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ORIGINAL ARTICLE

Clinical grading and color Doppler ultrasonography-based grading of varicocele: how compatible are the two grading systems?

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Abstract

Objective Inhere, we compared two of the most common grading systems based on color Doppler ultrasonography (CDU) and physical examination in patients suspected of varicocele.

Methods This is a cross-sectional study. Overall, 66 patients clinically suspected of varicocele were visited by an attending urologist and a radiologist for physical examination and CDU. Varicocele was then graded according to the WHO criteria and Sarteschi criteria. For comparing the results of the two grading systems, each grading systems was then categorized into four scoring groups. Clinical- and CDU-based scoring, and mean maximum variceal vein diameter (MMVD) were evaluated and compared.

Results The two scoring systems were statistically similar ($p<0.001$). CDU scoring of right and left testicles had significant agreement with clinical scoring of varicocele ($\kappa=0.723$ and $\kappa=0.809$, respectively; $p<0.001$). MMDV was associated with clinical (right sided: $r=0.681$; left sided: $r=0.797$; $p<0.001$) and ultrasonography scoring (right sided: $r=0.648$; left sided: $r=0.821$; $p<0.001$).

Conclusion Grades zero, one and two in ultrasonographic grading are most compatible with grade zero (sub-clinical) in clinical evaluation; so these grades most probably remain undetected in routine physical examination. Furthermore, grade three in ultrasonography and grade one in clinical grading, grade four in ultrasonography and grade two in clinical grading, and finally grade five in ultrasonography and grade three in clinical grading are most compatible. So, by deducting two grades from the ultrasonography grading of varicocele measured by the Sarteschi method, one can obtain a compatible estimate of the clinical grading.

Keywords Varicocele · Grading · Color Doppler ultrasonography · Clinical

Introduction

A retrograde flow in the spermatic veins can lead to dilation in the pampiniform plexus, which is termed as varicocele. The condition is known to be associated with infertility (20–40%) and is present in an estimated 15–20% of healthy men [1, 2]. Majority (90%) of varicoceles are left sided;

Implication for health policy makers/practice/research/medical education To this date, there is no definite guideline mandating the use of color Doppler ultrasonography among patients suspected of varicocele. Defining differences and the similarities between the two most common grading systems of varicocele will able the physician and international committee to assess the need for color Doppler ultrasonography aside from the initial physical examination.

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however, literature has proposed varicocele to be a bilateral disease [3–5].

The ground stone diagnostic method for varicoceles has long been considered to be physical examination [6]. On the other hand, imaging has provided a more precise and detailed tool for the evaluation of varicoceles. Imaging modalities include: venography, tomography, scintigraphy, ultrasonography and computerized tomography [7]. Among these, color Doppler ultrasonography (CDU) is the most widely used and established imaging method for the assessment of varicocele. CDU provides a non-invasive and relatively cheap method of diagnosis by evaluating vascular flow within the testes. Furthermore, compared to venography (gold standard diagnostic modality), CDU renders high sensitivity and specificity (97% and 94%, respectively) [7, 8]. CDU detects varicocele on the basis of enlarged scrotal vein diameter or by showing blood reflux within the pampiniform plexus during the Valsalva maneuver [9].

The American Society of Reproductive Medicine (ASRM) and the American Urological Association (AUA) have been against the routine use of imaging modalities for the evaluation of varicocele, especially among those patients with non-palpable changes within the scrotum [6, 10]. On the other hand, confirmation of varicocele with CDU after diagnosis using physical examination is recommended, according to the European Association of Urology [11]. Thus, to this date, there is no definite guideline mandating the use of CDU among patients suspected of varicocele.

In this study, for the first time, we determined to compare two of the most common grading systems based on CDU and physical examination, to better evaluate the efficacy of the two diagnostic methods compared to one another among patients suspected of varicocele.

Patients and methods

Study setting and design

This is a cross-sectional study, conducted in Faghihi hospital (one of the main referral centers in Southern Iran), affiliated to Shiraz University of Medical Sciences, Shiraz, Iran.

Patients with clinical symptoms suspected of varicocele including testicular pain, edema and a positive history of infertility who referred to the mentioned health care center were considered for inclusion in the study.

Those who did not give their approval for entering the study, those with a positive history of scrotal surgery or hernia repair, those with a history of urogenital infections, and those who did not refer for their ultrasonography evaluations after their initial urology visits, were excluded from the study.

Study protocol

Patients were initially visited by an attending urologist for physical examination. For clinical evaluation, patients were seated in a warm and private room to ease the relaxation of the scrotal skin. Initial examination was done in the standing position, followed by examination in the supine position, with and without the Valsalva maneuver. Varicocele was then graded according to the WHO criteria (three grades) [12].

After this, patients were referred to the radiology department for CDU. The scrotum was covered and supported in a towel and a warmed gel was then placed on the site of ultrasonography. CDU was performed using a 5–12-MHz linear array transducer (Samsung, WS 80, South Korea) by an experienced radiologist. During ultrasonography, patients were first examined in the supine position. Any kind of abnormality was ruled out using gray-scale mode. After this, patients were examined in a standing position with and without the Valsalva maneuver, to evaluate venous reflux in bilateral inguinal canals and in the pampiniform plexus veins. In CDU, as patients were standing, both at rest and during the Valsalva maneuver, diameter of the largest vein within the pampiniform plexus was measured. The Valsalva maneuver was repeated three times and the diameter was registered three consecutive times bilaterally. Finally, a mean was obtained and considered as the mean maximum venous diameter. CDU grading was done according to the Sarteschi [13] criteria and varicocele was classified into five groups.

To minimize bias, clinical and CDU grading were done by a single urologist and a single radiologist who were blinded to the grading of one another.

For comparing the results of the two grading systems (clinical grading and CDU-based grading), each grading system was categorized into four scoring groups. Regarding clinical grading, those with grade zero (subclinical) were scored 1, those with grade one were scored 2, those with grade two were scored 3 and finally those with a clinical grade of three were scored 4.

Regarding ultrasonographic grading, those with CDU grades zero, one and two were scored 1, those with grade three were scored 2, those with grade four were scored 3 and finally those with CDU grade five were scored 4.

In the end, clinical scoring and CDU scoring were compared. Furthermore, mean maximum variceal vein diameter was also compared based on the clinical and ultrasonographic grading.

Ethical consideration

The study protocol was approved by the Institutional Review Board (IRB) of Shiraz University of Medical Sciences. All patients gave their written and informed consent to enter the study. None of the patients' personal data were disclosed and patients' secrecy of data was maintained throughout the study.

Statistical analysis

Data were analyzed using the SPSS® software for windows®, version 24, (SPSS Inc., Chicago, IL, USA). The Chi-square test was used for comparison of qualitative variables. For evaluating the association between scoring based on CDU and based on physical examination, the inter-rater agreement was assessed using the Cohen's kappa index. Moreover, for evaluating the association between mean maximum diameter of variceal veins with clinical and ultrasonography scoring, the Spearman's correlation test was used. Data are presented as frequency and percentage or means plus–minus standard deviations, where appropriate.

A p value of less than 0.05 was considered as statistically significant.

Result

Overall, 66 patients entered the study. Baseline characteristics of patients are displayed in Table 1.

Comparison of ultrasonography and clinical scoring showed that the two scoring systems were statistically similar (regarding their distribution in each of the classes) ($p < 0.001$) (Table 2).

The association between ultrasonography scoring, clinical scoring, and mean maximum diameter of variceal veins was also considered. Results showed that ultrasonography scoring of the right and left testicles had significant agreement with clinical scoring of varicocele ($\kappa = 0.723$ and $\kappa = 0.809$, respectively; $p < 0.001$). Higher mean maximum diameter of variceal veins was significantly associated with higher clinical (right sided: $r = 0.681$; left sided: $r = 0.797$; $p < 0.001$) and ultrasonographic scoring (right sided: $r = 0.648$; left sided: $r = 0.821$; $p < 0.001$) (Table 3).

Table 1 Patients' baseline characteristics and Doppler sonography findings

Variables	Statistics		
Age (yrs)	23.16 ± 6.92		
	Right	Left	Total
Sonography grading			
0	3 (4.5)	1 (1.5)	4 (3)
1	9 (13.6)	1 (1.5)	10 (7.6)
2	20 (30.3)	6 (9.1)	26 (19.7)
3	25 (37.9)	16 (24.1)	41 (31.1)
4	9 (13.6)	26 (39.4)	35 (26.5)
5	0	16 (24.2)	16 (12.1)
Total	66 (100)	66 (100)	132 (100)
Clinical grading			
0	32 (48.5)	8 (12.1)	40 (30.3)
1	22 (33.3)	14 (21.2)	36 (27.3)
2	10 (15.2)	26 (39.4)	36 (27.3)
3	2 (3)	18 (27.3)	20 (15.2)
Total	66 (100)	66 (100)	132 (100)
Sonography scoring[a]			
1	33 (50)	8 (12.1)	41 (31)
2	25 (37.9)	17 (25.8)	39 (29.5)
3	7 (10.6)	25 (37.9)	33 (25)
4	1 (1.5)	16 (24.2)	19 (14)
Total	66 (100)	66 (100)	132 (100)
Clinical scoring[b]			
1	32 (48.5)	8 (12.1)	40 (30.2)
2	25 (37.9)	14 (21.1)	39 (29.5)
3	7 (10.6)	26 (39.3)	33 (25)
4	2 (3)	18 (27.2)	20 (15.1)
Total	66 (100)	66 (100)	132 (100)
Mean maximum diameter of variceal veins (mm)			
	2.15 ± 0.571	3.15 ± 1.11	

All data are presented as frequency (%); plus–minus values are mean ± standard deviations

[a]Regarding sonography grading, those with grades zero, one and two were scored 1, those with grade three were scored 2, those with grade four were scored 3 and finally those with CDS grade five were scored 4

[b]Regarding clinical grading, those with grade zero (subclinical) were scored 1, those with grade one were scored as 2, those with grade two as score 3 and finally those with a clinical grade of three were scored 4

Discussion

Inhere, we evaluated and compared the association between two of the most commonly used clinical- and ultrasonography-based grading systems of varicocele; we further evaluated the association between mean maximum diameter of the variceal veins with the two grading systems. We found that the two grading systems had a significant and strong agreement ($\kappa > 0.70$ and $p < 0.001$). We also found that mean maximum diameter of the variceal veins was also significantly associated with higher ultrasonography and clinical grading of varicocele.

Multiple grading systems exist according to CDU findings for the classification of varicocele severity which include the Sarteschi classification (used in our study) [13], the Dubin

Table 2 Relationship between clinical scoring and color Doppler Ultrasonography scoring

	Clinical scoring				*p* value
	1	2	3	4	
Sonography scoring					
1	37	4	0	0	<0.001
2	3	32	7	0	
3	0	3	26	3	
4	0	0	0	17	

Data are presented as frequency

Table 3 Association between clinical scoring, color Doppler ultrasonography scoring, and mean maximum venous diameter

	Clinical scoring		Sonography scoring	
	Right	Left	Right	Left
Sonography scoring				
Right	0.723**	–	–	–
Left	–	0.809**	–	–
Mean maximum diameter of variceal veins				
Right	0.681**	–	0.648**	–
Left	–	0.797**	–	0.821**

**$p < 0.001$

classification [14], and the grading system introduced by Chiou et al. in 1997 [15]; however, the Sarteschi and the Dubin criteria are the two most common grading systems used in clinical practice [7, 16]. In this study, we used the WHO criteria for physical examination and the Sarteschi criteria for CDU-based grading of varicocele. To the best of the authors' knowledge, this is the first study to evaluate the association between an ultrasonography-based grading and a clinical-based grading of varicocele.

In an older study by Gat et al. [17], CDU, physical examination and contact thermography were evaluated and compared against venography regarding their ability to diagnose varicocele. They found that palpation had an accuracy of 89.2% (sensitivity = 89.5% and specificity = 66.6%) and CDU had an accuracy of 97.9% (sensitivity = 98.9% and specificity = 33.3%) for the detection of left-sided varicocele; however, for right-sided varicocele, palpation had an accuracy of 25.1% (sensitivity = 8.8% and specificity = 33.3%) and CDU had an accuracy of 71.8% (sensitivity = 77.3% and specificity = 47.2%). These findings were compatible with our results, as we found that in right-sided varicocele, a weaker agreement is documented between CDU and physical examination grading systems ($\kappa = 0.723$ vs. $\kappa = 0.809$), although the agreement was statistically significant for both sides ($p < 0.001$).

Woldu et al. in 2013 [18] evaluated the effects of grade, maximum venous diameter, Tanner stage, testicular volume on testicular asymmetry. In their regression analysis, they found that only left-sided varicocele was a significant predictor of testicular asymmetry.

Pilatz et al. [5] evaluated the diagnostic value of CDU parameters (basal venous diameter, maximum venous diameter and peak retrograde flow) for predicting varicocele grade according to the WHO criteria. They found that among the 129 patients evaluated with clinical varicocele (258 testicles), increased varicocele grading based on CDU was associated with larger vein diameter within the pampiniform plexus ($p < 0.05$); furthermore, in their receiver-operator curve analysis, they found that maximum venous diameter was a good index at a cut-off of 2.45 mm (AUC = 0.904; sensitivity = 84%; specificity = 81%) and 2.95 mm (AUC = 0.673; sensitivity = 84%; specificity = 84%) for distinguishing between clinical and subclinical varicocele with and without the Valsalva maneuver, respectively. Our findings also showed mean maximum venous diameter to be significantly associated with bilateral varicocele scores; however, left-sided diameter (compared to right-sided venous diameter) had a stronger correlation with both clinical- and CDU-based scoring.

Although physical examination of varicocele is not considered an ideal modality [19] compared to CDU for the detection of varicocele, our study results show that two of the most common grading systems based on physical examination and CDU are similar and can possibly be used intermittently for the classification of varicocele severity. Our results are indirectly in favor of the guidelines of the ASRM and the AUA [6] that recommend against the routine use of CDU in clinical practice, as we found that clinical grading is very similar to that of CDU-based grading.

Defining the grade of varicocele is valuable as some studies have shown varicocele grading to be associated with poor semen analysis. Vivas-Acevedo et al. in a study published in 2010 [20] showed that among 363 patients with varicocele, individuals with grade three left-sided varicocele (clinical grading) had lower percentage of normal sperm morphology, compared to 155 controls (without varicocele). They concluded that perhaps varicocele grade could alter semen quality.

We propose future studies to simultaneously evaluate clinical value (such as effects on semen analysis) of ultrasonography- and palpation-based grading, compared to one another.

This study was not without limitation. Physical examination is limited by its subjective nature and patient body habitus, as some studies have documented significant differences between observers in estimating testicular size and varicocele grade [21]. The same issue exists with ultrasonography evaluation, as it is widely operator based. Unlike many previous studies [22–24], we specified the side of evaluation and the exact conditions (supine, standing, with and without Valsalva) by which physical examination and CDU grading

was done, which increases the accuracy of our results. In addition, we used two of the most common grading systems in clinical practice, which increases the applicability of our results.

Conclusion

Grades zero, one and two in ultrasonographic grading is most compatible with grade zero (sub-clinical) in clinical evaluation; so these grades most probably remain undetected in routine physical examination. Furthermore, grade three in ultrasonography and grade one in clinical grading, grade four in ultrasonography and grade two in clinical grading, and finally grade five in ultrasonography and grade three in clinical grading are most compatible. So by deducting two grades from the ultrasonography grading of varicocele measured by the Sarteschi method, one can obtain a compatible estimate of the clinical grading.

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Author contributions AAF: study design, study development, interpretation of data, critical revision of final draft. EY: study design, statistical analysis, preparation of manuscript, critical revision of final draft. MN: study design, statistical analysis, data gathering, critical revision of final draft. TE: statistical analysis, preparation of manuscript, interpretation of data, data gathering. AA: study design, study development, critical revision of final draft. PA: statistical analysis, preparation and critical revision of final draft

Compliance with ethical standards

Conflict of interest Authors have no conflict of interest to declare regarding the manuscript.

Informed consent Informed consent was obtained from all individual participants included in the study.

Statement of human rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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