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Original Article

VALIDATION OF ULTRASOUND EXAMINATION FOR ASSESSMENT OF THE ABDOMINAL VISCERAL FAT IN CLINICALLY SERIOUS OBESE PATIENT

Validação da ultrassonografia para a avaliação da gordura abdominal visceral em obesos clinicamente graves

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ABSTRACT - *Background*: Computerized tomography is the gold-standard for measurement of abdominal visceral fat. However, it is costly and involves submitting patients to ionizing radiation. ***Aim***: To validate the use of ultrasonography in assessing abdominal visceral fat among clinically serious obese patients of both genders. ***Methods***: The sample included adult patients with clinically serious obesity with body mass index of 40kg/m2 or from 35kg/m2 to 40kg/m2 with co-morbidities. Abdominal visceral fat thickness was measured using ultrasound and tomography. Two ultrasonographic exams were conducted to assess the interobserver reproducibility among a patient subsample. Validation was done by comparing these results with the tomographic findings. ***Results***: The study included 13 patients (61.54% female) with an average BMI of 38.82 kg/m2. In terms of validation, the result obtained from applying the Pearson correlation coefficient was equal to 0.94 (p = 0.0005), showing a strong positive correlation between the two measurements. As for the results for reproducibility, the interobserver was equal to 0.822, with a confidence interval of 95% (-0.076 to 0.980), revealing good interobserver agreement. The average difference between the two ultrasound interobserver examination was equal to 0.10 ± 1.51 (p=0.8898) and so not significant. Interobserver bias was also not significant. ***Conclusion***: The validation of ultrasonographic examination to replace tomographic method in assessing abdominal visceral fat among clinically serious obese patients was effective. The ultrasound measurement is independent of the examiner.

HEADINGS - Ultrasonography. Visceral fat. Obesity. Bariatric surgery.

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RESUMO – *Racional*: A tomografia computadorizada é o padrão-ouro para a medida da gordura abdominal visceral. No entanto é dispendiosa e envolve submeter os doentes à radiação ionizante. ***Objetivo***: Validar o método ultrassonográfico para avaliação da gordura abdominal visceral em obesos clinicamente graves de ambos os sexos. ***Métodos***: A amostra incluiu adultos com obesidade clinicamente grave que apresentavam índice de massa corporal de 40kg/m^2 ou entre 35kg/m^2 e 40kg/m^2 com comorbidades associadas. Os exames realizados para medição da espessura da gordura visceral foram: ultrassonografia e de tomografia computadorizada. Foram realizados dois exames para avaliação da reprodutibilidade interobservador em uma subamostra de pacientes. O estudo ultrassonográfico foi validado comparando-o aos resultados do exame tomográfico. ***Resultados***: Participaram do estudo 13 pacientes, sendo 61,54% mulheres com IMC médio de 38,82kg/m^2. A validação foi feita pelo coeficiente de correlação de Pearson resultando ser igual a 0,94 (p = 0,0005). Evidenciou-se correlação positiva e forte entre as duas medidas. Quanto aos resultados da reprodutibilidade, o coeficiente de correlação intraclasse interobservador foi igual a 0,822 com intervalo de confiança de 95% (-0,076 a 0,980), o que revela boa concordância interobservador. A diferença média entre os dois observadores na ultrassonografia foi igual a 0,10 ± 1,51 (p = 0,8898), não significativa e sem viés significativo interobservador. ***Conclusão***: Foi efetiva a validação do exame ultrassonográfico como substituição ao tomográfico para avaliar a gordura abdominal visceral entre obesos clinicamente graves. A medida ultrassonográfica independe do examinador.

DESCRITORES - Ultrassonografia. Gordura visceral. Obesidade. Cirurgia bariátrica.

INTRODUCTION

Obesity, characterized by body mass index (BMI) above 30 kg/m^2, is considered an epidemic and a major public health problem in many countries. Currently, in the world is more common to have obese adults than persons with malnutrition. Approximately half a billion adults worldwide is obese[9].

In Brazil, this number is growing, 12.5% among men and 16.9% among women[1]. As for moderate obesity (BMI>35kg/m^2) and morbidly obese (BMI> 40kg/m^2), the prevalence in Brazil for the population above 18 years are 0.6% and 3.0%, respectively[16].

Morbidly obese patients with moderate or with comorbidities (diseases aggravated by obesity and improving when it is treated effectively) life threatening situations - diabetes, sleep apnea, hypertension, dyslipidemia, coronary heart disease, osteoarthritis - are candidates for surgical treatment of obesity (bariatric surgery) and considered with clinically severe obesity[3].

Bariatric surgery is characterized as a well established and effective treatment for this population, it is the most effective treatment for the maintenance of weight loss over the long term and enables the improvement of the various comorbidities associated with obesity[2,12,17]. There is a need for further studies related to this specific population in Brazil.

Central obesity, characterized by the accumulation of fat in the trunk and abdomen has, as one of its components, visceral abdominal fat (GAV); to measure its thickness is of utmost importance, because it is a leading indicator of cardiovascular risk, due to metabolic changes resulting from this greasy deposit[10].

In recent decades, sophisticated techniques for assessing body fat showed that GAV is related to higher grades of morbidity, mortality and metabolic changes in obese [11.15].

Computed tomography (CT) is the gold standard method for the determination of GAV, due to its ability to differentiate between subcutaneous and visceral adiposity. Furthermore, the CT has the advantage of not depending on the operator's ability to identify the structures during the procedure, as it is not influenced by the pressure transducer on the abdomen during the measurements[7,14].

However, the CT method is expensive, not widely available; it subjects the patient to ionizing radiation, which limits its use, mainly in epidemiological research[13]. According to Williams et al. (1996)[18], the minimum GAV measured by CT at the level of L4-L5, above which the metabolic changes are clearly observed, is 110 cm^2 infemales. On the other hand, according to Despres & Lamarche (1993)[4], the value of 100 cm^2 for both genders is associated with significant changes in risk for cardiovascular disease and the above value of 130 cm^2 relates to profound metabolic deterioration.

Ultrasonography (US) has the advantage of being a low-cost, simple, practical, safe and free of radiation, despite the need for special equipment and trained[14] observers. Thus, US to measure GAV represents an evolution in the diagnosis of visceral obesity[13].

The aim of this study is to validate the method of ultrasound for evaluation of abdominal visceral fat in clinically severe obese, of both genders, using, as a reference method, the cerebral computed tomography. It has a secondary objective that is to evaluate the interobserver reproducibility of ultrasound examination for evaluation of visceral abdominal fat in clinically severe obese patients of both genders.

METHODS

This is a transversal validation study. The project was approved by the Research Ethics Committee of the Faculty of Health/University of Brasília, DF and the National Research Ethics of the National Health Council.

Patients participating on it were in the period immediately prior to Roux-en-Y gastric bypass bariatric surgery and had clinical severe obesity - body mass index (BMI) of 40 kg/m^2 (morbid obesity) or between 35 kg/m^2 and 40 kg/m^2 and comorbidities. The total sample consisted of 15 patients of both genders. The inclusion criteria were: patients referred for bariatric surgery and a BMI above 35 kg/m^2 and age above 18 years. Exclusion criteria were: pregnant women or patients over 65 years of age or heart problems and/or severe respiratory distress, considered high risk. Also, in the validation were excluded patients with more than 120 kg, the maximum weight to be supported by the gurney that CT is performed. These patients could be included in the reliability study for this there is no weight limit on the ultrasound machine.

The patients were divided into two subgroups. One of patients participating in the validation of the US examination in relation to CT for assessing the thickness of GAV - thus submitted to one CT scan and one U.S examination, both performed by the same examiner. Another group participated in the evaluation of the reproducibility of US examination, done by two different examiners, thus conducting two surveys of US made, each, by an different examiner. US examinations to assess its reproducibility were performed with a maximum 24 h using the same technique. The observers had no access to the results of measurements obtained between them, in order to avoid contamination of the samples.

The US examination was performed at the clinic BV Image, with the patient in the supine position on a machine with transverse transducer positioned perpendicularly to and across the skin in the region, 1 cm above the umbilicus in xifoumbilical line, without exerting pressure on the abdomen. Was considered the visceral fat thickness when measured in centimeters between the inner face of the rectus abdominis muscle and the posterior wall of the aorta in the midline of the abdomen with the patient in expiration[5]. Patients were fasted for 12 h to perform the US.

The total abdomen CT examination, was performed in at the University Hospital of Brasilia in a 6-channel helical CT scanner. For analysis of visceral fat, the same protocol was considered above (visceral fat thickness measured between the inner face of the rectus abdominis muscle and the posterior wall of

the aorta in the midline of the abdomen, but with the patient in inspiration, and quantified in centimeters), taking into account the region 1 cm above the umbilicus in xifoumbilical line. Data considered the analysis of abdominal visceral fat thickness by ultrasound computed tomography.

To examine the interobserver reproducibility of US measurements, was used the intraclass correlation coefficient, ICC model (2.1) with a range of 95% confidence level, as a measure of relative reliability. This coefficient was calculated for a two way ANOVA based on absolute agreement. ICC valuesgreater than 0.75 represent excellent agreement; values between 0.40 to 0.75 moderate agreement; and values below 0.40 low agreement (FLEISS, 1981). The paired Student's t test was used to test the absence of inter-bias, in the case of reproducibility. In validation to verify the correlation between CT and US, was employed the Pearson correlation coefficient. For purposes of analysis was used a significance level of 5%.The calculations were performed in SPSS 15 applications and SAS 9.2.

RESULTS

The study included 15 patients of both genders, nine women and six men. Two patients were excluded from the study due to the impossibility of visualization of the aorta during ultrasound or to the presence of metal pins in the body. So, were enrolled 13 patients, eight women and five men. Table 1 shows the profile of the study population (Table 1).

TABLE 1 - Demographic and anthropometric characteristics of the study population

	Validation patients (n=8)	Reproducibility patients (n=5)	Total patients (n=13)
Age (years)	38.25 ± 13.73	36.60 ± 8.96	37.62 ± 11.72
Male (%)	37.50	40.00	38.46
Female (%)	62.50	60.00	61.54
Weight (kg)	101.24 ± 13.03	114.24 ± 12.28	106.24 ± 13.88
Height (m)	1.65 ± 0.11	1.66 ± 0.05	1.65 ± 0.09
BMI (kg / m 2)	37.34 ± 2.30	41.20 ± 2.94	38.82 ± 3.13

From total patients, 61.54% were female. The average BMI was 38.82 kg/m^2 since the patients were candidates for bariatric surgery, all with severe obesity. The mean BMI was lower for patients who underwent a validation study of the reproducibility, since CT equipment had a limit of 120 kg; this did not occur wih the ultrasound validation studying reproducibility.

Regarding the results of the validation of the US in relation to CT scan, the correlation obtained by Pearson's correlation coefficient was equal to 0.94 (p=0.0005), showing a strong positive correlation between the two measures. Importantly, this result should be interpreted with caution, since the calculations obtained were based on a small sample (n=8). It is also important to mention that the CT measurements were performed with the patient in inspiration, and the US, on expiration. In the absence of bias, it is possible that the correlation is even better.

TABLE 2 - Mean measurements of the GAV according to gender

Study		Men	Women
Reproducibility	US 1st observer	10.00	7.57
	US 2nd observer	9.00	8.40
Validation	CT	13.83	10.36
	US	9.70	6.4

Regarding the results of reproducibility, the interobserver ICC was equal to 0.822 with a confidence interval of 95% (-0.076 to 0.980), which reveals an excellent interobserver agreement. Again, this result is due to the small sample in reproducibility study (n=5), resulting in a very extensive confidence interval. The average extent of the GAV in US on 1st observer was 8.54 ± 2.70 and for the other 8.64 ± 1.87, giving a mean difference between observers of 0.10 ± 1,51 (p=0.8898), not significant. Thus, the paired Student's t test proved the absence of a significant inter-observer bias.

DISCUSSION

According to the literature, there is no validation study of the US to assess the GAV in obese patients of both genders, which is a differentiation of the present study. With a population of only women, Ribeiro-Filho et al. (2003) performed a study to validate the test for GAV measurement using US but with measurement taken on anterior wall of the aorta of 100 adult women (20 to 65y) obese, with a BMI of 39.2±5.4 kg/m^2 (r=0.71, p<0.01). Another validation study using US in relation to CT was made by Radominski et al.(2000)[13], with 29 women (16-50y) with BMI between 24.07 kg/m^2 and 37.45 kg/m^2; were enrolled women with normal weight, with overweight and with obesity in the same study. Hirooka et al. (2005)[8] also assessed the validity of the US examination in relation to CT to assess the GAV with the same method of the present study, among 87 individuals of both genders, but no obese among patients.

Comparing the results of this study with the aforementioned, Ribeiro-Filho et al. (2003) found a correlation coefficient equal to 0.71 (p<0.01) and also proposed a value of 7 cm thick for the diagnosis of visceral fat in women. In the study done by Leite et al. (2000)[10], increased risk of cardiovascular disease has been linked to GAV values of 8 cm to 9 cm for women and men. In the present study, the higher measurements of the GAV (Table 2) indicate higher risk for cardiovascular disease. Radominski et al. (2000)[13] also conducted a validation study to assess the GAV successfully, but evaluating the visceral fat area, witch is not possible to be compared to this research. In the

study by Hirooka et al. (2005)[8], which also assessed the validity of the US examination with respect to CT in GAV by the method of this study, a good correlation was found between the two tests, with a coefficient of correlation 0.813 ($p<0.0001$).

The US examination was validated assessing the GAV in populations with varying profiles, but the current study was the first to perform this type of validation for clinically severe obese patients of both genders.

Evaluating similar studies in the literature, Hirooka et al. (2005)[8], also assessed the inter-observer reproducibility in a sample of the same size as the current study (n=5), with no significant difference between the measurements by the two examiners (p=.94). However, this reproducibility study included only healthy subjects with average BMI of 23.2 $kg/m^2 \pm 3.64$ kg/m^2. Another study examining the reproducibility of US for evaluation of GAV was made by Diniz et al. (2009)[5], with 50 patients of both genders, independently of BMI, by the method of this study. There was no significant difference between observers (p=0.7286). At the Student t test, there was a 95% significance. Observed high inter-observer correlation, with intraclass correlation coefficient of 0.91 (95% CI: 0, 86 to 0.95, $p<0.01$).

There is no published paper in which the reproducibility quality on US examination was not successful. It is possible that with the increase of the sample on the reproducibility of the results may be changed.

CONCLUSION

The validation of ultrasonographic examination to replace tomographic method in assessing abdominal visceral fat among clinically serious obese patients was effective. The ultrasound measurement is independent of the examiner.

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