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Establishment of normative data for maximal inspiratory pressure by using capsule-sensing pressure gauge device in healthy individuals -a pilot study

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Abstract

Study Design: A Cross-sectional study. **Background:** Work of respiratory system is done by diaphragm which is the core muscle for inspiration. To know its strength, themeasurement is done by suction device or negative pressure gauge in inspiration with help of closed valve at mouth. Maximal inspiratory pressure (MIP) is the prevalent method used in clinical practice to evaluate the inspiratory muscles strength.The negative pressure gauge device is newly invented device that measures respiratory muscle strength, as is easy to use, non in-vasive and light weight. Hence it is necessary to be aware of the normal values of inspiratory pressure by using CSPG devices in healthy individuals. **Objectives:** To established a normal value of inspiratory pressure in healthy individuals for capsule sensing pressure gauge. To see the correlation between I.C and MIP.**Method**: 207 normal healthy individuals were included in study. An instruction was given on CSPG device and readings of three trails were noted out of three, best value was observed for maximal inspiratory pressure. **Results:** A normal value was form by grading system in percentile method for CSPG-D. Correlation between MIP and I.C in normal healthy individuals showed significant value, r= 0.483,p=<0.01. **Conclusion:** The scoring system and normal value was described for capsule sensing pressure gauge device which showed 14.66 Kpa to 17.33Kpa shall be considered to normal value. Hence, the reference values for maximal inspiratory pressure indicate that the capsule sensing pressure gauge device is acceptable tool for assessing inspiratory muscle weakness in normal healthy individuals.

Keywords: CSPG-D (capsule-sensing pressure gauge device), MIP (maximal inspiratory pressure) ,IC (inspiratory capacity) .

Introduction

Numerous changes occur in respiratory system including anatomical, physiological and immunological with age , which structurally include malformation of thoracic spine and chest wall that disrupts the total system of pulmonary compliance, which in-turn increases the work of breathing. The lung tissue loses its normal structure and air spaces get dilated. [1]

During the process of aging, no gas exchange takes place, this affects arterial oxygen but carbon dioxide elimination is not impaired. By 20 to 25 years of age the lung tissues matures, and constant decline in lung function is seen as age increases.[1]

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Chest wall compliance is an essential part of respiratory system which is equal to the Change in volume relative to change in pressure. Thoracic compliance is associated with elasticity and load during inspiration and lung compliance with rate and force of expiration .[1]

Stiffening and calcification of thoracic cage due to age related kyphosis from osteoporosis reduces the movement of thoracic cage to inflate during inspiration and hence the diaphragm is at mechanical disadvantage to generate contraction.[1]

Respiratory muscles :

During quiet breathing, inspiration is brought chiefly by diaphragm and partly by intercostals muscles: here quiet expiration occurs passively by elastic recoil of the pulmonary alveoli and thoracic wall. Forced expiration occurs mainly by muscles of abdominal wall and latissimus dorsi.[2]

Vigorous activities may cause fatigue to diaphragm as is reduces blood flow to the limb during continuous activities and increases sympathetic vasoconstrictor outflow.[3]

PFT have a correlation with state such as aerobic exercise or yoga and non exercise Wassermann K et al. (1995). Pulmonary function tests (PFT) is one of the important tool for health evaluation and for mortality rate. This device is determined by force that react in opposite direction of motion of the body and elastic recoiling of lungs, respiratory muscles strength, compliance of thoracic cavity.[4]

Spirometry helps to detect and treat patients with lung disorders. It measures the lung volume that changes during forced breathing maneuvers. Volumes of lungs and their combinations measures various lung capacities as functional residual capacities, inspiratory capacity which is about 3,800ml.[6,17]

The core muscle of respiration which plays an important role during inspiration is the diaphragm; hence the inspiratory muscles strength is essential for inspiration. Measurement of respiratory muscle strength can be measure or observed by using Maximum voluntary ventilation (MVV) and maximum inspiratory pressure (MIP).

MIP is an indication to measure diaphragm strength by using mechanical vacuum gauge device with valve which is closed at mouth during inspiration. It is an indicator of inspiratory muscle strength and determinant of vital capacity.[1,16]

Studies showed MIP's have been cross-sectional, and primary objective has been established reference values rather than to evaluate the impact of age on function of diaphragm.[1]

Hyperinflation of lungs underlying secondary to lung disease may overload the respiratory muscle leading to diminished blood flow to the muscles resulting in weakness and fatigue of diaphragm and also increases recruitment and/or overuse of accessory muscles of inspiration[9].

In some articles, for measuring inspiratory muscle strength in COPD patients, they had measured Pi max which is an indicator for inspiratory muscles' strength and is defined as maximal inspiratory pressure that was measured at the mouth when patients were instructed perform maximal inspiratory effort against occluded airway.Devices like Digital manometer, Magnehelic pressure gauge, SNIP,Spirometry are use for assessment of inspiratory muscle strength and is used in clinical patient setup. As there is no report on normative values for CSPG-Device. So our aim is to used and assesses normative values for capsule sensing pressure gauge device to measure inspiratory muscle strength in normal individuals. [10,12,13,15]

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Method and Materials

Ethical clearance was obtained by the Institutional ethical committee. Participants were recruited for this study from a Dr.D.Y.Patil Physiotherapy college and medical college. A Screening of 300 individuals with age 18 to 40 years was done. A total of 207 participants fulfilling the inclusion and the exclusion criteria were recruited for the study. The purpose of the study was explained and the written consent was obtained from the participants. The participants were then randomly assigned by a simple sampling technique.

Inclusion criteria were-

1- Normal healthy subjects age 18-40 of either gender

Exclusion for any lung disease

1- History of previous ischemic heart disease and smokers (airflow limitation)
2- Any past medical history of Hypertension
3- Individuals having disorders that might affect test performance (like vomiting, nausea, vertigo)
4- Individuals having hemoptysis of unknown origin (FVC maneuvers may lead to aggravate pathological condition)
5- Patient with any neurological conditions (vagus nerve involvement ,defect in medulla oblongata , increased in intracranial pressure)
6- Patient with rib fracture or any chest shape deformity (lung volume affect and pain)
7- Individuals who have undergone recent eye surgery (increases in intraocular pressure during Spirometry)
8- Individuals having thoracic aneurysm (FVC may cause increase in thoracic pressure thus increasing risk rupture)

Patient was instructed and mechanism behind the capsule sensing pressure gauge wasexplained. Instruction like clamp a nose clip now exhale as much as possible in slow manner and then inhalemaximally as much as possible and hold breath about for 1sec so that reading can be noted. Instruction was explained properly after then as they known about the technique after then three trails were taken.

1- **Computerized Spirometry**

Patient was asked to sit comfortably. Device was given in hand and nose clip were held through nose and then they were told to inspire as much as possible. The readings of inspiratory capacity on the computer or the screen of the portable PFT was noted, Strong verbal encouragement will be given during the test.

Best of three inspiratory efforts will be used for analysis the observed values then was be converted to kilopascal to look for the correlation with the sucking pressure.

2- **Maximum inspiratory pressure (MIP)**

A capsule-sensing pressure gauge device was used to record the maximal inspiratory pressure of an individual had, which was basically used to attain an estimate value of diaphragm strength. Participant was instructed to sit on chair or stool comfortably and hold the gauge with both hands and to close his or her lips firmly around the flanged mouthpiece. A nose clip was applied to avoid nasal leak and participants were asked to exhale as much as possible (residual volume) and then to inhale maximally for > 1sec against the resistance of gauge.

Strong verbal encouragement was given during the test. Best of three inspiratory efforts were used for analysis. An interval of approximately one min was allowed to elapse between each effort. At the beginning of testing sessions, instructions about the procedure which was explained

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above was given in standardized manner all measurements was performed appropriately by trained physical therapist.

The readings or the values of Capsule-sensing pressure gauge device (maximal inspiratory pressure) and PFT(inspiratory capacity) device values was noted for each individuals in the data recording chart respectively.

Now each of these 207 samples readings was compared, The observed values of maximal inspiratory pressure and inspiratory capacity then was converted to kilopascal for correlation, whether the capsule-sensing pressure gauge device can be used as an alternative device to PFT. And to look whether inspiratory capacity is equal to maximal inspiratory muscle strength.

Figure-1 showing observed values for Maximal inspiratory pressure by capsule sensing pressure gauge device

Figure-1

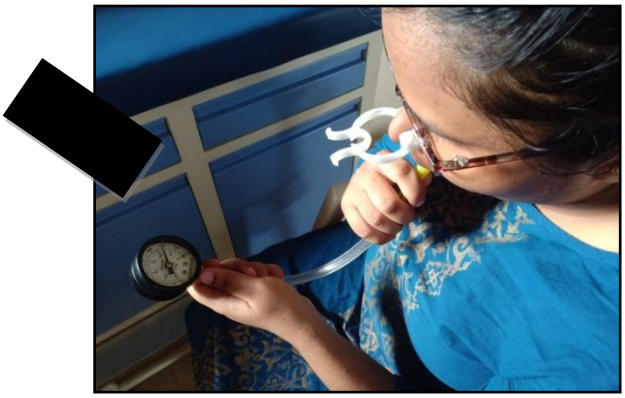

Figure-2 showing Observed values for inspiratory capacity by Computerized Spirometry.

Figure-2

Statistical Analysis

The data collected were analyzed using MedCalc (version 18.11.3). Total 207 participants were recruited in the study (68 male and 139 female) and statistical analysis was done to establish normative value for maximal inspiratory pressure by using capsule sensing pressure gauge device. Readings for measuring maximal inspiratory pressure by using CSPG gauge was

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considered on the basis of average value of three trails. These values were inserted in the software so as to obtain the percentile for each component. At 95% of confidential interval 5,20,40,60,80 and 95 percentiles were considered.

Results

This study was conducted on 207 subjects in normal healthy individuals. Inspiratory capacity was measured with PFT device and Maximal inspiratory pressure wasassessed by capsule sensing pressure gauge device. Correlation of maximal inspiratory pressure and inspiratory capacity were seen and was noted as outcome measures.

(Table no-1) and (graph 1) depicts age of individuals amongst the 207 samples Showing age wise distribution in percentage distributed as 18-25 constitute about 74.87 % , 26-35 constituted about 15.94 % and age of 36-40 was 9.17% respectively.

(Table no 2) and (graph 2) shows the results of Correlation between maximal inspiratory pressure (strength) and inspiratory capacity in normal healthy individuals .showing r= 0.483 and p= <0.001.

(Table no 3) and (graph 3) shows normative value which is describe according to percentile and absolute adjusted values for maximal inspiratory pressure by capsule sensing pressure gauge device in normal individuals.

Baseline Parameter

Table no 1 : Age of individuals

Age	18-25	26-35	36-40
Number of sample	155	33	19
Percentage	74.87%	15.94%	9.17%

VARIABLES	**MEAN±SD**
AGE	24.56±5.96

Table no 2

Correlation between maximal inspiratory pressure (strength) and inspiratory capacity in normal healthy individuals.

NORMAL	**MAXIMAL INSPIRATORY PRESSURE in Kpa**	**INSPIRATORY CAPACITY in Kpa**
Mean	15.15	0.026

Table no 3

Box plot for maximal inspiratory pressure measured by capsule sensing pressure gauge device in normal healthy individuals .

Variable	CSPG_in_kpa

Lowest value	2.66
Highest value	41.32
Arithmetic mean	15.96
Median	14.66
Standard deviation (S.D)	7.60

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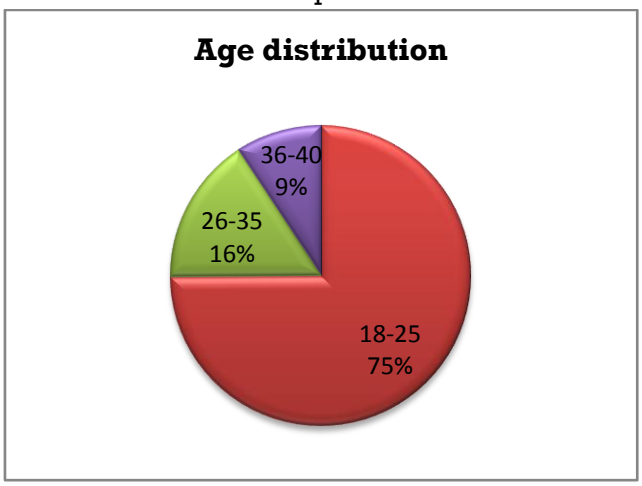
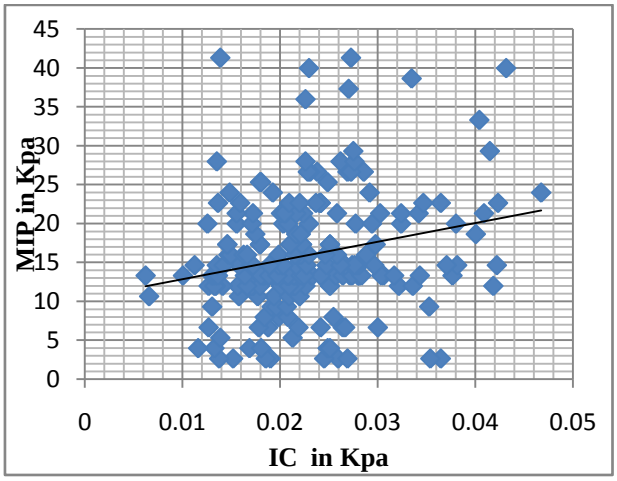
Percentiles	Mean	95% Confidence interval	Absolute adjusted Value
5	3.99	2.64 to 5.83	<9
20	11.99	9.33 to 11.99	9.01 to 12
40	13.33	13.33 to 14.66	13 to 15
60	15.99	14.66 to 17.33	16 to 18
80	21.33	19.99 to 22.66	19 to 21
95	28.19	26.66 to 38.41	>22

Graph-A



Graph-1 Shows age wise distribution.

Graph-B



r = 0.483

Graph 2: Shows Correlation between maximal inspiratory pressure and inspiratory capacity in normal healthy individuals, representing r value as 0.483

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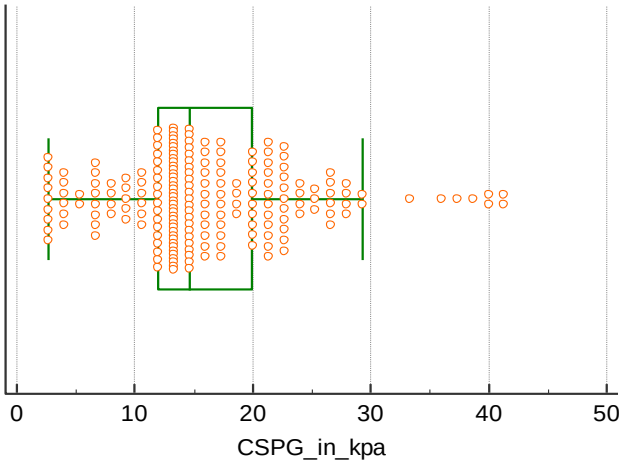
Graph-C



Graph -3 Represent box plot ,Consist of upper limit and lower limit by Non –parametric percentile method and at 50 percentile median showing 15.96 and p= <0.001.

Discussion

The pilot study was conducted to establish the normal value for capsule sensing pressure gauge device in normal healthy individuals. The present study assessed and measured the reading of maximal inspiratory pressure by using CSPG-D and readings of inspiratory capacity were observed by using computerized PFT device in normal individuals .Values for maximal inspiratory pressure was described in mmhg as unit and inspiratory capacity in liters this was then converted in Kpa (kilopascal) to look out for the correlation whether capsule sensing pressure gauge device can be used as an alternative device to PFT.

Total 300 individuals were screened and selected by simple random sampling method, Out of which 207 were engaged and were ready for the study. Data was assesses by using MED CAL software represented by box plot showing the lowest value about 2.66cm ,highest value 41.32cm, mean 15.96, median 14.66 and SD 7.60 respectively. Shapiro-Francia test was used for the distribution of normality, so by non –parametric percentile method values were form for lower limit was 2.66cm, upper limit was 38.39cm and standard error was 0.447 respectively.

The normative data of Capsule sensing pressure gauge device were categorized within 5 grades depending on percentile method. The reference values for CSPG tool were categorized as 'Poor' described as <20 percentile was 9.33Kpa to 11.99Kpa, were as grading between 20%-40% was considered as 'Average' values which was described in from of 9.33Kpa to 14.66Kpa, Grading between 40% to 60% percentile was 13.33Kpa to 17.33Kpa which was considered as Good ,Grading between 60%to80% percentile was 14.66Kpa to 22.66Kpa which was considered as Very good and Grading more than 80% of percentile was 26.66 Kpa to 38.41Kpa which was considered as Excellent respectively. These values were referred for MIP and were observed for CSPG-D in normal individuals.

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Observed values of maximal inspiratory pressure which was measured by CSPG-device were observed by taking three trails and out of that best trial were noted which showed standard deviation (SD) 47.45 and Mean 113.7.Readings of inspiratory capacity by computerized Spirometry was measured by taking three trials and out of that best trial reading were observed of each individuals, which showed standard deviation (SD) 0.61 and mean 1.90 respectively. Unit values of best trial for inspiratory capacity was measured in l/sec and unit for maximal inspiratory pressure was mesured in mmhg, this values for each individuals was converted into kilopascal as to observe the correlation for negative sucking pressure and inspiratory capacity of lungs. They showed Mean 0.026 and Standard deviation (SD) 0.00 for inspiratory capacity in kilopascals with 95% C.I. Mean value for maximal inspiratory pressure in Kpa was 0.025 to 0.026 , Standard deviation (SD) was 15.15.This was represented by scattered diagram with r=0.483, P< 0.001 which was considered significant in table 2.

Jalan S.N et all in 2015, did study on reliability of maximal inspiratory pressure measured using portable tool by capsule-sensing pressure gauge device in healthy individuals. They found that The intra-rater reliability ICC is 0.982 and inter-rater reliability ICC was found 0.922, suggesting that CSPG device is most important reliable tool for assessing strength of inspiratory muscle ,showing the reliability of >0.8 and does not require high number of repetition for this accuracy.[11]

Wolphat A, Lima V.F et all 2017 did the study on correlation of inspiratory muscle weakness and less oxygen uptake kinetics in chronic obstructive pulmonary disease. This study found a significant relation in 6MWT and Pimax, confirming that weakness of inspiratory muscle is related to functional capacity. [9]

Pessoa IMBS , Houri Neto M, 2014 did a study on predictive equations for respiratory muscle weakness according to International Brazilian guidelines. The study suggested that all Brazilian studies that used analog manometer had a compromise in the measurement accuracy.[7]

Study done by De Troyer, Estenne et al, they showed similar effects, which illustrates the theoretical normal and abnormal curvilinear relationships between respiratory muscle weakness (measured via pleural pressure) and Vital Capacity. However, they emphasized that reduced pulmonary compliance is often associated with chronic muscle weakness , which makes VitalCapacity less insensitive than expected as an indicator of weakness.

Braun et al 40 concluded that patients with uncomplicated neuromuscular disease are likely to have hyper-capnic respiratory failure if MIP is less than 30% predicted, but in this situation a Vital Capacity below 55% is equally useful indicator which serves as important predictor.

Conclusion

The current study established gender specific reference values for capsule sensing pressure gauge device In normal healthy individuals.

The scoring system and normal value was described for capsule sensing pressure gauge device which showed 14.66Kpa to 17.33Kpa shall be considered as normal value . Hence, the reference values for maximal inspiratory pressure indicate that the capsule sensing pressure gauge device is acceptable tool for assessing inspiratory muscle weakness in normal healthy individuals. As per the correlation between maximal inspiratory pressure or negative pressure and inspiratory capacity, cannot be purely correlated, so CSPG tool may be used as alternative device.

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Limitations

1- Male and female ratio was not equal (Samples were selected randomly from larger group. Each participant was chosen randomly as each member had equal chance to become sample population)
2- BMI was not taken into consideration which can be the important predictor for strength of inspiratory muscle and inspiratory capacity.
3- Numerous articles did not contain sufficient information and clinical relevance of data.

Clinical Implications

Taking into considerations of limitations listed above, further research can be done in larger population and can be used in clinical setup for the assessment criteria.Further study can be done on patients , pathological conditions and players

Source Of Funding self

References

1- Goodwin J, Sharma G, Et Al. Effect Of Aging On Respiratory System Physiology And Immunology. Clinical Interventions In Aging .2006;(3) ; 253-260.
2- Chaurasia B.D, Et Al. Textbook Of Human Anatomy, Upper Limb And Thorax : (15) ;207-208 .
3- Mishchenko V, Sawczyn S, Cybulska A, Pasek M,Et Al. Special Training Of Inspiratory Muscles In Fitness Activities And Exercise Capacity In Young Women, Hum Mov.2017:18(3);46-54.
4- Malik A, Malik S, Kumar S Et Al.Sports Specific Influence On Force Vital Capacity In University Players.2017:(4) ; 2347-6745
5- Sembulingam K, Sembulingam P Et Al. Essentials Of Medical Physiology,6th Edition:690-693.
6- Barrerio T.J, Perillo I Et Al. An Approach To Interpreting Spirometry.American Family Physician .2004:(69);1107-1114.
7- Pessoa Imbs, Houri Neto M , Montemezzo D,Silva Lam, Andrade Ad, Parreira Vf Et Al. Predictive Equations For Respiratory Muscle Strength According To International And Brazilian Guidelines. Braz J Phys Ther.2014:(5);410-418.
8- Larson J.L, Kim M.J, Sharp J.T, Larson D.A Et Al. Inspiratory Muscle Traning With A Pressure Threshold Breathing Device In Patients With Chronic Obstructive Pulmonary Diseases.1988:(138) ;689-696.
9- Wolpat A , Lima F.V , Silva F,M, Tochetto M , Grandi T , Zago J Et Al. Association Between Inspiratory Muscle Weakness And Slowed Oxygen Uptake Kinetics In Patients With Copd. Applied Physiology, Nutrition And Metabolism.2017;1-33.
10- Jalan N.S, Daftari S.S, Retharekar S.S, Rairekar S.A, Shyam A.M Et Al.Intra And Inter-Rater Reliability Of Maximum Inspiratory Pressure Measured Using A Portable Capsule-Sensing Pressure Gauge Device In Healthy Adults. Can J Respir Ther .2015:51(2);39-42.
11- Am J Et Al. Resp Crit Care Med ,American Thoracic Society/European Respiratory Society.Ats/Ers Statement On Respiratory Muscle Testing.2002:(166);518-624.
12- Evans A.J, Whitelaw A.W, Et Al. Assessment Of Maximal Respiratory Mouth Pressures In Adults. Respir Care ,2009:54(10);1348 –1359.

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www.pragatipublication.com
ISSN 2249-3352 (P) 2278-0505 (E)
Cosmos Impact Factor-5.960

13- Shahebjami H, Gartside P.S, Et Al Pulmonary Function In Obese Subjects With A Normal Fev/Fvc Ratio, Chest.1996: (110);1425-29.
14- Hossein S,Farzad M Et Al, Comparing The Effect Of Resistive Inspiratory Muscle Training And Incentive Spirometry On Respiratory Pattern Of Copd Patients.Evidence Based Care Journal,2016:6(3);45-54.
15- Stefanutti D And Fitting J.W,Et Al. Sniff Nasal Inspiratory Pressure,Reference Value In Causian Children,Resp Care.1999: (159);107-111.
16- Goligher C.E,Fan E,Herridge M Et All,Evolution Of Diaphragm Thickness During Mechanical Ventilation. Impact Of Respiratory Effort, American Journal Of Respiratory And Critical Care.2015: (192);1080-1088.
17- Wanger J,Clausen J.L,Coates A Et Al, Standardization Of Measurement Of Lung Volumes,European Respi Journal.2005: (26);153-161.

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