REVIEW OF COMPARATIVE STUDIES BETWEEN BONE DENSITOMETRY AND QUANTITATIVE ULTRASOUND OF THE CALCANEUS IN OSTEOPOROSIS

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Abstract

Objective: To assess the utility of quantitative ultrasound (QUS) of the calcaneus for diagnosing osteoporosis compared to the gold standard, bone densitometry using dual-emission X-ray absorptiometry (DXA), according to published reports.
Design: In this systematic review, the Medline/ /PUBMED, Medline Ovid and Journals@Ovid, and Wilson General Sciences Full Text database were used. The search strategy involved use of the following MeSH descriptors: [osteoporosis AND (densitometry OR ultrasonography)], and 39 articles published between 2001 and April 2010 were assessed. However, only six articles met the inclusion criteria: sensitivity and specificity of QUS, sample (women or men with no treatment or other disease likely to change bone mass index), devices used, comparative T-score between QUS of the calcaneus and DXA. The GE-Lunar Achilles and Hologic Sahara devices were used in most of the tests reported and were effective.
Results: All studies assessed compared QUS of the calcaneus to DXA of the lumbar spine or femoral neck, as the gold standard. QUS sensitivity ranged from 79% to 93% and specificity ranged from 28% to 90% when at the lower threshold. It is a controversial parameter, because the gold-standard threshold (T-score < -2.5, DXA) could not be used for QUS without errors in osteoporosis diagnosis. All studies had a threshold determined by the authors' criteria, with a variability of -1.7 (pDXA T-score) and -2.4 for QUS, leading to the same prevalence of osteoporosis, and a T-score of < -3.65 for QUS was equivalent to a T-score < -2.5 for DXA.

Conclusions: Based on the analysis of seven studies, we conclude that QUS of the calcaneus still cannot be used to confirm diagnosis of osteoporosis by comparing the results to those of patients who had already received such a diagnosis based on DXA. However, further research should be conducted in this area, because it is possible to improve the number diagnoses by varying the cutoff T-score. Furthermore, using QUS of the calcaneus was a helpful tool for assessing pathological fractures, whether or not they were associated with osteoporosis.

Keywords: Densitometry; Bone Mineral Density; Calcaneus/ultrasonography; Osteoporosis.

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Introduction

Osteoporosis is defined by the World Health Organization (WHO) as a disease characterized by reduced bone mass and microarchitectural deterioration of bone tissue, with consequent bone fragility and susceptibility[1-3] to fractures[4,5]. Such criteria have not been defined for men, who have larger bones with thicker cortices, although their density and trabecular architecture is similar to that of women[4]. The WHO's operational definition for osteoporosis is a BMD that is 2.5 SDs (T-scores) or more below the mean for young healthy adult women and the definition of osteopenia is a T-score between -1 and -2.5[1,11].

The disease affects approximately 200 million people worldwide, and is responsible for 1.5 million fractures annually in the USA[1,3]. In Latin America, the vertebral and femoral bones are affected in around 15% of women over the age of 50 years, with great social and economic impact[3].

Considering the increase in life expectancy, prevention and early diagnosis of osteoporosis may avoid frequent complications, such as fractures. Additionally, early diagnosis may contribute to reducing public health expenditures and the costs of rehabilitating these patients. In Latin American countries, the direct costs of disease reach US$4500–6000 per month, which may be higher than the per capita income in some of these countries[3].

Bone density evaluation for diagnosing osteoporosis can be performed by various methods, including bone ultrasound, bone densitometry, tomography, and radiographic exams. Bone densitometry using dual-emission X-ray absorptiometry (DXA) remains the gold-standard test for the diagnosis and quantification of osteoporosis, but access to this method is still restricted due to its high cost and limited availability in rural zones[2].

Quantitative ultrasound (QUS) of the calcaneus is a bone ultrasound method that provides a fast diagnosis with no radiation emissions and at relatively low cost[38]; it can also be used to predict the risk of fractures due to osteoporosis[1-3,5,13]. The calcaneus is especially suitable for obtaining a quantitative analysis because of its characteristics: a short, trabecular bone with a thin cortex[6]. It has a high metabolic turnover and a bone pattern similar to that of the spine. Because of its trabecular mechanical characteristics, the calcaneus undergoes static and dynamic stresses from orthostatism and the human walking mechanism. However, there is still no consensus on the accuracy of QUS of the calcaneus for identifying patients with osteoporosis.

QUS uses low-frequency ultrasonic waves to measure different bone properties by means of two parameters: the speed of sound (SOS, expressed as m/s) which means the necessary time to ultrasound waves go through a determined distance inside the calcaneus bone[7,11] and the attenuation of ultrasound broad bands (BUA, expressed by dH/MHz) which is a measure of the ultrasound variation of attenuation with the incident frequency of wave sound[7,11], generating a rigidity index called stiffness[12] of the bone or quantitative ultrasound index (QUI, expressed as a percentage of the result from young adults or the percentage of weight-matched references according to the manufacturer)[7,12]. Estimated Bone Mineral Density (EBMD expressed as g/cm^2) is the result of the combination of BUA and SOS that gives a BMD value, but it is important to note that QUS BMD is inferred from a linear combination of BUA and SOS and it is not an actual measurement of calcaneal BMD[6,41].

Its use has been satisfactorily described in the literature for predicting the risk of fractures[13] resulting from osteoporosis, but it has not been shown to be reliable for monitoring medication treatment of osteoporosis[3] because of differences between the equipment and parameters used[13].

Dual-energy x-ray absorptiometry (DXA) of the lumbar spine and femur head is the gold-standard test for bone evaluation. It generates T-score and Z-score based on the statistical unit of the standard deviation[5]. T-score is the number of standard deviations below the average for a young adult at peak bone density. Z-score is the number of standard deviations below an average person of the same age. There are different T-scores and Z-scores depending on the group used as a reference. BMD (expressed as g/cm^2)[11] calculated as the ratio of bone content to the scanned area is helpful to predict the risk of bone fracture[1,5] and BMC (expressed as kg)[5]. DXA quantifies bone *mass* but is incapable of providing information about bone *quality*. The quality and microarchitecture of the trabeculae correspond to up to 50% of the mechanical strength of bone. This is equivalent to a relationship of 0.43 between bone density and bone strength[6,7]. This relationship explains why in many cases the risk of fracture may be greater than the bone densitometry value would suggest, due to the fragile bone microarchitecture, which is not effectively diagnosed by densitometry. Additionally, it is an expensive test, there is a lack of equipment in places with less infrastructure[8,9], and it is generally difficult to extrapolate hip fracture risk parameters to other points of the skeleton, such as the lumbar spine[8].

The association between the DXA and QUS tests has been reported to present a margin of confidence of 90% in specificity and sensitivity[10], suggesting that bone mass density and evaluation performed by QUS may be equally predictive of risk of future fractures[11], since one Standard Desviation decreased in BUA increases two times the risk of hip fractures[3,13]. The aim of this review was to analyze comparative studies between DXA and QUS, verifying their applicability in the diagnosis of osteoporosis according to the WHO criteria, using DXA as the gold-standard technique.

Methods

The Medline/PUBMED, Medline Ovid and Journals@Ovid, and Wilson General Sciences Full Text databases were used in the literature review. In the search strategy, the following MeSH descriptors were used: [osteoporosis AND (densitometry OR ultrasonography)].

Thirty-nine articles published between 2001 and April 2010 were analyzed, and then either selected or excluded because they did not meet the following inclusion criteria: sensitivity and specificity of QUS compared to DXA, subjects in the sample (women and/or men who were not being treated with drugs that altered bone quality and without other comorbidities that altered the bone mass index), types of equipment, the presence of the QUS equipment brand used in the research, comparative T-score between the methods, and site for the performed test (Table I). As a result, only six studies were included, which included all of the variables discussed here (Table II).

Table I. Compared variables between published articles following or not the inclusion criteria

Variables Articles (author)	Sensitivity DXA/ /QUS	Specificity DXA/ /QUS	Devices used DXA/ /QUS	Subjects in the Sample (N)	BMD (T-Score) DXA/ /QUS	Site where which test were used DXA/QUS	Year of publication
EL Maghraoui et al.[5]	- / -	- / -	+	+	+ / +	+ / +	2009
Camozzi et al.[2]	- / -	- /-	+	+	+ / +	+ / +	2007
Canhão et al.[7]	- / -	- / -	+	+	- / +	- / +	2006
Hans et al.[8]	- /-	- / -	-	+	- / -	+ /+	2004
Frost et al.[6]	- / -	- / -	+	+	+ / +	+ / +	2001
Hans et al.[3]	**+ / +**	**+ / +**	**+**	**+**	**+ / +**	**+ / +**	**2009**
Arana-Arri E et al.[16]	- / +	- / +	-	+	- / +	- / +	2007
Jørgensen et al.[17]	+ / +	+ / +	-	+	+ / +	+ / +	2001
Imashuku et al.[10]	- / -	- / -	+	+	+ / +	+ / +	2007
Hodson, Marsh[18]	- / +	- / +	-	+	+ / +	+ / +	2003
Fukunaga, Sone, Yoshikawa[19]	- / -	- /-	-	-	- / -	+/ -	2006
Soontrapa, Soontrapa, Chaikitpinyo[20]	- / -	- / -	-	-	+ / +	+ / -	2009
Frost, Blake, Fogelman[21]	+ / +	+ / +	-	+	+ /+	+ /+	2002
El-Desouki, Sherafzal, Othman[22]	+ / +	+ / +	-	+	+ /+	+ /+	2005
Glüer et al[23]	- / -	- / -	-	+	- / -	+ / +	2005
Krieg et al[24]	- / +	- / +	-	-	- / -	- / +	2008
Hans, Krieg[25]	- / -	- / -	-	-	- / -	- / +	2008
Gudmundsdottir, Indridason, Franzson, Sigurdsson[11]	**+ / +**	**+ / +**	**+**	**+**	**+ / +**	**+ / +**	**2004**
Ikeda[13]	**+ / +**	**+ / +**	**+**	**+**	**+ / +**	**+ / +**	**2002**
Navas et al.[26]	- / -	- / -	+	+	+ / +	+ / +	2006
Pearson et al.[14]	**+ / +**	**+ / +**	**+**	**+**	**+ / +**	**+ / +**	**2003**
Wüster, Hadji[27]	- / -	- / -	-	-	- / -	- / +	2009
Kraemer, Nelson, Bauer, Helfand[15]	- / -	- / -	-	+	- / -	+ / +	2005
Dubois et al.[28]	+ / +	+ / +	-	+	- / -	+ / +	2001
Glüer et al.[29]	+ / +	+ / +	-	+	- / -	+ / +	2004
Nayak et al.[26]	+ / +	+ / +	-	+	+ / +	+ / +	2006
Stewart, Reid,[30]	- / +	- / +	+	+	+ / +	+ / +	2000
Relation among MRTA, DXA and QUS[31]	- / -	- / -	-	+	- / -	+ / +	2004

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Table I. Compared variables between published articles following or not the inclusion criteria *(continuation)*

Variables Articles (author)	Sensitivity DXA/ /QUS	Specificity DXA/ /QUS	Devices used DXA/ /QUS	Subjects in the Sample (N)	BMD (T-Score) DXA/ /QUS	Site where which test were used DXA/QUS	Year of publication
Schnabel et al[32]	+ / +	+ / +	-	+	+ / +	+ / +	2006
Frediani et al[33]	+ / +	+ / +	-	+	+ / +	+ / +	2005
Diessel et al[34]	- / -	- / -	+	+	- / -	+ / +	2006
Knapp[35]	- / +	- / -	-	-	- / -	- / -	2000
Trimpou et al[12]	**+ / +**	**+ / +**	**+**	**+**	**+ / +**	**+ / +**	**2010**
Mueller, Gandjour[36]	- / -	- / -	-	+	- / -	- / -	2008
Nayak, Roberts, Greenspan[37]	- / -	- / -	-	+	- / -	- / -	2009
VU THI THU HIEN et al[38]	- / -	- / -	+	+	- / +	- / +	2005
ZHU Z.Q.; LIU, W.; XU, C.L.; HAN, S.M.; ZHU, G.J.[39]	- / -	- / -	+	+	- / +	- / +	2008
Boonen et al[9]	**+ / +**	**+ / +**	**+**	**+**	**+/ +**	**+ / +**	**2005**
Mazariegos[40]	- / -	- / -	+	+	+ / +	+ / +	2004

* the article's sequence content is at the References

Table II. Selected published articles following the inclusion criteria

Variables Articles (author)	Sensitivity DXA/ /QUS	Specificity DXA/ /QUS	Devices used DXA/ QUS	Subjects in the Sample (N)	BMD (T-Score) DXA/ /QUS	Site where which test were used DXA/ /QUS	Year of publication
Hans et al[3]	+ / +	+ / +	+	+	+ / +	+ / +	2009
Gudmundsdottir, Indridason, Franzson, Sigurdsson[11]	+ / +	+ / +	+	+	+ / +	+ / +	2004
Ikeda et al[13]	+ / +	+ / +	+	+	+ / +	+ / +	2002
Pearson et al[14]	+ / +	+ / +	+	+	+ / +	+ / +	2003
Trimpou et al[12]	+ / +	+ / +	+	+	+ / +	+ / +	2010
Boonen et al[9]	+ / +	+ / +	+	+	+/ +	+ / +	2005

Results

All studies assessed compared QUS of the calcaneus to DXA of the lumbar spine or femoral neck, as the gold standard. Six articles met our inclusion criteria.

The included studies evaluated the compared specificity and sensibility between QUS and the gold-standard DXA of postmenopausal women, men over 70 years or both, without comorbidities that could influence the cutoffs measured to reach a threshold for QUS diagnosis, described the DXA and QUS equipments used, to assure that the manufacturers reference or the use of the phantom to avoid false-negatives and showed a comparative T--score between methods, according to their cutoffs

Table III. Comparison between the included articles according to the inclusion criteria

Selected Article	Population Characteristics	n. of Patients	Equipment used (QUS and DXA)	Specificity (QUS)	Sensibility (QUS)	Objectives of the study
Trimpou et al[12]	Women with Postmenopausal osteoporosis, aged between 53-73 years	80	Lunar Achilles; LUNAR DXP-L	36 – 57%	76 – 84%	7 years follow-up to validate QUS against DXA, as gold-standard
Boonen et al[9]	Post-menopausal women aged between 50-75 years	221	Hologic Sahara; QDR 4500a fan beam system (Hologic)	70.4%	67.6%	Evaluated the ability of QUS to diagnose osteoporosis
Gudsmundsdottir et al[11]	Random sample aged between 30-85 years (Caucasian population in Iceland)	1630 individuals (1041 females; 589 males)	Lunar Achilles Plus; Hologic QDR 4500	30 -62% for 50-65 years range; 26- 68% for 70-85 years range;(men) 13 – 47% for 70-85 years range	79 – 94% for 50-65 years range; 95- 71% for 70-85 years range; (men) 100–83% for 70-85 years range	Investigate age-related bone decline in men and women measured with QUS and DXA and to find a clinically cutoff level for QUS to detect Osteopenia or Osteoporosis according to DXA
Pearson et al[14]	Women aged between 33-86 years	99	Lunar Achilles Plus; GE Lunar Expert	60 ±10% (when compared to Spine BMD) 84±8% (when compared to Total Hip BMD)	59 ±10% (when compared to Spine BMD) 41±10% (when compared to Total Hip BMD)	Determine the optimal T-score between pDXA and QUS in comparison to DXA
Hans et al[3]	Comparison of 13 studies; women from EPIDOS Study	9561 patients; 5954 from EPIDOS Study	Lunar Achilles/ Hologic Sahara; Hologic QDR 4500 and LUNAR DXP-L	Near to 90% if the threshold is near to inferior parameter of DXA	Near to 90% if the threshold is near to superior parameter of DXA	Review the clinical use of QUS in the following wing settings: 1) the prediction of fracture risk; 2) the diagnosis of osteoporosis; 3) the initiation of osteoporosis treatment or prevention; 4) the monitoring of such treatment; 5) osteoporosis case finding
Ikeda et al[13]	Healthy Japanese women aged between 20-79 years, cohort randomly selected	659	Hologic Sahara; QDR 4500A, Hologic	65- 67% (when compared to Spine BMD) 72 – 74% (when compared to Total Hip BMD)	64- 65% (when compared to Spine BMD) 71% (when compared to Total Hip BMD)	Establish reference values of the QUS indices in healthy Japanese women of various ages and to propose a criterion for diagnosing osteoporosis by means of QUS indices

(Table III).

Several studies evaluated more than one of these parameters, however they were excluded because they did not meet all inclusion criteria. We focused our analysis on the comparison of the QUS of calcaneus and DXA for the diagnosis of Osteoporosis.

The cutoffs variables were measured using the following methods: The mean, standard deviation (S.D.) and the standard error of the mean (S.E.M.) were calculated using conventional methods[12], receiver operating characteristic (ROC) curves[3,9,11,13,14] and the areas under the curves AUCs were computed to determine the optimun T-score threshold for QUS measurements, the sensitivity and the specificity[9] and diagnostic accuracy of osteoporosis of each QUS[13].

Discussion

Six articles published between 2001 and 2010 that satisfied the inclusion criteria were analyzed. Considering that osteoporosis affects around 200 million persons worldwide, QUS has been proposed as a diagnostic tool because of its portability, low cost, and safety, although the gold-standard recommended by the WHO is DXA of the lumbar spine and femur head. In the six studies, the gold-standard was compared to the QUS method.

Based on the studies analyzed, the sensitivity of QUS compared to DXA showed a range of values: 86–93%[12], 79%[14], 90% for the superior parameter[3], 65-67% (when compared to Spine BMD) and 72–74% (when compared to Total Hip BMD)[13], and 67.6% for the 95% confidence interval[9]. Regarding specificity, the following values were reported: 28–44%[12], 64-65% (when compared to Spine BMD) and 71% (when compared to Total Hip BMD)[13], 90% for the inferior parameter[3], 65.8%[14], and 70.4%[9], demonstrating that variation in sensitivity depends on the change thresholds used for measuring deviation. However, when the sensitivity values were high, the method had an excellent negative predictive value (around 90%[9]) and median specificity value, which also improved when the threshold was reduced (although this slightly decreased its sensitivity).

According to Hans *et al.*[3], the highest number of reported tests have been performed using the GE-Lunar Achilles and Hologic Sahara machines, which have proven to be more effective than other devices. GE-Lunar Achilles was used in studies reported by Trimpou *et al.*[12], Pearson *et al.*[14], and Gudmundsdo *et al.*[11,12,15]. Hologic Sahara was mentioned by Ikeda *et al.* as performing well, and was also used by Boonen *et al.*, in conjunction with the Meditech DTU-One machine, for which no evidence has been reported for evaluating the risk of hip fractures, according to Hans *et al.*[3]. In their study, it was observed that the GE-Lunar Achilles was used in the majority of populations to evaluate the risk of fractures of the hip, spine, and other sites in the body, whereas the Hologic Sahara had been used with Caucasian and Japanese populations[3]. Regarding to WHO criteria, which is not applicable to QUS, women were also classified into WHO groups using the revised criteria for QUS that have been shown applicable to Sahara and DTUone devices[41], creating a standard T-score for these machines, however the different models were not comparable each other (Hologic Sahara and Lunar Achilles), even for the same index[13].

According to Ikeda *et al.*[13], 659 Healthy Japanese women aged between 20-79 years, from a second survey of a larger cohort study (JPOS study), that involved 2 cohorts in the northeastern part of Honshu main island and in Shikoku, were selected to establish reference values of the QUS indices and to propose a criterion for diagnosing osteoporosis by means of QUS indices. The vaue of Sahara as a diagnostic tool would be increased if the optimal site is determined to be the total hip in the future, however, the method did not increase sensitivity and specificity, making the diagnostic accuracy of QUS indices not superior than age which can be obtained very easily without any expensive machines.

In Hans *et al.*[3] a sample of 5,954 women ≥ 75 years participating in the EPIDOS study, analyzed using the same previously mentioned specificity and sensitivity values, showed 11% false positives and 13% false negatives. This suggests that the QUS method could be used to identify individuals with many or few risk factors for osteoporosis, and for values between the superior and inferior limits, and that DXA could be used as the definitive test and for follow-up in therapy.

In Pearson *et al.*[14], both methods did not show significant differences in performance, with the prevalence of osteoporosis of 46% at the spine and 24% at the total hip for the group measured with the QUS, very similar to those obtained by DXA measurements: 46% at the spine and 25% at the total hip, when applied to 99 women aged 33–86 years who had been referred to the bone metabolism clinic.

In Trimpou *et al.*[12] 80 women aged 53–73 years with osteoporosis or fractures were followed for a period of 7 years. They found that the sensitivity of the method was high, despite the low specificity, and concluded that DXA must be used as a diagnostic test, if available, before beginning the treatment of osteoporosis but the treatment may be initiated without this method if QUS shows a T-score < -3.65, particularly in the presence of fractures.

In Gudsmundsdottir *et al.*[11] a random sample of 1,630 individuals (1,041 women, 589 men) aged 30–85 years showed that loss of bone mass in relation to age was significantly higher when using QUS than when using DXA. Although QUS is not incorporated into the diagnosis of osteoporosis by the WHO, in the study, it was possible to exclude this diagnosis in 30–40% of the cases.

Boonen *et al.*[9] evaluated 221 post-menopausal women aged 50–75 years who had been referred to the Leuven University Center for Metabolic Bone Diseases for DXA, among whom 9 patients were receiving therapy for osteoporosis. It was possible to observe, within the 95% confidence intervals, a mean negative predictive value (NPV) of 89.8% and a mean positive predictive value (PPV) of 33.4%, indicating that the method was useful for diagnosing osteoporosis in the age range studied, compared to the gold-standard method. Nevertheless, the authors noted that a limitation of their study is the lack of a random sample, suggesting that care should be taken when attempting to generalize their data. Also, some of the subjects were receiving treatment for osteoporosis.

A point of controversy with regard to all of the studies is the cut-off point for the diagnostic determination of osteoporosis with the QUS method. No direct relationship can be made between the threshold accepted for DXA (a T-score < -2.5) and QUS without there being discrepancies between the number of patients diagnosed with osteoporosis by each method[3], in addition to variation in calibration of the machines, and the use (or not) of a phantom, a device incorporated at the quantitative ultrasound of calcaneus that calculate the interval of the transmitted wave between the device to the bone and the way back[3] which minimizes the possibility of error in the QUS readout, that also vary with porosity of this incorporated device[13].

In the studies analyzed, it was noted that the authors set a cut-off point determined at their discretion, ranging from -1.7 (pDXA T-score) and -2.4 for QUS, so as to define the same prevalence of osteoporosis[14]. In comparison to the gold-standard spine BMD the QUS T-Score vary from -1,51 to -1,58 and in comparison to gold-standard total hip BMD it vary from -1,88 to -1,90, and, when applied WHO criteria to QUS, the prevalence of osteoporosis appeared to be much lower than that for spine BMD.[13] Another study found that the T-score for QUS should be -1.61 to -1.72 compared to the threshold for DXA accepted by the WHO[9]. In a study on women aged 50–65 years, a T-score > -1.0 for QUS was applied for identifying normal BMD, whereas in the age range of 70–85 years, a T-score < -2.5 for women and < -0.6 for men were considered reasonable cut-off values for identifying normal BMD[12]. It has been reported that T-scores, and particularly a T-score value below -1.55 by QUS, have adequate discriminative power for the diagnosis of osteoporosis[13].

One limitation of this study was the difficulty in finding reports that satisfied all of the inclusion criteria, suggesting that better-designed, more standardized studies should be conducted. An important point, although it is not the main objective of the present study, is that QUS is a helpful tool for evaluating patients with pathological fractures, whether or not they present risk factors for osteoporosis. This reveals good utility for this diagnostic method, which may be used as a tool in triage for the evaluation of fractures due to osteoporosis and later referral of patients to a specialized center that uses DXA, for therapy and monitoring, if necessary.

Conclusions

QUS cannot yet be used to reliably confirm a diagnosis of osteoporosis by the gold-standard DXA test[1]. Indeed, there is great variation in the sensitivity and specificity of QUS, which results in more or fewer diagnoses depending on the T-score, both age and gender dependent, generating confusion. However, there was a large compatibility between the two methods based on the studies assessed in the present study. Further studies on the subject are necessary to determine criteria and a reliable correlation between QUS and DXA.

Nevertheless, with the technological advance, it is possible to improve the QUS devices to be used at the patients during the clinical treatment of Osteoporosis[3], since this method has good assessment of the quality of the bone and a high correlation with the clinical fracture risks[2], it can be used to exclude healthy individuals from further examinations.

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