microaspiration, and tracheal ischemic lesions. These complications are common in critically ill patients, and are associated with substantial morbidity and mortality. Recent data suggest beneficial effects of tapered cuffed tracheal tubes in reducing aspiration. However, clinical data are needed in critically ill patients to confirm this hypothesis. Polyurethane-cuffed tracheal tubes and continuous control of cuff pressure could be beneficial in preventing microaspiration and ventilator-associated pneumonia (VAP). However, large multicenter studies are needed before recommending their routine use. Cuff pressure should be maintained between 20 and 30 cmH₂O to prevent intubation-related complications. Tracheal ischemia could be prevented by manual or continuous control of cuff pressure.

CONCLUSIONS:

Microaspiration and ischemic tracheal lesions are common intubation-related complications. Prevention of these complications should take into account all pathophysiologic factors. Cuff pressure should be maintained between 20 to 30 cmH₂O, if possible using a device allowing continuous control. The polyurethane-cuffed tracheal tubes could be an interesting measure to prevent microaspiration and pneumonia. Clinical data are lacking to support the use of the tapered tracheal cuff to prevent microaspiration in critically ill patient. Further studies should determine the impact of continuous control of cuff pressure on the incidence of intubation-related complications, and evaluate the impact of cuff material and shape on microaspiration and VAP.
Decrease in cuff pressure during the measurement procedure: an experimental study

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Abstract

BACKGROUND:
To prevent endotracheal tube (ETT)-related complications during mechanical ventilation, ETT cuff pressure should be kept within proper range. In clinical settings, cuff pressure often decreases from target values.

METHODS:
We performed an experimental study to investigate the effects of measuring devices and endotracheal tubes on change in cuff pressure. We continuously measured cuff pressure by inserting a three-way stopcock in the middle of an ETT pilot balloon system. After adjusting the cuff pressure to 24 cmH₂O, we disconnected and reconnected each cuff inflator to the inflation valve of the ETT and measured the changes in the cuff pressure. We measured the change in cuff pressure with different ETT sizes, cuff shapes, brands of cuff inflator, and with and without added extension tubes.

RESULTS:
The cuff pressure decreased, on average, by 6.6 cmH₂O (standard deviation 1.9), when connecting the cuff inflator to the pilot balloon. The measured cuff pressure was less than 20 cmH₂O in 67% of the tests. The cuff pressure decreased more when an extension tube was used. The brand of cuff inflator made no difference to the pressure loss. The cuff pressure decreased more with ETTs of smaller size and with ETTs with pyriform cuffs.

CONCLUSIONS:
Procedures to connect cuff inflators to inflation valves resulted in the loss of cuff pressure by 6.6 cmH₂O on average.
Continuous Cuff Pressure Monitoring Using Cuff Sentry And Its Role In Preventing Microaspiration And Ventilator Associated Pneumonia In Critically Ill Patients.

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BACKGROUND:
Ventilator Associated Pneumonia (VAP) is associated with significant mortality and morbidity with increased need for mechanical ventilation in critically ill patients. A common cause of VAP is due to microaspiration from underinflation of the endotracheal or trachestomy tube cuff. Maintaining continuous cuff pressures >20CM H2O (cwp) using an automated device may help to prevent microaspiration and VAP caused from low cuff pressures. This study compared the efficacy of a continuous cuff pressure (CCP) device to maintain cuff pressures within a target range as well as BAL amylase levels as an assessment of microaspiration.

METHOD:
We prospectively studied cuff pressures for two 8 months periods in all mechanically ventilated patients in the medical intensive care unit (MICU) using either conventional manometry with manual inflation or with a CCP device. During the control period, cuff pressures were manually assessed every 4 hours and adjusted to maintain a pressure between 20-30 cm H2O. In the following 8 months period, the experimental group used a CCP device to maintain constant pressures within the same range without the need for manual inflation and pressures were similarly recorded every 4 hours. Outcome measures included documented cuff pressures, ventilator days and documented fluid amylase in all patients in which bronchoalveolar lavage (BAL) was performed.

RESULTS:
Recorded cuff pressure were more consistently in the target range using the continuous cuff pressures device 19 instances of cuff pressures < 20 cm H2O in 3307 ventilator days compared to manual monitoring and inflation with 801 instances of cuff pressures < 20 cm H2O in 3333 ventilator days. BAL fluid amylase was used a marker of aspiration and was lower in specimens collected from patients in the CCP device compared to patients receiving routine manual monitoring and inflation suggesting reduced micro aspiration.

CONCLUSION:
Use of a CCP device results in improved ability to maintain cuff pressures within a target range. BAL fluid amylase was also lower in the patients on a continuous pressure device compared to routine manual inflation suggesting lower risk of microaspiration with CCP device use. Routine use of CCP devices may be an effective measure to reduce VAP.

Sponsored Research - None

Abstract Link: http://tinyurl.com/n5n4a2n
Impact Of Continuous Cuff Regulation – Quality Improvement Initiative

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BACKGROUND:
Although we have practiced standard preventative “vent-bundle” interventions with a high percentage of compliance for several years, our VAP rate has continued to trend upward through 2013. Our rate, as reported by the infectious diseases department was 4.19 infection-related ventilator associated complications per 1,000 ventilator days (IVAC) in 2009. This rate continued increasing to a high of 6.62 for 2013. Recently, continuous cuff regulation (CCR) has been reported to have a favorable impact in lowering the occurrence of ventilator associated pneumonia.(1,2) We conducted a quality improvement initiative to determine if our recent intervention for implementing CCR had an impact on our IVAC rate.

METHODS:
In December, 2013 routine cuff checks guided by manometry and scheduled to be performed every 12-hours were discontinued. Standard vent-bundle measures continued to be practiced and monitored for compliance. CCR was implemented using 1 of 2 types of devices for all MV ICU patients. We used Hamilton Intellicuff™, (Hamilton Medical, Reno, NV), an option installed on 12-Hamilton G5 ventilators. CuffSentry™, (Outcome Solutions, Mocksville, NC), was used with all Puritan Bennett 840 ventilators, (Covidien, Carlsbad, CA), and the G5 ventilators not having the Intellicuff™ option installed. The goal was to maintain consistent cuff pressure (CP) targeting our standard of 30 cm H2O. IVACs continued to be monitored through April, 2014. The data were analyzed using independent t-test with p < 0.05 considered significant.

RESULTS:
Four months post-CCR intervention the IVAC rate was 4.44 per 1,000 ventilator days which decreased 33% from 2013; p = 0.04.

DISCUSSION:
Vent-bundle compliance remained at pre-CCR intervention levels suggesting that CCR intervention may have an important role in the avoidance of IVAC. Numerous evidence-based articles recommend maintaining CP between 20-30 cm H2O. Two recent articles suggest that CCR maintaining CP in this range lowered the rate of VAP. The result of our single intervention with CCR indicates agreement with the published evidence.

Sponsored Research - None

Abstract Link: http://tinyurl.com/n5n4a2n