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Can rehabilitative ultrasonography imaging utilised for activation of transversus abdominis in asymptomatic population?: A double-blinded randomised controlled-trial

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ABSTRACT

Study Design: Double-blinded Randomised Controlled Trial. *Participants:* 20 asymptomatic individuals with mean age of 23.60 ± 1.85 years (12males, 8 females) were included by random sampling into two groups, one was given visual feedback (experimental) & the other without feedback (control). Procedure was double-blinded in supine- hook lying (B-mode ultrasonography), transversus abdominis thickness (TrA) were measured during abdominal draw-in manoeuvre (ADIM). *Intervention:* Intervention for activation of the TrA was administered once/week for 6-weeks via ultrasonography. *Outcome measures:* Visual feedback via ultrasonography for measuring TrA thickness. *Results:* Repeated measures ANOVA analysis was run to determine any statistical difference between or within the groups. Logistic regression model was run to test association between age, gender, BMI (Body Mass Index) and desirable mean thickness of TrA. A multivariate logistic regression assessed influence of predictors from demographic variables (age, gender, BMI). RM- ANOVA indicate a statistically significant week-wise increase in thickness Wilk's lambda = 0.189, F = 12.03, $p < 0.001$. Follow - up comparisons indicated each pair (week-wise) difference was statistically significant, $p < 0.001$ with no significant difference between the groups ($p = 0.617, > 0.05$). Amongst the predictors BMI was found to be associated with increase activation of TrA. *Conclusion:* Visual biofeedback via ultrasonography increases muscle activation of TrA following a 6 - week intervention. The MCID (Minimal Clinical Important Difference) defined by the improvement was able to account for progress in asymptomatic population of 20-30 years.

Keywords: abdominals, ultrasonography, rehabilitation, physical therapy, visual biofeedback.

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1. INTRODUCTION

Quantifying muscle structure and function is a gold standard technique using magnetic resonance imaging (MRI). A rather less expensive, equally objective in measurement properties, is more portable, real-time, radiation-free, and involves clients more easily than MRI due to ease of understanding via the visual medium is utilized by researchers for muscle measurements during muscle activation. These imaging methods permit the deep musculoskeletal and fascial system to be visualized in its normal and dysfunctional state by providing information on the definite tension and sliding of the fascia, the inserted tendinous junction on the bone. The importance of the deep muscle corset concept or the corset-action embracing the lumbopelvic system has been extensively studied using real-time ultrasound. (Stokes and Young, 2009; Whittaker and Stoke, 2011; Whittaker, 2013).

Ultrasonography more specifically is an integral part of musculoskeletal imaging which can be used to visualize the concentric muscle contraction during which the cross-sectional thickness of the muscle increases and the longitudinal length shortens than the relaxed state. These observations are however in proportion to the muscle size and muscle activation which may depend on many factors like resting state, initial length, compliance, type of muscle architecture and orientation of fibers, type of contraction, intrinsic factors like fascia and musculotendinous junction extensibility, extrinsic factors like effect of the diaphragm or intra-abdominal pressure on the abdominal muscles, gravity amongst many others(Tahan et al., 2016; Pulkovski et al, 2012; Van and Introcaso, 1992; Teyhen and Koppenhaver, 2011).

Diagnosing and rehabilitating from a clinician’s point of view can be considered a very simple task depending on the skill. Nevertheless, understanding the complex corset - action, its importance to prevent dysfunction, pain, and disability by the client is a far-fetched thought. Involving the client by providing an almost visually simulated situation can overrule the risks on the client’s part. However, understanding the predicaments is only one of the slices of the whole picture. Nervous system can be focused to enhance motor control by the carryover effect. Though the utility is extending beyond its long-established use by radiologists and is no more used solely as a diagnostic but as a rehabilitative tool as well. The potential uses of ultrasonography have been documented by researchers and clinical practitioners (Hides et al., 1995; Fernandez et al., 2019). Variations in muscle thicknesses via muscle contractions can be judged by the muscle size, i.e., by measuring thickness and/or cross-sectional area, and muscle function can be assessed by the level of the timing of muscle activation, can be computed by reliability studies (Hebert et al., 2009). Muscle activation alters due to the initial length and contraction type (Koppenhaver et al., 2012; Cheng and Macintyre, 2011). Due to its varied advantages, Rehabilitative Ultrasonography Imaging (RUSI) has shaped out a meaningful role in rehabilitation. It is currently being used in physiotherapy practice to provide biofeedback of muscle activation (Teyhen et al., 2005).

Repeated stimulation of the neuromuscular system in the manner of effective feedback is essential to link it to the involuntary part of the musculoskeletal system. Determining muscle thicknesses in real-time in specific conditions allows the investigators to comment on the possible muscle function during voluntary muscle contraction. This quality aids the physiotherapist in distinguishing between the ideal and inappropriate activation of voluntary muscle action done by clients in the process of planning a rehabilitation protocol. To be precise these similar muscle thicknesses can vary in different backgrounds, ethnicity, race, gender, geographical conditions, type of lifestyle, comorbidities associated with age, and culture (Valera-Calero et al., 2021). From the above indicators, stems the need of our study to evaluate the responsiveness of Rehabilitative Ultrasonography Imaging (RUSI) as a biofeedback tool following a 6-week intervention for transversus abdominis (TrA) activation in the asymptomatic population. The Null hypothesis is there will be no difference in transversus abdominis thickness following a 6-week intervention in the asymptomatic population. TrA thickness (week 1) = TrA thickness (week 6).

2. MATERIALS & METHODS

The methodology was designed according to the CONSORT 2010 checklist for RCTs **(Figure *1*).** The trial was prospectively registered in Clinical Trial Registry- India CTRI/2019/12/022220 on 03/12/2019.A double-blinded, double-arm, randomized controlled trial was designed with 20 asymptomatic subjects (12 males, 8 females). The mean age (23.60 ± 1.85), BMI (23.55 ± 1.48) with gender (12 males, 8 females) were included. Human experimentation has been approved by the Institutional Ethical Committee, D.Y. Patil Medical College, Hospital & Research Centre (DYP/IEC/01-002/2019-Adated 10/08/2019)conducted in the Department of Radiology, D.Y. Patil Hospital & Research Centre, during the period of May 2019–January 2021.

Eligibility Criteria

Criteria for inclusion were age between 20-50 years, both genders, BMI (18.5 to 23), no h/o low back pain in the past 12 months. Multiparous women, those who had recent abdominal or spinal surgery in the past 2 years, gravid uterus (pre-screened by the radiologist), chronic debilitated, widespread neurological diseases, any fracture, dislocation, tumor of abdominal contents, spine or pelvis, acute urinary tract infections, menstruating females, and participants unable to tolerate the test positions (supine hook-lying) were excluded.

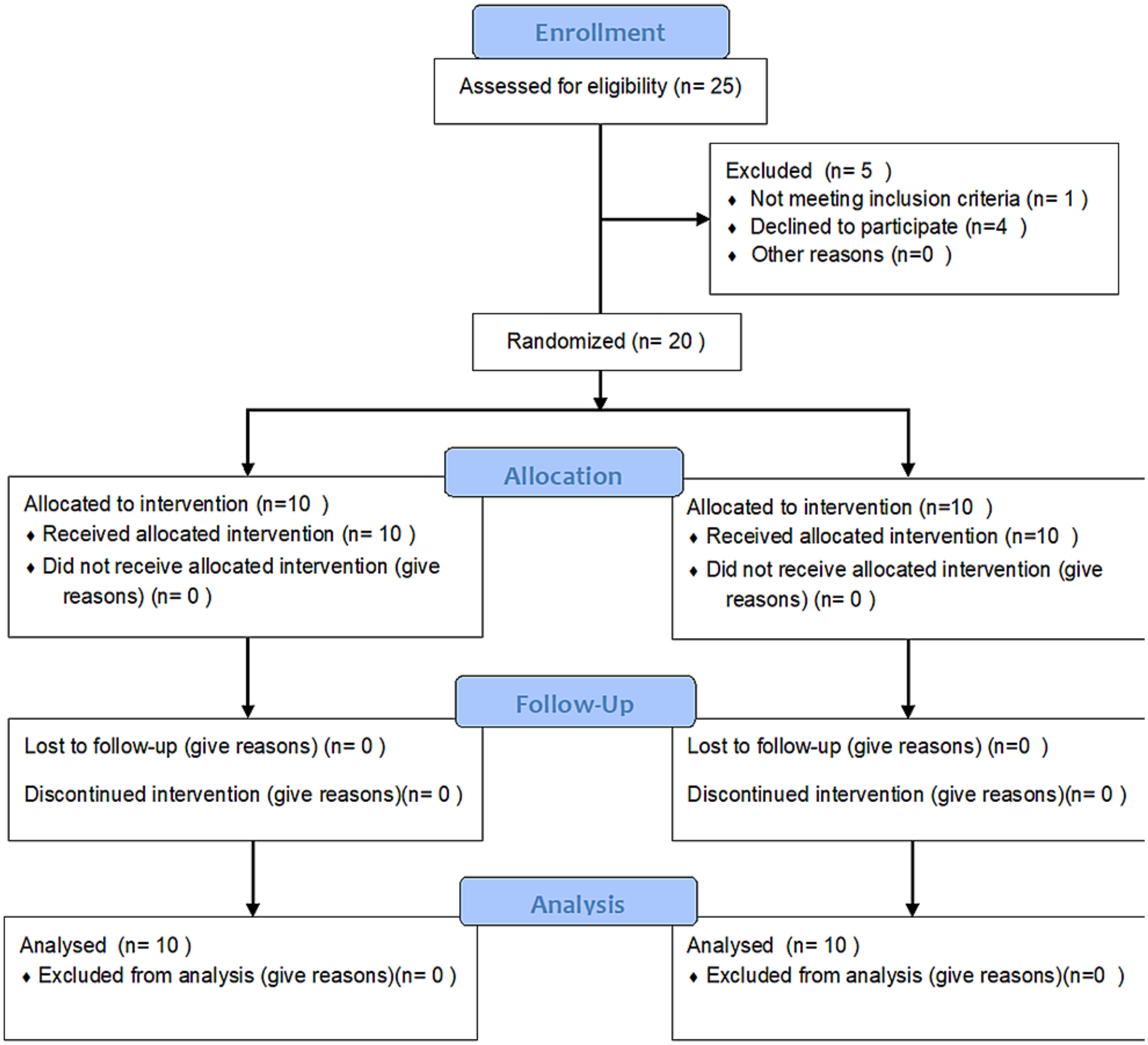

Figure 1: CONSORT flow diagram

Randomization & Recruitment

37 participants were screened for eligibility criteria, out of which 20 asymptomatic individuals with TrA dysfunction i.e., inability to maintain the pressure at 40 ± 5 mm Hg with the age of mean value 23.6 ± 1.85 years (12males, 8 females) were included by random sampling in groups of two, one was given visual feedback (experimental) & the other without feedback (control). The information regarding the recruitment was announced via word of mouth. Participants were selected by simple random sampling method using a chit method sequencing provided they fit in the eligibility criteria were provided with a participant information sheet about the procedure and a written informed consent. A pre-assessment was done using a data recording sheet for the eligibility screening.

Intervention

The test procedure was double-blinded & performed in supine- hook lying using B-mode ultrasonography, the thickness TrA was measured during abdominal draw-in manoeuvre (ADIM). Intervention for TrA activation was administered (3/week) with visual feedback (1/week) for a total of 6-weeks. Both the groups were trained for correct activation patterns thrice a week for 6 weeks. The 6-Level Core (Level 1 & 2) Progression was followed (Kisner and Colby, 2012). TrA thickness was calculated in centimetres every week by capturing the images.

Outcome

The action of TrA, IO &EO was explained using an educational anatomical video initially. A qualified, experienced radiologist was also involved in the study. Abdominal Drawing -in manoeuvre (ADIM) by Richardson was taught via verbal, tactile feedback (palpatory method) and visual method using the pressure biofeedback unit (PBU) with 5 trials to maintain the ADIM at 40mm Hg in supine as used conventionally (Park and Lee, 2013; Grooms et al., 2013). The ultrasonography machine GE Logistics with a 5 -10 MHz, linear array transducer in B-Mode.

Standardization

The probe transducer was positioned in the right midaxillary line between the 11th rib and right iliac crest. On the far-left side of the image, a hyper-echoic interface of the right thoracolumbar fascia is visible. This was considered as the standardized image for all measurements. Baseline thickness in a relaxed state was captured in supine hook-lying position of the TrA, IO (Internal oblique), EO (External oblique), and total lateral abdominal wall thickness (TrA + IO+ EO) by a qualified, experienced radiologist using UI. Right side images were measured for consistency. To control the influence of respiration, subjects will be given standardized instructions to perform ADIM as they exhale, Images will be captured during this exhalation period were done to avoid prospective potential confounders. The subject was initially blinded to the test procedure and was instructed verbally to "Take a deep breath in and, as you exhale, gently draw your navel up & in towards the spine. Continue breathing normally. Try to hold till 10 seconds." Subjects attempted to count for 1 to 10 loud enough during ADIM and at the 3rd - 5th second the radiologist was instructed to capture the image. Thicknesses were measured during ADIM (Richardson et al., 1992 & 1990; Lee, 2018; Lariviere, 2019; Richardson et al., 2004; Hodges, 1997).

Blinding

The subject was blinded to the test procedure and the ultrasonography screen till the ADIM, whereas was the latter shown the screen for the third measurement i.e., visual feedback and was instructed by the physical therapist to "look at the TrA (the deeper muscle and contract" during the second ADIM. The radiologist captured the data in form of images, so the physical therapist was automatically blinded from this procedure, thereby double-blinded. The likely biases like selection bias were reduced by random allocation and concealment. Double blinding between the physical therapist and radiologist ensured the risk (performance bias) to be as low as possible. Similarly, the thickness was reported in images to avoid any incomplete handling of the raw data, thereby keeping the attrition biases as low as possible.

Sample size

The sample size was calculated by the formula for two independent groups (pilot study) with a pooled standard deviation of 1.03, α = 0.05 with 90% power, Z value set at 1.96, and confidence interval of 95%, the sample size was 10 per age group using the formula for two sample situation for matched variables with a total sample size of 20.

3. RESULTS

Descriptive statistics for the participants in both groups are described (Table *1*). Repeated Measures ANOVA (post-hoc analysis): Data from 20 age-matched participants was analysed (10 experimental & 10 controls). Normality was assessed for the TrA thickness (week 1) variable using the Shapiro-Wilk test value of 0.056 (>0.05) (Table *2*). RM - ANOVA was run to determine any statistical difference exists week-wise and between the groups or within the groups (Table *3*, *4*).

Table 1: Descriptive statistics of Experimental and Control Group

E - Experimental Group, C - Control group, N - number of samples

Group		Mean	Std. Deviation	N
Week 1	E (with visual feedback)	.44	.20	10
	C (without visual feedback)	.48	.27	10
Week 2	E (with visual feedback)	.47	.22	10
	C (without visual feedback)	.49	.25	10
Week 3	E (with visual feedback)	.47	.18	10
	C (without visual feedback)	.51	.27	10

Week 4	E (with visual feedback)	.46	.18	10
	C (without visual feedback)	.54	.30	10
Week 5	E (with visual feedback)	.47	.20	10
	C (without visual feedback)	.55	.27	10
Week 6	E (with visual feedback)	.51	.20	10
	C (without visual feedback)	.57	.28	10

Table 2: Test for Normality for TrA thickness variable at Week 1 & Week 6.

	Kolmogorov-Smirnov			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Week 1	.193	20	.048	.888	20	.024
Week 6	.229	20	.007	.907	20	.056

Table 3: RM-ANOVA for week-wise intervention in both the groups.

a. Design: Intercept + Group within Subjects, b. Exact statistic, c. Alpha = 0.05

Effect		Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power [c]
Week	Pillai's Trace	.811	12.030[b]	5.000	14.000	.000	.811	60.151	1.000
	Wilks' Lambda	.189	12.030[b]	5.000	14.000	.000	.811	60.151	1.000
	Hotelling's Trace	4.296	12.030[b]	5.000	14.000	.000	.811	60.151	1.000
	Roy's Largest Root	4.296	12.030[b]	5.000	14.000	.000	.811	60.151	1.000

Table 4: Pairwise Comparisons between the groups.

C - Control group, E - Experimental group

Group		Mean Difference (I-J)	Std. Error	Sig.	95% C.I. for Difference[a]	
					Lower Bound	Upper Bound
E (with visual feedback)	C (without visual feedback)	-.054	.106	.617	-.277	.169
C (without visual feedback)	E (with visual feedback)	.054	.106	.617	-.169	.277

Responsiveness statistics (RS)

RS was calculated by testing the internal responsiveness (ability to measure a change) of ultrasonography by paired t-test, Effect size, and Guyatt's Index, whereas external responsiveness (extent of changes occurred) was assessed by ROC (Receiver Operating Curve), Regression analysis. A repeated-measures ANOVA (Analysis of Variance) test with post hoc analysis (Bonferroni correction: paired t-test) was run to determine whether there was any statistically significant difference between or within the groups. A linear logistic regression model was run to test the association between age, gender, BMI (independent variable), and TrA thickness (dependent variable). The influence of predictors was assessed from demographic variables (age, gender, BMI), and a multivariate logistic regression analysis was applied with derivation of a regression equation Y = 1.231 + 9.012 (change in TrA) + 0.42 (BMI) + 0.006 (Gender) + (-0.018) (Age) (Husted et al., 2000).

MCID (Minimal Clinical Important Difference)

For regression analysis, TrA thickness was categorized into binomial data i.e., the thickness of TrA < 0.06cm / 40% from the baseline thickness and the other category above the mentioned thickness. This cut-off value (MDD) was calculated using Guyatt's

Responsiveness Index: Average difference in score / √2 * Mean Square Error. The average difference in score was estimated by the average change in score among those patients rating some improvement i.e., thickness in TrA > 0.06cm minus the average score amongst those patients rating a lesser or no change in thickness. A repeated-measures ANOVA evaluated the null hypothesis that there is no change in participant's mean TrA thickness (0.44 to 0.51 cm) score when measured before, during, & after 6-week intervention in the asymptomatic population. The results of RM- ANOVA indicate a statistically significant week-wise increase in thickness, where Wilk's lambda = 0.189, F = 12.03, P < 0.001. We also noted the Effect Size i.e., partial eta square = 0.81 to denote practical significance based on Cohen's D indicating large responsiveness in effect size (power of the study = 1.00). Thus, there is significant evidence to reject the null hypothesis. Follow-up comparisons indicated that each pair (consecutive week-wise pair) difference was statistically significant, P < 0.001. An increase in thickness over a 6-week duration suggests that the experimental group (with visual feedback) performed slightly significantly better than the control group (without visual feedback) in activating the TrA muscle.

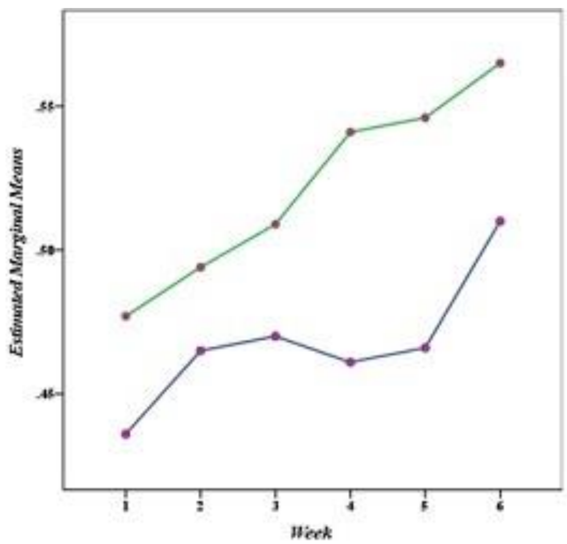

Figure 2: RM - ANOVA plot for estimated means of TrA muscle thickness in 6 weeks.

If Repeated Measures ANOVA (Figure 2) states there is a statistically significant difference during the 6-week intervention, the pairwise (week-wise) comparisons revealed that there was no difference between the groups (P = 0.617, > 0.05. A significant difference was seen within the groups (P < 0.001). Greenhouse - Geisser correction determined that mean TrA thickness differed statistically insignificantly between time points F (4.821, 58.082) = 5.000, P = 0.005. Post hoc analysis (Bonferroni correction) demonstrated that muscle thickness changes elicited a slight increase over 6 weeks. Linear Regression model (Table 5, 6) was run to model the relationship in (difference of mean TrA thickness) dependent variable and age, gender, BMI (independent variables). We attempted to predict the outcome of the dependent variable based on the predictors by transforming data into the ones who activated till the desired thickness and the ones who cannot activate. Blue-line: estimated means TrA thickness (Control), Green-line: estimated means of TrA thickness (Experimental).

Table 5: Linear Regression Model for mean TrA thickness with independent variables.

a. Predictors: (Constant), Age, Gender, Change in TrA, BMI. b. Dependent Variable: Diff<40%/0.06cm

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.780[a]	.609	.505	.3592	.609	5.839	4	15	.005

Receiver Operating Curve (ROC) was plotted (Figure 3) to describe the responsiveness in terms of sensitivity (probability of the UI measure to correctly classify patients who demonstrate clinical change) and specificity (probability of the UI to categorize patients who do not demonstrate change). Area under the curve was 0.84 signifying a good sensitivity and specificity by best classifying the patients (Figure 4).

Table 6: Coefficients a: a. Dependent Variable: Diff<40%/0.06cm

Regression Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	1.231	1.506		.818	.426
Change (TrA thickness)	9.012	1.950	.760	4.622	.000
BMI	-.042	.060	-.121	-.693	.499
Gender	-.006	.166	-.006	-.035	.973
Age	-.018	.049	-.064	-.364	.721

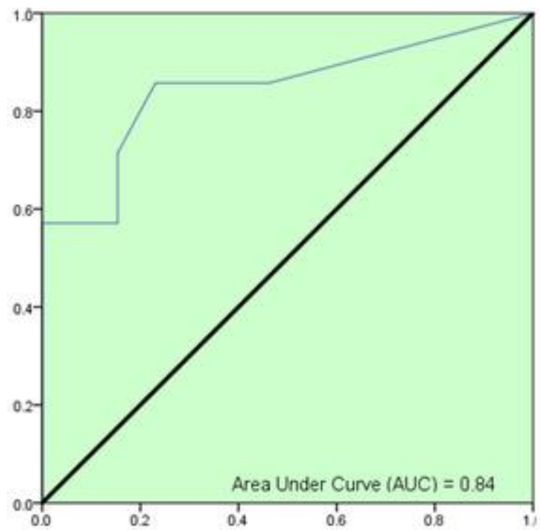

Figure 3: ROC curve for TrA thickness via ultrasonography after a 6 - week intervention.
X - axis : 1 - Specificity , Y - axis : Sensitivity, Area under Curve (AUC) = 0.84.

Figure 4: Ultrasonography imaging of abdominal muscles of the same individual.

4. DISCUSSION

To summarize, we estimated the effect of visual biofeedback via ultrasonography following a 6 - week intervention in the asymptomatic population. MCID values were derived for TrA thickness following a 6-week intervention in two groups (with & without feedback) and sensitivity, specificity of ultrasonography as a feedback tool was found.

We report the results of a double-blinded, double-arm, randomized controlled trial investigating the responsiveness of visual biofeedback via ultrasonography (TrA activation) in asymptomatic individuals diagnosed with TrA dysfunction. The dysfunction was diagnosed using PBU into two groups those who can and those who cannot maintain the pressure at 40 mm Hg. As verified by Grooms, 2013 that PBU has moderate specificity (0.77) in diagnosing TrA dysfunction. The study demonstrates that visual feedback does influence the thickness of the muscle in addition to the exercise intervention given to both the experimental and control group aimed at increasing the recruitment of TrA over a 6 - week duration. Results confirm the conclusions of Lariviere, 2019 & Lee, 2016. Lee and colleagues examined 30 healthy students into three groups of basic training, PBU, and USG based on feedback, where USG > PBU > basic training of ADIM. Lariviere and colleagues evaluated effectiveness of an 8 - week stabilization program on multifidus using UI (34 LBP participants) concluded improvements in disability and pain (Cancelliere et al., 2019; Finnoff et al., 2016).

The findings of our study indicate a difference after the 6-week intervention in the group which received visual biofeedback & that ultrasound imaging enhances the activation of muscles. Furthermore, the results are evident enough that UI can objectively measure muscle thickness and help in determining a relative change in muscle recruitment. Firing of the global muscles more than core muscles many a time incorrectly reflects this intra-abdominal pressure which is usually measured by a PBU in a clinical scenario. Feed forward strategies are pre-planned by the nervous system and represent the pattern of muscle activity initiated by the central nervous system in advance of predictable challenges to lumbopelvic stability to prepare for the perturbation (Henry and Teyhen, 2007). Rehabilitation exercises should emphasize the anti-gravity system and the effect can be studied on the corset action activation which is an important component of the lumbopelvic stability developing the building blocks for training the feed-forward mechanisms. This very reason should be the initial focus in prevention and rehabilitation programs i.e., training and re-training the corset- action. Once this corset-action becomes automatic, progressing to functional integration and goal achievability becomes less of a hindrance. The probable influencing factors could be an introduction of performance bias in subjects to overdo or overachieve a desired contraction or thickness leading to just an increased intra-abdominal pressure thereby not reflecting a correct or desired activation which would have prolonged. A prolonged training of more than 6 weeks or maybe more can help assess and quantify the effect visual feedback via ultrasonography has on the abdominal musculature. Along with the thickness change, evaluating the muscle memory, motor control & postural control becomes a necessity for long-term rehabilitation protocols which are specifically designed. These interventions can be studied in a controlled environment with and without limb loading in the asymptomatic and symptomatic populations altogether.

Pulkovski 2012, established a cut-off for this desired TrA muscle thickness in the healthy and LBP (chronic). But more than the thickness, variation between the achieved increase in thickness from the baseline provides a better clinical measure. As every individual, even though bounded by pre-set eligibility criteria have anatomical, physiological, and biomechanical variations. Hence, in the same muscle changes before and during activation via the ADIM guarantees an individual assessment of the activation by reducing the selective bias. A lesser value was assumed to prevent the floor and ceiling effect wherein the values plateaus after a certain point beyond which it is expected that the TrA will not increase in thickness, though the obliques together can continue increasing in thickness. To prevent this a lesser value or a difference corresponding to 40% / <0.06cm was selected as a predictor variable. This cut-off point or the minimal clinical detectable difference was presumed statistically significant at 0.06cm for TrA. Obliques on the other hand are expected to change their thickness by a minimal value, though lesser than the contraction of TrA. Thickness increase of IOEO and TrA go hand in hand. Nonetheless, the dominance of one companion over the other must be prevented by the mediation of external cues. Disregarding the IOEO and over-controlling the TrA at the premature level of rehabilitation should be an imperative step in clinical decision-making while evaluating a 'correct performance' of ADIM. Richardson, Hodges & Hides in their book has described in detail three observations that go hand in hand during an ADIM using PBU- the pressure change in mm Hg, spinal movement of the lumbar curve, and thirdly the bulging of the abdominals if any confirmed by palpation of the tensing fascial attachment (Costa et al., 2009; Valentin et al., 2021; Critchley D. 2002).

Pulkovski and the authors tried to distinguish whether TrA CR can predict between healthy controls and chronic low back pain. Proved TrA CR inconclusive as ROC (Receiver Operating Curve) analysis revealed poor and non-significant ability to classify between the groups (AUC = 0.06) which just failed to match the significant cut-off of 0.07. Although the difference between our study was that ROC was calculated on a 6 -week intervention population whereas they analysed ROC on a short-term thickness change. This explains the different values (AUC= 0.84). It justifies, USG proves to be more sensitive (probability of the ultrasonography measure to correctly classify patients who demonstrate clinical change) and specific (probability of the ultrasonography tool to measure to correctly classify patients who do not demonstrate change). AUC of 0.84 signifies a good sensitivity and specificity by best classifying the patients when used by visual biofeedback enhancing the TrA performance.

Limitations

A third trial arm would have been a possibility had it been compared with another instrument or tool which provides visual feedback perhaps the Pressure biofeedback Unit. Another effect of placebo was considered for the controlled group, though ultrasonography is real-time and very much dynamic this thought wasn't warranted. The cause and effect of feedback on activation of the TrA established the validity (internal). Although, the activation also needed assessment in terms of a cut-off value or a certain desirable increase in thickness from baseline and the other question was, whether this desirable thickness was meaningful clinically? To say the least, did the addition of feedback affect the population?

5. CONCLUSION

Our results provide evidence that visual biofeedback using ultrasound imaging influences transversus abdominis activation (6-week) intervention program in the asymptomatic population thereby accepting the alternate hypothesis. Responsiveness of Ultrasonography Imaging was thereby proven to have a higher sensitivity in detecting thickness change of TrA. Future studies can be conducted in prone where the activation of TrA can be objectively measured with the obliques under the effect of gravity.

A specific diagnosis depends on cost, timely tests, and correct interpretation. While we realize that there exist variations amongst the clinicians and their skills, have already established excellent Intra & inter-rater reliability and validity of ultrasonography. Ultrasound Imaging is a less costly, non-invasive, radiation-free, and portable unit that can be easily used. Though, the Indian scenario is slightly different (PC-PNDTA Act) which curbs the female infanticide rate permits the use of ultrasonography only by radiologists. Non-radiologists' physicians including physical therapists can however make use of it by working in collaboration with radiologists. Though training by non-radiologists is essential. Curriculum-based along with competency-based changes require extensive training by physiotherapists thereby helping in providing a great impetus in using technology to advance rehabilitation by policymakers.

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Critical revision of the manuscript for intellectual content: Ajit Dabholkar.

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Conflict of interests

The authors declare that there are no conflicts of interests.

Data and materials availability

All data associated with this study are present in the paper.

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