Diagnostic accuracy of ultrasonography-guided core needle biopsy for breast lesions

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INTRODUCTION This study aimed to assess the diagnostic accuracy of ultrasonography (US)-guided core needle biopsy (CNB) for breast lesions.

METHODS We performed US-guided CNB of 733 lesions in 674 women from January 2003 to December 2005. Surgical excision was performed on 331 lesions. We compared the histopathologic findings of the CNB specimens with those of surgical specimens or with patients' long-term follow-up images. We also calculated the agreement, underestimation, sensitivity and false-negative rates.

RESULTS The CNB results showed 334 breast cancers (46%), 28 high-risk lesions (5%) and 367 benign lesions (50%). Four (1%) lesions were categorised as inconclusive. The final diagnosis was breast cancer in 348 lesions. The kappa measure of agreement between the US-guided CNB results and surgical excision findings or follow-up results was 0.861 (p-value < 0.001). The underestimation rate was 40% (10 out of 25) for atypical ductal hyperplasia and 47% (14 out of 30) for ductal carcinoma *in situ* (DCIS). The CNB false negative rate and sensitivity for malignant lesions was 4% (14 out of 348) and 96% (334 out of 348), respectively.

CONCLUSION US-guided CNB is an accurate diagnostic alternative to surgical biopsy in patients with breast lesions detected via US, although the high underestimation rates in DCIS and high-risk lesions are still a concern.

Keywords: breast cancer, diagnosis, needle biopsy, ultrasonography
Singapore Med J 2012; 53(1): 40–45

INTRODUCTION

It is important to obtain a histological diagnosis of cancer before proceeding for surgery, despite the reasonable accuracy of mammography.[1] Although fine needle aspiration cytology (FNAC) is the preferred initial diagnostic procedure in many breast centres,[1,2] it is unreliable and prone to sampling errors.[2] Surgical biopsy is the 'gold standard' for diagnosis, but due to the associated morbidity, interference with definitive surgery for cancer, high cost and cosmetic problems,[2,3] it is not the initial biopsy method of choice. Percutaneous core needle biopsy (CNB) under imaging guidance could avoid all the previously mentioned potential problems, as well as decrease any postoperative scarring that may influence the diagnostic accuracy of the mammogram.[4] Whenever feasible, CNB is performed under ultrasonography (US) guidance for convenience, improved patient comfort and avoidance of ionising radiation.[3,5]

CNB suffers, to a lesser degree, from a lack of accuracy relative to surgical biopsy. The factors that affect the accuracy of CNB include the characteristics of the lesion, the experience of the radiologist, the type of machine used for guidance and the number of core specimens.[3,4,6] It has been recommended that at least four core specimens be obtained.[3] The accuracy of US-guided CNB also varies in terms of histological findings. For example, it has been reported that the accuracy was 64.7% in terms of histological type, 100% when diagnosing direct invasion to the adjacent fat tissue, 82.4% in diagnosing lymphatic invasion, 82.4% in determining venous invasion, 94.1% in determining the histological grade and 82.4% in detecting intraductal components.[2] A study in 2005 reported that the false-negative rate of a 14-gauge US-guided CNB was 3.7% and the sensitivity of US-guided CNB for the diagnosis of breast cancer was 96.3%.[7]

Although it has been recommended that US-guided CNB can replace surgical and FNAC as a standard procedure for histological diagnosis of breast tumours,[2] the diagnostic accuracy of US-guided CNB for breast lesions has never been evaluated at our institution. The present study aimed to estimate the accuracy of US-guided CNB in terms of its agreement with surgical biopsy and the results of follow-up, as well as to estimate the underestimation rate, false negative rate and sensitivity of the procedure performed at our institution.

METHODS

At the Breast Diagnostic Centre, a tertiary referral centre at Ramathibodi Hospital, Bangkok, Thailand, we performed US-guided 14-gauge CNB on all referred patients with image-detected suspicious breast lesions or lesions highly suggestive of malignancy, who did not have a bleeding diathesis and who gave their informed consent. Patients with probable benign and benign lesions also underwent CNB if the patient or referring physician strongly requested for the biopsy. This was a retrospective study of female patients who underwent CNB between January 2003 and December 2005. The study

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was conducted with institutional review board approval and given a waiver of patient informed consent, as it was a review of routine clinical data.

Mammography was performed in craniocaudal (CC) and mediolateral-oblique (MLO) views by using two mammography machines, Lorad M-IV (Lorad, Danbury, CT, USA) and Senographe DMR (GE Medical Systems, Milwaukee, WI, USA). After November 2004, mammography was obtained using a digital mammography unit (Selenia, Lorad, Danbury, CT, USA). An additional US (HDI 5000, Philips Ultrasound Inc, Bothell, WA, USA) of the breasts was performed in most of the patients. The final risk category was based on the combined results of the mammography and US, according to the American College of Radiology Breast Imaging Reporting and Data Systems (BI-RADS), 4th edition.

US-guided CNB was performed for lesions seen on US with a 14-gauge needle automated biopsy gun (MDTECH, Gainesville, FL, USA). We employed a high-resolution US unit with 12.5-MHz linear array transducer (HDI 5000) to guide the biopsy needle. Prior to the introduction of the needle, a small incision was made under local anaesthesia as close to the breast lesion as possible. During the procedure, we ensured the correct placement of the needle by directly visualising the needle tips with orthogonal imaging. Radiologists who specialise in breast imaging performed all the biopsies. According to standard protocol, we attempted to obtain six core samples per lesion. We also obtained data on the size of the lesion and the BI-RADS classification from medical records. The maximum diameter of the lesion was determined by US. The gold standard diagnosis of breast lesions was open surgical excision. In patients who did not undergo surgical biopsy, we based the diagnosis of a benign lesion on the results of follow-up imaging studies performed for at least two years after the initial CNB.

The results of CNB were categorised as benign, malignant, high-risk or inconclusive. High-risk lesions included atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), lobular carcinoma *in situ* (LCIS) and borderline phyllodes tumour. Biopsy results were defined as inconclusive if the biopsy material was of insufficient quality for a definitive histological diagnosis. Open surgical biopsy results were categorised in the same manner. Each CNB specimen was examined on a routine clinical practice basis, and was therefore usually seen and reported by one pathologist. Occasionally, when the findings were unclear, a group of pathologists would examine the specimen, and the report of a consensus or disagreement would be provided to the clinician. In such cases, the final pathology for the purpose of the present study would be the highest risk pathology documented in the medical records.

The underestimation rate of CNB-diagnosed high-risk lesions was defined as the proportion of lesions diagnosed as high-risk by CNB that were upgraded to ductal carcinoma *in situ* (DCIS) or invasive cancer after surgical excision.[8] The underestimation rate of CNB-diagnosed DCIS lesions was defined as the proportion of lesions diagnosed as DCIS by CNB but upgraded to invasive cancer after surgical excision.[8] Lesions not removed by subsequent surgical excision from the underestimation rate analysis were excluded. The false-negative rate was defined as the proportion of all breast cancers with a benign, high-risk or inconclusive diagnosis on US-guided CNB.[8] The sensitivity rate was defined as the proportion of malignancies that was identified by US-guided CNB.[8] The crude agreement rate was defined as the proportion of lesions correctly identified as benign, malignant or high-risk by US-guided CNB.[8]

For lesions not surgically excised, a final diagnosis of benign was defined as those with a benign or inconclusive CNB result as well as stable or improved follow-up imaging findings at least two years after the initial CNB. A final diagnosis of high-risk was defined as a high-risk CNB result as well as stable or improved follow-up imaging findings after two or more years, or a benign lesion with progressing image findings. A CNB diagnosis of malignancy was regarded as the final diagnosis if no surgical excision was performed on the lesion.

Continuous variables (age at initial examination, size of lesion and number of core biopsies) were summarised as mean (standard deviation [SD]) and median (range), while categorical variables (personal/family history of breast cancer, breast density, BI-RADS category, imaging findings and pathologic status) were summarised as counts and percentages. The agreement between the diagnostic methods was measured using kappa statistics. All lesions were assumed to be statistically independent. Statistical significance was defined as $p \leq 0.05$. All statistical analyses were performed using Stata v.9 (StataCorp, College Station, TX, USA) statistical software.

RESULTS

A retrospective review of medical records from January 2003 to December 2005 revealed 812 consecutive patients who underwent US-guided CNB. 138 patients, for whom subsequent surgical biopsy results or two-year follow-up data were not available, were excluded from the study. A total of 674 women with 733 breast lesions were included in the study. Their mean age was 50 ± 9.6 (range 16–85) years. Of the 674 patients, 49 had biopsies of two separate lesions and five had biopsies of three separate lesions. Only 6% (38 out of 671) and 1% (four out of 658) of patients had a personal and familial history of breast cancer, respectively. The breasts were almost entirely fat or had scattered fibroglandular densities in 4% (23 out of 612) and 17% (103 out of 612) of patients, respectively. The breasts of 62% of patients (379 out of 612) were heterogeneous and those of 17% of patients (107 out of 612) were extremely dense. The characteristics of the lesions are shown in Table I.

US-guided CNB was performed in 733 lesions, of which 331 were also surgically excised and 295 were stable or decreased in size on follow-up imaging for at least 24 months. The mean number of cores was 5.8 ± 1.4, with 70% of lesions (511 out of 733) sampled with six or more cores. The pathologic results of the CNB were 46% malignant (n = 334), 5% high-risk (n = 28) and 50% benign

Table I. Characteristics of breast lesions.

Characteristic/finding	No. (%)
Lesions detected on physical examination (n = 729)	206 (28)
Lesions detected on mammography (n = 685)	498 (73)
Lesions detected on the left side (n = 733)	395 (54)
Lesions seen on mammography (n = 498)	
Mass	306 (61)
Calcification	49 (10)
Mass with calcification	74 (15)
Architectural distortion	32 (6)
Asymmetrical density	33 (7)
Others	4 (1)
Lesions seen on US (n = 733)	
Mass	621 (85)
Mass with calcification	86 (12)
Microcalcification	2 (0.27)
Architectural distortion	14 (2)
Others	10 (1)
Size of lesion seen on US (cm) (n = 729)	
Mean ± SD	1.7 ± 1.5
Median; range	1.3; 0.3–9.0
US BI-RADS (n = 733)	
2	15 (2)
3	55 (8)
4A	97 (13)
4B	301 (41)
4C	41 (6)
5	220 (30)
6	4 (1)
No. of core biopsies (cores) (n = 729)	
Mean ± SD	5.8 ± 1.4
Median; range	6; 1–15
Initial core needle biopsy result (n = 733)	
Benign lesion	367 (50)
Inconclusive	4 (1)
High risk (ADH, ALH)	28 (4)
DCIS	42 (6)
Invasive cancer	292 (40)
Final pathologic diagnosis (n = 733)	
Benign lesion	357 (49)
High risk	28 (4)
DCIS	28 (4)
Invasive cancer	320 (43)

US: ultrasonography; SD: standard deviation; BI-RADS: breast imaging reporting and data system; ADH: atypical ductal hyperplasia; ALH: atypical lobular hyperplasia; DCIS: ductal carcinoma *in situ*

Table II. Pathological results of ultrasonography-guided core needle biopsy in malignant breast lesions.

Findings	No. of lesions
DCIS	42
Invasive cancer	
Invasive ductal carcinoma	242
Invasive ductal carcinoma with DCIS	17
Invasive lobular carcinoma	8
Mucinous carcinoma	8
Medullary carcinoma	2
Non-Hodgkin's lymphoma	2
Papillary carcinoma	1
Others	12

DCIS: ductal carcinoma *in situ*

Table III. Pathological results of ultrasonography-guided core needle biopsy in benign breast lesions.

Findings	No. of lesions
Fibroepithelial lesions	43
Fibroadenoma	84
Fibrocystic change	59
Sclerosing adenosis	22
Intraductal papilloma/papillomatosis	17
Inflammatory/infectious process	18
Benign phyllodes tumour	3
Nonspecific benign pathology	10
Normal breast tissue	3
Fibroadenoma with fibrocystic change	6
Fibroadenoma with intraductal papilloma	3
Fibrocystic change with intraductal papilloma	13
Fibroadenoma with sclerosing adenosis	2
Fibrocystic change with sclerosing adenosis	2
Sclerosing adenosis with intraductal papilloma	3
Fibrocystic change with sclerosing adenosis with intraductal papilloma	2
Fibroepithelial lesion with sclerosing adenosis	1
Fibrocystic change with inflammation	2
Fibroepithelial lesion with intraductal papilloma	1
Others	73

(n = 367). In four (1%) cases, the pathologist was unable to make a histological diagnosis due to poor quality of the CNB specimens. Of the 28 high-risk lesions, 25 were subsequently excised surgically. The detailed pathological diagnoses for the malignant and benign lesions are presented in Tables II and III, respectively.

In Tables IV and V, we present a cross tabulation of the CNB, surgical excision or follow-up results. Based on the results, we calculated the agreement, sensitivity and underestimation rates. The crude agreement was 92.0%, the expected agreement was 42.1% and the Kappa measure of agreement was 0.861 ($p < 0.001$). The underestimation rate of CNB-diagnosed DCIS lesions was 46.7% (14 out of 30). The underestimation rate of CNB-diagnosed high-risk lesions was 40% (10 out of 25). These underestimation rates were calculated only for lesions that were subsequently excised surgically. All CNB-diagnosed high-risk lesions that were subsequently excised were ADH.

The agreement between the CNB results and final diagnoses was not significantly affected by age. For patients aged ≥ 60 years (n = 624), the crude agreement was 89.9%, the expected agreement 43.0% and the kappa measure 0.823. For patients aged < 60 years (n = 109), the crude agreement was 92.3%, the expected agreement 43.5% and the kappa measure 0.864. The agreement for patients aged < 30 years was not calculated due to the small sample size (n = 13). We also examined the possible risk factors associated with underestimation in CNB high-risk and DCIS lesions (Table VI). Although no factors were clearly or strongly related to underestimation, there was a tendency for younger women with larger mass lesions located at the lower quadrants of the breast

Table IV. Agreement between initial CNB diagnosis and final pathological diagnosis.

CNB\final	Benign	High-risk	DCIS	Invasive	Total
Benign	355	9	1	2	367
Inconclusive	2	1	0	1	4
High-risk	0	18	4	6	28
DCIS	0	0	16	26	42
Invasive cancer	0	0	7	285	292
Total	357	28	28	320	733

CNB: core needle biopsy; DCIS: ductal carcinoma *in situ*

Table V. Underestimation rates of ADH and DCIS lesions on CNB (for lesions undergoing subsequent surgical excision).

Final\CNB lesion	No. (%)	
	ADH (n = 25)	DCIS (n = 30)
Benign	0 (0.0)	0 (0.0)
High-risk (ADH)	15 (60.0)	0 (0.0)
DCIS	4 (16.0)	16 (53.3)
Invasive cancer	6 (24.0)	14 (46.7)
Underestimation rate	10 (40.0)	14 (46.7)

CNB: core needle biopsy; ADH: atypical ductal hyperplasia; DCIS: ductal carcinoma *in situ*

Table VI. Characteristics of ADH and DCIS lesions with underestimation compared to those without underestimation.

Characteristic	No. (%)		p-value*
	No underestimation (n = 31)	Underestimated (n = 24)	
Mean age ± SD (yrs)	53.5 ± 9.4	50.0 ± 8.9	0.171
Median size of lesion; range (cm)	1.0; 0.4–9.0	1.3; 0.5–8.2	0.537
Personal history of breast cancer	2/30 (7)	0/24 (0)	0.497
Mammographic breast density			
Less dense	3/26 (12)	7/20 (35)	0.077
More dense	23/26 (88)	13/20 (65)	
Lesions seen on mammogram			
Yes	24/28 (86)	16/21 (76)	0.394
No	4/28 (14)	5/21 (24)	
US finding			
Pure mass lesions	21/31 (68)	17/24 (71)	0.810
Calcification with/without mass	10/31 (32)	7/24 (29)	
US BI-RADS classification			
4	25/31 (81)	15/24 (63)	0.134
5	6/31 (19)	9/24 (37)	
Mean no. of cores ± SD	6.2 ± 2.3	5.6 ± 1.3	0.244
Location of lesion			
Upper outer quadrant	19/31 (61)	8/24 (33)	0.040
Lower outer quadrant	12/31 (39)	16/24 (67)	

*According to unpaired *t*-test, Wilcoxon rank-sum test, chi-square test or Fisher's exact test, as appropriate.
ADH: atypical ductal hyperplasia; DCIS: ductal carcinoma *in situ*; SD: standard deviation; US: ultrasonography; BI-RADS: breast imaging reporting and data system

and with BI-RADS 5 US findings not seen on mammography to have CNB-underestimated lesions.

Open surgical excision was performed in 81 of the 367 benign lesions diagnosed by CNB. In 285 of these benign lesions, the follow-up imaging findings were stable or improved for at least 24 months, and the lesions were therefore assumed to be benign. One benign lesion on CNB progressed on follow-up imaging at 23 months and was assumed to be high-risk, even though subsequent re-biopsy was not performed. Malignancy was found on open surgical excision in three CNB-benign lesions. Eight lesions were found to be high-risk on open surgical excision. The underestimation rate of CNB-diagnosed benign lesions was therefore 3.3% (12 out of 367).

Of the 348 lesions with a final diagnosis of malignancy, the initial CNB diagnoses were 334 malignant lesions, ten high-risk, three benign and one inconclusive, giving a CNB sensitivity of 96% (334 out of 348) and a false-negative rate of 4% (14 out of 348). The clinical, imaging and pathologic details of the four malignant cases with benign and inconclusive US-guided CNB results are shown in Table VII. The sensitivity of CNB for diagnosing breast cancer was not affected by age; the sensitivity was both 96% for patients aged ≥ 60 years (72 out of 75) and < 60 years (262 out of 273).

Of the two lesions with inconclusive CNB results that were surgically excised, one was high-risk and the other was malignant on final diagnosis. The other two inconclusive lesions had stable follow-up imaging finding at 27 and 43 months; hence, they were assumed to be benign (Table VIII). No serious complications associated with CNB, such as mastitis, large haematoma or pneumothorax, were recorded during the study period. Information on minor complications such as minor bleeding, ecchymosis or breast pain was not obtained for the present study.

DISCUSSION

Imaging-guided CNB is an established technique for diagnosis of palpable or non-palpable breast lesions seen on imaging studies.[9] CNB is more accurate that FNAC, and does not incur the costs and complications of open surgical biopsy. Surgical excision could be avoided in cases of benign lesions diagnosed via CNB.[7] When a breast lesion is visible on US, the latter is often used to guide CNB due to its many advantages. There is no ionising

Table VII. Characteristics of patients with false-negative US-guided CNB results.

Age (yrs)	Lesion on US	Echo pattern	BI-RADS classification	Diameter of lesion (mm)	Histologic finding		Delay in surgical excision (mths)
					CNB specimen	Surgical excision	
45	Mass	Hypoechoic	2	11	Fibroadenoma	IDC	21
75	Mass	Hypoechoic	4B	27	Not remarkable	IDC	32
45	Mass	Hypoechoic	4B	16	Fibrocystic disease	DCIS	24
47	Mass	Hypoechoic	4B	9	Insufficient tissue for diagnosis	IDC with DCIS	6

US: ultrasonography; BI-RADS: breast imaging reporting and data analysis; CNB: core needle biopsy; IDC: invasive ductal carcinoma; DCIS: ductal carcinoma *in situ*

Table VIII. Characteristics of patients with inconclusive US-guided CNB results.

Age (yrs)	Lesion on US	BI-RADS classification	Diameter of lesion (mm)	Histologic finding on surgical excision/follow-up US	No. of cores	Final diagnosis
53	Mass	4B	5	ADH	7	High risk
47	Mass	4B	9	IDC with DCIS	6	Malignant
44	Mass	3	12	Stable at 27 months	6	Benign
56	Mass	4A	5	Stable at 43 months	6	Benign

US: ultrasonography; BI-RADS: breast imaging reporting and data analysis; ADH: atypical ductal hyperplasia; IDC: invasive ductal carcinoma; DCIS: ductal carcinoma *in situ*

radiation involved unlike in stereotactic-guided biopsy, and the patient is relatively comfortable. In addition, the hardware can be easily obtained and used, and the procedure is fast, low-cost and done in real-time.[7] A relatively large number of cores can easily be removed under US guidance. In the present study, six or more cores were removed from 70% of all lesions with a median size of 1.3 cm.

The results of the present study confirmed that US-guided CNB is an accurate and reliable method for diagnosis of breast lesions. The kappa measure of agreement between the CNB results and the final diagnoses was 0.861, indicating a high level of agreement, and appeared to be similar for older (age ≥ 60 years) and younger (age < 60 years) age groups. The sensitivity of CNB in detecting malignant lesions was 96%. The CNB false-negative rate of 4% in the present study was acceptable compared with previously reported rates of 0%–12%.[7-10]

However, a significant problem with US-guided CNB is the high rate of histological underestimation.[10-12] The most important histological underestimation occurs when the results of CNB reveal high-risk (e.g. ADH) or DCIS lesion while the remaining unsampled lesion contains malignancy or invasive cancer.[11,12] The underestimation rate of ADH in a CNB specimen may be as high as 56%.[10] Although ADH shares many features with DCIS, it is less extensive. For example, a lesion that fulfils all the criteria of DCIS but involves only a single duct is diagnosed as ADH.[11] Therefore, a CNB diagnosis of ADH may, in fact, be underestimating a DCIS lesion. ADH is a risk factor for cancer and can also be found alongside invasive cancer.[11-13] In the present study, the underestimation rate of CNB-diagnosed ADH was 40% (10 out of 25), while that of DCIS lesions was 16% (four out of 25) and invasive cancer 24% (six out of 25). Although the present underestimation rate is comparable to the average US-guided CNB underestimation rate of ADH in previous studies (range 0%–100%; mean 46%),[8] the reliability of the measured rates was limited by the small number of ADH lesions found in all the studies.

A meta-analysis of underestimation of high-risk lesions in stereotactic-guided biopsy showed a rate of 40%,[13] which was comparable to that of the present study. Thus, our data supports the hypothesis that US-guided 14-gauge CNB is as accurate as stereotactic-guided breast biopsy in the diagnosis of high-risk lesions. The underestimation rate of CNB-diagnosed DCIS lesions in the present study was 46.7% (14 out of 30). Although relatively high, this rate was within the range seen in previous studies of US-guided CNB (15%–50%).[8,12] To help predict the presence of an invasive cancer when DCIS is found on CNB, sonographic features such as a detectable solid component either inside dilated ducts or associated with microcalcifications, as well as a lesion > 2 cm, are frequently associated with the presence of an invasive component.[14]

The present study did not confirm that calcifications seen on US were more predictive of invasive cancer. However, according to Table VI, larger tumours tend to be histologically underestimated on CNB. Our study found that when a CNB revealed ADH or DCIS, underestimation is more likely to occur if the lesion is found in a younger woman with larger mass lesions located at the lower quadrants of the breast and with BI-RADS 5 US findings not seen on mammography. Also, there is a tendency for fewer cores to be removed in underestimated lesions. In order to avoid underdiagnosing malignant lesions from CNB specimens, it may be prudent for patients with the characteristics described above to undergo open biopsy, or for the interventionist to remove more than six cores. Nonetheless, given the unpredictability and high underestimation rates of ADH and DCIS lesions in the present study, the practice of complete excision of all such lesions when detected by CNB, so as not to miss any coexisting malignancy or invasive cancer, should continue to be advocated.[11,12]

There are certain limitations in the present study. Firstly, lesions with benign CNB results that were not proven by surgical excision and did not have a follow-up of at least two years were excluded. Therefore, selection bias may exist, and it is possible

that there were more false-negative diagnoses in the excluded cases. Secondly, not all patients who were initially diagnosed as having ADH had an excisional biopsy subsequently. There may have been coexisting cancers in this group, and thus, the underestimation rate of ADH lesions may be inaccurate. Lastly, as 12 DCIS lesions were not removed by surgical excision, they were therefore excluded from the calculation of DCIS underestimation rate, rendering the calculated rate less precise. Although having a group of dedicated pathologists examine the CNB specimens may enable more malignancy or invasive cancers to be detected, thus lowering the underestimation rate, doing so would mean deviating from the situation seen in clinical practice, where only one pathologist would usually be examining the specimen.

In conclusion, US-guided CNB is an accurate diagnostic alternative to surgical biopsy in patients with sonographically detected breast lesions. However, radiological-pathological correlation and appropriate follow-up of benign lesions are essential for avoiding misdiagnosis. High-risk and DCIS lesions seen on CNB require subsequent excisional biopsy in order to avoid underestimation.

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