Research Article

Assessing the Reliability of the Dynamic-Index of Inspiratory Muscle Strength in Cardiac Surgery Candidates

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Running title: The Reliability of the S-Index in Heart Patients

Abstract:

Background: The inspiratory muscle strength is one of the important predictors in development of pulmonary complications after cardiac surgery. The Strength-Index (S-index), a novel non-invasive tool, dynamically assesses inspiratory muscles, which is associated with lower risks for heart patients than static tests. This study aims to investigate the reliability of the S-Index in patients preparing for cardiac surgery.

Methods: This study involved 20 preoperative cardiac surgery candidates (11 males, 9 females, mean age 56 ± 13 years). The S-Index, peak inspiratory flow (PIF), and vital capacity (VC) were evaluated using the Power Breath K5 - electronic respiratory device. These measurements were conducted by an examiner at two distinct intervals, spaced one hour apart. The average and best values for each index were evaluated for reliability using the Intra-class Correlation Coefficient (ICC).

Results: the study revealed excellent (ICC>.9) and good (ICC>.8) intra-examiner reliability, respectively for the best and average values of the S-index and PIF. Also the results of the present study showed excellent intra-examiner reliability for the best and average values of the VC (ICC>.9)

Conclusion: The ICC results of the present study showed that the S-index can be used to determine the dynamic strength of the inspiratory muscles with an Acceptable repeatability in cardiac surgery candidates. One of its advantages could be determining the appropriate load in inspiratory muscle training (IMT) exercises, during the hospitalization phase of these patients in a dynamic manner without breath holding.

Keywords: Dynamic inspiratory strength, Heart surgery, Reliability

Introduction:

Coronary artery bypass grafting (CABG) surgery, which is the main treatment for coronary artery diseases (CAD), can lead to post-operative pulmonary complications (POPC) in the intensive care unit due to the anesthesia process and disruption of normal ventilation function (1-3). In general, chest related Surgical interventions can lead to alterations in the efficiency, and length-tension relationship of the respiratory muscles (4). A decrease of 27% and 62% of maximal inspiratory pressure (MIP) has been reported following the first week of CABG and heart valve replacement surgeries, respectively (5,6). Its demonstrated that, performing inspiratory muscle training with threshold loading (TL-IMT), before and after heart surgeries significantly reduces the risk of POPCs, through improvements in the pulmonary function tests and inspiratory muscle strength (IMS) (7,8). Recently, following the use of IMT exercises in the inpatient phase of cardiac surgeries, positive changes have been reported, in the dynamic inspiratory strength or strength-index (S-index), in addition to the MIP or static strength of these muscles (9).

The MIP that is commonly used to measure IMS, captures the pressure plateau created after maximal inspiration through a closed valvular system, thus measuring the static strength of the inspiratory muscles (10, 11). On the other hand, the S-index a novel tool, offers a dynamic assessment of IMS and is non-invasive, resistance-free (through an open valve system), and easy to use (11, 12). Probebly, the recent method poses less risks for patients with prior vascular conditions (13). There was reported a strong correlation between MIP and S-index in measuring the IMS in healthy people, but with different types of muscle contractions (11). In the S-index, the Maximum pressure that generated during a deep breath and against a linear resistance (without breath holding), is measured by converting flow to pressure (11). Because of the role of the patient in maximal voluntary effort, in the mouth pressure tests, there may be variations in the results in multiple measurements (14).

The reliability of measuring dynamic inspiratory muscle strength through the S-Index in cardiac surgery candidates has not been reported to date. This present study aims to assess the reliability of measuring the S-Index with an electronic respiratory device (Power Breath K5) in patients scheduled for heart surgeries.

Materials and Methods:

Study participants:

This study was conducted in the Cardiac Surgery Center of Shahid Modares Hospital in Tehran, between July 2024 and September 2024. This study was a single-blind clinical trial (participants), and Repeatability tests were conducted by an experienced physiotherapist with a decade of clinical practice involving cardiovascular patients. An informed consent form was obtained from all the participants. This study was approved by the ethics committee of Shahid Beheshti University of Medical Sciences with the IR.SBMU.RETECH.REC.1401.058 code, also the clinical trial code of IRCT20220801055596N1 have been gotten for it.

After the initial assessment. The inclusion criteria were as follows:

1. patients aged between 30 and 70, that identified as potential candidates for heart surgery, and admitted to the hospital for pre-operative assessments.
2. The Ability to perform and completion the respiratory tests.
3. The ejection fraction (EF) above 40% (15).
4. Cardiac classification one or two, based on the New York Heart Association (NYHA) classification (15).

individuals were excluded from the study if they presented any of the following criteria:

1. history of prior heart surgeries (6).
2. Suffering from chronic obstructive pulmonary disease (COPD) (16).
3. Use of medications impacting neuromuscular function or causing cognitive confusion (17).
4. Prior engagement in IMT exercises or respiratory muscle tests (17).

Patients demonstrating non-cooperation, a lack of willingness to participate in the research, inability to complete breathing tests, a failure to comprehend the technique employed, or signs of hemodynamic instability during the tests were also excluded (18, 19).

Figure 1 shows the consort flow diagram from the entry and exit of participants to this study.

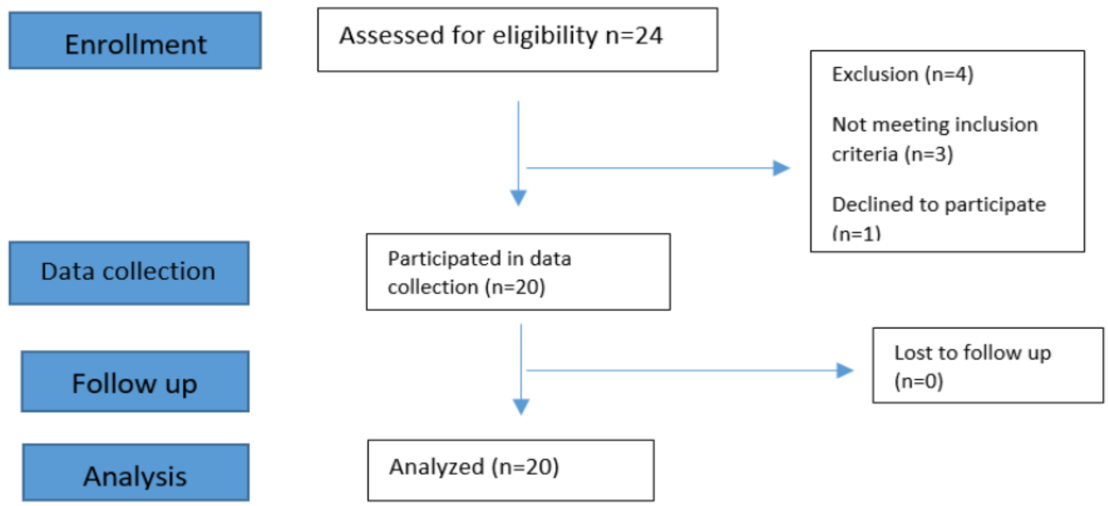

Figure 1: Consort flow diagram

Respiratory tests:

To assess the intra-examiner reliability for breathing tests, measurements were taken at precisely an-hour interval and under identical conditions. To assess respiratory muscle function, an electronic respiratory device (Power Breath K5, 2010 HaB International Ltd, UK) was utilized in this study, providing linear resistance during inhalation. The evaluation focused on the dynamic strength of inspiratory muscles, utilizing the S-index parameter. Additionally, the device automatically recorded peak inspiratory flow (PIF) and vital capacity (VC) parameters during each assessment, and their reliability also evaluated in this study. To perform this test, the patient was placed on a chair in a sitting position without leaning. In order to prevent air leakage, a nose clip was used, and the patient kept the mouth piece of the device filter tightly with his lips. First, the patient was asked to perform a deep exhalation until the lung is in the residual volume (RV) state, then, following a strong verbal order from the examiner, perform a maximal inhalation. Then he exhaled again and repeated the above process 3 times. The highest point of the pressure curve over time and in each effort was considered as the peak in the S- index, which was displayed in the Breath-Link software connected to the device.

This entire process was replicated an hour later in the same conditions without the patient engaging in any physical exercise, drug intervention, or laboratory examination and The evaluation was carried out by the same examiner as in the initial session. In this way, for each of the mentioned indices, including S-Index, PIF, and VC, 2 values including the best value (best of 3 efforts) and the average value (Average of 3 efforts), in each measurement was recorded and stored.

Statistical Analysis:

In order to calculate the intra-rater reliability, of the respiratory tests with the electronic device (Power Breath K5), we calculated the intra-class correlation coefficient (ICC) for the best and average values of S-Index, PIF and VC, which were obtained from this device. The ICCs less than 0.5, between 0.75-0.5, between 0.9-0.75, and more than 0.9, were considered poor, moderate, good and excellent respectively.

We also used Bland-Altman diagram, to show the degree of agreement achieved for each indicator between two measurement times.
The standard error of measurement (SEM) and the minimal detectable change (MDC), were also calculated for further assessing the response stability.
The statistical analysis was conducted using SPSS 25 version software with a significance level of $P<0.05$.

Results:
The patient distribution included 7 candidates for heart valve replacement surgery (HVRS), 12 for CABG, and 1 for atrial septal defect (ASD). Initially, a thorough physical examination and medical history assessment were conducted by the examiner, and the demographic and medical information of the patients was documented in tables. An overview of this information is presented in table 1.

Table 1: Demographic characteristics and comorbidities of the subjects

Characteristic	Mean ± SD	Min-max
Age (years)	56±13	33-78
Height (cm)	163±10	145-181
Weight (kg)	70±11	53-95
BMI (kg/m2)	26±4.03	18-35
EF%	49±9	25-60
FEV1/FVC	81±9	50-100

*BMI (body mass index), EF (ejection fraction), FEV1 (forced vital capacity in 1 second), FVC (forced vital capacity)

Also a summary of the results of the statistical indicators of the desired values at the first and second tests can be seen in Table 2.

Table 2 – Statistical indicators during the two tests

Indices	Mean ± SD		Minimum		Maximum	
	T1	**T2**	**T1**	**T2**	**T1**	**T2**
S-index(A)	32.37±16.38	34.64±17.09	10.09	8.83	70.82	72.19
S-index(B)	38.90±21.22	39.67±20.53	10.58	9.08	84.19	80.76
PIF(A)	1.74±1.02	1.87±1.05	0.35	0.28	4.10	4.19
PIF(B)	2.11±1.28	2.18±1.26	0.38	0.29	4.84	4.65
VC(A)	1.69±0.80	1.80±0.82	0.30	0.25	3.33	3.62
VC(B)	2.01±0.81	2.01±0.80	0.32	0.35	3.30	3.68

*S-index: strength index, PIF: peak inspiratory flow, VC: vital capacity, A: average values, B: best values, T1: first test, T2: second test.

ultimately, a summary detailing the outcomes of the intra-rater reliability assessment between the two tests conducted on the targeted variables is presented in Table 3.

Table 3 - Reliability Test Results

indices	Intra-class Correlation (ICC)	95% Confidence Interval		P-Value	SEM	MDC
		Lower Bound	**Upper Bound**			
S-index (A)	0.86	0.69	0.94	0.001>	6.08	16.87
S-index (B)	0.90	0.78	0.96	0.001>	6.43	17.84
PIF(A)	0.86	0.69	0.94	0.001>	0.30	0.83
PIF(B)	0.90	0.77	0.96	0.001>	0.27	0.75
VC(A)	0.91	0.79	0.96	0.001>	0.29	0.82
VC(B)	0.95	0.89	0.98	0.001>	0.25	0.69

*S-index: strength index, PIF: peak inspiratory flow, VC: vital capacity, A: average values, B: best values, SEM: standard error of measurement, MDC: minimal detectable change

As can be seen in this table, the ICC results, showed excellent repeatability, in all of the mentioned values (ICC>.9), and good repeatability for the average values of the S-index and PIF (ICC>.8).

The diagram of “Bland and Altman” for these values at two mentioned times, presented in figure 2.

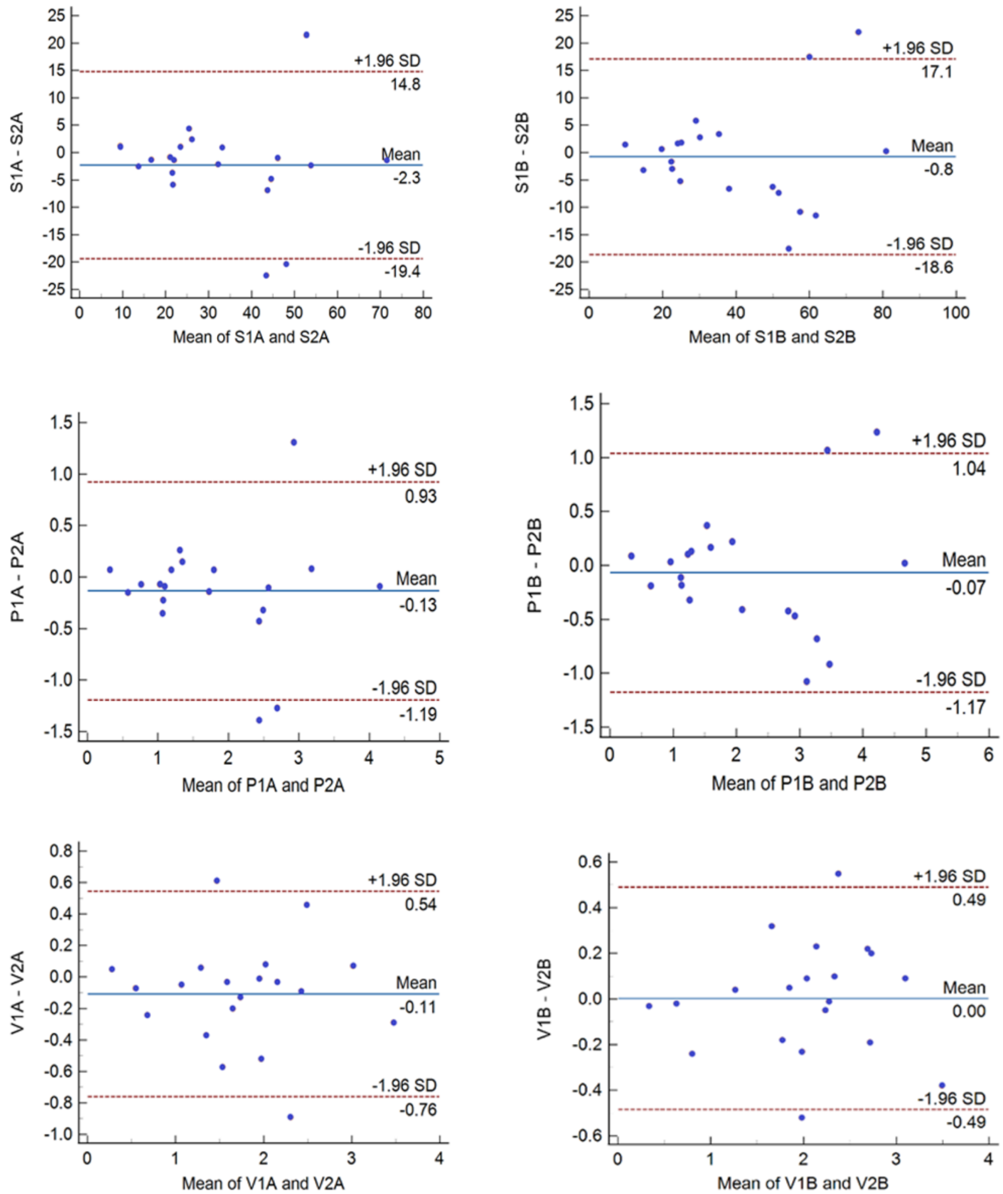

Figure 2: Bland and Altman diagram indicates the obtained difference from S-Index, PIF, and VC at two measurement times (1 & 2), by one examiner. For each person, the difference between two measurements is placed on the Y axis, and the average of these two numbers is placed on the X axis. A: Average S-index (SA), B: Best S-index (SB), C: Average PIF (PA), D: Best PIF (PB), E: Average VC (VA), F: Best VC (VB)

In these graphs, the limits of agreement are marked as standard deviations (red broken line) from either side of the mean difference (solid blue line), and as can be seen, more than 95% of the difference in two tests for all indices, are within this limits, indicating good agreement of the measurements.

Discussion:

The primary objective of our study was to assess the intra-examiner reliability of the S-index by an electronic respiratory device (Power Breath K5), which is also used for TL-IMT exercises in cardiac and respiratory patients. The ICC results were in the good and excellent ranges, So the protocol used in this study facilitated both best and average measurements across three consecutive breaths.

Based on the study of TK Koo the ICCs between 0.9-0.75, and greater than 0.9 are considered good and excellent respectively (20). We also used the Bland-Altman diagram, and the use of this graphical method with simple calculations has been able to complete the repeatability evaluations (21). If the points are evenly distributed between the limits in this diagram, it indicates good agreement between the two tests (22).

The effect of performing limb exercises on improving the quality of life in the first phase of cardiac rehabilitation, has already been well demonstrated as well as the effect of the performing environmental aerobic exercises on improving cardiac parameters such as systolic and diastolic blood pressure (23, 24). On the other hand, IMT can affect cardiovascular autonomic modulation, muscle metabolism, and vascular function (25). An emerging trend in recent years, particularly among the heart and respiratory patients, is the increased utilization of IMT as a type of breathing exercise (9, 19, 26-28). In some cases, these exercises commence from the patient's admission to the hospital for surgery and continue until discharge (6).

To measure the maximum strength of inspiratory muscles in the cardiac studies, the MIP index (static measure of IMS), was employed during the Muller maneuver (10, 11). A new study extended the evaluation by incorporating the S-index alongside the MIP to measure the muscle strength changes following TL-IMT in patients undergoing cardiac surgeries (9).

So far, in a small number of studies, different methods have been used to determine the reliability of the S-Index. In a study the reliability of the S-index in HF patients was examined through 10 breathing maneuvers to obtain the highest values, they reported an intra-examiner ICC of 0.97 using a 2-day interval between two breathing maneuvers (29). In the present study, the intra-examiner reliability ICC was 0.86 for the average S-Index and 0.90 for the Best S-Index, derived from three consecutive attempts, and it was achieved in the two days remaining until the operation.

Also the intra examiner reliability of the same device concerning MIP, PIF, and VC parameters were examined in the stroke patients, with 3 trials at 2 attempts, and The highest values obtained were recorded, in this way The ICC obtained for the S-index, PIF and VC were 0.98, 0.99 and 0.95, respectively (10).

It appears that conducting more repetitions leads to more reproducible results concerning the S-index. This is investigated in the healthy subjects that a minimum of 8 repetitions is necessary to obtain reproducible results of S-index (12). Meanwhile, by using 3 consecutive maneuvers to obtain MIP and S-index values, a linear relationship and good agreement between these two static and dynamic tests have been reported in another study (11).

It has been indicated that performing Müller's maneuver during the MIP test could be associated with risks such as decreased EF and increased heart rate (HR) in cardiac patients (13). Consequently, utilizing the dynamic test of respiratory muscle strength (S-index) can be beneficial. As demonstrated in the present study, this test exhibits acceptable reliability in this group of patients even without a previous respiratory training warm-up before the test and just in 3 repetitions. This becomes particularly significant when aiming to augment the regulatory load in IMT exercises on a daily basis, emphasizing the importance of employing maneuvers involving lesser risk for heart patients.

Additionally, since IMT exercises follow a flow-pressure type pattern and are based on the principle of specificity, which is also pertinent to respiratory muscles, assessing muscle strength through the dynamic S-Index at both times of pre and post-exercise could offer a more accurate measure. This would aid in determining the appropriate protocol and load considerations (17, 30).

it is better to use 50% of MIP in order to maximally affect the respiratory muscles and the cardiovascular system by respiratory loading exercises in healthy people, and to minimize the effects of hyperventilation and dyspnea (31). Thus far, various protocols have been utilized to determine the load, that used for IMT exercises in inpatient phase of cardiac surgeries, for example at two studies the 40% of MIP were employed (32, 33), While in another study, 15% MIP was used as a criterion (27), However none of these protocols have employed the S-index as a loading criterion.

On the other hand, it has been shown in a study that engaging in IMT exercises post-heart surgery can positively impact both the MIP and S-index of the inspiratory muscles, but it's noteworthy that the values obtained for these two variables were notably distinct (9). This could be because of the differences in the neural activation and recruitment of diaphragm and chest wall muscles during static and dynamic maneuvers, that is due to the changes in the functional residual capacity (FRC) and muscle length – tension relationship (34). In fact, in the S-index that is a dynamic maneuver, the air flow is used to determine the amount of pressure, so the way of physiological processing during this maneuver will be different compared to the MIP that is a static maneuver, however it has been reported low difference between these two methods in the patients with heart failure (29). Anyway, since IMT exercises are presented as a dynamic maneuver, the importance of determining the load through dynamic indicators can be more important here.

in the explanation of the formula for predicting the strength of the IMS by dynamic method in healthy people, various parameters such as the results of the spirometry tests and the level of cardiovascular fitness (obtained from 6 minute walk test) can be effective, which suggests the close relationship between S-index and the lung function level (35). also, it has been seen that the amount of electrophysiological activity of respiratory muscles obtained from Electromyography (EMG) during different maneuvers for recording maximum inspiratory pressures, such as MIP and Sniffing, is different (36). These cases can be taken into consideration in examining the S-index test in cardiac patients to clarify the physiological and biomechanical dimensions in the future studies.

Limitations:

1. In this study, patients were admitted to the hospital, one or two days before the operation. It is suggested that in the future studies, the S-index test reliability assessment, could be performed on two consecutive days, in addition to one day only.
2. In this study, only the intra-rater reliability was assessed. It is suggested that in the future studies, the inter-rater reliability (within two examiner) of the S-index, can be done.
3. It is suggested to use more number of repetitions in the future studies to obtain the maximum values of the S-index.

Conclusion:

This study was conducted to determine the intra- examiner reliability of the S-Index in patients who are candidates for heart surgery. The outcomes of this study confirm the reliable measurement of this index, along with other indices (PIF and VC), utilizing the electronic respiratory device (Power Breath K5). This emphasizes the device's credibility and suitability for use in similar studies.

Conflict of interest:
No conflict of interests.

Authors contributions:
Conceptualization: Sedigheh Sadat Naimi, Bahareh Mehregan Far, seyed Ahmad Raeissadat; Methodology: Bahareh Mehregan Far, Sedigheh Sadat Naimi, Mahmod Beheshti Monfared; Investigation: Bahareh Mehregan Far, Sedigheh Sadat Naimi, Mohsen Abedi; Data Analysis: Alireza Akbarzadeh Baghban, Parsa Salemi, Hasan Shamsi; Writing-original draft: Bahareh Mehregan Far, Sedigheh Sadat Naimi, Mohsen Abedi, Writing-review, and editing: Bahareh Mehregan Far, Sedigheh Sadat Naimi, Hasan Shamsi, Parsa Salemi

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